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 healthcare industry, lower health care costs, and enhance
patient care, we launched the Meaningful Measures Initiative in October 2017. This initiative is one component of our agency-wide Patients Over Paperwork Initiative, 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;
- 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;

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- 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**

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

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 healthcare 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. This initiative aims to empower patients by ensuring that they control their healthcare 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 healthcare 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. This administration is dedicated to putting patients first, empowering consumers of healthcare 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 healthcare.

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 of which are directly applicable to the prioritized specialties of general medicine/crosscutting and orthopedic surgery. Finally, on September 21, 2018, CMS awarded seven 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,

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and focus on outcome measures, including patient-reported and functional-status measures, to better reflect what matters most to patients.\textsuperscript{15}


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 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.

3. MIPS Program Details

a. MIPS Eligible Clinicians

Under §414.1305, a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, is defined as any of the following (excluding those identified at §414.1310(b)): a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and a group that includes such clinicians. Section 1848(q)(1)(C)(II) of the Act provides the Secretary with discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include physical therapists, occupational therapists, or qualified speech-language pathologists; qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act); certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietitians or nutrition professionals.

As discussed in the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we received feedback from non-physician associations representing each type of additional eligible clinician through listening sessions and meetings with various stakeholder entities and through public comments discussed in the CY 2017 Quality Payment Program final rule (81 FR 77038). Commenters generally supported the specification of such clinicians as MIPS eligible clinicians beginning with the 2021 MIPS payment year. In order to assess whether these additional eligible
clinicians could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We finalized in the CY 2018 Quality Payment Program final rule (82 FR 53780), that having sufficient measures for the quality performance category, means having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician. For the improvement activities performance category, we stated the belief that all MIPS eligible clinicians will have sufficient activities applicable and available. We focused our analysis on the quality and improvement activities performance categories because these performance categories require submission of data. We did not focus on the Promoting Interoperability performance category because there is extensive analysis regarding who can participate in the Promoting Interoperability performance category under the current exclusion criteria. In addition, in section III.I.3.h.(5) of this final rule, we are finalizing a policy to automatically assign a zero percent weighting for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians. We did not focus as part of our analysis on the cost performance category because we are only able to assess cost performance for a subset of eligible clinicians—specifically, those who are currently eligible as a result of not meeting any of the current exclusion criteria. So the impact of the cost performance category for these additional eligible clinicians will continue to be considered but is currently not a decisive factor for successful participation in MIPS. From our analysis, we found that improvement activities would generally be applicable and available for each of the additional eligible clinician types. However, for the quality performance category, we found that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available.
As discussed in section III.I.3.h.(2)(b)(iii) of this final rule, for the quality performance category, we are finalizing our proposals to remove several MIPS quality measures. In the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we explained that if those measures were finalized for removal, we anticipated that qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals would each have less than 6 MIPS quality measures applicable and available to them. However, if the quality measures were not finalized for removal, we would reassess whether these eligible clinicians would have an adequate amount of MIPS quality measures available to them. We proposed to include these additional clinicians in the MIPS eligible clinician definition if we found that they do have at least 6 MIPS quality measures available to them. As discussed in “Appendix 1: Finalized MIPS Quality Measures”, TABLE Group C. of this final rule, we are retaining one of the MIPS quality measures that was proposed for removal: “Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use” (Quality #185). We do not believe that this measure is applicable to any of the proposed additional eligible clinicians. Therefore, it does not affect the number of available measures for these clinicians. We refer readers to section III.I.3.h.(2) of this final rule for more information regarding quality measures.

We focused on the quality performance category because the quality and improvement activities performance categories require submission of data. We believed there would generally be applicable and available improvement activities for each of the additional eligible clinician types, but that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available if the proposed MIPS quality measures were removed from the program. In our analysis, we did find QCDR measures approved for the CY 2018 performance period that are either high priority and/or outcome measures that, if approved for
the CY 2019 performance period, may be applicable to these additional eligible clinicians. However, this would necessitate that the clinician utilize a QCDR in order to be successful in MIPS. Further, we have heard some concerns from the non-physician associations, through written correspondence, that since their clinicians would be joining the program 2 years after its inception, we should consider several ramp-up policies in order to facilitate an efficient integration of these clinicians into MIPS. We note that the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold that will be used in the Quality Payment Program Year 6. Therefore, if specified as MIPS eligible clinicians beginning with the 2021 MIPS payment year, the additional eligible clinicians would have 4 years in the program in order to ramp up. Conversely, if specified as MIPS eligible clinicians beginning in a future year, they would be afforded less time to ramp up the closer the program gets to Quality Payment Program Year 6.

We requested comments on our proposal to amend §414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at §414.1310(b)): a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, a clinical social worker (as defined in section 1861(hh)(1) of the Act), a clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and a group that includes such clinicians. Alternatively, we proposed that if the quality measures proposed for removal were not finalized, then we would include additional eligible clinician types in the definition of a MIPS eligible
clinician beginning with the 2021 MIPS payment year (specifically, qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals), provided that we determine that each applicable eligible clinician type would have at least 6 MIPS quality measures available to them. In addition, we requested comments on: (1) specifying qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year; and (2) delaying the specification of one or more additional eligible clinician types as MIPS eligible clinicians until a future MIPS payment year.

The following is a summary of the public comments received on our proposals and our responses:

**Comment:** Many commenters supported our proposal to expand the definition of MIPS eligible clinicians to physical therapists, occupational therapists, clinical social workers, and clinical psychologists. A few commenters encouraged us to ensure that a reasonable number of measures are maintained for these newly eligible clinicians. Other commenters specifically discussed adding qualified audiologist and qualified speech-language pathologists as MIPS eligible clinicians, stating that there are enough discipline-specific measures for these clinicians to be included in the program. One commenter specifically stated that registered dietitians have seven quality measures on which to report, and, therefore should be included in the program. A few commenters requested that we include the following additional clinicians as MIPS eligible clinicians: nurse navigators, oncology staff nurses, and clinical pharmacists, stating that adding more clinicians would enable better understanding of healthcare data across other specialties.
Response: We appreciate the additional information provided regarding the quality measures available to the additional eligible clinicians. After review of the additional information regarding quality measures we revisited our findings and found support for the comments. We were persuaded by the arguments of the specialties who requested to be included in the program including: physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and dieticians or nutrition professionals. However, we believe that clinical social workers may not have six applicable quality measures to report. For example, some measures may contain CPT codes utilized by clinical social workers, but may not be applicable to their practice. We do believe that there is at least one quality measure that clinical social workers could report for MIPS. We encourage the clinicians within the specialty provide feedback during the specialty measure set solicitation process to create a measure set applicable to clinical social workers for implementation in future rulemaking. This will ensure proper scoring based on applicable measures and will not hold clinical social workers accountable for measures that are outside their scope. Therefore, we are modifying our proposal by removing clinical social workers from our proposed list and including qualified speech-language pathologists, qualified audiologists, and registered dieticians who were not in our proposed list but have requested inclusion as MIPS eligible clinicians. We are finalizing to modify §414.1305 the definition of a MIPS eligible clinician to include: beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; a qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians. We note that we do not have discretion under the statute to include clinicians other than those specified in
section 1848(q)(1)(C)(II) of the Act. Thus, nurses and pharmacists would not be able to participate in MIPS.

Comment: A few commenters requested that clinical social workers not be included in MIPS. They stated several reasons why they believe that clinical social workers should not be included in MIPS: (1) many of their clinicians are solo or small group practices and do not have the technology infrastructure in place to effectively meet expectations in the Promoting Interoperability performance category; (2) many are in private practice and have limited ability to influence the overall care of patients limiting their ability to manage the overall cost of the beneficiary; (3) while there are more than six measures available in the mental/behavioral health measure set there are only four claims measures appropriate for use by clinical social workers as determined by eligible CPT codes and scope of practice; and (4) some of the available MIPS CQM measures are limited by patient diagnosis, such as dementia, which may further limit a clinical social workers ability to effectively report on six quality measures, as there are only two outcome measures in the Mental/Behavioral health measure set for clinical social workers and they require the utilization of the PHQ-9 measure which is only reportable via EHR. When a clinical social worker does not utilize EHR technology there may be further limitations to reporting adequate measures.

Response: After review of the additional information regarding quality measures, we revisited our findings and found support for the comments. We were persuaded by the arguments of the specialties who requested to be included in the program including: physical therapists; occupational therapists; speech-language pathologists; audiologists; clinical psychologists; and dieticians or nutrition professionals. We understand the issues that have been highlighted by the commenters and believe that some clinical social workers may have a difficult
time successfully participating in MIPS. Therefore, we agree that clinical social workers should not be added as a MIPS eligible clinician at this time. However, we do believe that they may be able to participate at some point in the future. From our analysis, clinical social workers may not have six applicable quality measures to report at this time. For example, some measures may contain CPT codes utilized by clinical social workers, but may not be applicable to their practice. We do believe that there is at least one quality measure that clinical social workers could report for MIPS. Therefore, we are modifying our proposal by removing clinical social workers and certified nurse-midwives from our proposed list and including qualified speech-language pathologists, qualified audiologists, and registered dieticians who were not in our proposed list but have requested inclusion as MIPS eligible clinicians. We are finalizing to modify §414.1305 the definition of a MIPS eligible clinician to include, beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; a qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians. We encourage clinicians who are not eligible to participate in MIPS to voluntarily report on applicable measures and activities for MIPS. The data received will not be used to assess performance for the purpose of the MIPS payment adjustment; however, these clinicians will have the opportunity to access feedback on their submitted MIPS data. We agree that the two outcome measures within the mental/behavioral health specialty measure set do require the utilization of the PHQ-9 to measure the depression outcome; however, we disagree with the commenter as this is not restricted to EHR and available by MIPS CQMs Specification.
**Comment:** One commenter recommended that we adopt a standard definition of a Quality Payment Program eligible provider, eligible clinician and/or an eligible professional as it continues to expand the list of eligible clinicians. The commenter recommended the word “physician” be replaced with provider and/or clinician, stating that this terminology better reflects the collaboration of the current inter-professional healthcare team.

**Response:** We understand the commenter to be suggesting that we unify the definitions of eligible clinician and MIPS eligible clinician. While we agree that a unified definition might have certain benefits, we believe that two separate definitions are necessary as the two tracks of the Quality Payment Program (MIPS and APM) have distinctly different requirements for participation and the term eligible clinicians reflects a broader set of clinician types than the term MIPS eligible clinicians. We note that both terms already refer to clinicians.

**Comment:** Some commenters stated that inclusion of these additional eligible clinicians in the program with just two months’ notice is overly burdensome and would ultimately prove counterproductive. One commenter stated that because of the limited scope of MIPS reporting that is applicable to these specialties, we should carefully evaluate whether the expense and added burden of reporting for these specialties is commensurate with the benefits. Another commenter noted that these clinicians tend to have a high patient turnover rate, which could make certain measures challenging. Several commenters opposed expanding the definition of eligible clinician to the proposed clinician types, stating that the clinician types do not, as a general rule, encompass the same types of workflows as current MIPS eligible clinicians, and, therefore, adding these clinicians could increase the cost, time, and effort for reporting and documentation. Many commenters requested we create ramp-up policies for the additional eligible clinicians, such as a pick-your-pace approach or a 1-year delayed effective date.
Likewise, a few commenters requested that we allow the additional clinicians to opt-in for the first year in which they are eligible to participate. A few commenters requested that we consider a one-time bonus payment for voluntary reporting, and requested modified quality benchmarks, performance thresholds, reporting requirements, and data completeness requirements.

Response: We acknowledge that adding these additional clinicians will require some adaptation to the current systems and processes and will take careful consideration by measure stewards to determine the appropriateness of adding clinician encounters to align with measure intent. However, we believe the benefits outweigh the costs as these clinicians are an integral part of the health care delivery team. We believe that all eligible clinicians benefit from participation in quality reporting under MIPS and help reach one of our strategic objectives to improve beneficiary outcomes and engage and empower consumers by providing healthcare information useful for driving value and making healthcare decisions. Regarding measures that are considered challenging, the additional clinicians should choose measures and activities that are applicable and meaningful to them. As noted in the proposed rule (83 FR 35884), the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold that will be used in the Quality Payment Program Year 6. Therefore, if specified as MIPS eligible clinicians beginning with the 2021 MIPS payment year, the additional eligible clinicians would have 4 years in the program in order to ramp up. Conversely, if specified as MIPS eligible clinicians beginning in a future year, they would be afforded less time to ramp up the closer the program gets to Quality Payment Program Year 6. In addition, for the first 2 years of MIPS, clinicians who are not MIPS eligible had the opportunity to voluntarily report to become familiar with MIPS measures and reporting. For these reasons, we do not believe we should adopt policies such as those suggested by the
commenters. We note that additional eligible clinicians that exceed at least one, but not all, of the low-volume threshold criteria will have the opportunity to opt-in to participate in MIPS as discussed in section III.I.3.c.(5) of this final rule. We do not agree with offering a one-time bonus payment for voluntary reporting as section 1848(q)(1)(C)(vi) of the Act precludes the application of a MIPS adjustment factor (or additional MIPS adjustment factor) to an individual who is not a MIPS eligible clinician. Finally, as these additional clinicians will be defined as MIPS eligible clinicians, they will be subject to the same requirements as other MIPS eligible clinicians, including quality benchmarks, performance thresholds, reporting requirements, and data completeness requirements.

Comment: Several commenters requested that we provide targeted education on program requirements to additional eligible clinicians. Specifically, the commenters urged us to provide compliance support to small practices, by creating an industry pathway to EHR reporting. A few commenters requested that we convene a Technical Expert Panel (TEP) comprised of individuals representing the additional eligible clinician types to inform adaptation of the Quality Payment Program to meet their needs.

Response: We have consistently provided targeted education on program requirements in the past and intend to continue doing so through various means including: webinars, national provider calls, virtual office hours, speaking engagements, and tailored educational resources for the additional clinicians. No cost technical assistance is also available by contacting the Quality Payment Program Service Center by phone at 1-866-288-8292, (TTY) 1-877-715-6222 or by email at QPP@cms.hhs.gov. 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. We appreciate the suggestion to convene a TEP comprised of the additional clinicians. We will continue to explore additional opportunities for this type of engagement in the future.

Comment: Many commenters noted their concern regarding whether the Quality Payment Program could be utilized for these new clinician types, asking us to consider if these clinicians are able to meet MIPS reporting requirements across all performance categories before expanding the list of MIPS-eligible clinicians. Specifically, some commenters stated that the Promoting Interoperability performance category would be difficult to meet without a change in meaningful use guidelines, noting that because these clinicians rarely bill the clinician group directly and may not be integrated with the clinician group’s EHR, interoperability remains a material issue. These commenters requested that we weight the Promoting Interoperability performance category at zero percent or allow new eligible clinicians to opt-in to this performance category. Another commenter requested clarification on whether the proposal to automatically assign a zero percent weighting for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians applies to both individual clinicians and groups. Another commenter asked for clarification regarding if they could continue to report as a group. One commenter questioned whether the additional clinicians would be removed from the denominator for these measures. Other commenters asked for clarification on how quality measures will be captured as most of these clinicians may not have electronic medical records (EMRs).

Response: In the CY 2019 PFS proposed rule (83 FR 35883 through 35884) to assess whether these additional eligible clinicians could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the
additional eligible clinician types. We did not focus on the Promoting Interoperability performance category because for CY 2019 we are finalizing to automatically assign a zero percent weighting for the Promoting Interoperability performance category which will be reweighted to the quality performance category for these new types of MIPS eligible clinicians. In response to the comment, the proposal to automatically assign a zero percent weighting for the Promoting Interoperability performance category does apply to both individual clinicians and groups. Clinicians may choose to report for MIPS as an individual or as part of a group. If the clinician chooses to report as part of a group, then under the policy we established previously (82 FR 53687), all of the MIPS eligible clinicians in the group must qualify for a zero percent weighting in order for the Promoting Interoperability performance category to be reweighted in the final score. We refer readers to section III.I.3.h.(5)(h)(ii) of this final rule for further details on the policy that we are finalizing in this rule to automatically assign a zero percent weighting for the Promoting Interoperability performance category. Regarding data submission requirements for quality measures, the additional eligible clinicians may submit their quality data through the same data collection types available to all MIPS eligible clinicians including eCQMs, MIPS Clinical Quality Measures (MIPS CQMs), QCDR measures, Medicare Part B claims measures, CMS Web Interface measures, the CAHPS for MIPS survey, and administrative claims measures which may be submitted via one of the submission types including: direct; log in and upload; log in and attest; Medicare Part B claims; and the CMS Web Interface. We refer readers to section III.I.3.h.(1) in this final rule for further information regarding performance category measures and reporting.
Comment: A few commenters requested that we be certain that we are operationally prepared to support reporting and scoring for the additional eligible clinician types, as clinicians have experienced operational data submissions issues in the past.

Response: We intend to have our Quality Payment Program portal ready to accept and process data for all MIPS eligible clinicians for 2021 MIPS payment year.

Comment: Several commenters requested clarification on how our proposal would apply to eligible clinicians billing under a hospital- or facility-based TIN. A few commenters stated that the rule does not indicate whether hospitals should report the NPI of these clinicians on the UB-04 claims used by hospitals and cautioned that adding these clinician types to UB-04 claims would entail significant administrative burden to hospitals. One commenter also stated that the majority of facility-based outpatient therapy claims do not contain the rendering NPI and usually contain just a facility NPI; therefore, most facility-based outpatient therapy claims will not be eligible for MIPS. A few commenters said that due to a technicality in how facility-based claims (such as those submitted by inpatient rehabilitation facilities) are submitted, only independently rendered, private practice outpatient therapy services will be included in MIPS, and facility-based outpatient therapy will generally not be included. One commenter recommended that we operationalize the inclusion of facility-based clinicians in MIPS by treating the facility NPI as a MIPS-participating NPI and allow the facility to report measures under MIPS like a group.

Another commenter argued that facility-based outpatient therapy clinicians should be included in the program. A few commenters sought clarification of how clinicians of therapy services in skilled-nursing facilities will be treated, stating that assessing individual clinicians for quality and adjusting payment poses unique challenges in this setting.
Response: These additional clinicians will be defined as MIPS eligible clinicians and will be subject to the same requirements as other MIPS eligible clinicians billing under a hospital- or facility-based TIN. MIPS eligible clinician may report as an individual or as part of a group. We finalized at §414.1380(e)(2)(i) and (ii) the determination of a facility-based individual and facility-based group. A facility-based individual is a MIPS eligible clinician that furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting based on claims for a period prior to the performance period as specified by CMS. A facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group’s TIN meet the facility-based individual determination. Therefore, if a MIPS eligible clinician is submitting their data as part of a facility-based group their NPI number would need to be annotated on the claim which is part of normal billing practices. We refer readers to section III.I.3.h.(2)(a)(iv) of this final rule for further details regarding the application of facility-based measures. The definition of a hospital-based clinician finalized at §414.1410 is primarily applicable to the Promoting Interoperability performance category. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53684) for details on a hospital-based clinician. We are aware that facility-based outpatient therapy and skilled nursing facility claims do not contain the rendering NPI and usually contain just a facility NPI; therefore, facility-based outpatient therapy and skilled nursing facility claims will not be eligible for MIPS. For those billed Medicare Part B allowed charges we are able to associate with a MIPS eligible clinician at an NPI level, such covered professional services furnished by such clinicians would be included for purposes of applying any MIPS payment adjustment. It is our intention to provide clinicians with their eligibility status prior to the performance period through the Quality
Payment Program portal eligibility determination tool. This should allow clinicians to know ahead of time whether they are included in MIPS or not. We will take these comments into consideration in future rulemaking.

**Comment:** A few commenters noted that adding physical and occupational therapists would affect the determination of practice size. One commenter expressed concern that groups may lose their small group status even though the composition of the practice did not change.

**Response:** We do not anticipate that the small practice size determination will be affected by adding additional clinicians to the definition of MIPS eligible clinician. Small practice is defined at §414.1305 to mean a practice consisting of 15 or fewer eligible clinicians. Thus, the definition of small practice already accounts for all eligible clinicians in the practice, including those that we are adding to the definition of MIPS eligible clinician.

**Comment:** One commenter requested clarification regarding how the additional MIPS eligible clinicians would be subject to payment reductions if they do not meet the performance requirements under MIPS.

**Response:** The additional eligible clinicians, who are not otherwise excluded, will be included in the performance requirements for a MIPS eligible clinician for CY 2021 payment year. In addition, MIPS eligible clinicians are subject to the MIPS payment adjustment factor. Clinicians who are considered MIPS eligible and who do not report under MIPS may receive a final score of zero and an associated negative payment adjustment of 7 percent during the CY 2021 payment year.

**Comment:** Some commenters stated that the additional clinician types could water down the performance pool, and increasing the number of participants will create increased
competition for an additional performance threshold, making it more difficult for disadvantaged clinicians to meaningfully participate in MIPS.

**Response:** Although the number of MIPS eligible clinicians will increase, we do not anticipate that the additional clinicians will substantially change the total number of MIPS eligible clinicians or make it more difficult for other clinicians to meaningfully participate in MIPS. Regarding the additional performance threshold, we note that the eligible clinician must first qualify for the additional performance threshold for exceptional performance. We do not believe that the addition of new clinician types to be MIPS eligible implies they are going to perform at a level that qualifies for the additional performance threshold. We refer readers to Table 98 in section VII (Regulatory Impact Analysis) of this final rule for information regarding the impact of expanding the definition of MIPS eligible clinicians on the total number of MIPS eligible clinicians and the total estimated PFS amount paid.

**Comment:** One commenter believed it was unnecessary to include the proposed additional eligible clinicians as they would more than likely be ineligible because they would fall below the low-volume threshold.

**Response:** We understand that some of the additional eligible clinicians may not exceed the low-volume threshold. However, as discussed in section III.I.3.c.(5) of this final rule, we are also finalizing an opt-in option that will allow eligible clinicians to opt-in to MIPS if the eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold criteria. In addition, MIPS eligible clinicians may participate in MIPS as part of a group or virtual group which should improve their ability to exceed the low-volume threshold. We believe this option would allow the additional eligible clinicians the opportunity to participate in MIPS if they desired to do so.
Comment: Several commenters suggested that there is misalignment between the proposed expanded list of eligible clinician types for the MIPS and the scope of clinician types for the Advanced Alternative Payment Model path under the Quality Payment Program. Specifically, a few commenters noted that, currently, a number of clinician types (for example, clinical psychologists and certified nurse midwives) could be in an Advanced APM, but that we are proposing to include clinician types for MIPS that may not be eligible for the Advanced APM path under the Quality Payment Program. Thus, commenters suggested that we standardize the included clinician types across the Quality Payment Program unless there are appropriate clinical reasons for differences. One commenter requested clarification as to whether physical, occupational, and speech therapists, as eligible clinicians, can participate in the Advanced APMs path under the Quality Payment Program. Another commenter requested that we provide guidance on how APM entities, ACOs, and other health care organizations should identify these clinician types on their clinician participation lists.

Response: We note that the proposed expanded list of eligible clinician types for the MIPS is not misaligned with the scope of eligible clinicians for the Advanced APMs path under the Quality Payment Program. In accordance with section 1848(q)(1)(C)(i)(I) of the Act, we defined MIPS eligible clinician for the 2019 and 2020 MIPS payment years to include only physicians (as defined under section 1861(r) of the Act), physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (and groups that include these clinicians). In contrast, we explained in the CY 2017 Quality Payment Program final rule (81 FR 77405 through 77406), for the Advanced APM path under the Quality Payment Program, the term “eligible clinician” is defined in section 1833(z)(3)(B) of the Act (by cross-reference to the definition of “eligible professional” in section 1848(k)(3)(B) of the Act), and includes:
physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians or nutrition professionals, physical or occupational therapists, qualified speech-language pathologists, and qualified audiologists, and a group that includes these professionals. Our proposed expansion of the list of MIPS eligible clinician types would actually align with the current scope of eligible clinicians under the Advanced APM path of the Quality Payment Program. Currently, any of those eligible clinicians who participate sufficiently in Advanced APMs can become QPs for a year and receive the associated APM Incentive Payment. We note that each APM has its own focus, and many offer participation opportunities for a broad scope of eligible clinicians. Although the design of existing or future APMs is beyond the scope of this final rule, we welcome ideas on how to further engage the full scope of eligible clinicians as we work hard to develop more APM opportunities. Additionally, we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77442) that the eligible clinicians for whom we would make QP determinations would be all the eligible clinicians participating in an APM Entity in an Advanced APM, as identified at each of three snapshot dates, during a QP Performance Period. The eligible clinicians for whom we make QP determinations are those identified on an Advanced APM’s Participation List or Affiliated Practitioner List on one of those three dates. Lastly, we note that decisions about the eligible clinicians that are included on the Participation List or Affiliated Practitioner List for any particular Advanced APM are made based on the specific terms and conditions of the Advanced APM, which can vary based on the model test, entities involved, payment arrangements, and other factors.

After consideration of the public comments received, we are finalizing a modification of our proposal to amend §414.1305 to revise the definition of a MIPS eligible clinician, as
identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at §414.1310(b)): a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians.

b. MIPS Determination Period

As discussed in the proposed rule (83 FR 35884 through 35886), currently MIPS uses various determination periods to identify certain MIPS eligible clinicians for consideration for certain applicable policies. For example, the low-volume threshold, non-patient facing, small practice, hospital-based, and ambulatory surgical center (ASC)-based determinations are on the same timeline with slight differences in the claims run-out policies, whereas the facility-based determinations has a slightly different determination period. The virtual group eligibility determination requires a separate election process. We proposed to add a virtual group eligibility determination period beginning in CY 2020 as discussed in section III.I.3.f.(2)(a) of this final rule. In addition, the rural and HPSA determinations do not utilize a determination period.

Under §414.1305, the low-volume threshold determination period is described as a 24-month assessment period consisting of an initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period, and a second 12-month segment that spans
from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12–month segment will continue to be excluded under §414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12–month segment analysis. For the 2020 MIPS payment year and future years, each segment of the low-volume threshold determination period includes a 30–day claims run out.

Under §414.1305, the non-patient facing determination period is described as a 24–month assessment period consisting of an initial 12–month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and a second 12–month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12–month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12–month segment analysis. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30–day claims run out.

In the CY 2018 Quality Payment Program final rule (82 FR 53581), we finalized that for the small practice size determination period, we would utilize a 12-month assessment period, which consists of an analysis of claims data that spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 30-day claims run out.
In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240), we finalized that to identify a MIPS eligible clinician as hospital-based we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53684 through 53685), we finalized that to identify a MIPS eligible clinician as ASC-based, we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we discussed, but did not finalize, our proposal or the alternative option for how an individual clinician or group would elect to use and be identified as using facility-based measurement for the MIPS program. Because we were not offering facility-based measurement until the 2019 MIPS performance period, we did not need to finalize either of these for the 2018 MIPS performance period. However, as discussed in section III.I.3.i.(1)(d) of this final rule, we proposed to amend §414.1380(e)(2)(i)(A) to specify a criterion for a clinician to be eligible for facility-based measurement. Specifically, that is, the clinician furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the
calendar year 2 years prior to the applicable performance period and ending on September 30 of
the calendar year preceding the applicable performance period with a 30-days claims run out.
We did not propose to utilize the MIPS determination period for purposes of the facility-based
determination because for the facility-based determination, we are only using the first segment of
the MIPS determination period. We are using the first segment because the performance period
for measures in the hospital value-based purchasing program overlapped in part with that
determination period. If we were to use the second segment, we could not be assured that the
clinician actually worked in the hospital on which their MIPS score would be based during that
time. We believe this approach provides clarity and is a cleaner than providing a special
exception for the facility-based determination in the MIPS determination period for the second
segment. We refer readers to section III.I.3.i.(1)(d) for further details on the facility-based
determinations and the time periods that are applicable to those determinations.

In the CY 2018 Quality Payment Program final rule (82 FR 53602 through 53604), we
finalized that for the virtual group eligibility determination period, we would utilize an analysis
of claims data during an assessment period of up to 5 months that would begin on July 1 and end
as late as November 30 of the calendar year prior to the applicable performance period and
include a 30-day claims run out. To capture a real-time representation of TIN size, we finalized
that we would analyze up to 5 months of claims data on a rolling basis, in which virtual group
eligibility determinations for each TIN would be updated and made available monthly. We
noted that an eligibility determination regarding TIN size is based on a relative point in time
within the 5-month virtual group eligibility determination period, and not made at the end of
such 5-month determination period. Beginning with the 2019 performance period, we proposed
to amend §414.1315(c)(1) to establish a virtual group eligibility determination period to align
with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. We refer readers to section III.I.3.f.(2)(a) of this final rule for further details on this proposal.

In addition, we have established other special status determinations, including rural area and HPSA. Rural area is defined at §414.1305 as a ZIP code designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available. HPSAs are defined at §414.1305 as areas designated under section 332(a)(1)(A) of the Public Health Service Act.

We understand that the current use of various MIPS determination periods is complex and causes confusion. Therefore, beginning with the 2021 MIPS payment year, we proposed to consolidate several of these policies into a single MIPS determination period that would be used for purposes of the low-volume threshold and to identify MIPS eligible clinicians as non-patient facing, a small practice, hospital-based, and ASC-based, as applicable. We did not propose to include the facility-based or virtual group eligibility determination periods or the rural and HPSA determinations in the MIPS determination period, as they each require a different process or timeline that does not align with the other determination periods, or do not utilize determination periods. We invited public comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

There are several reasons we believe a single MIPS determination period for most of the eligibility criteria is the most appropriate. First, it would simplify the program by aligning most of the MIPS eligibility determination periods. Second, it would continue to allow us to provide
eligibility determinations as close to the beginning of the performance period as feasible. Third, we believe a timeframe that aligns with the fiscal year is easier to communicate and more straightforward to understand compared to the current determination periods. Finally, it would allow us to extend our data analysis an additional 30 days.

It is important to note that during the final 3 months of the calendar year in which the performance period occurs, in general, we do not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. We refer readers to section III.I.3.i.(2)(b) of this final rule for more information on the proposed reweighting policies for MIPS eligible clinicians who join an existing practice or who join a newly formed practice during this timeframe.

We requested comments on our proposal that beginning with the 2021 MIPS payment year, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) an initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. The first segment would include a 30-day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. For example, a clinician could use the quarterly snapshots to understand their eligibility status between segments. Specifically, we believe the quarterly snapshots would be helpful for new TIN/NPIs and TINs created between the first
segment and the second segment allowing them to see their preliminary eligibility status sooner. Without the quarterly snapshots, these clinicians would not have any indication of their eligibility status until just before the submission period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold, or a MIPS eligible clinician that is identified as non-patient facing, a small practice, hospital-based, or ASC-based, as applicable, during the first segment would continue to be identified as such for the applicable MIPS payment year regardless of the second segment. For example, for the 2021 MIPS payment year, the first segment would be October 1, 2017 through September 30, 2018, and the second segment would be October 1, 2018 through September 30, 2019. However, based on our experience with the Quality Payment Program, we believe that some eligible clinicians, whose TIN or TIN/NPIs are identified as eligible during the first segment and do not exist in the second segment, are no longer utilizing these same TIN or TIN/NPI combinations. Therefore, because those TIN or TIN/NPIs would not exceed the low-volume threshold in the second segment, they would no longer be eligible for MIPS. For example, in the 2019 performance period a clinician exceeded the low-volume threshold during the first segment of the determination period (data from the end of CY 2017 to early 2018) under one TIN; then in CY 2019 the clinician switches practices under a new TIN and during segment two of the determination period. Therefore, it is determined that the clinician is not eligible (based on CY 2019 data) under either TIN. This clinician would not be eligible to participate in MIPS based on either segment of the determination period because the TIN that was assessed for the first segment of the determination period no longer exists. So there are no charges or services that would be available to assess in the second segment for that TIN and the new TIN assessed during the second segment was not eligible. In this scenario, though the clinician exceeded the low-volume
threshold criteria initially, the clinician is not required to submit any data based on TIN eligibility determinations. However, it is important to note that if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, these eligible clinicians could be eligible for MIPS. For example, the eligible clinician may not find their TIN or TIN/NPI in the Quality Payment Program lookup tool but may still be eligible if they exceed the low-volume threshold in the second segment. We proposed to incorporate this policy into our proposed definition of MIPS determination period at §414.1305. We also requested comments on our proposals to define MIPS determination period at §414.1305 and modify the definitions of low-volume threshold, non-patient facing, a small practice, hospital-based, and ASC-based at §414.1305 to incorporate references to the MIPS determination period.

The following is a summary of the public comments received on our proposals and our responses:

**Comment:** Several commenters supported our proposal, noting that the varying determination periods add unnecessary confusion and this policy would reduce complexity. One commenter recommended we continue our efforts to align the determination period with facility-based, virtual groups, and rural and HPSA eligibility determinations.

**Response:** We appreciate the commenters’ support.

**Comment:** Some commenters stated that in order for clinicians to successfully perform over a 12-month period for the cost and quality performance categories, the clinician must know before the start of the performance period their full eligibility status for MIPS.

**Response:** We understand that it is important for clinicians to know their eligibility status prior to the performance period. It is our intention to provide eligibility determinations as close to the beginning of the performance period as feasible. We would like to assure commenters that
we are working diligently to provide clinicians with this information at the earliest time possible.

Comment: A few commenters supported using quarterly snapshots for the second segment of the MIPS determination period to show preliminary eligibility status. One commenter recommended that the first quarterly snapshot for the second segment be mandated to be available in the look-up tool no later than January 1, 2019, the first day of the CY 2019 performance period. One commenter recommended that if a clinician does not exceed the low-volume threshold during the quarterly snapshots, then they should be automatically excluded from MIPS unless further snapshots allow for an opt-in similar to the proposed low-volume threshold opt-in policy.

Response: While the statute does not require the use of quarterly snapshots, we believe the snapshots may provide useful information for eligible clinicians. Therefore, we are working to provide the quarterly snapshots, if feasible. In addition, it is important to note that the quarterly snapshots are being provided for informational use only and are not final until after the second segment of the MIPS determination period closes and a reconciliation between the segments occurs. Since the quarterly snapshots are not final this information is subject to change and should not be considered the final eligibility determination. The eligibility determination will be made after a reconciliation of the first and second segment of the MIPS determination period.

Comment: Several commenters did not support the proposed 24-month MIPS determination period, with most arguing for a single determination period. These commenters recommended that the MIPS determination period be a single, 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. Another
commenter stated that a preliminary assessment for the exclusions would be useful, but the final decision should be made only based on performance period data. One commenter stated that the two segments lead to confusion and uncertainty about participation status and requested that the second segment have an end date and notification date prior to the start of the performance year. Another commenter opposed the shift in determination period dates unless the eligibility tool on the Quality Payment Program website is updated in a timely fashion prior to the performance year.

Response: If we had a singular eligibility determination period we would not be able to identify eligible clinicians who switch practices between the first and second segments of the MIPS determination period. We estimate that this would affect approximately 13 percent of MIPS eligible clinicians who may switch practices between the first and second determination periods. If we did not conduct the first segment analyses then there would be no way to inform clinicians of their eligibility status prior to the performance period. The second segment accounts for the identification of additional, previously unidentified individual eligible clinicians and groups who do not exceed the low-volume threshold or meet other special circumstances. It is our intention that the eligibility tool on the Quality Payment Program website will be updated to provide eligibility determinations prior to the start of the performance period.

Comment: A few commenters noted the challenge for clinicians who exceeded the low-volume threshold during the first segment of the MIPS determination period and then discovered late in the performance period, after the second segment of the MIPS determination period that they are no longer eligible. One commenter suggested that if a clinician exceeds the low-volume threshold during the second segment of MIPS eligibility determination period, the clinician should remain excluded unless the clinician opts-in. One commenter noted that these issues may
be less of a problem if the opt-in proposal is finalized. Another commenter requested the definition of the MIPS determination period be expanded to account for scenarios when an eligible clinician or group exceeded the low-volume threshold during the first segment but falls below the low-volume threshold during the second segment or when a eligible clinician or group is not categorized as a special status (such as non-patient facing) during the first segment but gains special status during the second segment.

Response: We agree that the issues identified by the commenters may be alleviated with the opt-in policy. If an eligible clinician finds out following the second segment of the MIPS determination period that they are no longer eligible to participate in MIPS and they meet the requirements of the opt-in policy they may choose to participate in MIPS by opting-in to MIPS. Regarding changing statuses between the two segments of the MIPS determination period, we are finalizing the definition of the MIPS determination period at §414.1305(2) that subject to §414.1310(b)(1)(iii), an individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as having special status during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment. While we would like to ensure that there is as much flexibility as possible within the MIPS program, we believe it is important that MIPS eligible clinicians choose how they will participate in MIPS as a whole, either as an individual or as a group. Whether MIPS eligible clinicians participate in MIPS as an individual or group, it is critical for us to assess the performance of individual MIPS eligible clinicians or groups across the four
performance categories collectively as either an individual or group in order for the final score to reflect performance at a true individual or group level and to ensure the comparability of data.

After consideration of the public comments received, we are finalizing our proposal to define MIPS determination period at §414.1305 beginning with the 2021 MIPS payment year, as a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) an initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. The first segment would include a 30-day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. In addition, we are finalizing that subject to §414.1310(b)(1)(iii), an individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as having special status during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment. Finally, at §414.1305 we are finalizing our proposal to modify the definitions of low-volume threshold, non-patient facing MIPS eligible clinician, a small practice, hospital-based MIPS eligible clinician, and ASC-based MIPS eligible clinician at §414.1305 to incorporate references to the MIPS determination period.

c. Low-Volume Threshold
(1) Overview

As discussed in the CY 2019 PFS proposed rule (83 FR 35886), section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018, provides that, for performance periods beginning on or after January 1, 2018, the low-volume threshold selected by the Secretary may include one or more or a combination of the following (as determined by the Secretary): (1) the minimum number of part B-enrolled individuals who are furnished covered professional services (as defined in section 1848(k)(3)(A) of the Act) by the eligible clinician for the performance period involved; (2) the minimum number of covered professional services furnished to part B-enrolled individuals by such clinician for such performance period; and (3) the minimum amount of allowed charges for covered professional services billed by such clinician for such performance period.

Under §414.1310(b)(1)(iii), for a year, eligible clinicians who do not exceed the low-volume threshold for the performance period with respect to a year are excluded from MIPS. Under §414.1305, the low-volume threshold is defined as, for the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Part B–enrolled Medicare beneficiaries. In addition, for the 2020 MIPS payment year and future years, the low-volume threshold is defined as the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $90,000 or provides care for 200 or fewer Part B–enrolled Medicare beneficiaries. The low-volume threshold determination period is a 24–month assessment period consisting of: (1) an initial 12–month segment that spans from the last 4 months of the calendar year 2 years
prior to the performance period through the first 8 months of the calendar year preceding the performance period; and (2) a second 12–month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12–month segment will continue to be excluded under §414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12–month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60–day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30–day claims run out.

(2) Amendments to Comply with the Bipartisan Budget Act of 2018

In the CY 2019 PFS proposed rule (83 FR 35887), we proposed to amend §414.1305 to modify the definition of low-volume threshold in accordance with section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018. Specifically, we requested comments on our proposals that for the 2020 MIPS payment year, we will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold determination period.

The following is a summary of the public comments received on our proposals and our responses:

Comment: A few commenters supported the technical amendments passed by Congress
in the Bipartisan Budget Act of 2018, specifically noting support for the proposal to not use Part B drugs for the low-volume threshold determinations, and to rely instead on covered professional services (instead of all Medicare Part B items and services) to determine MIPS eligibility. Other commenters supported that items or services beyond the PFS, especially Part B drugs, would not be subject to the MIPS payment adjustment factor or the MIPS additional payment adjustment factor.

Response: We appreciate the commenters’ support.

Comment: One commenter expressed concern about using covered professional services for low-volume threshold determinations because it could make it difficult for eligible clinicians and groups to predict whether they are subject or excluded from MIPS. Additionally, the commenter recommended that we provide timely notification based on the results of the first determination period.

Response: We understand that utilizing covered professional services rather than all Medicare Part B items and services is a different approach to calculating the low-volume threshold. For the CY 2018 and CY 2019 MIPS payment years, we have utilized two calculations in order to make low-volume threshold determinations: the number of patients and the amount of allowed charges for each eligible clinician or group. These calculations were based on the patients who were furnished any Part B item or service, and on the allowed charges for all Part B items and services. Beginning for the 2020 MIPS payment year, the calculations will instead be based only on covered professional services. A clinician may identify and monitor a claim to distinguish covered professional services from Part B items and services by calculating one professional claim line with positive allowed charges to be considered one covered professional service. In addition, we believe the quarterly snapshots will be helpful for
new TIN/NPIs and TINs created between the first segment and the second segment allowing them to see their preliminary eligibility status sooner. In addition, we believe these policies will allow clinicians to understand their eligibility determination as close to the beginning of the performance period as feasible.

After consideration of the public comments received, we are finalizing our proposal to amend §414.1305 to modify the definition of low-volume threshold to mean for the 2020 MIPS payment year, we will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold determination period.

(3) MIPS Program Details

In the CY 2019 PFS proposed rule (83 FR 35887), we requested comments on our proposal to modify §414.1310 to specify in paragraph (a), Program Implementation, that except as specified in paragraph (b), MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019. We also requested comments on our proposal to revise §414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in §414.1305) and does not elect, as discussed in section III.I.4.e. of this final rule, to report on applicable measures and activities under MIPS. Finally, we requested comments on our proposal to revise §414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c)
of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

We did not receive any comments regarding these proposals.

We are finalizing our proposal to modify §414.1310 to specify in paragraph (a), Program Implementation, that except as specified in paragraph (b), MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019. We are also finalizing our proposal to revise §414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in §414.1305) and does not elect, as discussed in section III.I.4.e. of this final rule, to report on applicable measures and activities under MIPS. Finally, we are finalizing our proposal to revise §414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c) of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

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

In the CY 2018 Quality Payment Program final rule (82 FR 53591), we received several comments in response to the proposed rule regarding adding a third criterion of items and services for defining the low-volume threshold. We refer readers to that rule for further details.

As discussed in the CY 2019 PFS proposed rule (83 FR 35887) for the 2021 MIPS payment year and future years, we proposed to add one additional criterion to the low-volume threshold determination -- the minimum number of covered professional services furnished to
Part B-enrolled individuals by the clinician. Specifically, we requested comments on our proposal, for the 2021 MIPS payment year and future years, that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period will not exceed the low-volume threshold: (1) those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

For the third criterion, we proposed to set the threshold at 200 or fewer covered professional services furnished to Part B-enrolled individuals for several reasons. First, in the CY 2018 Quality Payment Program final rule (82 FR 53589 through 53590), although we received positive feedback from stakeholders on the increased low-volume threshold, we also heard from some stakeholders that they would like to participate in the program. Second, setting the third criterion at 200 or fewer covered professional services, combined with our proposed policy with respect to opting in to MIPS, allows us to ensure that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS. Finally, when we considered where to set the low–volume threshold for covered professional services, we examined two options: 100 or 200 covered professional services. For 100 covered professional services, there is some historical precedent. In the CY 2017 Quality Payment Program final rule (81 FR 77062), we finalized a low-volume threshold that excluded individual eligible clinicians or groups that have Medicare Part B allowed charges less than $30,000 or that provide care for 100 or fewer Part B-enrolled Medicare beneficiaries; we believe the latter criterion is comparable to 100 covered professional services. Conversely for 200 covered professional services, in the CY 2018 Quality Payment Program final rule with comment period (82 FR 53588), we discussed
that based on our data analysis, excluding individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to $90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries decreased the percentage of MIPS eligible clinicians that come from small practices. In addition, in the CY 2018 Quality Payment final rule (82 FR 53955), we codified at §414.1380(b)(1)(iv) that the minimum case requirements for quality measures are 20 cases, which both services thresholds being considered (100 or 200) exceed. We also codified at §414.1380(b)(1)(v) that the minimum case requirement for the all-cause hospital readmission measure is 200 cases, which only the 200 services threshold consideration exceeds. We believe that setting a threshold of 200 services for the third criterion, combined with our proposed policy for opting in to MIPS, strikes the appropriate balance between allowing a significant number of eligible clinicians the ability to opt-in (as described in this section) to MIPS and consistency with the previously established low-volume threshold criteria. In section VII.F.8.b. of this final rule, we estimated no additional clinicians would be excluded if we add the third criterion because a clinician that cares for at least 200 beneficiaries would have at least 100 or 200 services; however, we estimate 27,903 clinicians would opt-in with the low-volume threshold at 200 services, as compared to 12,242 clinicians if we did not add the third criterion. If we set the third criterion at 100 services, then we estimate 32,828 clinicians would opt-in.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the low-volume threshold criteria and the newly proposed criterion based on number of covered professional services. Many commenters noted this policy will reduce burden, will help mitigate adverse effects on solo and small or rural
practices, and combined with the opt-in policy, allow practices to transition into MIPS. Commenters specifically noted that the addition of the third criteria and the proposed opt-in policy will permit clinicians who are ready to participate if they had been previously excluded. Several commenters also mentioned the newly proposed criterion would increase the number of eligible clinicians that are able to participate in MIPS.

**Response:** We appreciate the commenters’ support.

**Comment:** One commenter noted concern that MIPS reporting requirements may place significant financial, administrative, and operational burdens on clinicians treating a low volume of Medicare patients.

**Response:** It is important to note that clinicians who treat a low-volume of Part B Medicare beneficiaries may be excluded from MIPS if they fall below the low-volume threshold.

**Comment:** Many commenters opposed the low-volume threshold criteria because they noted the thresholds for the individual criteria are too high and excluded too many clinicians and added complexity. Many of these commenters stated that the proposed low-volume threshold limits the number of clinicians in the budget neutral pool and effectively precludes MIPS eligible clinicians with good performance from earning more than a nominal payment adjustment. Several commenters expressed concern that eligible clinicians who make large financial commitments and organizational infrastructure modifications to obtain designation as exceptional performers would be adversely affected. A few commenters noted that practices with these types of clinicians do not have large compliance staff and other resources that larger groups have, and therefore, it may be difficult for these clinicians to report and navigate the program with short notice. Many commenters also stated the proposed low-volume threshold would not move the Quality Payment Program toward value and could jeopardize clinicians,
particularly those in small or rural practices, by leaving them unprepared should they become
MIPS eligible. One commenter expressed concern that the threshold could make it difficult to
benchmark data because fewer practices would be expected to participate in the program. One
commenter requested lowering the performance threshold to the $30,000 in Part B claims or 100
Part B patients threshold that we utilized for 2017 MIPS performance period or lowering the
criteria for the opt-in policy. A few commenters recommended that we consider revisiting the
low-volume thresholds to increase the percentage of clinicians that are eligible.

Response: We believe that the proposed low-volume threshold strikes the correct balance
by including a sufficient number of clinicians, while excluding those who are not quite ready to
participate and need additional time to prepare, such as clinicians in small and rural practices.
The addition of the third criterion for covered professional services, in conjunction with the opt-
in policy, creates a highly-desired opportunity to join MIPS and provides new flexibility for
clinicians otherwise excluded to drive value and improve patient outcomes when they are
prepared to meaningfully participate. We have heard feedback from many clinicians indicating
the desire to participate in MIPS. This feedback was especially prominent from clinicians in
small practices who were initially included in the 2017 performance year, but excluded in 2018
due to the increase in the low-volume threshold. The addition of the third criterion for covered
professional services, in conjunction with the opt-in policy, provides new flexibilities to
participate in MIPS, which creates opportunities for clinicians to drive value and improve patient
outcomes. While we understand that the inclusion of any new element may add complexity, we
believe that this enhancement will benefit both clinicians and beneficiaries. We will work
closely with the clinician and stakeholder community to develop educational resources to help
clarify the requirements and reduce any potential confusion. Further, we do not believe that the
addition of the third criterion for covered professional services will exclude more clinicians, as clinicians who are currently treating over 200 beneficiaries would likely also be furnishing over 200 covered professional services. As discussed, in section III.I.3.j. of this final rule, we are finalizing our proposal to increase the MIPS performance threshold to 30 points and the exceptional performance bonus to 75 points in 2019. We believe that this will likely result in an evolving distribution of payment adjustments for high performing clinicians who have made the investments to advance quality improvement, enhance clinical practice, and improve outcomes for beneficiaries.

We understand that some MIPS eligible clinicians may work in small group practices and may not have the same resources as a large group. As discussed in the proposed rule (83 FR 35882) we intend to continue to offer tailored flexibilities to help these clinicians to participate in the program. For example, we are finalizing 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 to amend our regulatory text to allow small practices to continue using the Medicare Part B claims collection type and submission types, either as an individual or as a group. Finally, small practices may continue to choose to participate in MIPS as a virtual group. In addition, we will continue offering the voluntary reporting option, and encourage clinicians to pursue this pathway so that they can familiarize themselves with the program requirements and prepare to participate in future years. We clarify that for the first several years of MIPS, which we view as transitional, we anticipate that the distribution of MIPS payment adjustments will be spread
across many more clinicians and groups due to the moderate performance thresholds and not necessarily because clinicians are excluded by the low-volume threshold. For example, in 2017, the performance threshold was set at 3 points, which resulted in an estimated participation rate of 91 percent of MIPS eligible clinicians. As discussed in section III.I.3.j. of this final rule, we are finalizing our proposal to increase the MIPS performance threshold to 30 points and the exceptional performance bonus to 75 points in 2019, which we anticipate will likely result in an evolving distribution of payment adjustments for high performing clinicians who have made the investments to advance quality improvement, enhance clinical practice, and improve outcomes for beneficiaries.

We do not believe that the total amount of dollars available for the payment adjustments is low because too many clinicians are excluded from the program. After incorporating the data submitted for the 2017 MIPS performance period (which we refer to as Quality Payment Program Year 1 data) to estimate the CY 2021 MIPS payment year, an estimated three-quarters (approximately $66.6B) of all PFS dollars will be included in the CY 2021 MIPS payment year. Of the remaining one-quarter (approximately $23.2B), only 2 percent (or less than 1 percent of total PFS dollars) were associated with clinicians who did not meet the low-volume threshold. The remaining clinicians excluded from the budget neutral payment adjustments were Qualifying APM Participants, clinicians with ineligible specialties, and newly enrolled clinicians (11 percent of total PFS dollars). We considered the impact of lowering the low-volume threshold to $30,000/100 beneficiaries/100 covered professional services from the finalized low-volume threshold of this final rule based on the budget neutrality distributions and the size of the total payments. As seen in Figure 1, reducing the low-volume threshold to $30,000/100
beneficiaries/100 covered professional services)\textsuperscript{16} leads to an increase in the number of MIPS eligible clinicians (by approximately 73,000 clinicians) and on the dollars available in the budget neutral pool ($131M), but has minimal impact on the maximum possible positive payment adjustment. The majority of clinicians excluded from MIPS with the higher low-volume threshold are clinicians in small practices with fewer than 15 clinicians. We understand the importance of ensuring meaningful participation in the program. We will continue to strike a balance between ensuring sufficient participation in MIPS while also addressing the needs of small practices that may find it difficult to meet the program requirements.

\textbf{FIGURE 1: Budget neutral pool for redistribution and maximum payment adjustment for different low-volume thresholds. (Estimates apply CY2019 MIPS performance period final policies)*}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|}
\hline
 & $30,000/100$ beneficiaries/100 covered professional services & $90,000/200$ beneficiaries/200 covered professional services \\
\hline
\textbf{Budget neutral pool for redistribution} & $441$ & $310$ \\
\hline
\textbf{Maximum payment adjustment} & 5.0\% & 4.7\% \\
\hline
\textbf{Number of MIPS Eligible Clinicians} & 871,238 & 797,990 \\
\hline
\end{tabular}
\end{table}

\textit{Data: CY 2019 Quality Payment Program Final Rule Regulatory Impact Analysis data; with 33 percent opt-in assumption. *The estimates presented only reflect the impact of lowering the low-volume threshold. All other model specifications are reflective of CY 2019 performance period finalized policies and the data sources described in the regulatory impact analysis of this final rule.***}

\textsuperscript{16}The estimated values when the threshold is set to $30,000/100$ beneficiaries/100 covered professional services are not reflective of actual MIPS results for the 2019 MIPS payment year. There are slight differences in data sources and methods compared to the 2019 MIPS payment year such as the low-volume threshold in this model is based on covered PFS services and the model assumes a 33 percent opt-in assumption and uses the QP thresholds for the 2019 QP performance period.
Comment: One commenter encouraged us to continue reviewing the low-volume threshold annually to ensure that the low-volume threshold serves the purpose of excluding those for which the work of MIPS reporting would outweigh the number of Medicare beneficiaries impacted. A few commenters stated that the burden and cost of reporting for those who do not exceed the low-volume threshold far exceeds any possible benefit.

Response: We are committed to continuing program simplification and burden reduction as we move into future years, including identifying additional opportunities to help clinicians successfully participate. We will continue to assess the low-volume threshold, as needed, to help reduce burden for clinicians, especially those in small and rural practices, who still find participation challenging. We believe that it is important to implement the low-volume threshold in a way that provides more time for clinicians to familiarize themselves with the performance requirements under MIPS and, most importantly, prepare to drive clinical quality improvement and improved outcomes for all Medicare beneficiaries. We refer readers to the regulatory impact analysis in section VII.F.8.b. of this final rule for further details on the burden and cost of reporting.

Comment: A few commenters requested that we clarify how a covered professional service would count when calculating the low-volume threshold. Other commenters supported defining the concept of a covered professional service as a single billing of a CPT code. One commenter suggested 15-minute increments as the defining characteristic of a professional service.

Response: For the CY 2018 and CY 2019 MIPS payment years, we have utilized two calculations in order to make low-volume threshold determinations: the number of patients and the amount of allowed charges for each eligible clinician or group. These calculations were
based on the patients who were furnished any Part B item or service, and on the allowed charges for all Part B items and services. Beginning for the 2020 MIPS payment year, the calculations will instead be based on covered professional services rather than all Part B items and services.

Comment: One commenter requested clarification on the definition of allowed charges for the low-volume threshold. The commenter asked if allowed charges is equivalent to the full PFS amount or the PFS amount minus the 20 percent co-pay. The commenter also asked about the applicable Multiple Procedure Payment Reduction for a given session. The commenter noted that each option would result in a different dollar amount.

Response: In general, allowed charges refers to the maximum amount Medicare will pay for a covered professional service under the PFS, which is the PFS fee schedule amount reduced by the applicable beneficiary co-payment. For purposes of MIPS low-volume threshold determinations, allowed charges are calculated before any Multiple Procedure Payment Reduction is applied. We refer readers to the CY 2018 Quality Payment Program final rule with comment period (82 FR 53578 through 53579) where we discuss the items and services to which the MIPS payment adjustment could be applied under Part B.

Comment: A few commenters requested we outline a plan for the low-volume threshold, such as a roadmap approach in which we propose and adopt lower thresholds for several performance years at a time. Additionally, the commenters requested that we describe if CMS has plans to include currently excluded clinicians in the MIPS program in the future. A few commenters asked for a report on the number of low-volume clinicians that elect to be eligible and for us to use this experience to modify the low-volume threshold criteria in future years to move more clinicians into value-based programs.
Response: We agree that providing more clarity and stability into the future of MIPS would be helpful and are interested in working with stakeholders on what such future changes should look like. We are working to provide as much consistency as possible for the low-volume threshold while being flexible and considering changing needs. We note that we are finalizing the low-volume threshold for the 2021 MIPS payment year and future years, as well. Regarding a report on the number of clinicians who are excluded due to the low-volume threshold but elect to opt-in to MIPS, we will consider this suggestion for our MIPS Experience Report.

After consideration of the public comments received, we are finalizing our proposal to modify the definition of low-volume threshold at §414.1305, to mean that for the 2021 MIPS payment year and future years, that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period will not exceed the low-volume threshold: (1) those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

(5) Low-Volume Threshold Opt-in

In the CY 2018 Quality Payment Program proposed rule (82 FR 30026), we proposed the option to opt-in to MIPS participation if clinicians might otherwise be excluded under the low-volume threshold. We received general support from comments received on that final rule (82 FR 53589). However, we did not finalize the proposal for the 2019 MIPS performance period at that time. We were concerned that we would not be able to operationalize this policy in a low-burden manner to MIPS eligible clinicians as it was proposed.
After consideration of operational and user experience implications of an opt-in policy, we proposed an approach we believed could be implemented in a way that provides the least burden to clinicians. As discussed in the CY 2019 PFS proposed rule (83 FR 35887 through 35890), we proposed to modify §414.1310(b)(1)(iii) to provide that beginning with the 2021 MIPS payment year, if an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold determinations, including as defined by dollar amount (less than or equal to $90,000) or number of beneficiaries (200 or fewer), or number of covered professional services (200 or fewer), then such eligible individual or group may choose to opt-in to MIPS.

This policy would apply to individual eligible clinicians and groups who exceed at least one, but not all, of the low-volume threshold criteria and would otherwise be excluded from MIPS participation as a result of the low-volume threshold. We believed that it would be beneficial to provide, to the extent feasible, such individual eligible clinicians and groups with the ability to opt-in to MIPS. Conversely, this policy would not apply to individual eligible clinicians and groups who exceed all of the low-volume threshold criteria, who unless otherwise excluded, are required to participate in MIPS. In addition, this policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria, who would be excluded from MIPS participation without the ability to opt-in to MIPS. Although we believe we proposed the appropriate balance for the low-volume threshold elements and the opt-in policy, we requested comments on other low-volume threshold criteria and supporting justification for the recommended criteria.

Under the proposed policies, we estimated clinician eligibility based on the following (we refer readers to the regulatory impact analysis in section VII.F.8.b. of this final rule for further details on our assumptions): (1) eligible because they exceed all three criteria of the low-volume
threshold and are not otherwise excluded (estimated 770,000 based on our assumptions of who did individual and group reporting); (2) eligible because they exceed at least one, but not all, of the low-volume threshold criteria and elect to opt-in (estimated 28,000 for a total MIPS eligible clinician population of approximately 798,000); (3) potentially eligible if they either did group reporting or elected to opt-in\(^{17}\) (estimated 390,000); (4) excluded because they do not exceed any of the low-volume threshold criteria (estimated 78,000); and (5) excluded due to non-eligible specialty, newly enrolled, or QP status (estimated 209,000).

We proposed that applicable eligible clinicians who meet one or two, but not all, of the criteria to opt-in and are interested in participating in MIPS would be required to make a definitive choice to either opt-in to participate in MIPS or choose to voluntarily report before data submission (83 FR 35888). If they do not want to participate in MIPS, they will not be required to do anything and will be excluded from MIPS under the low-volume threshold. For those who do want to participate in MIPS, we considered the option of allowing the submission of data to signal that the clinician is choosing to participate in MIPS. However, we anticipated that some clinicians who utilize the quality data code (QDC) claims submission type may have their systems coded to automatically append QDCs on claims for eligible patients. We were concerned that they could submit a QDC code and inadvertently opt-in when that was not their intention.

For individual eligible clinicians and groups to make an election to opt-in or voluntarily report to MIPS, they will make an election via the Quality Payment Program portal by logging into their account and simply selecting either the option to opt-in (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). Once the

\(^{17}\) A clinician may be in a group that we estimated would not elect group reporting, however, the group would exceed the low-volume threshold on all three criteria if the group elected group reporting. Similarly, an individual or group may exceed at least one but not all of the low-volume threshold criteria, but we estimated the clinician or group would not elect to opt-in to MIPS. In both cases, these clinicians could be eligible for MIPS if the group or individual makes choices that differ from our assumptions.
eligible clinician has elected to participate in MIPS, the decision to opt-in to MIPS will be irrevocable and cannot be changed for the applicable performance period. Clinicians who opt-in will be subject to the MIPS payment adjustment during the applicable MIPS payment year. Clinicians who do not decide to opt-in to MIPS will remain excluded and may choose to voluntarily report. Such clinicians will not receive a MIPS payment adjustment factor. To assist commenters in providing pertinent comments, we developed a website that provided design examples of the different approaches to MIPS participation in CY 2019. The website utilized wireframe (schematic) drawings to illustrate the three different approaches to MIPS participation: voluntary reporting to MIPS, opt-in reporting to MIPS, and required to participate in MIPS. The website provided specific matrices illustrating potential stakeholder experiences when opting-in or voluntarily reporting.

The option to opt-in to participate in the MIPS as a result of an individual eligible clinician or group exceeding at least one, but not all, of the low-volume threshold elements differs from the option to voluntarily report to the MIPS as established at §414.1310(b)(2) and (d). Individual eligible clinicians and groups opting-in to participate in MIPS will be considered MIPS eligible clinicians, and therefore subject to the MIPS payment adjustment factor; whereas, individual eligible clinicians and groups voluntarily reporting measures and activities for the MIPS are not considered MIPS eligible clinicians, and therefore not subject to the MIPS payment adjustment factor. MIPS eligible clinicians and groups that made an election to opt-in will be able to participate in MIPS at the individual, group, or virtual group level for that performance period. Eligible clinicians and groups that are excluded from MIPS, but voluntarily report, are able to report measures and activities at the individual or group level; however, such
eligible clinicians and groups are not able to voluntarily report for MIPS at the virtual group level.

In Table 31, we provided possible scenarios regarding which eligible clinicians may be able to opt-in to MIPS depending upon their beneficiary count, dollars, and covered professional services if the proposed opt-in policy was finalized.

<table>
<thead>
<tr>
<th>Beneficiaries</th>
<th>Dollars</th>
<th>Covered Professional Services</th>
<th>Eligible for Opt-in</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 200</td>
<td>≤ 90K</td>
<td>≤ 200</td>
<td>Excluded not eligible to Opt-in</td>
</tr>
<tr>
<td>≤ 200</td>
<td>≤ 90K</td>
<td>&gt; 200</td>
<td>Eligible to Opt-in, Voluntarily Report, or Not Participate</td>
</tr>
<tr>
<td>≤ 200</td>
<td>&gt; 90K</td>
<td>≤ 200</td>
<td>Eligible to Opt-in, Voluntarily Report, or Not Participate</td>
</tr>
<tr>
<td>&gt; 200</td>
<td>≤ 90K</td>
<td>&gt; 200</td>
<td>Eligible to Opt-in, Voluntarily Report, or Not Participate</td>
</tr>
<tr>
<td>&gt; 200</td>
<td>&gt; 90K</td>
<td>&gt; 200</td>
<td>Not eligible to Opt-in, Required to Participate</td>
</tr>
</tbody>
</table>

We recognize that the low-volume threshold opt-in option may expand MIPS participation at the individual, group, and virtual group levels. For solo practitioners and groups with 10 or fewer eligible clinicians (including at least one MIPS eligible clinician) that exceed at least one, but not all, of the elements of the low-volume threshold and are interested in participating in MIPS via the opt-in and doing so as part of a virtual group, such solo practitioners and groups will need to make an election to opt-in to participate in the MIPS. Therefore, beginning with the 2021 MIPS payment year, we proposed that a virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group will be treated as a MIPS eligible clinician for the applicable MIPS payment year.
During the virtual group election process, the official virtual group representative of a virtual group submits an election to participate in the MIPS as a virtual group to CMS prior to the start of a performance period (82 FR 53601 through 53604). The submission of a virtual group election includes TIN and NPI information, which is the identification of TINs composing the virtual group and each member of the virtual group. As part of a virtual group election, the virtual group representative is required to confirm through acknowledgement that a formal written agreement is in place between each member of the virtual group (82 FR 53604). A virtual group may not include a solo practitioner or group as part of a virtual group unless an authorized person of the TIN has executed a formal written agreement.

For a solo practitioner or group that exceeds only one or two elements of the low-volume threshold, an election to opt-in to participate in the MIPS as part of a virtual group would be represented by being identified as a TIN that is included in the submission of a virtual group election. Such solo practitioners and groups opting-in to participate in the MIPS as part of a virtual group would not need to independently make a separate election to opt-in to participate in the MIPS. We note that being identified as a TIN in a submitted virtual group election, any such TIN (represented as a solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold elements during the MIPS determination period is signifying an election to opt-in to participate in MIPS as part of a virtual group and recognizing that a MIPS payment adjustment factor would be applied to any such TIN based on the final score of the virtual group. For a virtual group election that includes a TIN determined to exceed at least one, but not all, of the low-volume threshold elements during the MIPS determination period, such election would have a precedence over the eligibility determination made during the MIPS determination period pertaining to the low-volume threshold and as a result, any such TIN would be considered MIPS
eligible and subject to a MIPS payment adjustment factor due the virtual group election. Furthermore, we note that a virtual group election would constitute an election to opt-in to participate in MIPS and any low-volume threshold determinations that result from segment 2 data analysis of the MIPS determination period would not have any bearing on the virtual group election. Thus, a TIN included as part of a virtual group election that submitted prior to the start of the applicable performance period and does not exceed at least one element of the low-volume threshold during segment 2 of the MIPS determination period, such TIN would be considered MIPS eligible and a virtual group participant by virtue of the virtual group’s election to participate in MIPS as a virtual group that was made prior to the applicable performance period. For virtual groups with a composition that may only consist of solo practitioners and groups that exceed at least one, but not all of the low-volume threshold elements, such virtual groups are encouraged to form a virtual group that would include a sufficient number of TINs to ensure that such virtual groups are able to meet program requirements such as case minimum criteria that would allow measures to be scored. For example, if a virtual group does not have a sufficient number of cases to report for quality measures (minimum of 20 cases per measures), a virtual group would not be scored on such measures (81 FR 77175).

We further noted that APM Entities in MIPS APMs, which meet one or two, but not all, of the low-volume threshold elements to opt-in and are interested in participating in MIPS under the APM scoring standard, would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS. For such APM Entities to make an election to opt-in to MIPS, they would make an election via a similar process that individual eligible clinicians and groups will use to make an election to opt-in. Once the APM Entity has elected to participate in MIPS, the decision to opt-in to MIPS is irrevocable and cannot be changed for the performance
period in which the data was submitted. Eligible clinicians in APM Entities in MIPS APMs that opt-in would be subject to the MIPS payment adjustment factor. APM Entities in MIPS APMs that do not decide to opt-in to MIPS cannot voluntarily report.

Additionally, we proposed for applicable eligible clinicians participating in a MIPS APM, whose APM Entity meets one or two, but not all, of the low-volume threshold elements rendering the option to opt-in and does not decide to opt-in to MIPS, that if their TIN or virtual group does elect to opt-in, it does not mean that the eligible clinician is opting-in on his/her own behalf, or on behalf of the APM Entity, but that the eligible clinician is still excluded from MIPS participation as part of the APM Entity even though such eligible clinician is part of a TIN or virtual group. This is necessary because low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMs, and therefore, the low-volume threshold opt-in option should similarly be executed at the APM Entity level rather than at the individual eligible clinician, TIN, or virtual group level. Thus, in order for an APM Entity to opt-in to participate in MIPS at the APM Entity level and for eligible clinicians within such APM Entity to be subject to the MIPS payment adjustment factor, an election would need to be made at the APM Entity level in a similar process that individual eligible clinicians and groups would use to make an election to opt-in to participate in MIPS.

We requested comments on our proposals: (1) to modify §414.1305 for the low-volume threshold definition at paragraph (3) to specify that, beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare
Part B-enrolled individuals; (2) that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report; and (3) to modify §414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable payment year.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the opt-in policy as proposed. Many commenters supported that clinicians electing to opt-in may have either a negative or positive payment adjustment. One commenter stated the opportunity for clinicians to opt-in to MIPS will help to offset the additional exclusions resulting from the addition of a third low-volume criterion. A few commenters noted the opt-in provides a participation opportunity for clinicians who bill low-cost services and would not otherwise exceed the low-volume threshold based on allowed charges. Other commenters noted that MIPS is the only way for MIPS eligible clinicians to earn a meaningful MIPS payment adjustment factor and opt-in is the only way for eligible clinicians who do not exceed the low-volume threshold to participate. Many commenters noted the policy provides flexibility and may encourage those clinicians who are not ready to have their payment affected by MIPS performance to test their ability to gather and
submit performance data and gain experience with MIPS.

**Response:** We appreciate the commenters’ support. We note that if an eligible clinician chooses to opt-in to MIPS then they will be subject to the MIPS payment adjustment during the applicable MIPS payment year. If a clinician is eligible to opt-in but does not want to participate in MIPS, and be subject to the MIPS payment adjustment, then we would encourage clinicians to voluntarily report.

**Comment:** Many commenters opposed the opt-in policy. A few commenters noted concern that the opt-in will reduce incentives to participate in MIPS, with one specifically stating it does not align with the agency’s stated goal for MIPS to be a pathway to eventual participation in APMs. Some commenters also noted concern with how the opt-in may affect the overall scores, stating that (1) the additional clinicians who voluntarily opt-in are likely to be above the MIPS threshold, and therefore may reduce the amount of positive MIPS payment adjustment factors for clinicians who are required to participate, (2) the opt-in will likely continue to flatten the clinician’s final score, lowering the overall aggregate increase, and (3) if too many eligible clinicians are excluded, positive payment adjustments would be insufficient to help offset the investments practices health systems must make to succeed under MIPS. Another commenter stated that CMS should identify a core set of data on MIPS and its various exclusions to be updated annually in conjunction with the proposed rule to allow stakeholders to follow the impacts of those exclusions longitudinally.

**Response:** While we encourage clinicians who are excluded to opt-in to the program once they are prepared to meaningfully participate as a means of driving value and improving outcomes for more Medicare beneficiaries, we believe that the opt-in policy does not undermine APM participation or the transition of clinicians from MIPS to APMs because the opt-in policy
is applied at the APM Entity level for clinicians and groups participating in APMs. For this final rule, we analyzed the impact of the opt-in policy by running models which incorporate the Quality Payment Program Year 1 submissions data. The models include eligibility without opt-in, opt-in based on a random sample of 33 percent of clinicians who can elect to opt-in, and opt-in where only high performers (that is, clinicians who can anticipate a positive adjustment) elect to opt-in. To model the situation where only high performers would opt-in to MIPS, we assumed 100 percent of clinicians with final scores above the additional performance threshold would opt-in and 50 percent of clinicians above the performance threshold but below the additional performance threshold would opt-in. We observed a very modest impact to the payment adjustment irrespective of the opt-in assumption used. Please see Figure 2 for the model by opt-in assumption. Lastly, we appreciate the request for additional core data to be made available, we will continue to work with stakeholders to identify the information that is valuable and release it accordingly.

**Comment:** Many commenters supported an opt-in policy, but believed the policy should be available to more clinicians. Of these commenters, most believed that the opt-in should be available even if the clinician did not exceed any of the low-volume criteria. A few commenters indicated that MIPS should be voluntary for all clinicians. One commenter requested that we make the opt-in policy retroactive to the MIPS 2018 performance period for year-to-year consistency, simplification, and to improve overall participation. Another commenter stated that the clinicians who switch practices in the last three months of MIPS performance period should be able to opt-in.

**Response:** We do not believe that we have the flexibility to allow any clinician who wishes to participate in MIPS to opt-in nor to retroactively apply the opt-in policy to the 2018
MIPS performance period. Finally, as discussed in the section III.I.3.b. of this final rule, during the final 3 months of the calendar year in which the performance period occurs, in general, we do not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. To clarify if an eligible clinician switches to an existing TIN or a new TIN they may be able to participate in MIPS as a group. However, they would not be able to participate as an individual.

Comment: Several commenters supported the proposal that eligible clinicians who are eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS. One commenter agreed that an affirmative election to report is necessary to avoid confusion and possible inadvertent claims submissions that might involuntarily opt-in a clinician to MIPS.

Response: We agree that even eligible clinicians submitting MIPS data via claims must make an affirmative election.

Comment: Several commenters sought clarification on the deadline to opt-in. A few commenters wondered if clinicians can choose to wait until the data submission deadline for a performance year, or whether they must elect to opt-in sooner than that. One commenter recommended that clinicians should have a deadline of no later than the last day in the month of February, or perhaps the 15th of March, for the performance period in which they intend to participate. This commenter stated that allowing the choice to opt-in at any point during the performance period will only increase participatory rates among clinicians or groups who have knowledge of favorable outcomes and will excuse those whose outcomes were undesirable. One commenter encouraged us to allow clinicians to opt-in at the time of data submission, as this would create the least amount of burden on clinicians who wish to opt-into the program.
Another commenter urged us to allow an opt-in decision at any point during the data submission window and to provide confirmation of the decision to opt-in. Another commenter stated that we should not make the opt-in decision irrevocable.

Response: We would like to create a process for eligible clinicians who wish to opt-in to MIPS that is the least burdensome but also provides the clinician with the most flexibility. We are exploring if we can operationally allow clinicians to opt-in at any time prior to the submission period and will provide further guidance via subregulatory guidance if this becomes available. We are finalizing at §414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. We agree that allowing clinicians the choice to opt-in at any point during the performance period may increase the potential that only high performers will opt-in, but we believe that this policy accounts for clinicians who identified in the second segment of the MIPS determination period. Also, we plan to monitor this issue and will address it through future rulemaking if necessary. Finally, regarding the opt-in decision being irrevocable, we believe it is necessary for the clinician to make a definitive decision regarding their participation in MIPS. If the decision to opt-in was not definitive then we believe the potential for a clinician to have an unfair advantage is increased by their ability to review their final feedback and scoring information available at submissions and subsequently alter their participation decision.
Comment: One commenter noted that with the manual election to indicate opt-in, the need for a low-volume threshold criterion based on professional services should not make a difference in a clinician's ability to opt-in. Other commenters opposed the requirement for the eligible clinician to manually opt-in, noting that it would add administrative burden. Another commenter stated that it is unnecessary to create a MIPS opt-in policy for some low-volume clinicians as they may not meet the case minimums for measures.

Response: We do not believe that the manual election to opt-in has relevance to the clinician’s covered professional services. We are providing the third criterion of covered professional services to expand the number of clinicians eligible to opt-in to the program. Regarding the manual election to opt-in, we believe this is the least burdensome approach to ensuring that clinicians are making an informed decision regarding their MIPS participation. We believe that most MIPS eligible clinicians that provide at least 200 covered professional service will be able to meet the case minimums for measures.

Comment: A few commenters requested additional clarification on the implication of the opt-in policy on the MIPS payment adjustment and on how we estimated the number of opt-in clinicians.

Response: We described our approach to estimating the opt-in policy in the regulatory impact analysis of the CY 2019 PFS proposed rule (83 FR 36057 through 36068). We sought comment on this approach and refer readers to the Regulatory Impact Analysis (RIA) in section VII. of this final rule for additional information. The RIA for this final rule examined the impact of the opt-in policy on payment adjustments by using two alternate opt-in assumptions: (1) if only clinicians with scores above the performance threshold opt-in (the actual opt-in is likely to be lower than this estimated number of clinicians opting-in); and (2) if none of the clinicians
elected to opt-in. See Figure 2 for a summary of the results. As shown in Figure 2, the opt-in policy was found to have a small impact on the budget neutral pool when we assumed a random 33 percent of clinicians would opt-in irrespective of their performance and a minimal impact on payment adjustments regardless of the opt-in assumption used. Given these findings, we chose to use the 33 percent opt-in assumption for all CY 2019 performance period estimates.

**FIGURE 2: Budget Neutral Pool for Redistribution and Maximum Payment Adjustment for Different Opt-in Assumptions**

![Graph showing budget neutral pool for redistribution and maximum payment adjustment for different opt-in assumptions](image)


**Comment:** A few commenters supported the proposal to only allow APM entities to opt-in as a group. One commenter urged us to explain in-depth the application of the low-volume threshold opt-in option for MIPS APM TINs.

**Response:** We explained the application of the low-volume threshold for APM Entities in MIPS APMs in detail in the CY 2019 PFS proposed rule (83 FR 35889) and refer readers to that discussion.

**Comment:** One commenter did not agree that performance category data submitted by a third party intermediary needed a separate opt-in election. The commenter stated that in these instances, the clinician or group has chosen to engage a third party intermediary for MIPS
reporting which the commenter believed is an affirmative event demonstrating intent to participate in the MIPS program. The commenter also noted that for clinicians or small-groups submitting quality data via QDC codes on claims, if those clinicians and/or small groups also submit any category data via a third-party intermediary, the Quality Payment Program portal, or the CMS Web Interface, that should be considered as an opt-in decision. One commenter requested that we provide a technical interface/API which allows clinicians and groups to opt-in through the service of third party intermediaries.

Response: We want to ensure that clinicians are making an informed decision regarding opting-in to participate in MIPS. It is imperative that they make a definitive decision since clinicians who opt-in will be subject to the MIPS payment adjustment during the applicable MIPS payment year. We believe that an election to opt-in to MIPS must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. In addition, in response to public comments, in instances where a third party intermediary is representing a MIPS eligible clinician, the third party intermediary must be able to transmit the clinician’s opt-in decision to CMS. We refer readers to section III.I.3.k. of this final rule for more information regarding third party intermediary requirements.

Comment: A few commenters requested information for clinicians and groups to make an informed choice about the opt-in. One commenter urged us to make it clear as to whether a clinician and group is eligible to opt-in to MIPS, what this decision could mean in terms of reducing or increasing their Medicare payments, and when the decision would be final. A few commenters requested the eligibility information prior to the start of the performance period, so that MIPS eligible clinicians and groups who want to opt-in to MIPS have the information
necessary to make an informed choice about their participation options. Other commenters requested information on how the two MIPS determination periods work with the opt-in policy.

Response: We understand that it is important for clinicians to know their eligibility status prior to the performance period. We are working to provide quarterly snapshots, if feasible. We believe these quarterly snapshots will provide important information to clinicians so that they may make informed decisions regarding whether they should opt-in to participate in MIPS. It is important to note that the quarterly snapshots are being provided for informational use only and not final until after the second segment of the MIPS determination period closes (which is September 30 of the calendar year in which the applicable performance period occurs) and a reconciliation occurs. Since the quarterly snapshots are not final this information is subject to change and should not be considered the final eligibility determination. The eligibility determination will be made after a reconciliation of the first and second segment of the MIPS determination period. We are finalizing at §414.1310(b)(1)(iii) under Applicability to specify exclusions that include, beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year.

Comment: One commenter recommended that we change the name of the voluntary participation option to ensure that clinicians do not confuse that option with opt-in participation. Since a voluntary participant is only reporting data, they suggested changing that category to Voluntary Reporting to ensure this is not confused with opt-in Participation.
Response: We agree and are modifying the participation terms on the Quality Payment Program website to provide clear directions. Therefore, we note that when clinicians are reporting for MIPS they may enter the Quality Payment Program portal to choose the appropriate MIPS participation. For those eligible clinicians or groups who exceed all three criteria of the low-volume threshold their participation will be automatically selected as they are required to participate. For individual eligible clinicians and groups who are qualified they may make an election to by choosing to either: agree to opt-in participation or to voluntarily report to MIPS, the clinician would make an election via the Quality Payment Program portal by logging into their account and simply selecting either the option to opt-in participation (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). So the three options when reporting data through the Quality Payment Program portal are: voluntary reporting, opt-in participation, and required to participate in MIPS. We referred readers to the Quality Payment Program at qpp.cms.gov/design-examples to review the finalized wireframe drawings.

After consideration of the public comments received, we are finalizing our proposals: (1) to modify §414.1305 for the low-volume threshold definition at paragraph (3) to specify that, beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals; (2) that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the
clinician is choosing to not report; and (3) to modify §414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under §414.1315 constitutes an election under this paragraph and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can constitute an election under this paragraph and result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year. We note that a virtual group election does not constitute a Partial QP election under revised §414.1310(b)(1)(ii). In order for an individual eligible clinician or APM Entity with a Partial QP status to explicitly elect to participate in MIPS and be subject to the MIPS payment adjustment factor, such individual eligible clinician or APM Entity would make such election during the applicable performance period as a Partial QP status becomes applicable and such option for election is warranted.

(6) Part B Services Subject to MIPS Payment Adjustment

Section 1848(q)(6)(E) of the Act, as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018, provides that the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor, apply to the amount otherwise paid under Part B with respect to covered professional services (as defined in subsection (k)(3)(A) of the Act) furnished by a MIPS eligible
clinician during a year (beginning with 2019) and with respect to the MIPS eligible clinician for such year.

In the CY 2019 PFS proposed rule (83 FR 35890), we requested comments on our proposal to amend §414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. We are making this change beginning with the first MIPS payment year and note that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician. We refer readers to section III.I.3.j. of this final rule for further details on this modification.

The following is a summary of the public comments received on our proposals and our responses:

Comment: One commenter stated that they support the technical amendment made by Congress in the Bipartisan Budget Act of 2018 to clarify that items or services beyond the PFS, especially Part B drugs, should not be included when determining MIPS eligibility and applying the MIPS payment adjustment.

Response: We appreciate the commenters’ support.

After consideration of the public comments received, we are finalizing our proposal to amend §414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional
services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. We are making this change beginning with the first MIPS payment year and note that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician.

d. Partial QPs

(1) Partial QP Elections within Virtual Groups

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustments (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year.
We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity’s election for the group to participate in MIPS would result in MIPS participation (81 FR 77449). For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician’s actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP’s behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

In the CY 2018 Quality Payment Program final rule, we clarified that in the case of an eligible clinician participating in both a virtual group and an Advanced APM who has achieved Partial QP status, that the eligible clinician would be excluded from the MIPS payment adjustment unless the eligible clinician elects to report under MIPS (82 FR 53615). As discussed in the CY 2019 PFS proposed rule (83 FR 35890 through 35891), we incorrectly stated that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for all Partial QPs. As such, we also incorrectly stated that all eligible clinicians who participate in a virtual group and achieve Partial QP status would remain subject to the MIPS payment
adjustment due to their virtual group election to report under MIPS, regardless of their Partial QP election. We note that an election made prior to the start of an applicable performance period to participate in MIPS as part of a virtual group is separate from an election made during the performance period that is warranted as a result of an individual eligible clinician or APM Entity achieving Partial QP status during the applicable performance period. A virtual group election does not equate to an individual eligible clinician or APM Entity with a Partial QP status explicitly electing to participate in MIPS. In order for an individual eligible clinician or APM Entity with a Partial QP status to explicitly elect to participate in MIPS and be subject to the MIPS payment adjustment factor, such individual eligible clinician or APM Entity would make such election during the applicable performance period as a Partial QP status becomes applicable and such option for election is warranted. Thus, we are restating that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period does not constitute an explicit election to report under MIPS as it pertains to making an explicit election to either report to MIPS or be excluded from MIPS for individual eligible clinicians or APM Entities that have Partial QP status.

Related to this clarification, we are finalizing in section III.I.4.e.(3) of this final rule to clarify that beginning with the 2021 MIPS payment year, when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician has the option to make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, he or she will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician does not make any affirmatively election to report to MIPS, he or she will not be subject to MIPS.
reporting requirements and payment adjustments. As a result, beginning with the 2021 MIPS payment year, for eligible clinicians who are determined to be Partial QPs individually, we will not use the eligible clinician’s actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election.

Therefore, the finalized policy in section III.I.4.e.(3) of this final rule eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period will constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs individually and make no explicit election to either report to MIPS or be excluded from MIPS. We believe this change is necessary because QP status and Partial QP status, achieved at the APM Entity level or eligible clinician level, is applied to an individual and all of his or her TIN/NPI combinations, whereas virtual group participation is determined at the TIN level. Therefore, we do not believe that it is appropriate that the actions of the TIN in joining the virtual group should deprive the eligible clinician who is a Partial QP, whether that status was achieved at APM Entity level or eligible clinician level, of the opportunity to elect whether or not to opt-in to MIPS.

e. Group Reporting

We refer readers to §414.1310(e) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593) for a description of our previously established policies regarding group reporting.

In the CY 2018 Quality Payment Program final rule (82 FR 53593), we clarified that we consider a group to be either an entire single TIN or portion of a TIN that: (1) is participating in MIPS according to the generally applicable scoring criteria while the remaining portion of the TIN is participating in a MIPS APM or an Advanced APM according to the MIPS APM scoring
standard; and (2) chooses to participate in MIPS at the group level. We further clarify that we consider a group to be an entire single TIN that chooses to participate in MIPS at the group level. However, individual eligible clinicians (TIN/NPIs) within that group may receive a MIPS payment adjustment based on the APM scoring standard if they are on the participant list of a MIPS APM. We proposed to amend §§414.1310(e) and 414.1370(f)(2) to codify this policy and more fully reflect the scoring hierarchy as discussed in section III.I.3.h.(6) of this final rule.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53593), one of the overarching themes we have heard from stakeholders is that we make an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. We stated that in future rulemaking, we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier. In the CY 2018 Quality Payment Program proposed rule (82 FR 30027), we solicited public comments on the ways in which participation in MIPS at the sub-group level could be established. In addition, in the CY 2018 Quality Payment Program final rule (82 FR 53593), we sought comment on additional ways to define a group, not solely based on a TIN. Because there are several operational challenges with implementing a sub-group option, we did not propose any such changes to our established reporting policies in this final rule. Rather, we are considering facilitating the use of a sub-group identifier in the Quality Payment Program Year 4 through future rulemaking, as necessary. In addition, it has come to our attention that providing a sub-group option may provide potential gaming opportunities. For example, a group could manipulate scoring by creating sub-groups that are comprised of only the high performing clinicians in the group.
Therefore, we requested comment on implementing sub-group level reporting through a separate sub-group sub-identifier in the Quality Payment Program Year 4 and possibly future years of the program.

In the CY 2019 PFS proposed rule (83 FR 35891) we requested comments on the following: (1) whether and how a sub-group should be treated as a separate group from the primary group: for example, if there is 1 sub-group within a group, how would we assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the sub-group level; (2) whether all of the sub-group’s MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the sub-group’s final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level; (3) possible low burden solutions for identification of sub-groups: for example, whether we should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt-in that we proposed and is discussed in section III.I.3.c.(5) of this final rule; and (4) potential issues or solutions needed for sub-groups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group. We also welcomed comments on other approaches for sub-group reporting that we should consider. We received many comments on group reporting and will take them into consideration for future rulemaking.

f. Virtual Groups

(1) Background

We refer readers to §414.1315 and the CY 2018 Quality Payment Program final rule (82 FR 53593 through 53617) for our previously established policies regarding virtual groups.

(2) Virtual Group Election Process
We refer readers to §414.1315(c) and the CY 2018 Quality Payment Program final rule (82 FR 53601 through 53604) for our previously established policies regarding the virtual group election process.

We proposed to amend §414.1315(c) to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of the proposed policy modification discussed below (83 FR 35891 through 35892).

Under §414.1315(c)(2)(ii), an official designated virtual group representative must submit an election on behalf of the virtual group by December 31 of the calendar year prior to the start of the applicable performance period. In the CY 2018 Quality Payment Program final rule (82 FR 53603), we stated that such election will occur via e-mail to the Quality Payment Program Service Center using the following e-mail address for the 2018 and 2019 performance periods: MIPS_VirtualGroups@cms.hhs.gov. Beginning with the 2022 MIPS payment year, we proposed to amend §414.1315(c)(2)(ii) to provide that the election would occur in a manner specified by CMS. We anticipate that a virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group via a web-based system developed by CMS. We believe that a web-based system would be less burdensome for virtual groups given that the interactions stakeholders would have with the Quality Payment Program are already conducted via the Quality Payment Program portal, and would provide stakeholders with a seamless user experience. Stakeholders would be able to make a virtual group election in a similar manner to all other interactions with the Quality Payment Program portal and would no longer need to separately identify the appropriate e-mail address to submit such an election and e-mail an election outside of the Quality Payment Program portal. The
Quality Payment Program portal is the gateway and source for interaction with MIPS that contains a range of information on topics including eligibility, data submission, and performance reports. We believe that using the same web-based platform to make a virtual group election would enhance the one-stop MIPS interactive experience and eliminate the potential for stakeholders to be unable to identify or erroneously enter the e-mail address.

We solicited public comment on this proposal, which would provide for an election to occur in a manner specified by CMS such as a web-based system developed by CMS.

The following is a summary of the public comments received regarding the proposal to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of providing for an election to occur in a manner specified by CMS, such as a web-based system developed by CMS, and our responses.

**Comment:** Several commenters supported the proposal to facilitate virtual group elections through the Quality Payment Program portal, as opposed to e-mail, and indicated that the use of portal would be less burdensome for virtual groups and facilitate a more seamless user experience. A few commenters noted that the web-based system linked to the existing portal could give interested participants an easier means of connecting with other possible virtual group members. The commenters recommended that CMS explore the inclusion/development of a platform within the portal that would facilitate interactions and connections between parties interested in forming or joining a virtual group. Additionally, the commenters requested that CMS clearly outline and provide additional guidance on the election process via the Quality Payment Program web site. Another commenter recommended that CMS devise, as part of the portal, a direct way for clinicians to confirm their virtual group-eligibility status with 100
percent reliability, and eliminate potential human errors when using a Quality Payment Program representative as an intermediary.

Response: We will consider various means for providing information and guidance to virtual groups regarding the election process, and explore options for facilitating and supporting virtual group formation and providing virtual group eligibility via the Quality Payment Program portal in future years. It should be noted that all necessary information pertaining to virtual groups will be published on the CMS web site prior to the virtual group election period, which occurs during the calendar before the start of the applicable performance period.

After consideration of the public comments, we are finalizing our proposal at §414.1315(c) to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of providing for an election to occur in a manner specified by CMS, such as a web-based system developed by CMS.

(a) Virtual Group Eligibility Determinations

For purposes of determining TIN size for virtual group participation eligibility for the CY 2018 and 2019 performance periods, we coined the term “virtual group eligibility determination period” and defined it to mean an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable performance period and includes a 30-day claims run out (82 FR 53602). We proposed to modify the virtual group eligibility determination period beginning with the 2019 performance period (83 FR 35892 through 35893). We proposed to amend §414.1315(c)(1) to establish a virtual group eligibility determination period to mean an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar.
year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. The virtual group eligibility determination period aligns with the first segment of data analysis under the MIPS eligibility determination period. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. TIN size inquiries would be made through the Quality Payment Program Service Center. For TINs that inquire about their TIN size during such 5-month timeframe, it should be noted that any TIN size information provided is only for informational purposes and may be subject to change; official eligibility regarding TIN size and all other eligibility pertaining to virtual groups would be determined in accordance with the MIPS determination period and other applicable special status eligibility determination periods. The proposed modification would provide stakeholders with real-time information regarding TIN size for informational purposes instead of TIN size eligibility determinations on an ongoing basis (between July 1 and November 30 of the calendar year prior to the applicable performance period) due to technical limitations.

For the 2018 and 2019 performance periods, TINs could determine their status by contacting their designated TA representative as provided at §414.1315(c)(1); otherwise, the TIN’s status would be determined at the time that the TIN’s virtual group election is submitted. We proposed to amend §414.1315(c)(1) to remove this provision since the inquiry about TIN size would be for informational purposes only and may be subject to change.

We believe that the utilization of the Quality Payment Program Service Center, versus the utilization of designated TA representatives, as the means for stakeholders to obtain information
regarding TIN size provides continuity and a seamless experience for stakeholders. We note that the TA resources already available to stakeholders would continue to be available. The following describes the experience a stakeholder would encounter when interacting with the Quality Payment Program Service Center to obtain information pertaining to TIN size. For example, the applicable performance period for the 2022 MIPS payment year would be CY 2020. If a group contacted the Quality Payment Program Service Center on September 20, 2019, the claims data analysis would include the months of October of 2018 through August of 2019. If another group contacted the Quality Payment Program Service Center on November 20, 2019, the claims data analysis would include the months of October of 2018 through September of 2019 with a 30-day claims run out.

We believe this virtual group eligibility determination period provides a real-time representation of TIN size for purposes of determining virtual group eligibility and allows solo practitioners and groups to know their real-time virtual group eligibility status and plan accordingly for virtual group implementation. Beginning with the 2022 MIPS payment year, it is anticipated that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about their TIN size. TIN size determinations would be based on the number of NPIs associated with a TIN, which may include clinicians (NPIs) who do not meet the definition of a MIPS eligible clinician at §414.1305 or who are excluded from MIPS under §414.1310(b) or (c).

We proposed to continue to apply the aforementioned previously established virtual group policies for the 2022 MIPS payment year and future years, with the exception of the following policy modifications:
- The virtual group eligibility determination period would align with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period.

- MIPS eligible clinicians would be able to contact their designated technical assistance representative or, beginning with the 2022 MIPS payment year, the Quality Payment Program Service Center, as applicable, to inquire about their TIN size for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in MIPS as part of a virtual group. We anticipate that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about virtual group participation eligibility.

- A virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group in a form and manner specified by CMS. We anticipate that a virtual group representative would make the election via a web-based system developed by CMS.

We also proposed updates to §414.1315 in an effort to more clearly and concisely capture previously established policies. These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text.

The following is a summary of the public comments received on these proposals and our
Comment: One commenter requested that CMS revisit the virtual group definition’s current limit of ten clinicians because the definition of eligible clinician will be expanded. The commenter recommended revising the definition and measure virtual groups by setting an attributed membership floor to improve reporting validity.

Response: In regard to determining TIN size for purposes of virtual group eligibility, we count each NPI associated with a TIN in order to determine whether or not a TIN exceeds the threshold of 10 NPIs, which includes clinicians who are eligible and not eligible for MIPS. We believe that such an approach provides continuity over time if the definition of a MIPS eligible clinician is expanded in future years under section 1848(q)(1)(C)(i)(II) of the Act to include other eligible clinicians (82 FR 53596). As discussed in the 2018 Quality Payment Program final rule (82 FR 53596 through 53597), we considered an alternative approach for determining TIN size, which would determine TIN size for virtual group eligibility based on NPIs who are MIPS eligible clinicians. However, as we conducted a comparative assessment of the application of such alternative approach with the current definition of a MIPS eligible clinician (as defined at §414.1305) and a potential expanded definition of a MIPS eligible clinician, we found that such an approach could create confusion as to which factors determine virtual group eligibility and cause the pool of virtual group eligible TINs to significantly be reduced once the definition of a MIPS eligible clinician would be expanded, which may impact a larger portion of virtual groups that intend to participate in MIPS as a virtual group for consecutive performance periods. Such impact would be the result of the current definition of a MIPS eligible clinician being narrower than the potential expanded definition of a MIPS eligible clinician. We did not pursue such an
approach given that it did not align with our objective of establishing virtual group eligibility policies that are simplistic in understanding and provide continuity.

Furthermore, we note that given that the TIN size is already based on the total number of NPIs within a TIN, the expanded definition of a MIPS eligible clinician will not impact the population of TINs eligible to form or join a virtual group. In regard to increasing the TIN size threshold of 10, section 1848(q)(5)(I)(ii) of the Act establishes a threshold of 10 and as a result, we do not have discretion to expand virtual group participation to TINs with more than 10 NPIs.

Comment: A few commenters supported our proposal to align the virtual group eligibility determination period with the first segment of the MIPS determination period for consistency. The commenters also supported the availability of TIN size information that can be considered by groups prior to submitting a virtual group election. One commenter requested that CMS provide notification regarding the timeframe for the virtual group election process each year.

Response: In regard to the virtual group election period, we publish the timeframe for virtual groups to make an election in subregulatory guidance (that is, materials published and posted on the CMS web site and information disseminated via a listserv) each year on the CMS website in advance of the start of the election period. Each year, the virtual group election period will occur prior to the start of an applicable performance period and have an end date of December 31.

Comment: One commenter requested clarification as to why a virtual group election must be made prior to the performance period and recommended that CMS postpone the deadline to the third quarter of the performance year.

Response: Section 1848(q)(5)(I)(iii)(I) of the Act provides that the virtual group election
process must include the following requirement: an individual MIPS eligible clinician or group electing to be in a virtual group must make their election prior to the start of the performance period and cannot change their election during the performance period.

After consideration of the public comments, we are finalizing our proposals to continue to apply the aforementioned previously established virtual group policies for the 2022 MIPS payment year and future years, with the exception of the following:

- The virtual group eligibility determination period is the first segment of the MIPS determination period (proposal finalized at §414.1315(c)(1)(ii)), which consists of an analysis of claims data during a 12-month assessment period (fiscal year) that begins on October 1 of the calendar year 2 years prior to the applicable performance period and ends on September 30 of the calendar year preceding the applicable performance period and includes a 30-day claims run out. As part of the virtual group eligibility determination period, TINs will be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which will begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. We refer readers to section III.I.3.b. of this final rule for more information regarding the MIPS determination period.

- MIPS eligible clinicians will be able to contact their designated technical assistance representative or, beginning with the 2022 MIPS payment year, the Quality Payment Program Service Center, as applicable, to inquire about their TIN size for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in MIPS as part of a virtual group. We anticipate that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about virtual group participation eligibility.
• A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified at §414.1315(b) (proposal finalized at §414.1315(c)(2)(ii)). We anticipate that a virtual group representative will make the election via a web-based system developed by CMS.

Also, we are finalizing updates to §414.1315 in an effort to more clearly and concisely capture previously established policies. The updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text.

We note that we are further revising §414.1315 to consolidate paragraphs (c)(2)(ii) and (iii) and redesignate paragraph (c)(2)(iv) as paragraph (c)(2)(iii) for clarity. Additionally, we are revising redesignated paragraph (c)(2)(iii) to refer to “the start of data submission” rather than “the start of an applicable submission period” because “submission period” is not an expressly defined term.

g. MIPS Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53617 through 53619), we finalized at §414.1320(c)(1) that for purposes of the 2021 MIPS payment year, the performance period for the quality and cost performance categories is CY 2019 (January 1, 2019 through December 31, 2019). We did not finalize the performance period for the quality and cost performance categories for purposes of the 2022 MIPS payment year or future years. We also redesignated §414.1320(d)(1) and finalized at §414.1320(c)(2) that for purposes of the 2021 MIPS payment year, the performance period for the Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).
As noted in the CY 2018 Quality Payment Program final rule, we received comments that were not supportive of a full calendar year performance period for the quality and cost performance categories. However, we continue to believe that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. As discussed in the CY 2019 PFS proposed rule (83 FR 35893), we believe that a longer performance period for the quality and cost performance categories will likely include more patient encounters, which will increase the denominator of the quality and cost measures. Statistically, larger sample sizes provide more accurate and actionable information. Additionally, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported. We also noted that the Bipartisan Budget Act of 2018 (Pub. L. 115-119, enacted February 9, 2018) has provided further flexibility to the 3rd, 4th, and 5th years of MIPS to help continue the gradual transition to MIPS.

Regarding the Promoting Interoperability performance category, we have heard from stakeholders through public comments, letters, and listening sessions that they oppose a full year performance period, indicating that it is very challenging and may add administrative burdens (83 FR 35893). Some stated that a 90-day performance period is necessary in order to enable clinicians to have a greater focus on the objectives and measures that promote patient safety, support clinical effectiveness, and drive toward advanced use of health IT. They also noted that as this performance category requires the use of CEHRT, a 90-day performance period will help relieve pressure on clinicians to quickly implement changes and updates from their CEHRT vendors and developers so that patient care is not compromised. Others cited the challenges associated with reporting on a full calendar year for clinicians newly employed by a health
system or practice during the course of a program year, switching CEHRT, vendor issues, system
downtime, cyber-attacks, difficulty getting data from old places of employment, and office
relocation. Most stakeholders stated that the performance period should be 90 days in perpetuity,
as this would greatly reduce the reporting burden (83 FR 35893).

In the CY 2019 PFS proposed rule (83 FR 35893), in an effort to provide as much
transparency as possible so that MIPS eligible clinicians and groups may plan for participation in
the program, we requested comments on our proposals at §414.1320(d)(1) that for purposes of
the 2022 MIPS payment year and future years, the performance period for the quality and cost
performance categories would be the full calendar year (January 1 through December 31) that
occurs 2 years prior to the applicable MIPS payment year. For example, for the 2022 MIPS
payment year, the performance period would be 2020 (January 1, 2020 through December 31,
2020), and for the 2023 MIPS payment year, the performance period would be CY 2021
(January 1, 2021 through December 31, 2021).

In addition, we requested comments on our proposal at §414.1320(d)(2) that for purposes
of the 2022 MIPS payment year and future years, the performance period for the improvement
activities performance category would be a minimum of a continuous 90-day period within the
calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including
the full calendar year. For example, for the 2022 MIPS payment year, the performance period
for the improvement activities performance category would be a minimum of a continuous 90-
day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through
December 31, 2020). For the 2023 MIPS payment year, the performance period for the
improvement activities performance category would be a minimum of a continuous 90-day
period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through
December 31, 2021) that occurs 2 years before the MIPS payment year (83 FR 35893).

Finally, we requested comments on our proposal to add §414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020) (83 FR 35893).

The following is a summary of the public comments received on these proposals and our responses:

**Comment:** Several commenters agreed with our proposal to maintain the quality and cost performance periods as a full calendar year that occurs 2 years prior to the applicable MIPS payment year, noting that this proposal provides some of the stability needed for MIPS. One commenter supported a full calendar year for the cost performance category as this allows for a greater number of cases to be included in each measure, which will give a more reliable performance result. Another commenter supported a full calendar year for the quality and cost performance categories because they stated that it is in the best interest of patients encouraging clinicians to evolve in their approach to delivering care.

**Response:** We appreciate the commenters’ support.

**Comment:** Several commenters opposed a full calendar-year performance period for the quality and cost performance categories and urged CMS to establish a minimum 90-day performance period, consistent with the other performance categories. Commenters noted that a
minimum of 90-day performance period would reduce the administrative burden in MIPS, align
the performance period across MIPS performance categories and allow the agency to shorten the
2-year lag between performance and payment. Other commenters requested that clinicians be
allowed to choose between 90 days up to a full year of reporting. Another commenter urged
CMS to consider adopting a 90-day performance period to capture eligible clinicians who may
join a group in the middle of a performance year. One commenter agreed with the challenges
CMS outlined in the proposed rule (83 FR 35893) regarding the Promoting Interoperability
performance category and stated that these various challenges create obstacles outside the control
of the clinician, which inhibits their ability to collect and report 12 months of MIPS data for the
quality performance category as well.

Response: We do not believe that it would be in the best interest of MIPS eligible
clinicians to have less than a full calendar year performance period for the quality and cost
performance categories for the 2022 MIPS payment year and future years, as we are maintaining
consistency with the performance period established for the first 3 MIPS payment years. We
believe this will be less burdensome and confusing for MIPS eligible clinicians. As discussed in
the CY 2018 Quality Payment Program final rule (82 FR 53618), statistically, larger sample sizes
provide more accurate and actionable information. Additionally, a full calendar year
performance period is consistent with how many of the measures used in our program were
designed to be reported and performed; some of the measures do not allow for a 90-day
performance period. We believe these issues make the quality performance category inherently
different for reporting requirements and measures than the Promoting Interoperability and
improvement activities performance categories. We do not believe reducing the performance
period for the quality and cost performance categories will alleviate any issues with clinicians
switching practices. Regarding reducing the 2-year lag between performance and payment, as noted in the CY 2017 Quality Payment Final Rule (81 FR 77077), the data submission activities and claims for services furnished during the 1 year performance period (which could be used for claims- or administrative claims-based quality or cost measures) may not be fully processed until the following year. These circumstances require adequate lead time to collect performance data, assess performance, and compute the MIPS adjustment so the applicable MIPS adjustment can be made available to each MIPS eligible clinician at least 30 days prior to when the MIPS payment adjustment is applied each year. Finally, in regard to the challenges we outlined in the proposed rule (83 FR 35893), these were specifically referring to the Promoting Interoperability performance category. We do not believe that these challenges affect the quality performance category, as well.

Comment: A few commenters noted that establishing a 90-day performance period would give CMS an opportunity to set benchmarks based on more current data, rather than from 4 years prior to the applicable MIPS payment year.

Response: We believe that benchmarks based on data from a 90-day performance period would be less reliable than those based on a full calendar year because fewer reported instances would meet the case minimum needed to be included in the benchmarks. This would also cause some measures to not have an available benchmark that could be used for scoring. In addition, using a 90-day performance period would not allow the creation of benchmarks from more current data. This is because we would still need to wait until the end of the data submission period before we could create the benchmarks based on data submitted by all MIPS eligible clinicians, and to publish historical benchmarks prior to the beginning of the performance period, we would still need to use data from 2 years prior to the performance period (4 years prior to the
MIPS payment year).

**Comment:** Several commenters supported the proposal to keep the minimum performance period for the improvement activities performance category at 90 days, noting the proposal maintains stability and simplifies the program. One commenter stated that practices should be able to complete improvement activities lasting 90 days even if the performance spans over two performance periods. The commenter stated that CMS should require practices to complete at least 45 consecutive days during each of two consecutive performance periods to equal a total of at least 90 days, noting that this lowers the burden on clinicians and further encourages participation in this performance category.

**Response:** We appreciate the support for our proposal. However, we do not agree that an improvement activity should be split into two, 45-day periods. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77186), after researching several organizations, we believe a minimum of 90 days is a reasonable amount of time required for performing an activity. We do not believe that performance periods as short as 45 days are sufficient for many of the available improvement activities to ensure that the activities being performed result in actual practice improvements.

**Comment:** One commenter opposed our proposal to keep the minimum performance period for the improvement activities performance category at 90-days and urged CMS to adopt a 12-month performance period. The commenter noted that a 12-month performance period may be in the best interest of patients and may evolve clinicians' approach to delivering care.

**Response:** We appreciate the commenters’ recommendation. However, we believe that a minimum of a continuous 90-day performance period is appropriate for MIPS eligible clinicians to perform improvement activities that would improve clinical practice and provides more
flexibility as some improvement activities may be ongoing, while others may be appropriately episodic.

Comment: Many commenters supported our proposal to keep the minimum performance period for the Promoting Interoperability performance category at 90 days, noting that this proposal maintains stability, helps reduce administrative burden, provides clinicians with the time needed to manage changes and updates from their CEHRT vendors and developers, allows for effective measurement, and allows clinicians the flexibility to address scheduled or unanticipated events such as switching EHR vendors, system downtime, and cyber-attacks without jeopardizing patient care. Several commenters requested that CMS consider extending this performance period beyond the CY 2020 MIPS performance period.

Response: We appreciate the commenters’ support. We believe it is premature to establish policy beyond CY 2020 at this time appreciating the continued work in this area across HHS. We are finalizing the Promoting Interoperability performance period specific to CY 2019. We will take the comment into consideration for future rulemaking.

Comment: One commenter requested that CMS investigate ways to shorten the time between performance periods and for future MIPS payment years in the Quality Payment Program. This commenter noted concern that 2 years is too long to impact practice patterns and lead to meaningful changes in behavior.

Response: We understand the commenter’s concern. However, as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77083), there is a “2-year lag” at this time, in order to account for the post-submission processes of calculating the MIPS eligible clinician’s final score, establishing budget neutrality and issuing the MIPS payment adjustment factors, and allowing for a targeted review period to occur prior to the application of the MIPS payment
adjustment. We will continue working to shorten the “2-year lag” that the commenter describes.

Comment: Several commenters urged CMS to consider the timing of previous year MIPS feedback reports, which are released in July after the close of the performance period, noting that this timeline does not allow for clinicians to make necessary changes before the beginning of the next performance period. Several commenters noted that, if the performance period was reduced to a 90-day minimum with the option to submit additional data, individuals and groups would have greater flexibility to incorporate previous MIPS feedback into their performance during the remaining portion of 2019, thereby increasing quality and patient safety, and to focus more of their attention on improving patient care.

Response: Regarding the release of the feedback reports for the 1st year of MIPS, we provided 3 rounds of feedback including: (1) round 1--at the point of submission feedback; (2) round 2--pre-performance feedback; and (3) round 3--performance feedback. First, in round 1, at the point of submission we provided real time feedback that was available from the opening to the close of the submission period. Second, in round 2, we provided pre-performance feedback, which was available at the beginning of the close of the submission period and updated the round 2 feedback as new data became available such as CAHPS for MIPS survey, all-cause readmission measure, and cost measures data. Third, in round 3, we provided performance feedback that while it looks similar to round 2 is different in that the data is final with no new data being added and the payment adjustment(s) is included. This is the data that can be used to determine if a targeted review is to be filed. Considering there are opportunities for a clinician to gain insight into their possible performance prior to the release of the performance feedback in July, we encourage MIPS eligible clinicians to review the preliminary feedback and make necessary process and performance improvements, as needed. While we agree that there is some
benefit to a 90-day performance period, we believe that more continuous feedback is more beneficial. We also note that operationally our goal is to provide as much continuous submission opportunity as we can support in the future, including allowing clinicians to submit data during the performance period, as feasible. The ability to receive more frequent and continuous submissions will further our ability to provide more frequent feedback to MIPS eligible clinicians.

Comment: A few commenters did not support the 90-day performance period for the Promoting Interoperability performance category and urged CMS to move to full calendar year reporting as soon as possible to achieve value-based care, stating that patients and families should be able to experience the benefits of health IT any day of the year, rather than a particular 3-month period. One commenter noted that a 12-month performance period would more effectively achieve the objectives of MACRA. One commenter also noted that requiring full-year reporting would be less burdensome because it aligns with performance period for the quality performance category. Finally, one commenter also noted that requiring full-year reporting is more likely to prompt changes to clinician workflows.

Response: Although the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period during the calendar year, clinicians may report for a period up to and including the full calendar year. In addition, we do not believe that the duration of the performance period is indicative of the availability of the EHR to patients. We believe it is likely that a clinician who uses an EHR for a period of 90 days will continue to use it year round.

Comment: One commenter urged us to consider the practical implications of a 90-day performance period for Promoting Interoperability measure reporting, emphasizing the need to
ensure MIPS eligible clinicians and groups maintain interoperability capabilities in months that are not in the Promoting Interoperability performance period. This commenter noted the reporting periods may vary across eligible clinicians and groups and that a 90-day performance period could reduce the MIPS program’s incentives for interoperability and may delay roll-out of enhanced interoperability functionality.

Response: While MIPS eligible clinicians are required to report for a minimum of 90 days, they have the flexibility to report for a longer performance if they choose. Further we believe that once CEHRT is being utilized by the MIPS eligible clinician, it will be used on an ongoing basis and not just during a 90-day performance period.

After consideration of the public comments received, we are finalizing our proposal at §414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. In addition, we are finalizing our proposal at §414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We are also finalizing our proposal to add at §414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Finally, we are finalizing revisions to §414.1320(b)(2) and (c)(2) to refer to the new name of the Promoting Interoperability performance category.
h. MIPS Performance Category Measures and Activities

(1) Data Submission Requirements

(a) Background

We refer readers to §414.1325 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77087 through 77095, and 82 FR 53619 through 53626, respectively) for our previously established policies regarding data submission requirements.

(b) Collection Types, Submission Types and Submitter Types

It has come to our attention that the way we have previously described data submission by MIPS eligible clinicians, groups and third party intermediaries does not precisely reflect the experience users have when submitting data to us. To clarify, we have previously used the term “submission mechanisms” to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted (for example, electronic clinical quality measures (eCQMs) reported via EHR) and to the entities submitting such data (for example, third party intermediaries on behalf of MIPS eligible clinicians and groups). To ensure clarity and precision for all users, we are proposing to revise existing and define additional terminology to more precisely reflect the experience users have when submitting data to the Quality Payment Program.

In the CY 2019 PFS proposed rule (83 FR 35894), we requested comments on our proposal to define the following terms at §414.1305:

- Collection type as a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: eCQMs; MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. The term MIPS CQMs would
replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures. These new terms are referenced in the collection type field for the following measure tables of the appendices in the CY 2019 PFS proposed rule (83 FR 36092 through 36358): Table Group A: Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years; Table Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years; Table C: Quality Measures Proposed for Removal from the Merit-Based Incentive Payment System Program for the 2019 Performance Period and Future Years; and Table Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years.

- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.

- Submission type as the mechanism by which a submitter type submits data to CMS, including, as applicable: direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We note that there is no submission type for the administrative claims collection type because we calculate measures for this collection type based on administrative claims data available to us.
In the CY 2019 PFS proposed rule (83 FR 35894), we solicited additional feedback and alternative suggestions on terminology that appropriately reflects the concepts described in the proposed definitions of collection type, submitter type and submission type, as well as the term MIPS CQMs to replace the formerly used term of registry measures.

The following is a summary of the comments we received on “Collection Types, Submission Types and Submitter Types”.

**Comment:** A few commenters supported the clarification of submission terms, stating that the new definitions recognize the complexity of measure types and submission options and reduce the potential for confusion. Commenters asked whether, if we finalize these terminology updates, educational information will be made available on the Quality Payment Program website so that clinicians will understand and appropriately apply these terms. One commenter also emphasized the importance of ensuring that submitting and attesting to measures is flexible and easy for clinicians to do.

**Response:** We intend to update the Quality Payment Program website appropriately and provide any relevant educational materials.

**Comment:** One commenter recommended that, if the “collection type” definition only refers to quality measures, CMS change “collection type” to “quality measure type” and requested that CMS provide a definition for data collection recognizing that all performance categories collect data. Another commenter also recommended that we recommend that we change “collection type” to “measure type” or “measure category” to more intuitively and accurately reflect the meaning of the term.

**Response:** The proposed definition of collection type states that it is specific to a set of quality measures. Therefore, we do not agree the suggested term of “quality measure type”
would be the most beneficial in clarifying the actual submission experience for the user, in comparison to how submission mechanisms were discussed in our previous policies. We also note that the usage of the term “quality measure type” is commonly used to refer to mean a specific type of measure such as process or outcome measure. While we agree that all performance categories do in fact collect data, for purposes of clarifying the user experience for data submission, it is most beneficial to only refer to data collection in regards to the quality performance category. The suggested terms “measure type” or “measure category” could create further misunderstanding of the intent of the definition. As far as “measure type”, there are other measures available in the program than just those available for reporting on in the quality performance category. For the term “measure category”, we disagree as this could give the implication that this is another performance category within the Quality Payment Program.

Comment: One commenter recommended that we change the term “submission type” to “submission method” and to define the mechanisms by which CMS means by “direct,” “log in,” “upload,” and “attest.”

Response: We agree that the term “submission method” is an appropriate term for the proposed definition. However, the term did not gain support during user testing that surpassed the proposed terms. According to feedback from user testing, the proposed terms of collection, submitter and submission type, were found to be intuitive and to match the user experience when submitting data to the Quality Payment Program. The direct, log in and upload, log in and attest modes of data submission will be discussed in further detail in forthcoming educational resources. We also encourage review of the terms and wireframes for the submission types on qpp.cms.gov/design-examples.
**Comment:** One commenter recommended that we change “submitter type” to “submitting entity” and define this as the entity who will be submitting the eligible clinician’s data.

**Response:** We believe that consistent terminology would be most beneficial in providing clarity for users submitting data to the Quality Payment Program. We also note that the term submitter type includes both entities that would submit on a clinician’s behalf, as well as actions made directly by clinicians or their practice.

After consideration of the public comments received, we are finalizing our proposal at §414.1305 to define the following terms:

- **Collection type** as a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: eCQMs; MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. The term MIPS CQMs would replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures. These new terms are referenced in the collection type field for the following measure tables of “Appendix 1: Finalized MIPS Quality Measures” in this final rule: Table Group A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years; Table Group B: Finalized New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years; Table Group C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years; and Table Group D: Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years.
- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.

- Submission type as the mechanism by which a submitter type submits data to CMS, including, as applicable: direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We note that there is no submission type for the administrative claims collection type because we calculate measures for this collection type based on administrative claims data available to us.

(c) Performance Category Measures and Reporting

We previously finalized at §414.1325(a) and (e), respectively, that MIPS eligible clinicians and groups must submit measures, objectives, and activities for the quality, improvement activities, and advancing care information performance categories and that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category; CMS will calculate performance on these measures using administrative claims data. In the CY 2019 PFS proposed rule (83 FR 35894), we proposed to amend §414.1325(a) to incorporate §414.1325(e), as they both address which performance categories require data submission; §414.1325(f) would be redesignated as §414.1325(e). We also proposed in the CY 2019 PFS proposed rule (83 FR
at §414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in §414.1380(e). We also recognized the need to clarify to users how they submit data to us. In the CY 2019 PFS proposed rule (83 FR 35894), there are five basic submission types that we proposed to define in MIPS: direct; log in and upload; login and attest; Medicare Part B claims; and the CMS Web Interface. We proposed to reorganize §414.1325(b) and (c) by performance category in the CY 2019 PFS proposed rule (83 FR 35894). We proposed in the CY 2019 PFS proposed rule (83 FR 35894) to also clarify at §414.1325(b)(1) that an individual MIPS eligible clinician may submit their MIPS data for the quality performance category using the direct, login and upload, and Medicare Part B claims submission types. In the CY 2019 PFS proposed rule (83 FR 35894), similarly, we proposed to clarify at §414.1325(b)(2) that an individual MIPS eligible clinician may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. As for groups, we proposed in the CY 2019 PFS proposed rule (83 FR 35894) to clarify at §414.1325(c)(1) that groups may submit their MIPS data for the quality performance category using the direct, login and upload, and CMS Web Interface (for groups consisting of 25 or more eligible clinicians) submission types. Lastly, we proposed to clarify at §414.1325(c)(2) that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types in the CY 2019 PFS proposed rule (83 FR 35894). We believe that these clarifications will enhance the submission experience for clinicians and other stakeholders. As technology continues to evolve, we will continue to look for new ways that we can offer further technical flexibilities on
submitting data to the Quality Payment Program. In the CY 2019 PFS proposed rule (83 FR 35894), we requested comment on these proposals. To assist commenters in providing pertinent comments, we developed a website that uses wireframe (schematic) drawings to illustrate a subset of the different submission types available for MIPS participation. Specifically, the wireframe drawings describe the direct, login and attest, and login and upload submission types. We refer readers to the Quality Payment Program at qpp.cms.gov/design-examples to review these wireframe drawings. The website will provide specific matrices illustrating potential stakeholder experiences when choosing to submit data under MIPS.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. Although we would like to move towards the utilization of electronic reporting by all clinicians and groups, we realize that small practices face additional challenges, and this requirement may limit their ability to participate. For this reason, we believe that Medicare Part B claims measures should be available to small practices, regardless of whether they are reporting as individual MIPS eligible clinicians or as groups. Therefore, we proposed amending §414.1325(c)(1) to make the Medicare Part B claims collection type available to MIPS eligible clinicians in small practices beginning with the 2021 MIPS payment year in the CY 2019 PFS proposed rule (83 FR 35894). Although this will limit the current availability of Medicare Part B claims measures for individual MIPS eligible clinicians that do not meet the definition of a small practice, it will expand the availability of such measures for small practices who choose to participate in MIPS as a group, which currently does not have a claims-based reporting option as a group.
Under §414.1325(c)(4), we previously finalized that groups may submit their MIPS data using the CMS Web Interface (for groups consisting of 25 or more eligible clinicians) for the quality, improvement activities, and promoting interoperability performance categories. In the CY 2019 PFS proposed rule (83 FR 35894 through 35895), we proposed that the CMS Web Interface submission type would no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability performance categories at §414.1325(c)(2). The CMS Web Interface has been designed based on user feedback as a method for quality submissions only; however, groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct, log in and attest or log in and upload submission types. We also recognized that certain groups that have elected to use the CMS Web Interface may prefer to have their data submitted on their behalf by a third party intermediary described at §414.1400(a). We recognized the benefit and burden reduction in such a flexibility and therefore proposed to allow third party intermediaries to submit data to the CMS Web Interface in addition to groups in the CY 2019 PFS proposed rule (83 FR 35895). Specifically, we proposed in the CY 2019 PFS proposed rule (83 FR 35895) to redesignate §414.1325(c)(4) as §414.1325(c)(1) and amend §414.1325(c)(1) to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups. To further our efforts to provide flexibility in reporting to the Quality Payment Program, we solicited comment in the CY 2019 PFS proposed rule (83 FR 35895) on expanding the CMS Web Interface submission type to groups consisting of 16 or more eligible clinicians to inform our future rulemaking.

We previously finalized at §414.1325(e) that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in
the quality performance category and that CMS will calculate performance on these measures using administrative claims data. We also finalized at §414.1325(f)(2), (which, as noted, we proposed to redesignate as §414.1325(e)(2)) that for Medicare Part B claims, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. We neglected to codify this requirement at §414.1325(e) (which, as noted, we proposed to consolidate with §414.1325(a)) for administrative claims data used to assess performance in the cost performance category and for administrative claims-based quality measures. Therefore, in the CY 2019 PFS proposed rule (83 FR 35895), we proposed to amend §414.1325(a)(2)(i) to reflect that claims included in the measures are those submitted with dates of service during the performance period that are processed no later than 60 days following the close of the performance period.

In the CY 2019 PFS proposed rule (83 FR 35895), a summary of these proposed changes is included in Tables 32 and 33. For reference, Table 32 summarizes the data submission types for individual MIPS eligible clinicians that we proposed at §414.1325(b) and (e) in the CY 2019 PFS proposed rule (83 FR 35895). Table 33 summarizes the data submission types for groups that we proposed at §414.1325(c) and (e) in the CY 2019 PFS proposed rule (83 FR 35895 through 35896). We requested comment on these proposals.

The following is a summary of the comments we received on “Performance Category Measures and Reporting”.

**Comment:** Many commenters supported our proposal to allow small practices to use the Medicare Part B claims-based reporting option for group reporting, with some noting that this option specifically relieves the burden on rural providers. However, several of these commenters opposed limiting the Medicare Part B claims reporting to only clinicians in small practices,
stating that many clinicians are excluded from the special small practice policies despite operating as small practices in all other respects, and there may be circumstances where reporting via Medicare Part B claims as individuals is the best option for clinicians in larger multispecialty practices to allow each clinician to focus on quality measures most relevant to his/her specialty and scope of practice. A few commenters stated that this policy would result in a negative impact on clinicians who are part of specialties that do not have relevant eCQMs available to them, but have nonetheless implemented workflows to support reporting data using Medicare Part B claims; requiring them to change these workflows based solely on practice size would cause unnecessary clinician burden without an offsetting benefit to the clinician already participating in the program. Therefore, these commenters recommended that CMS retain the Medicare Part B claims-based reporting option in the quality performance category for all clinicians regardless of practice size. One commenter also requested that we provide a definition for a small practice in the final rule.

Response: We likewise acknowledge that many clinicians that are not in a small practice currently report via Medicare Part B claims. However, as we previously expressed in the CY 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, as more measures are available through health IT mechanisms such as registries, QCDRs, and health IT vendors. We believe it is important to move away from manual methods of reporting and instead utilize more electronic methods such as using EHRs, registries, QCDRs. Also, as we have described above with our revised terms, clinicians that are part of a practice that opts not to work with a third party intermediary can submit data directly to us, which is a flexibility we have under MIPS that was not available under the legacy programs. We note that this change does not require the use of eCQMs by MIPS eligible clinicians that are not
considered to be part of a small practice. Rather, MIPS eligible clinicians that do not meet the
definition of a small practice will have the ability to select from all other collection types. We
refer readers to §414.130 for the definition of small practice.

**Comment:** A few commenters did not support the proposal to make the Medicare Part B
claims collection type available to clinicians in small practices, stating that it does not align with
the objectives of electronic reporting and Promoting Interoperability. Commenters specifically
stated that the small administrative burden to implement CEHRT exceeds the cost of the various
benefits of utilizing technology to improve the quality of care and that CEHRT is the only
method that is completely accurate based upon the patient record and prevents organizations
from “cherry-picking” patients to meet the 60 percent reporting threshold. One commenter also
noted that registries are available at very affordable costs for clinicians and groups. Another
commenter stated concern about how small and rural practices that have made the financial
investment into CEHRT would react to this proposed update, stating that the proposal sends an
inconsistent message to those small and rural psychiatric practices that made the financial
investment to adopt CEHRT.

**Response:** To clarify, our policy is to make the Medicare Part B claims collection type
only available to small practices. We agree that there are many benefits to CEHRT adoption and
also agree that many registries are available at low cost. We do not agree that this sends an
inconsistent message with the objectives of electronic reporting and Promoting Interoperability
as we still encourage all clinicians (small practices and non-small practices) to submit
electronically. However, we recognize that small practices have additional challenges and
believe that continuing to allow the Medicare Part B claims collection type only to small
practices is beneficial. To further highlight alignment in policy regarding small practices across
performance categories in MIPS, as discussed in section III.I.3.h.(5) of this final rule for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR.

**Comment:** Several commenters opposed the proposed removal of Medicare Part B claims-based reporting as an option for clinicians. One commenter noted concern because the proposal to expand the definition of a MIPS eligible clinician stated it would also coincide with a decrease in the number of group practices that will be considered a small practice. Commenters requested that CMS finalize a future timeframe for retiring the Medicare Part B claims based submission type for eligible clinicians, stating that: Medicare Part B claims based submission of quality data is still an extremely popular submission method in certain specialties; eliminating this reporting option may reduce the number of clinicians who participate in MIPS reporting; clinicians in many specialties, most notably those that are hospital based, will have to transition to use of a qualified registry or QCDR for quality measure reporting once claims based reporting is no longer an option, and this will require new and unplanned costs and further burden. Commenters also noted that clinicians who elect to report via Medicare Part B claims-based reporting, and choose to report topped out measures, are penalized in their quality score under current methods by receiving a maximum of 7 of 10 points for each topped out measure; therefore there is not an inappropriate incentive for continued use of this method. Another commenter stated that the removal of Medicare Part B claims reporting contradicts the provisions in the Bipartisan Budget Act of 2018 that moves the Agency toward accepting more claims data. Another commenter recommended waiting to see if the number of clinicians reporting through Medicare Part B claims increases over the next years and then determine if a future proposal is appropriate.
Response: We acknowledge that many clinicians that are not in a small practice currently report via Medicare Part B claims. However, we disagree that only allowing the reporting of this collection type to small practices forces non-small practices to transition to the use of a qualified registry or QCDR for quality measure reporting, as there are other collection types and submitter types available in which non-small practices can report (that is, eCQMs, MIPS CQMs, CMS Web Interface measures, the CMS approved survey vendor measure and Administrative claims measures). For example, a non-small practice that does not wish to enter into an arrangement with a third party intermediary can use the MIPS CQM collection type and either login and upload their data or use the direct submission type for the quality performance category. These submission types do not require the usage of a third party intermediary, but we note that there are certain technical capabilities that a practice must have to submit data in this manner. Additional details on the form and manner requirements of these submission types is available at qpp.cms.gov/design-examples.

We agree that choosing to report topped out measures is not incentivized. As discussed in the CY 2019 PFS proposed rule (83 FR 35894), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. This is a contributing factor as to why we are looking to decrease the usage of this option over time, as we have been signaling we would do for many years. We will continue to work with stakeholders on providing further transparency of the future of this collection type. It is unclear to what reference the commenter is discussing where the removal of claims reporting is a contradiction to provisions made in the Bipartisan Budget Act of 2018. We do not believe that this proposal is inconsistent with the Bipartisan Budget Act of 2018.
We do not believe further delay is warranted but will continue to work with stakeholders to provide further clarity on the future of this collection type. Lastly, we disagree that the expansion of the MIPS eligible clinician type as discussed in section III.I.3.c. will decrease the number of small practices. As defined at §414.1305, a small practice is a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. We note that this definition currently includes both eligible clinicians and MIPS eligible clinicians, and therefore, the expansion of the MIPS eligible clinician definition should not negatively impact a practice’s ability to be considered a small practice.

Comment: One commenter asked us to acknowledge that, from their experiences participating in MIPS for the CY 2017 transition period, when a group attests for promoting interoperability but uses Medicare Part B claims to submit for the quality performance category as individuals, every clinician must have quality data and this data does not roll-up to the group.

Response: In the CY 2017 Quality Payment Program final rule (81 FR 77087 through 77088), Tables 1 and 2 summarized allowable individual and group submission types. In the 2017 MIPS performance period, Medicare Part B claims submissions for the quality performance category could only be used by individuals, and no group score was calculated for this collection type. In this final rule, we are finalizing our proposal to allow small practices the option to report as individuals or a group using Medicare Part B claims data so that a group performance score can be calculated for quality and combined with other group scores from other performance categories.

Comment: One commenter urged CMS to provide greater detail about whether there is value in the data submitted through the Medicare Part B claims measure collection type, given the reduced number of clinically appropriate and applicable claims measures under Medicare
Part B, particularly considering data that is collected from claims forms contains minimal clinical information.

Response: Medicare Part B Claims Measure Specifications do provide value in the data submitted. Denominator eligibility can be determined by billing already included within a Medicare Part B Claim. The eligible clinician can submit a quality data code to attest to the quality action defined by the measure specification. The Medicare Part B Measure Specifications address a number of clinical outcomes on prevalent health conditions (for example, diabetes, hypertension). In addition to the outcomes, the Medicare Part B Claims Measure Specifications provide eligible clinicians who provide services in a small practice to participate within MIPS without incurring additional costs in data abstraction by third party intermediaries.

Comment: One commenter urged CMS to provide greater detail about whether small and rural practices who report their performance solely through Medicare Part B claims measures would be afforded the opportunity to submit fewer than 6 measures (including one outcome or high priority measure) as currently required. This commenter also urged CMS to provide greater detail about whether new Medicare Part B claims quality measures would be accepted for inclusion in the rulemaking process, or if only the current Medicare Part B claims quality measures would be continued for use by small and rural practices.

Response: We did not propose any changes to the quality performance submission criteria for the Medicare Part B claims collection type. We validate the availability and applicability of quality measures for clinicians who collect data via claims with fewer than six measures. Clinicians would only need to report the measures that are applicable. We refer readers to section III.1.3.1.(1)(b)(vii) of this final rule for more discussion on our data validation
process. Any updates to the measures list would go through future rulemaking. We want to clarify, that while reference was made to both small and rural practices by the commenter, this policy is limited to those that are small practices. We note that a practice that is small and rural would be eligible to use the Medicare Part B claims collection type, but only with meeting the special status designation of being a small practice.

**Comment:** One commenter requested clarification on how CMS would determine that a claims submission is intended for group reporting if the group is only submitting data for the quality performance category of MIPS.

**Response:** In the scenarios where we only receive Medicare Part B claims submissions for a practice for the quality performance category of MIPS, we intend on calculating the quality performance category for the practice as both a group and as individuals and will apply the quality performance category score that is the greater of the two. We considered requiring an election for assessment as a group but believe this would be unduly burdensome on small practices.

**Comment:** One commenter disagreed with our proposal to eliminate Web Interface reporting for the improvement activities and Promoting Interoperability performance categories, stating this reduces flexibility for groups and adds unnecessary complexity.

**Response:** We clarify that the CMS Web Interface has been designed as a method for quality submissions only, based on user feedback. As we developed the CMS Web Interface for usage under the Quality Payment Program, we engaged in user testing with stakeholders and the inclusion of the improvement activities and promoting interoperability performance categories within the CMS Web Interface tool negatively impacted the design. Instead, what users experienced for submissions in the first year of the program was a seamless interaction between
the CMS Web Interface and the ability to attest for these two performance categories. With the finalization of this policy, users will have the exact same experiences of reporting data for the promoting interoperability and improvement activities performance categories while still using the CMS Web Interface for the quality performance category. We reiterate that we are simply updating our policy to reflect the existing user experience that stakeholders encounter. We would also like to highlight that groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct and log in and upload, if they choose not to utilize the login and attest submission type.

**Comment:** One commenter supported our proposal to eliminate Web Interface reporting for the improvement activities and Promoting Interoperability performance categories.

**Response:** We appreciate the commenter’s support.

**Comment:** One commenter appreciated that we clarified that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types.

**Response:** Our intent was to provide clarity with the submission experience for clinicians and other stakeholders.

**Comment:** A few commenters supported our proposal to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups, which alleviates burden on group practices to report the data themselves.

**Response:** We appreciate the commenters’ support.

After consideration of the public comments received, we are finalizing our proposal to amend §414.1325(a) to incorporate §414.1325(e), as they both address which performance categories require data submission; §414.1325(f) will be redesignated as §414.1325(e). We are
finalizing our proposal at §414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in §414.1380(e). We are finalizing our proposals to reorganize §414.1325(b) and (c) by performance category and to clarify at §414.1325(b)(1) that an individual MIPS eligible clinician may submit their MIPS data for the quality performance category using the direct, login and upload, and Medicare Part B claims submission types. We are finalizing our proposal to clarify at §414.1325(b)(2) that an individual MIPS eligible clinician may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. We are finalizing our proposal to clarify at §414.1325(c)(1) that groups may submit their MIPS data for the quality performance category using the direct, login and upload, and CMS Web Interface (for groups consisting of 25 or more eligible clinicians) submission types. We are also finalizing our proposal to clarify at §414.1325(c)(2) that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. We are finalizing our proposal to amend §414.1325(c)(1) to make the Medicare Part B claims collection type available to MIPS eligible clinicians in small practices beginning with the 2021 MIPS payment year. We are finalizing our proposal at §414.1325(c)(2) to state that the CMS Web Interface submission type will no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability performance categories. We are finalizing our proposal to redesignate §414.1325(c)(4) as §414.1325(c)(1) and amend §414.1325(c)(1) to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups. We are finalizing our proposal to redesignate
§414.1325(f)(2) as §414.1325(e)(2) that for Medicare Part B claims, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. Lastly, we are also finalizing our proposal to amend §414.1325(a)(2)(i) to reflect that claims included in the measures are those submitted with dates of service during the performance period that are processed no later than 60 days following the close of the performance period. We received many comments on our comment solicitation to expand the scope of practices that can utilize the Web Interface and will take them into consideration for future rulemaking.

TABLE 32: Data Submission Types for MIPS Eligible Clinicians Reporting as Individuals

<table>
<thead>
<tr>
<th>Performance Category/Submission Combinations Accepted</th>
<th>Submission Type</th>
<th>Submitter Type</th>
<th>Collection Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>Direct Log in and upload Medicare Part B claims (small practices)</td>
<td>Individual or Third Party Intermediary</td>
<td>eCQMs MIPS CQMs QCDR measures Medicare Part B claims measures (small practices)</td>
</tr>
<tr>
<td>Cost</td>
<td>No data submission required</td>
<td>Individual</td>
<td>-</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>Direct Log in and upload Log in and attest</td>
<td>Individual or Third Party Intermediary</td>
<td>-</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>Direct Log in and upload Log in and attest</td>
<td>Individual or Third Party Intermediary</td>
<td>-</td>
</tr>
</tbody>
</table>

1 Third party intermediary does not apply to Medicare Part B claims submission type.
2 Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians’ billings on Medicare claims. NOTE: As used in this rule, the term “Medicare Part B claims” differs from “administrative claims” in that “Medicare Part B claims” require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.
### TABLE 33: Data Submission Types for MIPS Eligible Clinicians Reporting as Groups

<table>
<thead>
<tr>
<th>Performance Category/Submission Combinations Accepted</th>
<th>Submission Types</th>
<th>Submitter Type</th>
<th>Collection Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>Direct &lt;br&gt;Log in and upload CMS Web Interface (groups of 25 or more eligible clinicians) Medicare Part B claims (small practices)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Group or Third Party Intermediary</td>
<td>eCQMs &lt;br&gt;MIPS CQMs &lt;br&gt;QCDR measures &lt;br&gt;CMS Web Interface measures Medicare Part B claims measures (small practices) CMS approved survey vendor measure Administrative claims measures</td>
</tr>
<tr>
<td>Cost</td>
<td>No data submission required&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>Group</td>
<td>-</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>Direct &lt;br&gt;Log in and upload &lt;br&gt;Log in and attest</td>
<td>Group or Third Party Intermediary</td>
<td>-</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>Direct &lt;br&gt;Log in and upload &lt;br&gt;Log in and attest</td>
<td>Group or Third Party Intermediary</td>
<td>-</td>
</tr>
</tbody>
</table>

1. Third party intermediary does not apply to Medicare Part B claims submission type.
2. Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians’ billings on Medicare claims. **NOTE:** As used in this rule, the term “Medicare Part B claims” differs from “administrative claims” in that “Medicare Part B claims” require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

(d) Submission Deadlines

We previously finalized data submission deadlines in the CY 2017 Quality Payment Program final rule (81 FR 77095 through 77097) at §414.1325(f), which outlined data submission deadlines for all submission mechanisms for individual eligible clinicians and groups for all performance categories. As discussed in section III.I.3.h.(1) of this final rule, the term submission mechanism, that includes submission via the qualified registry, QCDR, EHR, Medicare Part B claims, the CMS Web Interface and attestation, does not align with the existing process of data submission to the Quality Payment Program. In the CY 2019 PFS proposed rule (83 FR 35896), we proposed to revise regulatory text language at §414.1325(f), which, as noted, we proposed to redesignate as §414.1325(e), to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories. In
the CY 2019 PFS proposed rule (83 FR 35896), we also proposed to revise §414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. We anticipate that in scenarios where the March 31st deadline falls on a weekend or holiday, we will extend the submission period to the next business day (that is, Monday). There also may be instances where due to unforeseen technical issues, the submission system may be inaccessible for a period of time. If this scenario were to occur, we anticipate that we will extend the submission period to account for this lost time, to the extent feasible. We note that this revision would also revise the previously finalized policy at §414.1325(e)(3) stating that data must be submitted during an 8-week period following the close of the performance period, and that the period must begin no earlier than January 2 and end no later than March 31 for the CMS Web Interface. In the CY 2019 PFS proposed rule (83 FR 35896), we proposed to align the deadline for the CMS Web Interface submission type with all other submission type deadlines at §414.1325(e)(1), while we also proposed to remove the previously finalized policy at §414.1325(e)(3) because it is no longer needed to mandate a different submission deadline for the CMS Web Interface submission type.

In the CY 2019 PFS proposed rule (83 FR 35896), we also proposed a number of other technical revisions to §414.1325 to more clearly and concisely reflect previously established policies.

The following is a summary of the comments we received on “Submission Deadlines”.

**Comment:** Several commenters supported our proposal to align the deadline for the CMS Web Interface submission type with all other submission type deadlines and appreciated further aligning deadlines within the program, stating that predictable and achievable deadlines are preferred for planning and education purposes. Another commenter urged us to make this new
deadline clear to physicians by emphasizing the different deadlines at the start of the performance year.

Response: We will take all feedback into consideration for future educational materials.

Comment: One commenter opposed our proposal to align the deadline for the CMS Web Interface submission type with all other submission type deadlines, stating that this flexibility is being used to shorten the deadline, and that the earliest deadline should be set at March 31.

Response: We disagree that this flexibility is being used to shorten the deadline. We clarify that it is no longer necessary to mandate a different submission deadline for the CMS Web Interface submission type and this proposal will bring further alignment amongst submission types. Furthermore, this policy extends the CMS Web Interface submission deadline by approximately 4 additional weeks.

After consideration of the public comments received, we are finalizing our proposal to redesignate §414.1325(f) as §414.1325(e), to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories. We are finalizing our proposal to revise §414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. We are also finalizing our proposals to align the deadline for the CMS Web Interface submission type with all other submission type deadlines at §414.1325(e)(1), and to remove the previously finalized policy at §414.1325(e)(3) because it is no longer needed to mandate a different submission deadline for the CMS Web Interface submission type.

(2) Quality Performance Category

(a) Background
We refer readers to §§414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

(i) Assessing Performance on the Quality Performance Category

As discussed in the CY 2019 PFS proposed rule (83 FR 35896), under §414.1330(a), for purposes of assessing performance of MIPS eligible clinicians on the quality performance category, we will use: quality measures included in the MIPS final list of quality measures; and quality measures used by QCDRs. We proposed to amend §414.1330(a) to account for facility-based measurement and the APM scoring standard. For that reason, we proposed at §414.1330(a) to specify, for a MIPS payment year, that we use the following quality measures, as applicable to assess performance in the quality performance category: measures included in the MIPS final list of quality measures established by CMS through rulemaking; QCDR measures approved by CMS under §414.1440; facility-based measures as described under §414.1380; and MIPS APM measures as described at §414.1370.

We did not receive any comments on the proposal of how we will assess performance in the quality performance category. Therefore, we are finalizing our proposal to amend §414.1330(a) to state that for a MIPS payment year, we use the following quality measures, as applicable, to assess performance in the quality performance category: measures included in the MIPS final list of quality measures established by CMS through rulemaking; QCDR measures approved by CMS under §414.1440; facility-based measures as described in §414.1380; and MIPS APM measures as described in §414.1370.

(ii) Contribution to Final Score
In the CY 2019 PFS proposed rule (83 FR 35896) under §414.1330(b)(2) and (3), we state that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician’s final score for the 2020 MIPS payment year and 30 percent of a MIPS eligible clinician’s final score for each MIPS payment year thereafter. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance with respect to the quality performance category, but that for each of the 1st through 5th years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points that is based on the cost performance category performance is less than 30 percent for the respective year. As discussed in section III.I.3.i.(c) of this final rule, we proposed to weight the cost performance category at 15 percent for the 2021 MIPS payment year. Accordingly, we proposed to amend §414.1330(b)(2) to provide that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician’s final score for the 2020 MIPS payment year, and proposed at §414.1330(b)(3) that the quality performance category comprises 45 percent of a MIPS eligible clinician’s final score for the 2021 MIPS payment year.

We received the following comments on our proposals regarding the quality performance category’s contribution to the final score proposal:

**Comment**: A few commenters supported our proposals.

**Response**: We thank the commenters for their support.

**Comment**: Several commenters did not support the proposed reduction of the quality performance category weight to 45 percent from 50 percent for the 2021 MIPS payment year, suggesting that CMS maintain the weight at 50 percent. The commenters indicated that
adjusting the weight downward sends the wrong message to physicians regarding quality of care and that de-emphasizing quality runs contrary to the aim of reforming toward a value-based system. Further, commenters stated that altering the weight prematurely leads to less stability with the program and adds complexity. A few commenters recommended that we transfer the weight from the improvement activity category as needed to preserve the weight of the quality category.

Response: As discussed in section III.I.3.h.(3) of this final rule, we are finalizing the proposal to weight the cost performance category at 15 percent for the 2021 MIPS payment year. Accordingly, section 1848(q)(5)(E)(i)(1) of the Act requires that the quality performance category weight to be 45 percent. While we understand that the quality performance category requires additional resources to report, we believe that we are measuring value by rewarding performance in quality while keeping down costs and that clinicians can influence the cost of services that they do not personally perform by improving care management with other clinicians and avoiding unnecessary services. Regarding the commenters’ recommendation that we reduce the weight of the improvement activities performance category to preserve the weight of the quality performance category, we note that we do not have discretion to reduce the weight of the improvement activities performance category except for scenarios where reweighting can occur due to measures and activities and not being available and applicable. Please refer to section III.I.3.i.(1)(e) for information on our reweighting policies.

As discussed in section III.I.3.h.(3) of this final rule, we are finalizing our proposal to weight the cost performance category at 15 percent for the 2021 MIPS payment year. After consideration of the public comments received, we are finalizing our proposal to amend §414.1330(b)(2) to provide that performance in the quality performance category comprises 50
percent of a MIPS eligible clinician’s final score for the 2020 MIPS payment year, and our proposal to amend §414.1330(b)(3) to provide that the quality performance category comprises 45 percent of a MIPS eligible clinician’s final score for the 2021 MIPS payment year.

(iii) Quality Data Submission Criteria

(A) Submission Criteria

(aa) Submission Criteria for Groups Reporting Quality Measures, Excluding CMS Web Interface Measures and the CAHPS for MIPS Survey Measure

In the CY 2019 Quality Payment Program proposed rule (83 FR 35896 through 35897), we referred readers to §414.1335(a)(1) for our previously established submission criteria for quality measures submitted via claims, registry, QCDR, or EHR. As discussed in section III.I.3.h. of this final rule, we proposed revisions to existing and additional terminology to clarify the data submission processes available for MIPS eligible clinicians, groups and third party intermediaries, to align with the way users actually submit data to the Quality Payment Program. For that reason, we proposed to revise §414.1335(a)(1) to state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs; or QCDR measures. Codified at §414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, eligible clinicians and groups must report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable. Furthermore, we proposed beginning with the 2021 MIPS payment year to revise §414.1335(a)(1)(ii) to indicate that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contain at least six measures. If the set contains fewer
than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. As discussed in section III.I.3.h. of this final rule, we proposed to limit the Medicare Part B claims submission type, and therefore, the Medicare Part B claims measures, to MIPS eligible clinicians in small practices. We refer readers to section III.I.3.h of this final rule for discussion of this proposal.

The following is a summary of the public comments on these proposals and our responses:

**Comment:** A few commenters did not support the proposed specialty or subspecialty measure set submission criteria, citing the potential difficulty in reporting measures within the set that are not applicable. One commenter requested that, if the proposal is finalized, CMS should clarify how the requirement applies when clinicians submit both MIPS CQMs and QCDR measures to meet the quality performance category requirements, recognizing that some eligible clinicians may not be able to meet the requirement to report on all measures within a specialty or subspecialty set. Another commenter recommended that CMS revise its data submission criteria pertaining to specialty and subspecialty measure sets and require clinicians to report at least one outcome or high priority measure.

**Response:** To clarify, should a MIPS eligible clinician choose to report on a specialty or a subspecialty measure set, they are only required to submit data on six measures within that set, provided the set contain at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they are required to report
on each measure that is applicable. If a MIPS eligible clinician chooses to report only on a specialty or subspecialty measure set and reports on less than 6 quality measures through either the MIPS CQM or Medicare Part B claims collection types, they will be subjected to the measure validation process that will validate whether the clinician actually had less than 6 measures available or applicable to their scope of practice. If a MIPS eligible clinician chooses to report via the QCDR measure collection type, they will be required to meet the reporting requirement of 6 quality measures. If a MIPS eligible clinician reports fewer than 6 quality measures through a QCDR, they will receive zero points for each unreported quality measure. As stated at revised §414.1335(a)(1)(ii), MIPS eligible clinicians are required to report at least one outcome measure, or if no outcome measures are available or applicable, report another high priority measure in lieu of an outcome measure.

Comment: One commenter sought clarification on the proposed specialty or subspecialty measure set submission criteria. Specifically, the commenter questioned what a MIPS eligible clinician or group is required to do if fewer than 6 measures apply to the MIPS eligible clinician within their specialty or sub-specialty domain. Additionally, the commenter requested clarification on whether outcome measures or high-priority measures for specialty sets were required.

Response: The clinician is required to report at least one outcome measure or, if an applicable outcome measure is not available, one other high priority measure. If a MIPS eligible clinician chooses to report on a specialty or subspecialty measure set, the set contains at least 6 quality measures, and the clinician reports on fewer than 6 measures through the MIPS CQM or Medicare Part B claims collection type, the clinician will be subjected to the measure validation process, which will validate whether fewer than 6 measures were actually available and
applicable to their scope of practice. If the measure validation process determines that at least 6 measures were available and applicable to the clinician’s scope of practice, they will receive zero points for each unreported measure. We refer readers to Appendix 1: Finalized MIPS Quality Measures in this final rule, where the specialty sets are finalized in Table Group B. There are high priority measures available in all the specialty sets, and therefore a MIPS eligible clinician should be able to select a specialty set that reflects their scope of practice, and be able to report on the measures within that set, including the high-priority measures.

After consideration of the public comments received, we are finalizing our proposal to amend §414.1335(a)(1) to state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs; or QCDR measures. Codified at §414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, they must report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable. We are also finalizing our proposal to amend §414.1335(a)(1)(ii) to state that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contains at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable.

(bb) Submission Criteria for Groups Reporting CMS Web Interface Measures

As noted in the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the established submission criteria for CMS Web Interface measures. For purposes of clarity and organization, we are finalizing a technical change by moving the regulation text on
the sampling requirements for reporting CMS Web Interface measures from §414.1335(a)(2) to §414.1340(c)(1). However, beginning with the 2021 MIPS payment year, we proposed to revise the terminology with which CMS Web Interface measures are referenced-to align with the updated submission terminology as discussed in section III.I.3.h. of this final rule. Therefore, we proposed to revise §414.1335(a)(2) from “via the CMS Web Interface-for groups consisting of 25 or more eligible clinicians only”, to “for CMS Web Interface measures”.

In order to ensure that the collection of information is valuable to clinicians and worth the cost and burden of collecting information, and address the challenge of fragmented reporting for multiple measures and submission options, we solicited comment on expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. Preliminary analysis has indicated that expanding the CMS Web Interface option to groups of 16 or more eligible clinicians would likely result in many of these new groups not being able to fully satisfy measure case minimums on multiple CMS Web Interface measures. However, we could possibly mitigate this issue if we require smaller groups (with 16-24 eligible clinicians) to report on only a subset of the CMS Web Interface measures, such as the preventive care measures. We solicited stakeholder feedback on the issue of expanding the CMS Web interface to groups of 16 or more, as well as other factors we should consider with such expansion. We received comments from stakeholders regarding expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. We thank commenters for their input and may take this input into consideration in future years.

As discussed in section III.F.1.c. of this final rule, changes proposed and finalized through rulemaking to the CMS Web Interface measures for MIPS would be applicable to ACO quality reporting under the Shared Savings Program. As discussed in Table Group D: Measures
with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years of the measures appendix of this final rule, we proposed to remove 6 measures from the CMS Web Interface in MIPS. If finalized, groups reporting CMS Web Interface measures for MIPS would not be responsible for reporting those removed measures. We refer readers to the quality measure appendix for additional details on the proposals related to changes in CMS Web Interface measures.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77116), the CMS Web Interface has a two-step attribution process that associates beneficiaries with TINs during the period in which performance is assessed (adopted from the Physician Value-based Payment Modifier (VM) program). The CAHPS for MIPS survey utilizes the same two-step attribution process as the CMS Web Interface. The CY 2017 Quality Payment Program final rule (81 FR 77116) noted that attribution would be conducted using the different identifiers in MIPS. For purposes of the CMS Web Interface and the CAHPS for MIPS survey, we clarified that attribution would be conducted at the TIN level (83 FR 35897).

We did not receive comments on the proposal to revise §414.1335(a)(2) from “via the CMS Web Interface for groups consisting of 25 or more eligible clinicians only”, to “for CMS Web Interface measures”.

We are finalizing revisions to §414.1335(a)(2) to state that via the CMS Web Interface measures for groups consisting of 25 or more eligible clinicians only, groups must report on all measure included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each module.

(cc) Submission Criteria for Groups Electing to Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey
As noted in the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the established submission criteria for the CAHPS for MIPS Survey at §414.1335(a)(3). However, beginning with the 2021 MIPS payment year, we proposed to revise §414.1335(a)(3) to clarify for the CAHPS for MIPS survey, for the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to us.

We did not receive comments on the proposal to clarify the requirement to use a CMS approved CAHPS for MIPS survey vendor.

We are finalizing our proposal to amend §414.1335(a)(3) to clarify for the CAHPS for MIPS survey that beginning with the 2021 MIPS payment year, for the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to us.

(B) Summary of Data Submission Criteria

In the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the quality data submission criteria for the 2021 MIPS payment year; however, as discussed in section III.I.3.h. of this final rule, we proposed changes to existing and additional submission related terminology. Similarly, although we did not propose changes to the data completeness criteria at §414.1340, we proposed changes to existing and additional submission related terminology. For that reason, we proposed to revise §414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group’s patients
that meet the measure’s denominator criteria, regardless of payer for MIPS payment year 2021; MIPS eligible clinicians and groups submitting quality measure data on the Medicare Part B claims measures must submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for the 2021 MIPS payment year; and groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey measure, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides. Tables 34 and 35 clearly capture the data completeness requirements and submission criteria by collection type for individual clinicians and groups.

**TABLE 34: Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2020 and 2021 MIPS Payment Years**

<table>
<thead>
<tr>
<th>Collection Type</th>
<th>Performance Period</th>
<th>Data Completeness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Part B claims measures</td>
<td>Jan 1- Dec 31</td>
<td>60 percent of individual MIPS eligible clinician’s, or group’s Medicare Part B patients for the performance period.</td>
</tr>
<tr>
<td>Administrative claims measures</td>
<td>Jan 1- Dec 31</td>
<td>100 percent of individual MIPS eligible clinician’s Medicare Part B patients for the performance period.</td>
</tr>
<tr>
<td>QCDR measures, MIPS CQMs, and eCQMs</td>
<td>Jan 1- Dec 31</td>
<td>60 percent of individual MIPS eligible clinician’s, or group’s patients across all payers for the performance period.</td>
</tr>
<tr>
<td>CMS Web Interface measures</td>
<td>Jan 1- Dec 31</td>
<td>Sampling requirements for the group’s Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group’s sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.</td>
</tr>
<tr>
<td>CAHPS for MIPS survey measure</td>
<td>Jan 1- Dec 31</td>
<td>Sampling requirements for the group’s Medicare Part B patients.</td>
</tr>
<tr>
<td>Clinician Type</td>
<td>Submission Criteria</td>
<td>Measure Collection Types (or Measure Sets) Available</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Individual Clinicians</td>
<td>Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.</td>
<td>Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individual clinicians in small practices only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.</td>
</tr>
<tr>
<td>Groups (non-CMS Web Interface)</td>
<td>Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.</td>
<td>Groups select their measures from the following collection types: Medicare Part B claims measures (small practices only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey - or reports on one of the specialty measure sets if applicable. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.</td>
</tr>
<tr>
<td>Groups (CMS Web Interface for group of at least 25 clinicians)</td>
<td>Report on all measures includes in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.</td>
<td>Groups report on all measures included in the CMS Web Interface measures collection type and optionally the CAHPS for MIPS survey. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.</td>
</tr>
</tbody>
</table>

We received comments on the proposal to revise §414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data must submit data on at least 60 percent of the MIPS eligible clinician or group’s patients that meet the measure’s denominator criteria, regardless of payer for MIPS payment year 2021:

**Comment:** One commenter requested that CMS clarify the 90-day performance period mentioned in Table 31 of the proposed rule. This commenter requested more information concerning to which measures the performance period would apply and expressed concerns about the differing performance period for measures.
Response: We clarify that in the CY 2019 PFS proposed rule (83 FR 35898), the reference in Table 31 to a 90-day performance period for certain measures was an inadvertent error. To clarify, there is no 90-day performance period for any MIPS quality measure. For the 2020 and 2021 MIPS payment years, the performance period is 12 months. Table 34 Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2020 and 2021 MIPS Payment Years has been updated to reflect this correction.

Comment: One commenter opposed a full calendar-year performance period given the proposed 60 percent data completion requirement for the quality performance category and the potential burden in developing and implementing new applicable measures.

Response: While the data completeness requirement will remain at 60 percent for the 2019 performance period, we have previously noted our interest in incorporating higher data completeness thresholds in future years to ensure a more accurate assessment of a MIPS eligible clinician’s performance on quality measures and to avoid measure selection bias as much as possible, but believe it should be done so in a gradual manner. In the CY 2019 PFS proposed rule (83 FR 35893), we noted our belief that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. A longer performance period for quality will likely include more patient encounters, which will increase the denominator of the quality measures reported. Statistically, a larger sample size provides more accurate and actionable information. Furthermore, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported.
Comment: A few commenters supported the fact that our proposal to maintain the 60 percent data completeness threshold and encouraged CMS to retain this policy for future program years.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS increase the data completeness threshold to 100 percent. Other commenters noted that because calculating and submitting an accurate reporting rate requires an analysis of a full set of data and is often a manual and error-prone process, they do not believe it significantly reduces provider burden to have a 60 percent data completeness threshold as compared to 100 percent.

Response: As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53632), we noted concerns about the unintended consequences of accelerating the data completeness threshold so dramatically, which may jeopardize a MIPS eligible clinician’s ability to participate and perform well in MIPS, particularly with those clinicians who are not as experienced with MIPS quality measure submission. While we do continue to monitor the data completeness threshold with future intentions of raising the threshold for data completeness, we want to ensure that the data completeness requirement is achievable by all MIPS eligible clinicians. We do agree that it is important to incorporate higher data completeness thresholds in future years to ensure a more accurate assessment of a MIPS eligible clinician’s performance on quality measures and to avoid measure selection bias as much as possible, but believe it should be done so in a gradual manner.

Comment: One commenter requested clarification on whether the data completeness criteria is 60 percent of the performance year, regardless of time, or if MIPS eligible clinicians are mandated to include 60 percent of their patient data from the calendar year.
Response: As stated at §414.1340(b)(2), MIPS eligible clinicians are required to submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period, as illustrated in Table 34.

Comment: One commenter expressed support for updating the terminology of the data completeness criteria, stating that it does not change the data completeness criteria from the previous years.

Response: We thank the commenter for their support. We clarify that we did not make any proposals or changes to the data completeness criteria, and only made changes to existing and additional submission related terminology, as explained in the CY 2019 PFS proposed rule (83 FR 35897).

After consideration of the public comments received, we are finalizing revisions to §414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or the eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group’s patients that meet the measure’s denominator criteria, regardless of payer for MIPS payment year 2021; MIPS eligible clinicians and groups submitting quality measure data on the Medicare Part B claims measures must submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for the 2021 MIPS payment year; and groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey measure, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides, as applicable.

(iv) Application of Facility-Based Measures
Under section 1848 (q)(2)(C)(ii) of the Act, the Secretary may use measures for payment systems other than for physicians, such as measures used for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. We refer readers to section III.I.3.i.(1)(d) of this final rule for a full discussion of facility-based measures and scoring for the 2021 MIPS payment year.

(b) Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups

Under the Annual List of Quality Measures Available for MIPS Assessment

(i) Background and Policies for the Call for Measures and Measure Selection Process

In the CY 2019 PFS proposed rule (83 FR 35898 through 35899), we noted that developed and announced our Meaningful Measures Initiative.\(^{18}\) By identifying the highest priority areas for quality measurement and quality improvement, the Meaning Measures Initiative identifies the core quality of care issues that advances our work to improve patient outcomes. Through subregulatory guidance, we will categorize quality measures by the 19 Meaningful Measure areas as identified on the Meaningful Measures Initiative website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html. The categorization of quality measures by Meaningful Measure area would provide MIPS eligible clinicians and groups with guidance as to how each measure fits into the framework of the Meaningful Measure Initiative.

\(^{16}\) Link to Meaningful Measures web page on CMS site to be provided at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.
Furthermore, under §414.1305, a high priority measure is defined as an outcome, appropriate use, patient safety, efficiency, patient experience or care coordination quality measure. Due to the immense impact of the opioid epidemic across the United States, we believe it is imperative to promote the measurement of opioid use and overuse, risks, monitoring, and education through quality reporting. For that reason, beginning with the 2019 performance period, we proposed at §414.1305 to amend the definition of a high priority measure to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority. Beginning with the 2021 MIPS payment year, we proposed to define at §414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures would include intermediate-outcome and patient-reported outcome measures. We requested comment on this proposal, specifically if stakeholders have suggestions on what aspects of opioids should be measured—for example, whether we should focus solely on opioid overuse. We summarize and respond to the comments received on this proposal below.

Previously finalized MIPS quality measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174) and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures finalized for inclusion in MIPS for the 2019 performance period and future years are found in Table Group A of the “Appendix 1: Finalized MIPS Quality Measures” of this final rule. The current specialty measure sets can be found in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). The finalized new and modified quality measure specialty sets can be found in Table Group B of the “Appendix 1: Finalized MIPS Quality Measures” of this final rule and
include new measures, previously finalized measures with modifications, and previously finalized measures with no modifications.

We note that modifications made to the specialty sets may include the removal of certain previously finalized quality measures. Certain MIPS specialty sets have further defined subspecialty sets, each of which constitutes a separate specialty set. In instances where an individual MIPS eligible clinician or group reports on a specialty or subspecialty set, if the set has less than six measures, that is all the clinician is required to report. MIPS eligible clinicians are not required to report on the specialty measure sets, but they are suggested measures for specific specialties. Please note that the finalized specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 9, 2018, we announced that we would be accepting recommendations for potential new specialty measure sets for Year 3 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2018 Quality Payment Program final rule, and includes recommendations to add or remove the current MIPS quality measures from the specialty measure sets. All specialty measure set recommendations submitted for consideration were assessed to ensure that they meet the needs of the Quality Payment Program.

In the CY 2017 Quality Payment Program final rule (81 FR 77137), we finalized that substantive changes to MIPS quality measures, to include but are not limited to, measures that have had measure specification changes, measure title changes, or domain changes. MIPS

17 Listserv messaging was distributed through the Quality Payment Program listserv on January 9th, 2018, titled: “CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2019 Program Year of Merit-based Incentive Payment System (MIPS).”
quality measures with finalized substantive changes can be found in Table Group D of the “Appendix 1: Finalized MIPS Quality Measures” of this final rule.

As referenced in the CY 2017 Quality Payment Program final rule (81 FR 77291), with regards to eCQMs, in the 2015 EHR Incentive Program final rule, CMS required eligible clinicians, eligible hospitals, and critical access hospitals (CAHs) to use the most recent version of an eCQM for electronic reporting beginning in 2017 (80 FR 62893). We proposed this policy for the end-to-end electronic reporting bonus under MIPS and encourage MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eCQM. We will not accept an older version of an eCQM as a submission for the MIPS program for the quality performance category or the end-to-end electronic reporting bonus within that category. MIPS eligible clinicians and groups reporting on the quality performance category are required to use the most recent version of the eCQM specifications. The annual updates to the eCQM specifications and any applicable addenda are available on the electronic quality improvement (eCQI) Resource Center website at https://ecqi.healthit.gov for the applicable performance period. Furthermore, as discussed in section III.E. of this final rule, the Medicaid Promoting Interoperability Program generally intends to utilize eCQM measures as they are available in MIPS. We refer readers to section III.E. of this final rule for additional details and criteria on the Medicaid Promoting Interoperability Program.

In MIPS, there are a limited number of CMS Web Interface measures. We solicited comment on building upon the CMS Web Interface submission type by expanding the core set of measures available for that submission type to include other specialty specific measures (such as surgery). We thank stakeholders for their comments, and will consider it for future rulemaking.
To provide clinicians with a more cohesive reporting experience, where they may focus on activities and measures that are meaningful to their scope of practice, we discuss the development of public health priority measurement sets that would include measures and activities across the quality, Promoting Interoperability, and improvement activities performance categories, focused on public health priorities such as fighting the opioid epidemic, in section III.I.3.h.(5), of this final rule. We refer readers to section III.I.3.h.(5) of this final rule for additional details on this concept.

We received comments on the proposal to revise the definition of a high priority measure, to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority; and the policy that MIPS eligible clinicians must use the most recent specification of MIPS eCQMs while reporting for MIPS:

Comment: A few commenters expressed concern with the proposals to revise the definition of high-priority measures to include opioid related quality measures and to add several new measures to the MIPS program specifically focused on opioid use. The commenters urged CMS to consider the unintended consequences that could result if seriously ill patients experience barriers to receiving appropriate pain management. Specifically, commenters stated that, if the proposed policies are finalized, they could create incentives to reduce opioid prescriptions, even for patients with debilitating pain resulting from advanced disease progression who would respond to opioid treatment with more potential benefit than risk. The commenters also asked CMS to consider protections that could be incorporated into opioid-focused measures, such as exceptions for patients receiving hospice and palliative care and other patients with advanced stage serious illness. Further, commenters suggested that CMS rely on clinical evidence regarding the reliability and validity of measures or activities to address public
health and safety concerns with opioids. One commenter also expressed concerns that measures may not take into account numerous factors that play a role in the opioid crisis, including habits outside of clinicians’ control such as combining opioids with other medicines, using opioid for something other than pain, and failure to adhere to medicines as prescribed. One commenter recommended including quality measures that address the application of non-addictive alternatives to pain management, whether in the form of pharmacotherapeutics, medication-assisted treatment, or non-pharmacological options.

Response: To clarify, our intention is not to create barriers for seriously ill patients receiving appropriate pain management, we encourage appropriate treatment, but also encourage proper monitoring, management, follow-up, and education of patients. We believe it is important to consider patients such as those receiving hospice and palliative care, and will discuss with measure stewards of opioid-related measures whether exceptions for such patients may be appropriate. Furthermore, we have considered the reliability and validity of measures, as we require that measures have completed reliability and validity testing prior to them being considered as quality measures in MIPS. We agree with commenters that the application of non-addictive alternatives to pain management is an important area to include in quality measurement, and encourage stakeholders to reach out to the measure stewards for the consideration of their suggestions. Based on the comments and concerns expressed by commenters, we are clarifying that the finalized definition of a high priority measure is broad enough to include all aspects of opioid-related measurement rather than focus on a specific aspect of opioid measurement. We believe there are multiple areas within opioid measurement that are important; for example (but not limited to): medication management, patient education, patient outcomes, monitoring, pain management, and follow-up.
Comment: Several commenters agreed that opioid-related measures should be categorized as high-priority measures due to national interest. The commenters encouraged CMS to evaluate the inclusion of any opioid-related measures, especially eCQMs that measure developers bring to the table. Commenters stated that any opioid-related quality measures, especially if designated as high-priority measures, need to recognize that numerous factors play a role in opioid use, including factors such as pain control, patient use of other medicines combined with opioids, patient use of opioids for something other than pain, and patient failure to adhere to medicines as prescribed. One commenter cautioned against focusing solely on overuse, but rather focus on a combination of how well patient's pain is controlled, if functional improvement goals have been met, and opioid use. A few commenters indicated that identifying patients by daily use and daily dosage may not, on its own, be a good indication of quality patient care. Commenters also encouraged CMS to include patient-reported outcomes measures that look at symptom management and pain interference.

Response: We will consider opioid-related quality measures as they are submitted through the call for measures process or as QCDR measures, and also encourage the development of fully tested eCQMs. We agree with the commenters that factors such as pain control, use of other medications, and adherence are all important factors and that overuse should not be the only focus of measurement. We encourage stakeholders to submit patient-reported outcomes measures that also relate to opioids during the call for measures process or as QCDR measures during the self-nomination process.

Comment: A few commenters expressed support of the policy to require the reporting of the most current version of the eCQM. One commenter recommended that to improve electronic capture, calculation, and reporting of quality measures, CMS should incent the use of
standardized semantic content from recognized developers. Further, the commenter encouraged CMS to incorporate this work into its implementation guides to ensure eCQM calculations and benchmarks are accurate and that EHRs are accurately capturing eCQMs. In addition, a commenter noted that to continue to encourage eCQM reporting, CMS should not remove the 8 eCQMs from the measure list in 2019 as proposed.

Response: We will take these recommendations into consideration for future years of MIPS. We note that eCQM calculation standards are also included as a part of ONC’s Health IT Certification Program to ensure accuracy and consistency. We refer readers to the 2015 Edition Health IT Certification Criterion at 45 CFR 170.315(c)(1) (Clinical quality measures) for additional information on the criteria. Furthermore, we have identified those 8 eCQMs for removal for reasons including the measure having high, unvarying performance rates, or the measure is being replaced by a more robust measure that has a more meaningful quality action. Quality actions include steps taken to advance the patient care provided, moving beyond documenting in the medical record or conducting a standard of care process. For example, was a follow-up examination conducted on the patient monitor changes in medical condition or did the specialist follow-up with the primary care physician to close the referral loop. We believe that it is important to have measures in the program that provide meaningful quality measurement, by demonstrating a performance gap and having a robust quality action.

Comment: A few commenters did not support the timeline for removing eCQMs from the measure set because of the time required for EHR vendors to modify systems. One commenter recommended supporting the last two versions of eCQMs to allow sufficient time for vendors and health care organizations to develop and deploy the latest eCQM versions.
Response: As described in the CY 2017 Quality Payment Program final rule (81 FR 77291), in the 2015 EHR Incentive Programs final rule, CMS required EPs, eligible hospitals, and CAHs to use the most recent version of an eCQM for electronic reporting beginning in 2017 (80 FR 62893). Furthermore, we update specifications annually in order to stay relevant with the clinical guidelines, updates to terminology, and to correct any identified issues. We will take this recommendation into further consideration, as we plan for our annual update process improvements.

Comment: A few commenters requested clarification on whether or not practices will be required to use 2015 Edition CEHRT for the entire performance year for quality and the latest version of eCQM to earn the end-to-end bonus.

Response: As described at §414.1305, the definition of CEHRT for 2019 and subsequent years is EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102), and has been certified to the 2015 Edition health IT certification criteria. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we finalized that the CEHRT bonus would be available to MIPS eligible clinicians who report via qualified registries, QCDRs, EHRs, or the CMS Web Interface for the Quality Payment Program, in a manner that meets the end-to-end reporting requirements. Thus, in order for practices to earn the end-to-end bonus for reporting eCQMs for the 2019 performance period, they will need to be reporting using the latest version of the eCQM and will need to use CEHRT that has been certified to the 2015 Edition.

Comment: A few commenters noted concern with the timeline for the approval and communication of updated quality measures with the 12-month performance period, noting that clinicians and groups relying on this information for measure selection are unable to easily
access a measure list until months after the performance period begins. Commenters also noted that QCDR measures have traditionally not been approved until the end of December preceding the performance year, leaving registries with limited time to update their dashboards in time for the January 1 start of the new performance year. Commenters stated that clinicians need additional time to work with their EHRs to ensure that they are capturing the elements necessary to report on a measure. Therefore, commenters urged CMS to approve and communicate updates earlier.

Response: With regard to MIPS quality measures, the final specifications of the measures can only be posted once the final rule is published. For Year 2 of the program there was a delay in posting the measures within the Quality Payment Program Explore Measures Tool due to technical difficulties. However, the measure specifications were made available on the Quality Payment Program resource library (http://qpp.cms.gov) prior to the beginning of the performance period. We will continue to post the year 3 measure specifications on the Quality Payment Program resource library prior to the beginning of the performance period and will make every effort to update the Quality Payment Program Explore Measures Tool with the year 3 measures prior to the performance period, or as close to the beginning of the performance period as technically feasible. We also note that we do not incorporate the QCDR measures into the Quality Payment Program Explore Measures Tool, rather these will be available on the Quality Payment Program resource library. During the limited timeframe available between November 1st and January 1st, we have reviewed over a thousand QCDR measure submissions for consideration in the upcoming MIPS performance period, communicated those decisions to the QCDRs, and posted the qualified postings by January 1 of the performance period. QCDRs and registries are notified prior to January 1 regarding which measures will be approved for the
upcoming performance period. In section III.I.3.k.(3) of this final rule, we describe the finalized policy to move the self-nomination period up to begin in July 1 and end on September 1, thereby giving us an earlier start to evaluate and make decisions on QCDR measures.

Comment: Many commenters stated that the current timeline for release of measure specifications in December is overly burdensome and hinders the consistency of measure data in terms of comparability of results over time as it does not allow adequate time to build and test systems prior to QCDRs reporting measures on January 1.

Response: We understand the commenters’ concerns, and interpret their reference to measures to mean the MIPS quality measure specifications not the QCDR measure specifications. We clarify that it is not technically feasible to release the MIPS quality measure specifications until the final rule is published. We will take the commenters suggestion in to consideration as we consider the operational feasibility of releasing the MIPS quality measure specifications earlier than December. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77368), in order for a QCDR to be approved for a given performance period, they must support the minimum of 6 quality measures to be approved. Similar to previous performance periods, we plan to provide QCDRs and qualified registries with time to select additional MIPS quality measures to support for the upcoming performance period based upon their review of the measure specifications. Furthermore, we note that we expect that QCDRs and qualified registries would be up and running by January 1 of the performance period to accept and retain data, to allow clinicians to begin their data collection on January 1 of the performance period. However, the data will not be submitted to us until the start of data submission for the 2019 performance period.
After consideration of the public comments received, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to define a high priority measure at §414.1305 as an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include intermediate-outcome and patient-reported outcome measures.

In the CY 2017 Quality Payment Program final rule (81 FR 77090), we indicated that we intend to reduce the number of claims-based measures in future program years as more measures become available through electronic collection types such as eCQMs or MIPS CQMs. In section III.1.3.h of this final rule, we are finalizing our proposal to limit the Medicare Part B claims collection type to small practices, which furthers our goal of moving away from Medicare Part B claims measures. We strongly encourage measure stewards to keep this in mind as they develop and submit measures for consideration, during the call for measures process (specifically for the MIPS quality performance category).

(ii) Topped Out Measures

In the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. After a measure has been identified as topped out for 3 consecutive years through the benchmarks, we may propose to remove the measure through notice and comment rulemaking. Therefore, in the 4th year, if finalized through rulemaking, the measure would be removed and would no longer be available for reporting during the performance period. We refer readers to the 2018 MIPS Quality Benchmarks’ file, that is located on the Quality Payment Program resource library

(https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-
library.html) to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks’ file. It should be noted that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2019 MIPS Quality Benchmarks’ file is released in late 2018.

In the CY 2019 PFS proposed rule (83 FR 35899 through 35900), we proposed that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. We are concerned that topped out non-high priority process measures require data collection burden without added value for eligible clinicians and groups participating in MIPS. It is important to remove these types of measures, so that available measures provide meaningful value to clinicians collecting data, beneficiaries, and the program. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency).

Since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle, we proposed to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53640). When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. Because
QCDRs have more flexibility to develop innovative measures, we believe there is limited value in maintaining topped out QCDR measures in MIPS.

We received comments on the following proposals: (1) once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle; and (2) to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule:

Comment: Several commenters supported the topped out proposal, stating that it would reduce clinician burden, discontinue measures that have limited value to the Quality Payment Program, and continue to focus on measures that are clinically meaningful to patients. One commenter noted that this proposal will allow CMS to differentiate between exceptional, high performing, and other clinicians. Several commenters recommended that topped out measures be removed regardless of the collection type.

Response: We disagree that topped out measures should be removed regardless of the collection type. There have been instances where measures have been specified through multiple collection types, but have only become topped out in one or two of the collection types. If there is an opportunity to collect more robust data on a measure, while the measure is not topped out for that particular collection type, we believe we should continue to do so.

Comment: Several commenters did not support the proposal to exclude QCDR measures from the topped out timeline, indicating that review processes for QCDR and MIPS measures should be standardized and provide clinicians, groups, and measure stewards sufficient notice to review and potentially replace topped out measures. One commenter indicated that applying the
topped out policy to QCDR measures will also ensure consistency across the program and minimize complexity. A few commenters indicated that maintaining QCDR measures in the program for a minimum number of years will also limit measures with sufficient historical data to set a benchmark that permits the evaluation of performance. Several commenters noted that removal of topped out QCDR measures would limit the number of specialty-specific measures available and stated that and the proposal does not allow sufficient time and volume of cases to determine if QCDR measures have a valid benchmark. One commenter recommended a two-year retention policy for extremely topped out QCDR measures to reduce burden and confusion for clinicians.

Response: We note that the process and timeline in which MIPS quality measures and QCDR measures are approved for a given MIPS performance period is different, as is the criteria for consideration. QCDRs are expected to be nimble and innovative enough to develop QCDR measures that are robust in their quality action and demonstrate a performance gap. We believe topped out measures do not add value in the realm of quality measurement, and believe they should be removed from the program as appropriate. We do not agree that removing topped out QCDR measures would create complexity, since it is a well-established process that QCDR measures are reviewed for approval on an annual basis, and is something that stakeholders should be aware of. We also do not believe that topped out QCDR measures should be retained in the program for 2 years; this may inadvertently impact a high performing clinician who may not receive a high score when compared to other clinicians reporting on the same measure. For example, a clinician whose performance rate is at 96 percent on a topped out measure may receive fewer points than another clinician whose reporting rate is at 98 percent on the same measure, when both performance rates would be considered high performing. We do not agree
that the removal of topped out QCDR measures would impact the number of available specialty-specific measures available, since QCDR measures are reviewed and approved on a more accelerated timeline in comparison to the MIPS quality measures. Furthermore, MIPS eligible clinicians who wish to use QCDRs, are not limited to reporting on QCDR measures.

**Comment:** Many commenters did not support the proposal to allow the identification and removal of extremely topped out measures. Several commenters noted that removal of measures will have a large impact on small practices and specialists who have limited options regarding relevant quality measures. Several commenters stated that more time is needed to determine if measures are truly topped out because benchmarks may reflect the performance of only top-performing clinicians rather than performance across all clinicians. They stated that additional time would allow for the collection of more robust data. Many commenters stated that topped out measures should all have the same 4-year timeline because the process to develop a measure that could replace a topped out measure is lengthy and recommended close communication with measure stewards. A few commenters recommended a 2-year timeline for the removal of extremely topped out measures. A few commenters encouraged CMS to defer to measure developers and national endorsement organizations to define which measures are topped out. One commenter noted that additional factors should be taken into consideration prior to removing an extremely topped out measure, including the type of measure, the length of time the measure is reported, measure steward and specialist input, performance results, reporting options, data sources, small sample size, public health issues covered, and whether measures are used in other programs. One commenter recommended that prior to removing a topped out measure, CMS be transparent about the data used to determine topped out status, so the public has an understanding of how many clinicians reported the measure and the performance rate.
Response: We note that in addition to the quality measures available in the MIPS quality measure set, QCDR measures are also available. We review measure benchmarks as a part of our process for identifying topped out and extremely topped out measures and believe that extremely topped out measures, such as those with an average mean performance within the 98th to 100th percentile, leave no room for further quality improvement, thereby providing clinicians little value. We utilized the 2018 quality measure benchmarks as a part of the criteria used to identify those measures for removal. The benchmarks are reflective of the performance of those clinicians who have reported on the measure and will continue to do so should the measure be available in the program which is why we do not believe there will be variances in the high performing data submitted if the measure is retained. We do not believe that we should retain the extremely topped out measures within a 4 year timeline because the measures take a lengthy time to replace. While the timeline to add MIPS quality measures does typically take about 2 years, we note there are additional measures (QCDR measures) available for reporting through QCDRs. We appreciate the commenters’ feedback suggesting we defer to measure developers and national endorsement organizations to define which measures are topped out; we can take this suggestion in to future consideration. In the CY 2019 PFS proposed rule (83 FR 35900), we stated we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency). We encourage stakeholders to continue to submit quality measures that address measurement gaps as we incrementally remove quality measures that are extremely topped out, merely reflect the standard of care without a quality action, or are duplicative of other more robust quality measures, as we believe they no longer provide meaningful measurement to clinicians.
After consideration of the public comments received, we are finalizing our proposal that once the measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. However, we will also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to CMS).

We are also finalizing our proposal to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53640). When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

(iii) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal.

We have previously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 Quality Payment
Program final rule (81 FR 77101), we explained that we believe that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive. In the CY 2018 Quality Payment Program quality measure set, 102 of the 275 quality measures are process measures that are not considered high priority. As discussed above, beginning with the 2021 MIPS payment year, we proposed to define at §414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Because the removal of all non-high priority process measures would impact most specialty sets, nearly 94 percent, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate.

As described in the CY 2019 PFS proposed rule (83 FR 35900), beginning with the 2019 performance period, we proposed to implement an approach to incrementally remove process measures where prior to removal, consideration will be given to, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure’s performance data.
- Whether the measure is designated as high priority or not.
- Whether the measure has reached an extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful
distinctions and improvement in performance can no longer be made, as described in section III.1.3.(b)(ii) of this final rule.

We received the following comments on the proposal to implement a process to incrementally remove process measures:

Comment: While some commenters supported the inclusion of population measures, several commenters recommended the removal of population health measures, which it believed are often incorrectly attributed, especially for specialty clinicians and rural clinicians, and often have a very low statistical reliability at the individual clinician and group practice levels.

Response: We believe that population measures may reduce burden on clinicians and allow for assessment of public health issues on a larger scale. Reliability is one of the many important and scientific issues that CMS addresses and tests during our measure development process regardless of measure type (that is, whether the measures are population-based or provider-specific measures). We recognize that specialty clinicians and rural clinicians may be more likely to have a smaller sample size, and that this may result in lower reliability. At the same time, we also recognize that many clinicians or groups may have sufficient volume depending on the measures under development, and because measure reliability also depends on the particular cohort and outcome of the specific measures under development. As part of the CMS standardized measure development process, we will address the reliability issue in several ways. We will consult national experts and stakeholders including health care providers and patients in conceptualizing and selecting measures for development and conduct rigorous testing of the measure reliability and volume threshold for use.

Comment: Many commenters supported the removal of 34 MIPS measures to align with CMS’s Meaningful Measures framework and allow eligible clinicians to reduce and prioritize
other measures, providing a focus on improving patient care and outcomes. A few commenters encouraged CMS to continue to review its quality measure sets to identify the most meaningful measures and further align hospital and clinician reporting requirements.

Response: We agree that alignment across quality programs is important in an effort to reduce clinician burden, and will seek to continue to look for ways to align with other programs while maintaining the objective and goals of MIPS through future rulemaking.

Comment: Many commenters did not support the proposal to remove measures, stating that many specialists will not have enough relevant measures to meet reporting requirements, clinicians may still be required to report removed measures to other payers, and process measures are under the control of the clinician and often important when coupled with other measures including cost measures. A few commenters indicated that important quality of care aspects may only be captured by a process measure, even those that are topped out. One commenter disagreed with the removal of topped out measures generally until the vast majority of peer reviewed literature demonstrates a significant change in practice patterns. One commenter recommended delaying the removal of measures, to allow time for clinicians to comply with program requirements.

Response: We note that prior to proposing to remove quality measures from the program, we take into consideration the impacts the removal would have on the number of measures available to clinicians in the program. We do not agree that we should delay the removal of measures. We continue to believe that non-high priority process measures impose data collection burden without adding value for eligible clinicians and groups participating in MIPS. Typically, process measures merely reflect the standard of care and do not have a robust quality action. In many instances, process measures have high, unvarying performance leaving no room for
improvement. We understand that there are some process measures that are valuable, but believe that it is important that they address one of the high priority areas and demonstrate a performance gap in order to be meaningful. Furthermore, we do understand that important quality of care aspects may only be captured by some topped out process measures, and encourage clinicians to continue to measure and monitor their progress in these areas; however, we do not believe that these measures provide value or should be tied to a pay for performance program such as MIPS. If a MIPS quality measure is removed from the program, it is because the measure no longer has value in the performance payment program; however, we believe that clinicians can still collect and evaluate data on these metrics for their own internal quality improvement goals or areas of improvement as outlined in peer reviewed literature. We are aware that there are certain process measures that may be required to be reported to other payers; however, note that this difference may reflect different underlying goals of their program. Another consideration is that these process measures with high, unvarying performance, may also impact a MIPS eligible clinician’s ability to receive a high score in the quality performance category. While we agree that process measures are under the control of the clinician and often important when coupled with other measures including cost measures, we do not believe that this justifies retaining extremely topped out measures in MIPS.

Comment: Several commenters expressed concern about the timeline for removing measures. A few commenters requested that CMS maintain the 4-year measure removal policy since it would give clinicians, professional societies, and third party vendors (for example, registries) some time to prepare and develop an alternative reporting strategy. One commenter recommended an incremental phased approach according to a specified timeline, similar to the 4-year timeline currently in place for removing topped out measures from the program in order to
ensure that the removal of the measures is truly warranted and to allow clinicians time to begin implementing other measures for reporting purposes. One commenter recommend that CMS only propose removal of measures during the official measure process to assist with predictability.

Response: To clarify, similar to how MIPS quality measures are proposed and finalized into the MIPS program through notice-and-comment rulemaking, we utilize a similar approach for removing measures from the program. We do not believe that a 4-year timeline to remove all measures is appropriate. A topped out measure timeline that is 4 years long is appropriate for measures with high performance where special scoring caps are applied as a response to the high unvarying performance; however, we are still finalizing the policy to remove extremely topped out measures (within the 98-100 percent range) through the following rulemaking cycle after the measure is identified as extremely topped out. This is to note that there are exceptions to the 4 year timeline, and in instances where there are more robust measures being proposed and finalized, we believe it is appropriate to remove duplicative measures through notice-and-comment rulemaking without consideration to a longer timeline. In addition, measures that are not maintained or updated to reflect current clinical guidelines are not reflective of a clinician’s scope of practice, should also be proposed for removal in the next rulemaking cycle. Furthermore, the removal of low-bar, standard of care process measures aligns with our goals to have more outcomes based measures in the program. Furthermore, a 4-year timeline does not take into consideration that we may propose new quality measures that are more robust in their quality action that would deem the existing process measure to be duplicative. Also, as process measures top out, they will inadvertently impact a clinician’s ability to achieve a high score for that specific measure. As stated earlier above, we will only propose the removal of MIPS quality
measures through formal notice-and-comment rulemaking, and we believe that this annual process will provide stakeholders with sufficient notice and opportunity to voice their concerns on specific measure removals through the public comment process.

**Comment:** One commenter also requested that CMS evaluate measures for removal based on the collection type. They stated that the differences in collection types can be enough of a workflow and cost consideration in alterations that it should be a factor in the consideration of measures removal. For example, there are several eCQMs proposed for removal due to a duplicative measure being available; however, in most instances, that duplicative measure is not available as an eCQM. This would potentially force practices to maintain relationships and pay for reporting through multiple vendors to maintain their list of measures.

**Response:** Initially, we proposed to remove specific MIPS quality measures that were duplicative of new, robust measures. We have taken the comments into consideration and in instances where the new measure does not have eCQM available as a collection type, we have decided not to remove the existing (duplicative) measure for the eCQM collection type only. We refer readers to Appendix 1: Finalized Quality Measures of this final rule for additional detail on these eCQMs. We clarify that we do look at the availability of measures through the different collection types as we review measures for possible inclusion or removal, and will continue to monitor and consider the availability through the collection types as criteria when removing quality measures from MIPS.

After consideration of the public comments received, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to implement an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to:
• Whether the removal of the process measure impacts the number of measures available for a specific specialty.

• Whether the measure addresses a priority area highlighted in the Measure Development Plan: https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html.

• Whether the measure promotes positive outcomes in patients.

• Considerations and evaluation of the measure’s performance data.

• Whether the measure is designated as high priority or not.

• Whether the measure has reached an extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

(iv) Categorizing Measures by Value

In the CY 2019 PFS proposed rule (83 FR 35900), we outlined the various types of MIPS quality and QCDR measures available for reporting in the quality performance category, such as outcome, high-priority, composite, and process measures, we acknowledge that not all measures are created equal. For example, the value or information gained by reporting on certain process measures does not equate that which is collected on outcome measures. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collecting the information.

Based on this, we solicited comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. For example, higher value measures that are considered “gold” standard, which could include outcome measures, composite measures, or measures that address agency priorities
(such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high value measure. Measures that are considered second tier, or at a “silver” standard would be measures that are considered process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement; or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures would be considered “bronze” measures. We refer readers to section III.1.3.i.(1)(b)(xi) of this final rule for discussion on the assignment of value and scoring based on measure value.

We have received comments from stakeholders regarding categorizing measure by value. We thank commenters for their input and may take this input into consideration in future years.

(3) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77162 through 77177, and 82 FR 53641 through 53648, respectively).

(a) Weight in the Final Score

In the CY 2018 Quality Payment Program final rule, we established that the weight of the cost performance category would be 10 percent of the final score for the 2020 MIPS payment year (82 FR 53643). We had previously finalized in the CY 2017 Quality Payment Program final rule at §414.1350(b)(3) that beginning with the 2021 MIPS payment year, the cost performance category would be 30 percent of the final score, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act (81 FR 77166). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018, enacted on February 9, 2018, amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies
to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, this provision shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I), which we discuss in section III.I.3.h.(3)(b)(i) of this final rule.

In light of these amendments, in the proposed rule (83 FR 35900 through 35901), we proposed at §414.1350(d)(3) that the cost performance category would make up 15 percent of a MIPS eligible clinician’s final score for the 2021 MIPS payment year. As discussed in section III.I.3.h.(3)(b)(iv) of this final rule, §414.1350(b) will be redesignated as §414.1350(d). We proposed to delete the existing text under §414.1350(b)(3) and address the weight of the cost performance category for the MIPS payment years following 2021 in future rulemaking. We also proposed a technical change to the text at §414.1350(b) (redesignated as §414.1350(d)) to state that the cost performance category weight will be as specified under redesignated §414.1350(d), unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act (83 FR 35901).

We believe that measuring cost is an integral part of measuring value, and we believe that clinicians have a significant impact on the costs of patient care. However, we proposed to only modestly increase the weight of the cost performance category for the 2021 MIPS payment year from the 2020 MIPS payment year because we recognize that cost measures are still relatively early in the process of development and that clinicians do not have the level of familiarity or
understanding of cost measures that they do of comparable quality measures (83 FR 35900 through 35901). As described in section III.I.3.h.(3)(b)(ii) of this final rule, we are finalizing the addition of 8 episode-based measures to the cost performance category beginning with the 2019 MIPS performance period. This is a first step in developing a more robust andclinician-focused measurement of cost performance. We will continue to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years. Introducing more measures over time would allow for more clinicians to be measured in this performance category. It would also allow time for more outreach to clinicians to better educate them on the cost measures. We considered maintaining the weight of the cost performance category at 10 percent for the 2021 MIPS payment year as we recognize that clinicians are still learning about the cost performance category and being introduced to new measures. We invited comment on whether we should consider an alternative weight for the 2021 MIPS payment year.

The following is a summary of the public comments received on these proposals and our responses:

**Comment:** Several commenters supported our proposal to increase the weight of the cost performance category to 15 percent for the 2021 MIPS payment year, noting the importance of managing cost in measuring the value of a clinician as well as the opportunity to gradually increase the weight of the performance category.

**Response:** We thank the commenters for their support for this proposal.

**Comment:** Several commenters opposed our proposal to increase the weight of the cost performance category to 15 percent for MIPS payment year 2021. They believed that the increased flexibility provided by the Bipartisan Budget Act of 2018 should be used to maintain
the weight at 10 percent for MIPS payment year 2021 and in future years. Some commenters requested that the weight of the cost performance category not be increased until CMS can address issues of social and complexity risk factors and of clinical risk adjustment for measures in areas such as oncology. Some commenters suggested maintaining the weight of the cost performance category at 10 percent until CMS is able to provide more detailed and actionable performance data and develop more reliable and valid measures.

Additionally, several commenters opposed our proposal to increase the weight of the cost performance category because we proposed to add new episode-based measures (as detailed in section III.I.3.h.(3)(b)(ii) of this rule) and clinicians should have time to learn about these measures before the category weight is increased. Additionally, several commenters suggested CMS wait to increase the cost performance category weight until sufficient episode groups exist for additional specialties.

**Response:** We continue to investigate ways to best accommodate the issue of clinical and social risk adjustment in measures contained in the cost performance category. All measures included in the cost performance category are adjusted for clinical risk. We have adopted a complex patient bonus at the final score level that adjusts again for patient clinical complexity as well as some elements of social complexity. We also continue to consider ways to offer actionable feedback on cost measures to clinicians in the future.

In regards to the episode-based measures, we do not believe the introduction of these new measures should mean that the weight of the performance category should be maintained, especially since stakeholders had the opportunity to gain experience with the new measures through field testing in the fall of 2017. The performance category also still includes two measures that were used in the first 2 years of MIPS. The Bipartisan Budget Act of 2018 gave
CMS increased flexibility to establish the weight of the cost performance category for the first 5 years of MIPS, but the weight is still required to be 30 percent beginning with the 2024 MIPS payment year. Therefore, we believe it is necessary to begin adjusting the weight gradually, including increasing the weight to 15 percent for the 2021 MIPS payment year. We will concurrently look to increase the number of clinicians who are measured in the cost performance category by developing and considering for inclusion in the Quality Payment Program more episode-based measures that cover additional types of clinicians and specialties.

After consideration of the public comments, we are finalizing our proposal at §414.1350(d)(3) to weight the cost performance category at 15 percent for the 2021 MIPS payment year as proposed. Additionally, we are also finalizing our proposal to delete the existing text under §414.1350(b)(3) and address the weight of the cost performance category for the MIPS payment years following 2021 in future rulemaking as proposed. Finally, we are finalizing our proposed technical change to the text at §414.1350(b) (redesignated as §414.1350(d)) to state that the cost performance category weight will be as specified under redesignated §414.1350(d), unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, as proposed.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are ready for adoption under the cost performance category and move towards the goal of increasing the weight to 30 percent of the final score. To provide for a smooth transition, we anticipate that we would increase the weight of the cost performance category by 5 percentage points each year until we reach the required 30 percent weight for the 2024 MIPS payment year. We invited comments on this approach to weighting the cost performance category for the 2022 and 2023 MIPS payment years, considering our
flexibility in setting the weight between 10 percent and 30 percent of the final score, the availability of cost measures, and our desire to ensure a smooth transition to a 30 percent weight for the cost performance category. We appreciate the comments we received and will consider them as we develop proposals for future rulemaking.

(b) Cost Criteria

(i) Background

Under §414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. In the CY 2018 Quality Payment Program final rule, we established two cost measures (total per capita cost measure and Medicare spending per beneficiary (MSPB) measure) for the 2018 MIPS performance period and future performance periods (82 FR 53644). These measures were previously established for the 2017 MIPS performance period (81 FR 77168). We will continue to evaluate cost measures that are included in MIPS on a regular basis and anticipate that measures could be added or removed through rulemaking as measure development continues. In general, we expect to evaluate cost measures according to the measure reevaluation and maintenance processes outlined in the “Blueprint for the CMS Measures Management System” (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf). As described in section 2 of the Blueprint for the CMS Measures Management System Version 14.0, we will conduct annual evaluations to review the continued accuracy of the measure specifications. Annual updates ensure that the procedure, diagnostic, and other codes used in the measure account for updates to coding systems over time. To the extent that these updates would constitute a substantive change to a measure, we would ensure the changes are proposed for adoption through rulemaking. We will
also comprehensively reevaluate the measures every 3 years to ensure that they continue to meet measure priorities. As a part of this comprehensive reevaluation, we will gather information through environmental scans and literature reviews of recent studies and new clinical guidelines that may inform potential refinements. We will also analyze measure performance rates and re-assess the reliability and validity of the measures. Throughout these reevaluation efforts, we will summarize and consider all stakeholder feedback received on the measure specifications during the implementation process, and may seek input through public comment periods. In addition, the measure development contractor may acquire individual input on measures by convening Technical Expert Panels (TEPs) and clinical subcommittees. Aside from these regular measure reevaluations, there may be ad-hoc reviews of the measures if new evidence comes to light which indicates that significant revisions may be required.

We will also continue to update the specifications to address changes in coding, risk adjustment, and other factors. The process for updating measure specifications will take place through ongoing maintenance and evaluation, during which we expect to continue seeking stakeholder input. As we noted above, any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking. We appreciate the feedback that we have received so far throughout the measure development process and believe that stakeholders will continue to provide feedback to the measure development contractor on episode-based cost measures by submitting written comments during public comment opportunities, by participating in the clinical subcommittees convened by the measure development contractor, or by attending education and outreach events. We will take all comments and feedback into consideration as part of the ongoing measure evaluation process.
As we noted in the CY 2017 Quality Payment Program final rule (81 FR 77137) regarding quality measures, which we believe would also apply for cost measures, some updates may incorporate changes that would not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. As described in section 3 of the Blueprint for the CMS Measures Management System Version 14.0, if substantive changes to these measures become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the Measure Applications Partnership (MAP). The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. They also consider whether the measures are scientifically acceptable and reflect current clinical guidelines.

Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I) requiring the Secretary to post on the CMS website information on cost measures in use under MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of stakeholder engagement, and the percent of expenditures under Medicare Part A and Part B that are covered by cost measures. This information shall be posted no later than December 31 of each year beginning with 2018. We expect this posting will provide a list of the cost measures
established for the cost performance category for the current performance period (for example, the posting in 2018 would include a list of the measures for the 2018 MIPS performance period), as well as a list of any cost measures that may be proposed for a future performance period through rulemaking. We will provide hyperlinks to the measure specifications documents and include the percent of Medicare Part A and Part B expenditures that are covered by these cost measures. The posting will also include a list and description of the measures under development at that time. We intend to summarize the timeline for measure development, including the stakeholder engagement activities undertaken, which may include a TEP, clinical subcommittees, field testing, and education and outreach activities, such as national provider calls and listening sessions. Finally, the posting will provide an overview of potential future topics in cost measure development, such as any clinical areas in which measures may be developed in the future (83 FR 35901 through 35902).

(ii) Episode-Based Measures for the 2019 and Future Performance Periods

Episode-based measures differ from the total per capita cost measure and MSPB measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given timeframe.

We discussed our progress in the development of episode-based measures in the CY 2018 Quality Payment Program proposed rule (82 FR 30049 through 30050) and received significant positive feedback on the process used to develop the measures as well as the measures’ clinical focus that was informed by expert opinion (82 FR 53644 through 53646). The specific measures selected for the initial round of field testing were included based on the volume of beneficiaries impacted by the condition or procedure, the share of cost to Medicare impacted by the condition
or procedure, the number of clinicians/clinician groups attributed, and the potential for alignment with existing quality measures.

We have developed episode-based measures to represent the cost to Medicare for the items and services furnished to a patient during an episode of care (“episode”). Episode-based measures are developed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode’s timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts. Episode-based measures are calculated using Medicare Parts A and B fee-for-service claims data and are based on episode groups. Episode groups:

- Represent a clinically cohesive set of medical services rendered to treat a given medical condition.
- Aggregate all items and services provided for a defined patient cohort to assess the total cost of care.
- Are defined around treatment for a condition (acute or chronic) or performance of a procedure.

Items and services in the episode group could be treatment services, diagnostic services, and ancillary items and services directly related to treatment (such as anesthesia for a surgical procedure). They could also be items and services that occur after the initial treatment period that may be furnished to patients as follow-up care or to treat complications resulting from the treatment. An episode is a specific instance of an episode group for a specific patient and clinician. For example, in a given year, a clinician might be attributed 20 episodes (instances of
the episode group) from the episode group for heart failure. In section III.I.3.h.(3)(b)(iv) of this final rule, we discuss the attribution rules for cost measures.

After episodes are attributed to one or more clinicians, items and services may be included in the episode costs if they are furnished within a patient’s episode window. Items and services will be included if they are the trigger event for the episode or if a service assignment rule identifies them as a clinically related item or service during the episode. The detailed specifications for these measures, which include information about the service assignment rules, can be reviewed at qpp.cms.gov.

To ensure a more accurate comparison of cost across clinicians, episode costs are payment standardized and risk adjusted. Payment standardization adjusts the allowed amount for an item or service to facilitate cost comparisons and limit observed differences in costs to those that may result from health care delivery choices. Payment standardized costs remove any Medicare payment differences due to adjustments for geographic differences in wage levels or policy-driven payment adjustments such as those for teaching hospitals. Risk adjustment accounts for patient characteristics that can influence spending and are outside of clinician control. For example, for the elective outpatient PCI episode-based measure, the risk adjustment model may account for a patient’s history of heart failure.

The measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644). These processes included convening a TEP and clinical subcommittees to solicit expert and clinical input for measure development, conducting national field testing on the episode-based cost measures developed, and seeking input from clinicians and stakeholders through engagement activities. Seven clinical
subcommittees were convened through an open call for nominations between March 17, 2017 and April 24, 2017, composed of nearly 150 clinicians affiliated with almost 100 specialty societies. These subcommittees met at an in-person meeting and through webinars from May 2017 to January 2018 to select an episode group or groups to develop and provide detailed clinical input on each component of episode-based cost measures. These components included episode triggers and windows, item and service assignment, exclusions, attribution methodology, and risk adjustment variables.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53645), we provided an initial opportunity for clinicians to review their performance based on the new episode-based measures developed by the clinical subcommittees in the fall of 2017 through national field testing.

During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form. We received over 200 responses, including 53 comment letters, during the field test feedback period. We shared the feedback on the draft measure specifications with the clinical subcommittees who considered it in providing input on measure refinements after the end of field testing. A field testing feedback summary report is publicly available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-field-testing-feedback-summary-report.pdf.

To engage clinicians and stakeholders, we conducted extensive outreach activities including hosting National Provider Calls (NPCs) to provide information about the measure development process and field test reports, and to give stakeholders the opportunity to ask questions.
The new episode-based measures developed by the clinical subcommittees were considered by the NQF-convened MAP, and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement. We intend to submit these episode-based measures to NQF for endorsement in the future. The MAP provides an opportunity for an interdisciplinary group of stakeholders to provide input on whether the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. Following the successful field testing and review through the MAP process, we proposed to add 8 episode-based measures listed in Table 36 as cost measures for the 2019 MIPS performance period and future performance periods (83 FR 35902).

The attribution methodology for these measures is discussed in section III.I.3.h.(3)(b)(iv)(B) of this final rule. The detailed specifications for these measures can be reviewed at qpp.cms.gov. These specifications documents consist of (i) a methods document that outlines the methodology for constructing the measures, and (ii) a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides a high-level overview of the measure development process, including discussion of the detailed clinical input obtained at each step, and details about the components of episode-based cost measures: defining an episode group; assigning costs to the episode group; attributing the episode group; risk adjusting episode group costs; and aligning cost with quality. The methods document also contains the detailed measure methodology that describes each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the codes used in the specifications, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjustors.
TABLE 36: Episode-Based Measures Proposed for the 2019 MIPS Performance Period and Future Performance Periods

<table>
<thead>
<tr>
<th>Measure Topic</th>
<th>Measure Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective Outpatient Percutaneous Coronary Intervention (PCI)</td>
<td>Procedural</td>
</tr>
<tr>
<td>Knee Arthroplasty</td>
<td>Procedural</td>
</tr>
<tr>
<td>Revascularization for Lower Extremity Chronic Critical Limb Ischemia</td>
<td>Procedural</td>
</tr>
<tr>
<td>Routine Cataract Removal with Intraocular Lens (IOL) Implantation</td>
<td>Procedural</td>
</tr>
<tr>
<td>Screening/Surveillance Colonoscopy</td>
<td>Procedural</td>
</tr>
<tr>
<td>Intracranial Hemorrhage or Cerebral Infarction</td>
<td>Acute inpatient medical condition</td>
</tr>
<tr>
<td>Simple Pneumonia with Hospitalization</td>
<td>Acute inpatient medical condition</td>
</tr>
<tr>
<td>ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)</td>
<td>Acute inpatient medical condition</td>
</tr>
</tbody>
</table>

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters supported our proposed adoption of the 8 episode-based measures under the cost performance category for the 2021 MIPS payment year. These commenters noted their support for the significant clinician input into the measures.

Response: We thank the commenters for their support.

Comment: Several commenters supported the development of episode-based measures but expressed concern about including them in the MIPS cost performance category for the 2019 MIPS performance period. They recommended that there be additional time for clinicians to understand and address their performance on the measures. One commenter indicated that although the measures had been made available as part of field testing in the fall of 2017, the feedback that was made available did not facilitate action to improve on the part of the clinician. Another commenter suggested that CMS use 2019 as a pilot year to better test these new episode-based measures.

Response: We will continue to work to make clinicians more familiar with the measures through education and outreach activities. For example, we have held cost performance category
webinars to help clinicians understand the cost measures in use for the MIPS 2018 performance period, and expect to hold similar webinars in the future. We believe that the extensive field testing activities conducted in the fall of 2017 in combination with future education and outreach will help to ensure clinicians will understand these episode-based measures and what actions they could take to improve their performance in the measures. We do not believe that an additional year of pilot testing is necessary at this time given the field testing and extensive involvement of clinicians in the development of these measures.

**Comment:** Many commenters requested more detailed feedback on cost measures in order to improve their performance, stating that it is difficult to manage costs without receiving data on the patients attributed to them for purposes of the cost measures. Some commenters requested that CMS provide information on attributed patients on a regular basis, such as quarterly. Some commenters expressed concern that in contrast with the Value Modifier program, CMS has not provided detailed feedback on cost measures, such as identifying beneficiaries and the services they received for the 2017 MIPS performance period. One commenter also suggested the use of an alternative metric, such as the average ratio of the observed cost compared to the expected cost, as a final comparison for the episode-based measures, as they believe this to be more informative and actionable for clinicians.

**Response:** We have conducted user research on the feedback provided for the first year of MIPS. In addition to that feedback, we are also reviewing the QRURs from the legacy VM program and conducting user research about what is valuable within the information provided historically. We are committed to maturing the feedback experience for year 2 and may consider providing beneficiary-level data on cost measures in the future. Additionally, while we are unsure whether or not the average ratio of the observed cost to expected cost would be more...
informative than our current feedback reports, we will continue to monitor the information provided, and explore ways to provide actionable information to clinicians as we develop the measures for the cost performance category.

**Comment:** A few commenters supported the development and inclusion of episode-based measures but expressed concern that measures for their particular specialty or focus area, such as urology, chiropractic medicine, and medical oncology, were not yet included. A few commenters suggested that CMS continue to engage with stakeholders and provide a transparent process as CMS continues to develop additional episode-based measures. One commenter recommended that CMS develop or include quality measures in tandem with cost measures to prevent unintended consequences of attempts to reduce cost which could adversely affect quality of care.

**Response:** We continue to work to develop new episode-based measures that could be considered for inclusion in the cost performance category in future years. We expect that future measures may apply to a greater range of specialties and clinical areas, such as urology and the other focus areas suggested by commenters. Section 1848(r)(2)(D)(i)(I) of the Act requires us to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. While we have developed some episode-based measures to target that goal as required, we shall continue our work to develop additional measures focusing on both additional specialty types as well as consider the important issue of measuring both cost and quality. By continuing to gather detailed clinician and expert input on episode-based measures, such as through clinical subcommittees and technical expert panels, we hope to identify and mitigate potential unintended consequences at each stage of measure development and testing.
Comment: A few commenters expressed concern with the overall process for adding episode-based measures to the MIPS program on an annual basis. They indicated that while clinician input is valuable in defining the measures, it is also of particular importance to have an underlying structure for episode-based measures that defines responsibility for patients as they cross between multiple episodes. They opposed inclusion of episode-based measures until these issues are addressed. Additionally, several commenters offered alternative frameworks to consider in the future development of episode-based measures, including moving towards a tool that offers a multi-payer perspective. One commenter urged CMS to develop episode-based measures that are specific to discrete episodes of care. A few commenters encouraged CMS to consider other factors when developing episode-based measures including Activities of Daily Living (ADLs), counter quality measures, patient specific pricing, and medical innovations.

Response: We rely on a comprehensive framework and systematic process for creating episode-based measures that account for the roles and responsibilities of individual clinicians in the care of individual patients experiencing specific health conditions. This framework has been applied in constructing all of the new cost measures for use in MIPS, and in revising episode groups that had been developed under section 1848(n)(9)(A) of the Act. Our current process includes: (1) a transparent conceptual framework for creating episodes of care that assigns costs for patients to those clinicians with the ability to influence those costs; (2) a mechanism for incentivizing high quality treatment that lowers preventable high cost future adverse health events; and (3) a data-driven stakeholder input process for acquiring and implementing clinical input that ensures clinical face validity and actionability of constructed episode-based cost measures. This framework was developed in part based on stakeholder comments on measures in the Value Modifier program and overcomes the fundamental shortcomings of earlier episode
grouping approaches previously studied by CMS. Shortcomings of previously studied episode grouping approaches included lack of actionability arising from the unpredictable and clinically inappropriate assignment of costs, limited relevance as episode constructions did not focus on the role of attributed clinicians in providing patient care, and limited transparency arising from the use of complicated software algorithms.

Our conceptual framework provides a comprehensive foundation for episode-based measures that can be used to incentivize high-value care by attributed clinicians at each stage of the patient care continuum, and allows for progressively adding new episode-based measures in a logically cohesive and consistent manner. The framework involves three distinct types of episode groups: procedural, acute inpatient medical condition, and chronic. Procedural episode groups are triggered by performance of a major procedure, acute inpatient medical condition episode groups are triggered by evaluation and management claims during hospitalizations with specific DRGs, and chronic condition episode groups are triggered by evaluation and management claims with particular diagnoses. Attribution is determined by the clinician(s) involved in the triggering claims, with consistent rules within each type of episode group. Services, and their associated costs, are assigned to an episode based on a clinical determination of whether a service is under the influence of the attributed clinician (for example, routine follow-up care or adverse health outcomes such as a readmission). Clinical determinations of service assignment are made using common criteria and methods across episode groups, to encourage distinctions in service assignment and reflect differences in clinical influence across episode groups. Risk adjustment employs a common starting point of the CMS-HCC model across episode groups, but risk adjustment models can be enhanced by the use of risk factors specifically adapted for each episode group. This allows, for instance, for adjustments to be
made for an acute condition episode group based on whether the condition is a stand-alone presentation of the condition versus the exacerbation of an ongoing chronic condition. The framework also allows for complete stratification in risk adjustment through the use of episode sub-groups, with the definition of sub-groups (such as unilateral vs. bilateral) being based on common principles across episode groups. Episodes from distinct episode groups can overlap with one another to ensure that each clinician treating a patient with multiple health issues has incentives for providing high value care. When a given service is clinically related to only one overlapping episode, it is assigned only to that one. When a service is clinically related to two overlapping episodes, it is assigned to both to ensure joint accountability. Since each episode’s cost is compared to a risk-adjusted expected cost only for other episodes from the same episode group, there is no issue of double counting. This approach allows for development of distinct episode groups that cover a patient’s care continuum, including an underlying chronic condition as well as a procedure or treatment for an exacerbation. As an example, a patient receiving chronic care for coronary artery disease (CAD) (a chronic episode) could have an acute incidence of STEMI requiring PCI for stabilization (an acute inpatient medical condition episode), and due to having severe CAD could later receive a coronary artery bypass graft (CABG) procedure (a procedural episode). This logically, cohesive framework for episode group development avoids a series of challenges raised by previously studied episode grouping approaches that assign services to only a single episode, including lack of transparency and predictability in what an attributed clinician will be held accountable for at the beginning of an episode. For information on how this framework has been operationalized, refer to the measure specifications available at https://qpp.cms.gov.
Using this conceptual framework, we have created a concrete process for developing new measures over time. To prioritize the areas for development of the new cost measures, our measure development contractor convened a clinical committee, comprised of over 70 clinicians affiliated with over 50 specialty societies that provided input necessary to develop a public posting of 117 episode groups for development in December 2016. We then used criteria vetted by a standing technical expert panel—comprised of 19 clinicians, health researchers, and representatives of patient advocacy organizations—to divide these 117 episode groups into 18 clinical areas. The prioritization criteria focused on identifying areas where potential episode-based measures could affect the highest number of beneficiaries and clinicians, address particularly high cost procedures and conditions, provide an opportunity for improvement, and best align with quality measures.

Our measure development contractor has and is continuing to convene clinical subcommittees for each of the priority clinical areas. The composition of a subcommittee for an area principally consists of practicing clinicians who are candidates for attribution of episode-based measures developed for that area. Each clinical subcommittee prioritizes specific episode measures for development within its area based on the criteria above. The structure for developing specific cost measures relies on a systematic data-based conceptual framework for triggering logic, cohort definition, attribution, and cost assignment. For the 8 episode-based measures discussed in this rule, nearly 150 clinicians affiliated with 98 specialty societies participated in the clinical subcommittees in the creation of these measures. After positive reception of the initial development process, 267 clinicians affiliated with more than 120 specialty societies are now participating in the clinical subcommittees and workgroups developing 11 additional episode-based cost measures. The structure of episode-based cost
measure development provides a vehicle for continued stakeholder engagement as additional measures are developed in the future.

Comment: A few commenters recommended that episode-based measures not be included in the MIPS cost performance category if the measures have not been endorsed by the NQF or supported by the MAP. They stated that the NQF process gives important insights into the reliability, validity, and usability of measures.

Response: The episode-based measures were reviewed by the MAP and received the recommendation of “conditional support for rulemaking,” with the MAP recommending that the measures be submitted for NQF endorsement. This review provided stakeholders with additional public comment opportunities, which the MAP considered along with submission materials regarding the scientific acceptability, reliability, validity, and usability of the measures. We intend to submit the episode-based measures for NQF endorsement in an upcoming review cycle.

Comment: One commenter expressed concern that particular episode-based measures did not properly account for risk because of the nature of their construction and lack of clinical data. Specifically, this commenter stated that a combined measure of intracranial hemorrhage and cerebral infraction would produce distortions in results. This commenter also stated that risk adjustment for this measure did not include a measure of stroke severity. Another commenter expressed uncertainty about the risk adjustment methodology and also suggested the use of both inpatient and outpatient claims data to obtain a complete understanding of the patient’s risk factors. One commenter suggested excluding Implantable Cardioverter Defibrillator (ICD) implantation MS-DRGs (222-227) from the Elective Outpatient PCI and STEMI with PCI measures to ensure there are no adverse incentives to providing a service that is both covered and clinically indicated. One commenter expressed concern that the episode-based measure for
Revascularization for Lower Extremity Chronic Critical Limb Ischemia should have a longer measurement period. One commenter requested that post-discharge events unrelated to the initial pneumonia hospitalization and any hospice costs be excluded for the Simple Pneumonia episode-based measure. The same commenter also stated that new episodes for the same measure should not be started for a patient if they already have an ongoing episode.

Response: We understand the interest in risk adjustment and other aspects of measure construction. To summarize, the risk adjustment for the eight episode-based measures includes risk adjustors from the CMS-HCC model and additional measure-specific risk adjustors recommended by the Clinical Subcommittee for the measure. Risk adjustors are defined using the beneficiary’s Medicare claims history (including inpatient, outpatient, and Part B Physician/Supplier claims) during the period prior to the start of the episode. Claims from the triggering hospitalization or on the triggering Part B Physician/Supplier claim are typically not included, as we understand it may be difficult to discern which claims are due to complications and which were already present at the initiation of the episode. We believe that utilizing the claims from the look back window adequately identifies patient comorbidities. To address the specific comments, we believe that the Intracranial Hemorrhage and Cerebral Infarction measure accurately assesses clinician cost performance as there are separate sub-groups for Intracerebral Hemorrhage and Cerebral Infarction such that patients within each sub-group are compared only with each other (that is, a patient being treated for Cerebral Infarction would only be compared to other patients being treated for Cerebral Infarction). The risk adjustors for this measure were developed with significant input from a Neuropsychiatric Disease Management Clinical Subcommittee, which recommended specific risk adjustors that include MS-DRG severity for Intracranial Hemorrhage or Cerebral Infarction and Nonspecific Cerebrovascular Disorders.
Additional risk adjustors were included to account for comorbidities that could lead to worse outcomes such as aphasia and dysphagia. However, measures of stroke severity such as the NIH stroke scale were not included in the risk adjustment model to avoid possible unintended consequences (for example, coding of higher severity for improvement of individual episode risk adjustment) and to avoid penalizing clinicians who do not code for severity, especially since ICD-10-CM codes for NIH Stroke Scale have only been operational since October 2017. The Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure has a 30-day pre-trigger period and a 90-day post-trigger period. This episode window was determined through extensive input from a Peripheral Vascular Disease Management Clinical Subcommittee, which we believe to be an appropriate length of time for which the attributed clinician can reasonably influence services. The measure specifications, including the post-discharge assigned services, for the Simple Pneumonia with Hospitalization measure were developed with significant clinical input from the Pulmonary Disease Management Clinical Subcommittee, which only assigned services they believed the attributed clinician could reasonably influence. For this reason, the costs associated with the hospice setting are not assigned to Simple Pneumonia with Hospitalization episodes. We will conduct annual evaluations to review the continued accuracy of the measure specifications. Finally, we do not exclude episodes if a patient already qualifies for another episode since we believe that allowing for overlapping episodes incentivizes communication and care coordination as a patient progresses through the care continuum. For example, if a patient is re-hospitalized for pneumonia after an initial pneumonia episode, this triggers two separate episodes of care for pneumonia. The risk adjustment model adjusts for differences in clinical complexity at the time each episode begins. This ensures that the attributed clinicians managing each hospitalization
face analogous incentives to provide the patient high value care. The assigned services for the STEMI with PCI and Elective Outpatient PCI measures were developed with input from the Cardiovascular Disease Management Clinical Subcommittee, with the goal of capturing complications of Myocardial Infarction (MI) or Heart Failure (HF) admissions. Given this clinical intent of the measure, we believe that MS-DRGs with MI or HF in the measure (MS-DRGs 222-223: Defib with Cath with MI/HF) are appropriate to include as assigned services. We agree, however, with the comment about removing assignments of the MS-DRGs without MI or HF (MS-DRGs 224-225: Defib with Cath without MI/HF and MS-DRGs 226-227: Defib without Cath without MI/HF), as these are more likely to be elective ICD placements. Given the scope of the measure, we believe it is appropriate to assign services that are part of an admission for MI or HF, while excluding services that are elective. To maintain a consistent framework across all measures, we are implementing this revision where relevant in STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Critical Limb Ischemia.

Comment: One commenter expressed concern with the possibility of high cost variation for some episode-based measures depending on the codes that trigger the episodes or the place of service in which an episode is triggered. To account for this variation, the commenter suggested incorporating a sub-group based on the triggering DRG code for the Intracranial Hemorrhage or Cerebral Infarction measure and the STEMI with PCI measure, a sub-group based on triggering procedure code for the Elective Outpatient PCI measure, and a place of service sub-group for the Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure and Screening/Surveillance Colonoscopy measure.
Response: The measure specifications, including the episode triggers and the sub-groups for each measure, were determined with significant clinical input from the Clinical Subcommittees that developed each episode-based measure. To adjust for patient differences outside attributed clinicians’ influence, the Clinical Subcommittees could choose to risk adjust for a specific patient factor or sub-group by that factor. Risk adjustment ensures that a measure accounts for average cost differences associated with the specific factor, while sub-grouping involves estimating an entirely separate risk adjustment model for patients with that factor. Sub-grouping is only appropriate in cases where a sufficient number of episodes are present in the sub-population to ensure a statistically meaningful model and where a separate model for the sub-population is necessary. Balancing these considerations, the Clinical Subcommittees addressed concerns raised by the commenter by: including indicators for MS-DRG in risk adjustment models for the Intracranial Hemorrhage or Cerebral Infarction measure and the STEMI with PCI measure to reflect the presence of Complication or Comorbidity (CC) or Major Complication or Comorbidity (MCC); and including place of service factors in risk adjustment models for the Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure and the Screening/Surveillance Colonoscopy measure. For the Elective Outpatient PCI measure, the current inclusion of other risk adjustment factors is designed to control for factors outside of the clinician’s influence that may dictate the particular triggering procedure used.

Comment: Several commenters expressed support for the episode-based measure development process implemented by CMS that incorporates significant stakeholder input as well as support for the measures. One commenter commended CMS for convening the Clinical Subcommittees, specifically noting that they believed members of the subcommittee that developed the Screening/Surveillance Colonoscopy measure were part of a successful and
deliberative process. Two commenters also supported the Routine Cataract with IOL Implantation measure, stating the measure accurately reflected the costs of the procedure and will provide actionable data to clinicians. Another commenter expressed appreciation for the pace of the development process and urged CMS to continue this level of engagement with stakeholders in other areas of the Quality Payment Program.

Response: We recognize the importance of clinician input in developing episode-based measures that provide actionable data and aim to continue this level of engagement in the development of future episode-based measures for MIPS.

Comment: One commenter supported the total per capita cost measure and stated it is the best initial metric for assessing the cost-effectiveness of primary care providers while fulfilling MACRA’s mandate to evaluate a primary care provider’s cost performance.

Response: We agree that this measure is important as a measure of the overall cost of care, even as we develop episode-based measures which are also important measures of the cost of care.

Comment: Several commenters opposed the continued inclusion of the total per capita cost measure and the MSPB measure in the cost performance category. They stated that the measures included all services provided to a patient, even those for which the attributed clinician could not control. One commenter requested that these measures only be applied to primary care clinicians and not to specialists. Finally, one commenter expressed concerns with how total per capita cost measure has not yet been endorsed by NQF, and MSPB measure has only been endorsed at the facility-level.

Response: While we appreciate the interest in the total per capita cost and MSPB measures’ NQF endorsement status, we continue to believe that these measures are tested and
reliable for Medicare populations and provide an important measurement of clinician cost performance (82 FR 53644) while we continue to develop episode-based measures that precisely identify services that are part of an episode that could be considered directly under the control of a clinician. Versions of the total per capita cost and MSPB measures were included in the QRURs and used in the VM for many years before the implementation in MIPS. These measures have an important place in cost measurement given that the episode-based measures will only apply to a subset of clinicians at this time.

The total per capita cost measure uses a primary care attribution method in which a specialist would not be attributed a patient unless that patient did not see a primary care clinician (based on the Medicare specialty) during the year. For some patients who do not see a primary care clinician in a year, a specialist may serve as a primary care clinician due to an underlying disease or condition which the specialist focuses on. For the MSPB measure, we do not believe it is appropriate to limit attribution to primary care clinicians as specialists may perform procedures or manage patients in the hospital and can have a significant influence on the overall spending during the hospitalization.

Both the total per capita cost and MSPB measures are being refined as part of the measure maintenance and re-evaluation process, incorporating substantial stakeholder input. We are completing an extensive outreach initiative in the fall of 2018 to share performance information with clinicians as part of field testing, a part of measure re-evaluation. After considering the stakeholder feedback on these refinements, we may propose the re-evaluated measures for use in MIPS to replace the current versions of the measures in the program.

Comment: Several commenters expressed concern about the risk and specialty adjustment methods used in the measures that are part of the cost performance category. In
particular, several commenters stated that measures do not appropriately account for sociodemographic status, which can drive differences in average episode costs. Additionally, commenters noted that measures did not take into account the risks associated with complex or dual-eligible patients or patients seen by certain specialists. Another noted the lack of risk-adjustment for cancer treatment. One commenter also expressed concern about the differences in case-mix across specialties for a given measure, specifically STEMI with PCI. The commenter stated that under this measure, hospitalists may be attributed episodes that include more medically complex patients who require post-ICU care on a general medicine floor, making these hospitalists appear to be costlier than other clinicians.

Response: We understand stakeholders’ concerns regarding risk adjustment for social risk factors and dual eligible status. As we have previously stated, we are concerned about holding clinicians to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We recognize the concern regarding risk adjusting for complex patients, including those with cancer treatment, and regarding the variation in case-mix across specialties for a given episode. Our risk adjustment methodology, which employs a common starting point of the CMS-HCC model across episode groups and can include the use of risk factors specifically adapted for each episode group is designed to account for patient comorbidities that predict a complex
hospitalization and lead to higher costs that are outside the influence of attributed clinicians, regardless of which specialty designations those clinicians choose to identify.

**Comment:** Several commenters requested that certain clinicians be excluded or included in the cost performance category on the basis of their type of practice, particularly non-patient facing clinicians.

**Response:** We have established a policy to assign a zero percent weight to the cost performance category if there are not sufficient measures applicable and available to a MIPS eligible clinician (see, for example, 81 FR 77322 through 77325). We believe it is possible that a clinician may not have sufficient cost measures applicable or available to them based on their specialty or type of practice, including clinicians who are non-patient facing. We continue to work to expand the reach of the cost performance category to as many clinicians as possible, including non-patient facing clinicians in accordance with section 1848(q)(2)(C)(iv) of the Act.

After consideration of the public comments, we are finalizing our proposal to include the 8 episode-based measures listed in Table 36 in the cost performance category beginning with the 2019 MIPS performance period with a modification to the STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Critical Limb Ischemia episode-based measures to remove assignments of the MS-DRGs without MI or HF (MS-DRGs 224-225: Defib with Cath without MI/HF and MS-DRGs 226-227: Defib without Cath without MI/HF).

(iii) Reliability

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. We seek to ensure that MIPS eligible clinicians are measured reliably. In the CY 2017 Quality Payment Program final rule, we finalized a case minimum of 20 for the episode-based measures specified
for the 2017 MIPS performance period (81 FR 77175). We examined the reliability of the proposed 8 episode-based measures listed in Table 36 at various case minimums and found that all of these measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. Furthermore, these case minimums would balance the goal of increased reliability with the goal of adopting cost measures that are applicable to a larger set of clinicians and clinician groups. Our analysis indicated that the case minimum for procedural episode-based measures could be lower than that of acute inpatient medical condition episode-based measures while still ensuring reliable measures.

Table 37 presents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability, as well as the mean reliability for the subset of TINs and TIN/NPIs who met the proposed case minimums of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures for each of the proposed episode-based measures. Each row in Table 37 provides the percentage of TINs and TIN/NPIs who had reliability of 0.4 or higher among all the TINs and TIN/NPIs who met the case minimum for that measure during the study period (6/1/2016 to 5/31/2017).
TABLE 37: Percentage of TINs and TIN/NPIs with 0.4 or Higher Reliability from June 1, 2016 to May 31, 2017 at Proposed Case Minimums

<table>
<thead>
<tr>
<th>Measure name</th>
<th>Percentage TINs with 0.4 or higher reliability</th>
<th>Mean Reliability for TINs</th>
<th>Percentage TIN/NPIs with 0.4 or higher reliability</th>
<th>Mean Reliability for TIN/NPIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective Outpatient Percutaneous Coronary Intervention (PCI)</td>
<td>100.0%</td>
<td>0.73</td>
<td>84.1%</td>
<td>0.53</td>
</tr>
<tr>
<td>Knee Arthroplasty</td>
<td>100.0%</td>
<td>0.87</td>
<td>100.0%</td>
<td>0.81</td>
</tr>
<tr>
<td>Revascularization for Lower Extremity Chronic Critical Limb Ischemia</td>
<td>100.0%</td>
<td>0.74</td>
<td>100.0%</td>
<td>0.64</td>
</tr>
<tr>
<td>Routine Cataract Removal with Intraocular Lens (IOL) Implantation</td>
<td>100.0%</td>
<td>0.95</td>
<td>100.0%</td>
<td>0.94</td>
</tr>
<tr>
<td>Screening/Surveillance Colonoscopy</td>
<td>100.0%</td>
<td>0.96</td>
<td>100.0%</td>
<td>0.93</td>
</tr>
<tr>
<td>Intracranial Hemorrhage or Cerebral Infarction</td>
<td>100.0%</td>
<td>0.70</td>
<td>74.9%</td>
<td>0.48</td>
</tr>
<tr>
<td>Simple Pneumonia with Hospitalization</td>
<td>100.0%</td>
<td>0.64</td>
<td>31.8%</td>
<td>0.40</td>
</tr>
<tr>
<td>ST-Elevation Myocardial Infarction (STEMI) with PCI</td>
<td>100.0%</td>
<td>0.59</td>
<td>100.0%</td>
<td>0.59</td>
</tr>
</tbody>
</table>

Based on this analysis, we proposed at §414.1350(c)(4) and (5) a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures beginning with the 2019 MIPS performance period (83 FR 35904). We stated that these case minimums would ensure that the measures meet the reliability threshold for groups and individual clinicians. We stated that we believe that the proposed case minimums for these procedural and acute inpatient medical condition episode-based measures would achieve a balance between several important considerations. In order to help clinicians become familiar with the episode-based measures as a robust and clinician-focused form of cost measurement, we want to provide as many clinicians as possible the opportunity to receive information about their performance on reliable measures. This is consistent with the stakeholder feedback that we have received throughout the measure development process. We stated that we believe that calculating episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians and clinician group practices.
We stated that we recognize that the percentage of TIN/NPIs with 0.4 or greater reliability for the Simple Pneumonia with Hospitalization measure, while still meeting our reliability threshold, is somewhat lower than that of the other proposed acute inpatient medical condition episode-based measures, as well as all of the proposed procedural episode-based measures. For this reason, we considered an alternative case minimum of 30 for both TIN/NPIs and TINs for this measure. At this case minimum, 100 percent of TIN/NPIs would have 0.4 or greater reliability and the mean reliability would increase to 0.49 for TIN/NPIs and 0.70 for TINs. However, the number of TINs and TIN/NPIs that would meet the case minimum for this important measure would decrease by 29 percent for TINs and by 84 percent for TIN/NPIs. We invited comments on this alternative case minimum for TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization episode-based measure.

We previously finalized a case minimum of 35 for the MSPB measure (81 FR 77171), 20 for the total per capita cost measure (81 FR 77170), and 20 for the episode-based measures specified for the 2017 MIPS performance period (81 FR 77175). We proposed to codify these final policies under §414.1350(c) (83 FR 35904).

In general, higher case minimums increase reliability, but also decrease the number of clinicians who are measured. We aim to measure as many clinicians as possible in the cost performance category. Some clinicians or smaller groups may never see enough patients in a single year to meet the case minimum for a specific episode-based measure. For this reason, we solicited comment on whether we should consider expanding the performance period for the cost performance category measures from a single year to 2 or more years in future rulemaking. We believe this would allow us to more reliably measure a larger number of clinicians. However, we are also concerned that expanding the performance period would increase the time between the
measurement of performance and the application of the MIPS payment adjustment. In addition, it would take a longer period of time for us to introduce new cost measures as we would expect to adopt them through rulemaking prior to the beginning of the performance period.

The following is a summary of the public comments received on these proposals and our responses:

**Comment:** Many commenters expressed concern with the reliability thresholds that we use to inform the determination of case minimums in the cost performance category. Several of these commenters suggested that measures should have case minimums that would reflect 0.8 reliability for all TINs and TIN/NPI combinations. One commenter stated that using a low reliability threshold would result in measuring the acuity of patients as opposed to the performance of a clinician. Another commenter suggested that we consider whether a standard case minimum for all episode group should continue to be set or case minimums should be set accordingly for each individual measure. One commenter also suggested increasing to a 20 episode case minimum for procedural episode-based measures.

**Response:** Because we aim to balance the need for consistent program standards with ensuring that measures are reliable, we proposed to set a different case minimum for the procedural and acute inpatient medical condition episode-based measures. We aim to measure cost for as many clinicians as possible, and limiting measures to reliability of 0.7 or 0.8 would result in few individual clinicians with attributed cost measures. In addition, a 0.4 reliability threshold ensures moderate reliability for most MIPS eligible clinicians and group practices that are being measured on cost. Under the proposed case minimum of 10 episodes for the procedural episode-based measures, the reliability of the measures already exceeds the 0.4 reliability threshold we have previously established, with most having higher than 0.7 reliability.
Using a 20 episode case minimum, while having a slight increase in reliability, will reduce clinician coverage. Therefore, retaining the proposed case minimum of 10 episodes for the procedural measures allows us to maximize the number of clinicians covered by these measures, while still exceeding the 0.4 moderate reliability threshold. We will continue to evaluate reliability as we develop new measures and propose them for inclusion in MIPS in future rulemaking.

**Comment:** Several commenters supported our alternative proposal for a case minimum of 30 for the Simple Pneumonia with Hospitalization measure. The commenters stated that using a more reliable measure would be preferred over measuring more clinicians.

**Response:** We agree that our proposed alternative case minimum of 30 episodes for the Simple Pneumonia with Hospitalization measure would have slightly higher reliability, but we also believe that maintaining a consistent case minimum across all acute inpatient medical condition episode-based measures would accurately and reliably assess cost measure performance for a large number of clinicians and clinician groups. We believe it is in the interests of MIPS participants, particularly specialists who treat patients for this condition, to have this new episode-based measure available to them. A consistent case minimum for acute inpatient medical condition episode-based measures would also make it easier for clinicians to understand because it establishes cohesiveness across the different measures as stakeholders are still becoming familiar with these new measures. The mean reliability of the Simple Pneumonia with Hospitalization measure at 20 episodes exceeds the 0.4 reliability threshold (indicating moderate reliability) for TINs and meets that threshold for TIN/NPIs.

**Comment:** One commenter stated that small practices are less reliably measured by cost measures and that it will be difficult for small practices to analyze cost data in order to improve.
Response: While we have not examined the issue of practice size in relation to the reliability of the cost measures, we have examined the issue of case size in relation to the reliability of cost measures. The results of the analysis of episode-based cost measures can be found in our National Summary Data Report on Eight Wave 1 Episode-Based Cost Measures at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Updated-2017-National-Summary-Data-Report.pdf. To some degree, the size of a practice correlates with the case size for cost measures, as an individual clinician can only see so many patients. We believe that establishing case minimums that are based on moderate reliability allow us to measure all clinicians and groups that meet those case minimums. We note that the scores on the measures in the cost performance category are only a component of the MIPS final score, which also includes a small practice bonus available within the quality performance category to accommodate the issues that may be faced by small practices.

After consideration of the public comments, we are finalizing our proposed case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures beginning with the 2019 MIPS performance period at §414.1350(c)(4) and (5) as proposed. We are also finalizing our proposal to codify our previously finalized case minimum of 35 for the MSPB measure, 20 for the total per capita cost measure, and 20 for the episode-based measures specified for the 2017 MIPS performance period at §414.1350(c) as proposed. We will take the comments we received on expanding the performance period for measures in the cost performance category into account for future rulemaking.

(iv) Attribution
(A) Attribution Methodology for Cost Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169; 77174 through 77176), we adopted final policies concerning the attribution methodologies for the total per capita cost measure, the MSPB measure, and the episode-based measures specified for the 2017 MIPS performance period in addition to an attribution methodology for individual clinicians and groups. We proposed to codify these final policies under §414.1350(b).

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters expressed concern with the attribution methods finalized in the 2017 Quality Payment Program final rule (81 FR 77168 through 77169), which we proposed to codify. These commenters stated that it was unclear to clinicians which patients would be attributed to them. They recommended a number of methods to improve this process, such as offering feedback on the patients that may be attributed to a clinician at some time during the performance period or allowing clinicians to define attribution with the use of patient relationship codes.

Response: We will continue to look at ways to facilitate the engagement of clinicians in the measures in the cost performance category and will look into offering as much information as is feasible to clinicians.

Comment: Several commenters expressed concern with the attribution methodology for the total per capita cost measure that we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169), which we proposed to codify. In particular, they expressed concerns with the identification of clinicians such as nurse practitioners and physician assistants.
as primary care clinicians under this methodology, because many of them work in specialist practices.

**Response:** We believe that attribution methods that include nurse practitioners (NP) and physician assistants (PA) as primary care clinicians best represents the role they play in clinical care. Under the attribution methodology for the total per capita cost measure, a patient who saw a primary care physician more often than an NP or PA in a specialty practice would be attributed to that primary care physician. As we have observed in rulemaking for the Value Modifier (79 FR 67961), including NPs and PAs in the first step of attribution in the total per capita care cost measure did not significantly affect the attribution of patients.

**Comment:** Several commenters expressed concern with the attribution methods used for the MSPB measure for which we finalized policy in the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169) and which we proposed to add to regulatory text. Many of the commenters expressed concern that the method of attribution was assigning patients to non-patient facing specialists such as pathologists and radiologists because they may provide expensive services, but do not provide overall care management for the patient. A few commenters requested that non-patient facing clinicians not be attributed this measure.

**Response:** We believe that the MSPB measure continues to be an important measure of the overall cost of care for a patient and the clinician who provides the plurality of care. We believe that a clinician who provides the plurality of care in a hospital has opportunities to affect the cost of care for that patient. In some cases that may be a non-patient facing clinician, who in order to provide the plurality of care, would have provided a significant amount of service to a hospitalized patient.
After consideration of the public comments, we are finalizing our proposal to codify the previously adopted final policies at §414.1350(b) as proposed.

(B) Attribution Rules for the Episode-Based Measures

In section III.I.3.h.(3)(b)(ii) of this final rule, we finalized 8 episode-based measures for the cost performance category for the 2019 MIPS performance period and future performance periods, which can be categorized into two types of episode groups: acute inpatient medical condition episode groups, and procedural episode groups. These measures only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given period of time. The attribution methodology will be the same for all of the measures within each type of episode groups—acute inpatient medical condition episode groups and procedural episode groups. Our approach to attribution will ensure that the episode-based measures reflect the roles of the individuals and groups in providing care to patients.

For acute inpatient medical condition episode groups specified beginning in the 2019 performance period, we proposed at §414.1350(b)(6) to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (E&M) claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization (83 FR 35905). We stated that a trigger inpatient hospitalization is a hospitalization with a particular MS-DRG identifying the episode group. These MS-DRGs, and any supplementary trigger rules, are identified in the measure specifications posted at qpp.cms.gov. The measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple
TIN/NPIs in a single TIN, the episode is only counted once in the TIN’s measure score. We stated that we believe that establishing a 30 percent threshold for the TIN would ensure that the clinician group is collectively measured across all of its clinicians who are likely responsible for the oversight of care for the patient during the trigger hospitalization.

This proposed attribution approach differs from the attribution approach previously established for episode-based measures for acute inpatient medical conditions specified for the 2017 performance period in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175). The previous approach attributed episodes to TIN/NPIs who individually exceed the 30 percent E&M threshold, while excluding all episodes where no TIN/NPI exceeds the 30 percent threshold. Throughout the measure development process, stakeholders have discussed the team-based nature of acute care, in which multiple clinicians share management of a patient during a hospital stay. The previous approach outlined in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175) does not capture patients’ episodes when a group collaborates to manage a patient but no individual clinician exceeds the 30 percent threshold. Based upon stakeholder feedback, our proposed approach emphasizes team-based care and expands the measures’ coverage of clinicians, patients, and cost.

We provided an example to illustrate the proposed attribution rules for acute inpatient medical condition episode groups in the proposed rule (83 FR 35905).

For procedural episode groups specified beginning in the 2019 MIPS performance period, we proposed at §414.1350(b)(7) to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes (83 FR 35905). These trigger services are identified in the measure specifications posted at qpp.cms.gov. We stated that the measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to
the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN’s measure score. We stated that we believe this approach best identifies the clinician(s) responsible for the patient’s care. This attribution method is similar to that used for procedural episode-based measures in the 2017 MIPS performance period but more clearly defines that the services must be provided during the episode and how we would address instances in which two NPIs in the same TIN provided a trigger service.

The following is a summary of the public comments received on these proposals and our responses:

Comment: One commenter supported our proposed attribution methods for the procedural and acute inpatient medical condition episode-based measures.

Response: We appreciate the support of the commenter.

Comment: A few commenters agreed with the importance of shared accountability in attribution, with one commenter noting that they believed the proposed methodology represented a novel approach to this shared accountability. However, a few commenters opposed our proposed attribution methodology for acute inpatient medical condition episode-based measures. A few commenters recommended that the required percentage be increased. A few commenters expressed concern that a single patient could be attributed to many clinicians in a practice if they participated in MIPS as individuals under this proposed attribution method. This commenter stated that a clinician billing for a single service during a hospitalization could not be expected to have a significant effect on costs. A few commenters stated that this change in attribution
methodology had been made following the episode-based measure field testing and could undercut the viability of measures established with clinical input.

**Response:** We appreciate the support for the emphasis on team-based care and shared accountability in the attribution methodology. We also appreciate the interest in increasing the E&M threshold percentage as part of the attribution methodology for the acute inpatient medical condition episode-based measures. While there is interest in increasing the E&M threshold and concern about the impact of the proposed attribution methodology on clinicians participating in MIPS as individuals, we believe that the methodology as proposed appropriately balances the interest in team-based care and enabling as many clinicians as possible to be attributed to these new acute inpatient medical condition episode-based measures. Specifically, we believe that an E&M threshold requirement of 30 percent reflects stakeholder input throughout the measure development process to reasonably reflect the nature of care in an inpatient setting, and it is in the interests of a large number of clinicians and clinician groups to be able to access these episode-based measures. We disagree that the proposed methodology undercuts the viability of the episode-based measures. Each component of the measures reflects feedback that the measure development contractor has gathered from clinical subcommittees, a technical expert panel, and public comments, including during field testing in 2017. We believe that the changes made to the attribution methodology after field testing reflect the purpose of such testing – which we believe goes beyond the typical testing associated with many performance measures – to reveal issues and to gather stakeholder feedback to inform potential measure refinements. This included feedback on the importance of incorporating considerations of care coordination into the attribution methodology. We believe that a clinician participating as an individual who bills one E&M claim within a TIN that has 30 percent of the total E&Ms for that trigger inpatient stay
does not necessarily have limited influence on episode costs due to the nature of inpatient care involving teams. In addition, we seek to incentivize clinicians to engage in greater care coordination throughout a patient’s trajectory. The case minimum of 20 for acute inpatient medical condition episode-based measures as finalized above ensures that clinicians are reliably measured in providing care to beneficiaries with those specific conditions. We note that the mean reliability for the measures meets or exceeds the established 0.4 reliability threshold under this attribution methodology for TINs and TIN/NPIs.

**Comment:** Some commenters expressed concern with our procedural episode groups proposal to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes. One commenter suggested that a clinician should be required to bill at least two service codes in order to be attributed a procedural episode in order to increase the reliability of the measure. One commenter recommended that a single clinician should not be solely attributed the costs for a patient based on the provision of a trigger service, but that the responsibility should be shared among all clinicians who treated the patient during the episode. One commenter stated that the same patient would be attributed twice if a two-stage procedure were performed.

**Response:** We believe that in the case of a procedural episode, the clinician who performs the service has a significant influence on the costs of care that are part of the episode that follows the provision of that service. These clinicians perform significant therapeutic and diagnostic services, and the episode-based measures are intended to limit costs to those which the clinician can affect, such as by avoiding complications or better managing the patient during the episode. In many cases, it would not be practical to require more than a single service, such as in cases of surgical services which may encompass much of the period of the episode.
After consideration of the public comments, we are finalizing as proposed our proposal at §414.1350(b)(6) for acute inpatient medical condition episode groups specified beginning in the 2019 performance period, to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (E&M) claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization. Additionally, we also finalizing as proposed our proposal at §414.1350(b)(7) for procedural episode groups specified beginning in the 2019 MIPS performance period, to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(4) Improvement Activities Performance Category

(a) Background

In CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we codified at §414.1355 that the improvement activities performance category would account for 15 percent of the final score. We refer readers to section III.I.3.i.(1)(e) of this final rule where we proposed to modify §414.1355 to provide further technical clarifications. In addition, in the CY 2018 Quality Payment Program final rule (82 FR 53649), we codified at §414.1380(b)(3)(iv) that the term recognized be accepted as equivalent to the term certified when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS. We also finalized at §414.1380(b)(3)(x) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or
comparable specialty practice (82 FR 53655). We refer readers to section III.I.3.i.(1)(e)(i)(D) of this final rule for details on our proposals regarding patient-centered medical homes.

In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at §414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Further, in that final rule (81 FR 77190), we codified at §414.1365 that the improvement activities performance category would include the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. We also codified subcategories for improvement activities at §414.1365 (81 FR 77190).

We also previously codified in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77180 and 82 FR 53651, respectively) data submission criteria for the improvement activities performance category at §414.1360(a)(1). In addition, we established exceptions for: small practices; practices located in rural areas; practices located in geographic HPSAs; non-patient facing individual MIPS eligible clinicians or groups; and individual MIPS eligible clinicians and groups that participate in a MIPS APM or a patient-centered medical home submitting in MIPS (81 FR 77185, 77188). Specifically, we codified at §414.1380(b)(3)(vii) that non-patient facing MIPS eligible clinicians and groups, small practices, and practices located in rural areas and geographic HPSAs receive full credit for the improvement activities performance category by selecting one high-weighted improvement activity or two medium-weighted improvement activities; such practices receive half credit for the improvement activities performance category by selecting one medium-weighted improvement activity (81 FR 77185). We refer readers to section III.I.3.i.(1)(e)(i)(B) of this final rule for our proposals related
to that provision. In addition, we specified at §414.1305 that rural areas refers to ZIP codes designated as rural, using the most recent HRSA Area Health Resource File data set available (81 FR 77188, 82 FR 53582). Lastly, we finalized the meaning of Health Professional Shortage Areas (HPSA) at §414.1305 to mean areas as designated under section 332(a)(1)(A) of the Public Health Service Act (81 FR 77188). In the CY 2018 Quality Payment Program final rule (82 FR 53581), we modified the definition of small practices at §414.1305 to mean practices consisting of 15 or fewer eligible clinicians.

In the CY 2019 PFS proposed rule (83 FR 35906 through 35912), we requested comments on our proposals to: (1) revise §414.1360(a)(1) to more accurately describe the data submission criteria; (2) delete §414.1365 and move improvement activities subcategories to §414.1355(c); (3) update the criteria considered for nominating new improvement activities; (4) modify the Annual Call for Activities timeline for the CY 2019 performance period and future years; (5) add 6 new improvement activities for the CY 2019 performance period and future years; (6) modify 5 existing improvement activities for the CY 2019 performance period and future years; and (7) remove 1 existing improvement activity for the CY 2019 performance period and future years. In addition, we also requested comments on our proposals with respect to the CMS Study on Factors Associated with Reporting Quality Measures for the CY 2019 performance period and future years the following proposals: (1) change the title of the study to CMS Study on Factors Associated with Reporting Quality Measures; (2) increase the sample size to a minimum of 200 participants; (3) limit the focus group requirement to a subset of the 200 participants; and (4) require that at least one of the minimum of three required measures be a high priority measure. We are also making clarifications to: (1) considerations for selecting
improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

These topics are discussed in more detail below.

(b) Submission Criteria

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77181) for submission mechanism policies we finalized and codified for the transition year of MIPS. In the CY 2018 Quality Payment Program final rule (82 FR 53651), we continued these policies for future years. Specifically, we finalized that for MIPS Year 2 and future years, MIPS eligible clinicians or groups must submit data on MIPS improvement activities in one of the following manners: qualified registries; EHR submission mechanisms; QCDR; CMS Web Interface; or attestation. Additionally, we finalized that for activities that are performed for at least a continuous 90-days during the performance period, MIPS eligible clinicians must submit a yes response for activities within the improvement activities inventory. In addition, in the case where an individual MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, we finalized that the MIPS eligible clinician or group must certify all improvement activities were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf (82 FR 53650 through 53651). We also updated §414.1360 to reflect those changes (82 FR 53651). We refer readers to section III.I.3.h.(1) of this final rule, MIPS Performance Category Measures and Activities, where we discuss our finalized policies to update the data submission process for MIPS eligible clinicians, groups and third party intermediaries, by updating our terminology. We also refer readers to changes to §414.1325 for data submission requirements. In the CY 2019 PFS proposed rule (83 FR 35906),
we proposed those changes to more closely align with the actual submission experience users have.

In alignment with those proposals, we also proposed to revise §414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, in the CY 2019 PFS proposed rule (83 FR 35906), we proposed that instead of “via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,” as currently stated, we revised the first sentence to state that data would be submitted “via direct, login and upload, and login and attest” as discussed in section III.1.3.h.(1)(b) of this final rule. In addition, we proposed to add further additions to §414.1360(a)(1) to specify, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

We did not receive any comments on these proposals. Therefore, we are finalizing our proposals, as proposed, to revise the first sentence of §414.1360(a)(1) to state that data must be submitted via direct, login and upload, and login and attest. In addition, we are finalizing our proposal, as proposed, to update §414.1360(a)(1) to specify: submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(c) Subcategories

In the CY 2017 Quality Payment Program final rule (81 FR 77190), we finalized at §414.1365 that the improvement activities performance category includes the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. It has since come to our attention that it is unnecessary to have a separate regulation text included under §414.1365 since the subcategories are not a component of the scoring calculations. Therefore, in the CY 2019 PFS
proposed rule (83 FR 35906 through 35907), we proposed to delete §414.1365 and move the same improvement activities subcategories to §414.1355(c). We reiterate that we did not propose any changes to the subcategories themselves. These subcategories are:

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.
- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.
- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.
- Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.
- Participation in an APM.
- Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.
- Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active
duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician 
volunteer participation in domestic or international humanitarian medical relief work.

- Integrated behavioral and mental health, such as measuring or evaluating such 
  practices as: Co-location of behavioral health and primary care services; shared/integrated 
  behavioral health and primary care records; cross training of MIPS eligible clinicians, and 
  integrating behavioral health with primary care to address substance use disorders or other 
  behavioral health conditions, as well as integrating mental health with primary care. 

The following is a summary of the public comments received on our proposals and our 
responses:

Comment: One commenter supported the definition of achieving health equity and 
underserved populations. The commenter recommended that we explicitly include people with 
limited English in those groups.

Response: We will take this suggestion into consideration for the future.

After consideration of the public comments received, we are finalizing our proposal, as 
proposed, to delete §414.1365 and move the same improvement activities subcategories to 
§414.1355(c).

(d) Improvement Activities Inventory

In the CY 2019 PFS proposed rule (83 FR 35907 through 35910), we proposed to: (1) 
adopt one new criterion and remove one existing criterion for nominating new improvement 
activities beginning with the CY 2019 performance period and future years; (2) modify the 
timeframe for the Annual Call for Activities; (3) add 6 new improvement activities for the CY 
2019 performance period and future years; (4) modify 5 existing improvement activities for the 
CY 2019 performance period and future years; and (5) remove 1 existing improvement activity
for the CY 2019 performance period and future years. We are also making clarifications to: (1) considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial Improvement Activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive Improvement Activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the Improvement Activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at www.qpp.cms.gov during the Annual Call for Activities.

(A) Criteria for Nominating New Improvement Activities
In the CY 2019 PFS proposed rule (83 FR 35907 through 35908), we proposed to add one new criterion and remove a previously adopted criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders would apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660):

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family’s point of view;
- Support the patient’s family or personal caregiver;
- Activities that may be considered for an advancing care information bonus;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes; or

CMS is able to validate the activity.

(bb) New Criteria

We believe it is important to place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities for inclusion in the Inventory, because their inclusion raises awareness for clinicians about the urgency of the situation and to promote clinician adoption of best practices to combat those public health emergencies. A list of the public health emergency declarations is available at https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx. Therefore, in the CY 2019 PFS proposed rule (83 FR 35907 through 35908), we proposed to adopt an additional criterion entitled “Include a public health emergency as determined by the Secretary” to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. We invited public comment on our proposal.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the additional criterion for nominating improvement activities to include public health emergencies, noting that such activities are important for patient care and will help raise clinician awareness and promote best practices related to the medically appropriate, evidence-based, and safe use of opioids in treating chronic and acute pain and the use of non-opioid pain management treatment alternatives. One commenter stated this criteria could help ensure patients receive the most appropriate pain and substance use disorder treatments. Another commenter stated this criteria could support efforts
to mobilize health care resources to assist those in need and aid providers in relief efforts.

  **Response:** We appreciate the commenters’ support.

  **Comment:** One commenter requested clarification regarding whether a public health emergency is required to be listed for an improvement activity to be considered and whether the improvement activities will be removed once the public health emergency has been resolved.

  **Response:** A list of federal public health emergency declarations is available at [https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx](https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx). Modifications to existing improvement activities in the Improvement Activities Inventory, including whether an improvement activity should be removed due to a change in a public health emergency status, will be considered through the formal Annual Call for Activities on a case-by-case basis.

  **Comment:** A few commenters did not support the proposed addition of the public health emergency criteria. One commenter stated there is a need for adequate notice and tracking mechanisms and recommended that improvement activities should progress through the formal review process. Another commenter recommended a process outside the Annual Call for Activities that enables clinicians to propose an activity for immediate implementation during a public health emergency declaration and that such activities remain optional and be granted full credit even if the duration does not span at least 90 continuous days.

  **Response:** We agree that there is a need for adequate notice in order to allow clinicians time to prepare. To be clear, Improvement Activities will continue to be proposed and adopted via rulemaking; we are merely adding a new criteria such that public health emergencies are considered when stakeholders nominate improvement activities and while we select improvement activities for proposal and adoption into the Inventory. We do not agree that we should create a separate process outside of the Annual Call for Activities or that such activities
should remain optional and be granted full credit even if the duration does not span at least 90 continuous days. In the CY 2017 Quality Payment Program final rule (81 FR 77186), we specified at §414.1360 that MIPS eligible clinicians or groups must perform improvement activities for at least 90 consecutive days during the performance period for improvement activities performance category credit.

Comment: One commenter suggested that there should be a bonus associated with the submission of an improvement activity regarding a public health emergency.

Response: We disagree as we do not believe the submission of an improvement activity should get bonus points. We are not able to provide bonus points for improvement activities at this time.

After consideration of the public comments received, we are finalizing our proposal, as proposed to adopt an additional criterion entitled “Include a public health emergency as determined by the Secretary” to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years.

(cc) Removal of One Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209), we adopted a policy to award a bonus to the Promoting Interoperability performance category score for MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category. We included a designation column in the Improvement Activities Inventory at Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817) that indicated which activities qualified for the Promoting Interoperability (formerly Advancing Care Information) bonus codified at §414.1380(b)(4)(i)(D).
In the CY 2019 PFS proposed rule (83 FR 35982), under the Promoting Interoperability performance category, we proposed a new approach for scoring that moves away from the base, performance, and bonus score methodology currently established. This new approach removes the availability of a bonus score for attesting to completing one or more specified improvement activities using CEHRT beginning with the CY 2019 performance period and future years. As a result, we do not believe the criterion for selecting improvement activities for inclusion in the program entitled “Activities that may be considered for an advancing care information bonus” remains relevant. Therefore, we proposed to remove the criterion for selecting improvement activities for inclusion in the program entitled “Activities that may be considered for an advancing care information bonus” beginning with the CY 2019 performance period and future years (83 FR 35908).

If our proposals to add one criterion and remove one criterion are adopted as proposed, the new list of criteria for nominating new improvement activities for the CY 2019 performance period and future years would be as follows:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family’s point of view;
- Support the patient’s family or personal caregiver;
● Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
● Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
● Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
● Include a public health emergency as determined by the Secretary; or
● CMS is able to validate the activity.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposal, as proposed, to remove the criterion entitled “Activities that may be considered for an advancing care information bonus” beginning with the CY 2019 performance period and future years. We note that this policy is being finalized in alignment with those in section III.I.3.h.(5)(d)(ii) of this final rule.

(B) Considerations in Selecting Improvement Activities

As noted in the CY 2017 Quality Payment Program final rule, we intend to use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program (82 FR 53659). However, we clarify here that those criteria are but one factor in determining which improvement activities we ultimately propose. For example, we also generally take into consideration other factors, such as whether the nominated improvement activity uses publically available products or techniques (that is, does not contain proprietary products or information limiting an activity) or whether the nominated improvement activity duplicates any currently adopted activity (83 FR 35908).

(C) Weighting of Improvement Activities
Given stakeholder feedback requesting additional transparency regarding the weighting of improvement activities (82 FR 53657), in the CY 2019 PFS proposed rule (83 FR 35908 through 35909), we summarized considerations we have previously used to assign weights to improvement activities included in the Improvement Activities Inventory (see Appendix 2: Improvement Activities, Tables A and B). We also made a few clarifications and solicited comment for future weighting considerations. These topics are discussed in more detail below.

(aa) Summary of Past Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77191), we explained that to define the criteria and establish weighting for each activity, we engaged multiple stakeholder groups, including the Centers for Disease Control and Prevention, Health Resources and Services Administration, Office of the National Coordinator for Health Information Technology, SAMHSA, Agency for Healthcare Research and Quality, Food and Drug Administration, the Department of Veterans Affairs, and several clinical specialty groups, small and rural practices and non-patient facing clinicians. Activities were proposed to be weighted as high based on the extent to which they align with activities that support the patient-centered medical home, since that is the standard under section 1848(q)(5)(C)(i) of the Act for achieving the highest potential score for the improvement activities performance category, as well as with our priorities for transforming clinical practice (81 FR 77191). Activities that require performance of multiple actions, such as participation in the Transforming Clinical Practice Initiative (TCPI), participation in a MIPS eligible clinician’s state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) were also proposed to be weighted as high (81 FR 77191). We also stated that we believe that high-weighting should be used for activities that
directly address areas with the greatest impact on beneficiary care, safety, health, and well-being (81 FR 77194). In the past, we have given certain improvement activities high-weighting due to the intensity of the activity; for example, one improvement activity was changed to high-weighting because it often involves travel and work under challenging physical and clinical circumstances (81 FR 77194). Also, we note that successful participation in the CMS Study on Factors Associated with Reporting Quality Measures as discussed in section III.I.3.h.(4)(e) of this final rule would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities guidelines (81 FR 77197).

(bb) Clarifications

In this final rule, we are clarifying: (a) our consideration of giving high-weighting due to activity intensity; and (b) differences between high- and medium-weighting.

(AA) High-Weighting Due to Activity Intensity

As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To elaborate, we believe that an activity that requires significant investment of time and resources should be high-weighted. For example, we finalized the CAHPS for MIPS survey as high-weighted (81 FR 77827), because it requires a significant investment of time and resources. As part of the requirements of this activity, MIPS eligible clinicians: (1) must register for the CAHPS for MIPS survey; (2) must select and authorize a CMS-approved survey vendor to collect and report survey data using the survey and specifications provided by us; and (3) are responsible for vendor’s costs to collect and report the survey (ranges from approximately $4,000 to $7,000 depending on services requested).
In contrast, we believe medium-weighted improvement activities are simpler to complete and require less time and resources as compared to high-weighted improvement activities. For example, we finalized the Cost Display for Laboratory and Radiographic Orders improvement activity as medium-weighted (82 FR 54188), because the information required to be used is readily available (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html) at no cost through the Medicare clinical laboratory fee schedule and can be distributed in a variety of manners with very little investment (for example, it may be displayed in the clinic, provided to patients through hardcopies, or incorporated in the electronic health record).

(BB) High- Versus Medium-Weighting

We recognize that we did not previously explicitly state separate considerations for medium-weighted activities. This is because an improvement activity is only either high or medium-weighted. In this final rule, we are clarifying that an improvement activity is by default medium-weight unless it meets considerations for high-weighting as discussed previously (83 FR 35909).

(cc) Request for Comments

We intend to more thoroughly revisit our improvement activity weighting policies in next year’s rulemaking. We invited public comment on the need for additional transparency and guidance on the weighting of improvement activities as we work to refine the Annual Call for Activities process for future years. Furthermore, in light of the finalized policy to remove bonus points for improvement activities that may be applicable to the Promoting Interoperability performance category as discussed in sections III.I.3.h.(4)(d)(i)(A)(cc) and III.I.3.h.(5)(d)(ii), we recognize the need to continue incentives for CEHRT. Therefore, for future consideration, we
solicited comment on potentially applying high-weighting for any improvement activity employing CEHRT. We also invited public comment on any other additional considerations for high- or medium-weighting.

Comment: One commenter supported more transparency regarding the differences between high-weight and medium-weight activities and encouraged continued education related to the improvement activities performance category as new activities are added. Another commenter recommended that improvement activities related to Continuing Medical Education (CME) be weighted in a bifurcated manner with more substantial CME’s potentially counting as high-weighted.

Response: We will take these comments into consideration as we develop future policy.

(D) Timeframe for the Annual Call for Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would accept submissions for prospective improvement activities and modifications to existing improvement activities at any time during the performance period to be added to the Improvement Activities Under Review (IAUR) list, for the applicable performance period, which would be displayed on a CMS website following the close of the Annual Call for Activities. In addition, we finalized that for the Annual Call for Activities, only nominations and modifications submitted by March 1st would be considered for inclusion in the IAUR list and Improvement Activities Inventory for the performance period occurring in the following calendar year (82 FR 53660). For example, for the CY 2018 Annual Call for Activities, we received nominations for new and modified improvement activities from February 1st through March 1st. Currently, an improvement activity nomination submitted during the CY 2018 Annual Call for Activities would be vetted in CY 2018, and after review, if accepted by CMS, would be proposed during
the CY 2018 rulemaking cycle for possible implementation in the CY 2019 performance period and future years.

However, the previously established timeline, which includes prospective new and modified improvement activities submission period, review, and publication of proposed improvement activities for implementation in the next performance period, has become operationally challenging. Based on our experience over the past 2 years, we have found that processing and reviewing the volume of improvement activities nominations requires more time than originally thought. In addition, preparations and drafting for annual rulemaking begin around the time of the close date for the current Annual Call for Activities (that is, March 1st), leaving incorporation into the proposed rule challenging. Therefore, in the CY 2019 PFS proposed rule, beginning with the CY 2019 performance period, we proposed to: (1) delay the year for which nominations of prospective new and modified improvement activities would apply; and (2) expand the submission timeframe/due date for nominations (83 FR 35909).

Beginning with the CY 2019 performance period, we proposed to change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year’s rulemaking cycle for possible implementation in a future year. This timeframe parallels the Promoting Interoperability performance category Annual Call for EHR Measures timeframe available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html. For example, an improvement activity nomination submitted during the CY 2020 Annual Call for Activities would be vetted, and if accepted by CMS, would be proposed during the CY 2021 rulemaking cycle for possible implementation starting in CY 2022. We believe this change would give us
adequate time to thoroughly vet improvement activity nominations prior to rulemaking (83 FR 35909).

Second, beginning with the CY 2019 performance period, we proposed to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations. We believe this change would assist stakeholders by providing additional time to submit improvement activities nominations. Consistent with previous policy, nominations for prospective new and modified improvement activities would be accepted during the Annual Call for Activities time period only and would be included in the IAUR displayed on a CMS website following the close of the Annual Call for Activities (83 FR 35909).

The following is a summary of the public comments received on our proposals and our responses:

**Comment:** Several commenters supported the proposed change to the Annual Call for Activities timeframe citing that the modified timeline provides a longer window during which to propose new improvement activities, allows for more advance notice to implement new activities that have been finalized, aligns the Annual Call for Activities with the Annual Call for Measures, and reduces overall program complexity. One commenter noted the new timeframe would ensure that the inventory includes an appropriate number of measures that are meaningful to each specialty, including non-physician Medicare clinicians, and that are appropriate for the patient-centered health care team and have a positive impact on patient care.

**Response:** We appreciate the commenters’ support.

**Comment:** Several commenters did not support the proposed extension of the timeframe for the Annual Call for Activities and recommended that we maintain the current schedule.
because this would ensure the improvement activities inventory include activities that are timely, important, relevant, and meaningful to the evolving practice of medicine and to public health.

One commenter noted extending the timeframe from submission to implementation is a barrier to previously stated goals in aligning improvement activities with the quality improvement cycle. Another commenter noted the benefit of being able to modify or add measures each year outweighs the need for additional submission time and that improvement activities do not require the same reliability and validity testing necessary for successful quality measures and that improvement activities be considered annually informed by the quality improvement cycle. One commenter stated the proposal would impede the ability of groups to create activities that raise awareness of novel or pressing issues and promote best practices in a timely manner. Another commenter urged us to take a modified approach to its proposal in which the timeframe to modify existing measures would be shorter than that for new measures. One commenter stated that delaying consideration of improvement activities until the following year’s rule making does not appropriately reward early adopters of activities and suggested that early adopters of an improvement activity could be given credit.

Response: Although improvement activities do not have the same testing requirements as quality measures, we believe that improvement activities are equally important in facilitating clinical practice improvement. As such, sufficient time is needed to thoroughly review all submissions to ensure we maintain an inventory that is both meaningful and robust. In addition, we cannot increase the submission period without increasing our review period. It would not be operationally feasible to do otherwise. We also do not believe that there is a benefit to providing for a review period that does not allow for an adequate time to thoroughly vet improvement activity nominations prior to rulemaking. However, we will continue to monitor the timeline to
assess if there are any future improvements that can be made to more quickly incorporate new improvement activities into the program when feasibly possible. We disagree that the timeframe would impede the promotion of best practices or awareness of improvement-related activities or issues because stakeholders are not precluded from referencing that a particular activity has been submitted for consideration as part of the Annual Call for Activities to raise awareness and promote best practices. We recognize that the proposed extended timeframe does not align with the submission, review, and implementation of quality measures as part of the Annual Call for Measures; however, we note our proposal parallels our timeframe with the Promoting Interoperability performance category Annual Call for EHR Measures timeframe (we refer readers to section III.1.3.h.(5)(f) of this final rule for more information) and achieves alignment between those performance categories.

After consideration of the public comments received on our proposal, we are finalizing our proposal, as proposed, to change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that beginning with the CY 2019 performance period, improvement activities nominations received in a particular year will be vetted and considered for the next year’s rulemaking cycle for possible implementation in a future year. In addition, we are finalizing our proposal, as proposed, to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations beginning with the CY 2019 performance period.

(ii) New Improvement Activities and Modifications to and Removal of Existing Improvement Activities
In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. We referred readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Table F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized Improvement Activities Inventory. In the CY 2019 PFS proposed rule (83 FR 36359 through 36368), for CY 2019 performance period and future years, we proposed 6 new improvement activities; we also proposed to: (1) modify 5 existing activities; and (2) remove 1 existing activity. We also proposed changes to our CMS Study on Factors Associated with Reporting Quality Measures in section III.I.3.h.(4)(e) of this final rule.

Comment: A few commenters supported the overall approach for the improvement activities performance category because of its goal-oriented and technology-neutral approach to compliance, stating that this provides the flexibility needed for clinicians to select the most effective approaches for their patients that could include connected health technology innovations. One commenter supported the stability in the improvement activities performance category and the transparent process for adding improvement activities to the inventory.

Response: We appreciate the commenters’ support.

A summary of the public comments received on specific improvement activities proposals and our responses may be found in Tables A and B of Appendix 2: Improvement Activities in this final rule.

(e) CMS Study on Factors Associated with Reporting Quality Measures

(i) Background
In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In CMS’ quest to create a culture of improvement using evidence based medicine on a consistent basis, fully understanding the strengths and limitations of the current processes is crucial to better understand and improve these current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77196). The lessons learned in this study on practice improvement and measurement may influence changes to future MIPS data submission requirements. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians (81 FR 77196). This study shall inform us on the root causes of clinicians’ performance measure data collection and submission burdens, as well as challenges that hinder accurate and timely quality measurement activities. Our goals are to use high quality, low cost measures that are meaningful, easy to understand, operable, reliable, and valid. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77195) the CMS Study on Burden Associated with Quality Reporting goals are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring:

- A more data driven approach to quality measurement.
- Measure selection unconstrained by a CEHRT program or system.
- Improving data quality submitted to CMS.
- Enabling CMS to get data more frequently and provide feedback more often.

This study evolved into “CMS Study on Burdens Associated with Reporting Quality Measures” in the CY 2018 Quality Payment Program final rule (82 FR 53662).
This study is ongoing, participants are recruited on a yearly basis for a minimum period of 3 years, and current participants can opt-in or out when the study year ends (81 FR 77195). Successful participation in the study would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities requirements (81 FR 77197). To meet the study requirements, study participants must partake in two web-based survey questionnaires, submit data for at least three MIPS clinician quality measures to CMS during the CY 2019 performance period, and be available for selection and participation in at least one focus group meeting (82 FR 53662).

Although we did not propose any changes to the study purpose, aim, eligibility, or credit, in the CY 2019 PFS proposed rule (83 FR 35910 through 35911), we proposed, for the CY 2019 performance period and future years, changes to the: (1) title of the study; (2) sample size to allow enough statistical power for rigorous analysis within some categories, (3) focus group and survey requirements; and (4) measure requirements. These proposals are discussed in more detail below.

(ii) Title

In the CY 2019 PFS proposed rule (83 FR 35910), beginning with the CY 2019 performance period, we proposed to change the title of the study from “CMS Study on Burdens Associated with Reporting Quality Measures” to “CMS Study on Factors Associated with Reporting Quality Measures” to more accurately reflect the study’s intent and purpose. To assess the root causes of clinician burden associated with the collection and submission of clinician quality measures for MIPS, as depicted in CY 2017 Quality Payment Program final rule (81 FR 77195), replacing “Burden” with “Factors” in the title will eliminate possible response or
recall bias that may occur with data collection. Having “burden” in the study title may elicit the
tendency of survey participants reporting more on their perception of burden and challenges,
and/or suppressing other factors that are associated with their quality measure data collection and
submission, that may be relevant to examining the root cause of burden.

The following is a summary of the public comments related to our proposal and our
response:

Comment: One commenter supported the title change stating that the terminology
changes will attract a more diverse group of study participants and encourage clinician
participants in the study who will work to simplify measures and ensure that that measures bring
maximum value to CMS, clinicians, and beneficiaries.

Response: We appreciate the commenters’ support.

After consideration of the comments, we are finalizing our proposal, as proposed, to
change the title of the study from “CMS Study on Burdens Associated with Reporting Quality
Measures” to “CMS Study on Factors Associated with Reporting Quality Measures” beginning
with the CY 2019 performance period.

(iii) Sample Size

(A) Current Policy

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we initially finalized
a sample size of 42 participants (comprising of groups and individual MIPS eligible facilities).
In the CY 2018 Quality Payment Program final rule (82 FR 53661), we increased that number
and finalized a sample size of a minimum of 102 individual and group participants for
performance periods occurring in CY 2018 for the following categories:
- 20 urban individuals or groups of < 3 eligible clinicians, - (broken down into 10 individuals & 10 groups).
- 20 rural individuals or groups of < 3 eligible clinicians - (broken down into 10 individuals & 10 groups).
- 10 groups of 3-8 eligible clinicians.
- 10 groups of 8-20 eligible clinicians.
- 10 groups of 20-100 eligible clinicians.
- 10 groups of 100 or greater eligible clinicians.
- 6 groups of > 20 eligible clinicians reporting as individuals - (broken down into 3 urban & 3 rural).
- 6 specialty groups - (broken down into 3 reporting individually & 3 reporting as a group).
- Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

(B) New Sample Size

In the CY 2019 PFS proposed rule (83 FR 35910 through 35911), we proposed to again increase the sample size for the CY 2019 performance period and future years from a minimum of 102 to a minimum of 200 MIPS eligible clinicians, which will enable us to more rigorously analyze the statistical difference between the burden and factors associated within the categories listed above. This proposed increase in sample size would provide the minimum sample needed to get a significant result with adequate statistical power to determine whether there are any statistically significant differences in quality measurement data submission associated with: (1) the size of practice or facility; (2) clinician specialty of practice; (3) region of practice; (4)
individual or group reporting; and (5) clinician quality measure type. This rigorous statistical analysis is important, because it facilitates tracing the root causes of measurement burdens and data submission errors that may be associated with various sub-groups of clinician practices using quantitative analytical methods. We believe that a larger sample size would also account for any attrition (drop out of study participants before the study ends). Therefore, we proposed that the new sample size distribution would be:

- 40 urban individuals or groups of < 3 eligible clinicians, - (broken down into 20 individuals & 20 groups).
- 40 rural individuals or groups of < 3 eligible clinicians - (broken down into 20 individuals & 20 groups).
- 20 groups of 3-8 eligible clinicians.
- 20 groups of 8-20 eligible clinicians.
- 20 groups of 20-100 eligible clinicians.
- 20 groups of 100 or greater eligible clinicians.
- Up to 6 groups of > 20 eligible clinicians reporting as individuals - (broken down into 3 urban & 3 rural).
- Up to 6 specialty groups - (broken down into 3 reporting individually & 3 reporting as a group).
- Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

The following is a summary of the public comments related to our proposals and our responses:
**Comment:** One commenter supported the continuation of the study to gather data on clinical improvement activities and measurement to examine clinical quality workflows and data and the proposal to increase the sample size of the study, stating that this would be a simpler approach and allow more clinicians to participate and increase the ability to conduct rigorous statistical analysis with sufficient power.

**Response:** We appreciate the commenter’s support.

**Comment:** One commenter recommended that clinicians located in both urban and rural health practitioner shortage areas and clinicians who serve a high proportion of low-income patients and patients of color be included as study participants.

**Response:** We have been recruiting participants from health practitioner shortage areas, as well as areas with high proportion of patients of color and minority groups.

**Comment:** One commenter requested that CMS assure the quality reporting burden study includes a sample of clinicians with multiple special status categories, such as Certified Registered Nurse Anesthetists, citing there is likely a sufficient number of clinicians that meet the CMS special status requirements in the six specialty groups. The commenter also requested CMS ascertain the burden placed on special status clinicians in outpatient and ASC facilities.

**Response:** We appreciate the commenter’s recommendation. The study welcomes all MIPS eligible clinicians, including Certified Registered Nurse Anesthetists, and non-MIPS clinicians to apply. We hope to further expand the scope of the study in the future.

After consideration of the comments received, we are finalizing our proposal, as proposed, to increase the sample size for the CY 2019 performance period and future years from a minimum of 102 to a minimum of 200 MIPS eligible clinicians.

(iv) Focus Group
(A) Current Policies

We previously finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195) that for the transition year of MIPS, study participants were required to attend a monthly focus group to share lessons learned in submitting quality data along with providing survey feedback to monitor effectiveness. The focus group includes providing visual displays of data, workflows, and best practices to share amongst the participants to obtain feedback and make further improvements (81 FR 77196). The focus groups are used to learn from the practices about how to be more agile as we test new ways of measure recording and workflow (81 FR 77196). In the CY 2018 Quality Payment Program final rule (82 FR 53662), for Year 2 and future years, we reduced that requirement and finalized that study participants would be required to complete at least two web-based survey questionnaire and attend up to 4 focus group sessions throughout the year, but certain study participants would be able to attend less frequently. Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data (82 FR 53662). The purpose of reducing focus group attendance and survey participation was to ease requirements for MIPS eligible clinicians or group of clinicians who may have nothing new to contribute, without compromising the minimum sample needed for focus groups. For example, if a MIPS eligible clinician submitted all 6 measures after collecting 90 days of data and attended the first available focus group and/or survey, the clinician may have nothing new or relevant to discuss with the research team on subsequent focus groups and/or surveys.

(B) New Requirements for Focus Group and Survey Participation

Although we proposed in the section previously to increase the sample size of the study to a minimum of 200 MIPS eligible clinicians, we do not believe we need focus groups for the
entirety of that population. We believe that requiring focus groups for all proposed minimum of 200 MIPS eligible clinicians would only result in bringing the data to a saturation point, a situation whereby the same themes and information are recurring, and no new insights are given by additional sources of data from focus groups.

Instead, we believe that selecting a subset of clinicians, purposively, to participate in focus groups would be a more appropriate approach because that would allow us to understand the experience of select clinicians without imposing undue burden on all. This study is voluntary as clinicians nominate themselves to participate and we select a cohort from among these volunteers. Therefore, in the CY 2019 PFS proposed rule (83 FR 35911), we proposed to make the focus group participation a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Those selected would be required to participate in at least one focus group meeting and complete survey requirement, in addition to all the other study requirements. As previously established, each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. This requirement would continue to apply for each selected subset participating in a focus group.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposals, as proposed, to make the focus group participation a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Those selected would be required to participate in at least one focus group meeting and complete the survey requirements, in addition to all the other study requirements (81 FR 77195).

(v) Measure Requirements
(A) Current Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we finalized that for CY 2017, MIPS eligible clinicians or groups participating in the CMS Study would submit their data and workflows for a minimum of three MIPS clinician quality measures that are relevant and prioritized by their practice. One of the measures must be an outcome measure, and one must be a patient experience measure (81 FR 77196). We also finalized that for future years, participating MIPS eligible clinicians or groups would select three of the measures for which they have baseline data from the 2017 performance period to compare against later performance years. We note that participating MIPS eligible clinicians could elect to report on more measures originally as this would provide more options from which to select in subsequent years for purposes of measuring improvement. In the CY 2018 Quality Payment Program final rule, we finalized for the Quality Payment Program Year 2 and future years, that study participants could submit all their quality measures data at once, as it is done in the MIPS program, (qpp.cms.gov) (82 FR 53662).

(B) Measure Requirements

In the CY 2019 PFS proposed rule (83 FR 35911), we proposed to continue the previously required minimum number of measures. That is, for the CY 2019 performance period and future years: participants must submit data and workflows for a minimum of three MIPS quality measures for which they have baseline data. However, instead of requiring one outcome measure and one patient experience measure as previously finalized, we proposed that, for the CY 2019 performance period and future years, at least one of the minimum of three measures must be a high priority measure as defined at §414.1305. As defined there and discussed in section III.I.3.h.(2) of this final rule, a high priority measure means an outcome, appropriate use,
patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures includes intermediate-outcome and patient-reported outcome measures. We believe that focusing on high priority measures, rather than patient experience measures, is important at this time, because it better aligns with the MIPS quality measures data submission criteria. We invited public comment on our proposal.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposal, as proposed, that for the CY 2019 performance period and future years, at least one of the minimum of three measures must be a high priority measure as defined at §414.1305.

We note that although the aforementioned activities (that is, the CMS Study on Factors Associated with Reporting Quality Measures) constitute an information collection request as defined in the implementing regulations of the Paperwork Reduction Act of 1995 (5 CFR part 1320), the associated burden is exempt from application of the Paperwork Reduction Act. Specifically, section 1848(s) (7) of the Act, as added by section 102 of MACRA (Pub. L. 114-10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures.

(5) Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category)

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of CEHRT as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the advancing care information performance category, and it is reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the
MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the advancing care information performance category.

(b) Renaming the Advancing Care Information Performance Category

In this final rule, we are adopting several scoring and measurement policies that will bring the performance category to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we renamed the advancing care information performance category to the Promoting Interoperability (PI) performance category. We believe this change will help highlight the enhanced goals of this performance category. We are finalizing revisions to the regulation text under 42 CFR part 414, subpart O, to reflect the new name.

(c) Certification Requirements beginning in 2019

Under the definition of CEHRT under §414.1305, for the performance periods in 2017 and 2018, MIPS eligible clinicians had flexibility to use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two Editions, to meet the objectives and measures specified for the Promoting Interoperability performance category (82 FR 53671 through 53672). As we finalized previously (82 FR 53671-53672) beginning with the performance period in 2019, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria as specified at §414.1305. We believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. In reviewing the state of health information technology, it is clear the 2014 Edition certification criterion are out of date and insufficient for clinician needs in the evolving health information technology (IT) industry. It will be beneficial to health IT developers and health care providers to move to more up-to-date
standards and functions that better support interoperable exchange of health information and improve clinical workflows.

We received many comments regarding the requirement to use the 2015 Edition of CEHRT beginning in 2019. As we stated in the CY 2019 PFS proposed rule (83 FR 35912 through 35913), we did not propose to change the requirement. Because the requirement was not a subject of this rulemaking, we are not responding to the comments we received, although we may consider them to inform our future policy making in this subject area.

(d) Scoring Methodology

(i) Scoring Methodology for 2017 and 2018 Performance Periods

Section 1848(q)(5)(E)(i)(IV) of the Act states that 25 percent of the MIPS final score shall be based on performance for the Promoting Interoperability performance category. Accordingly, under §414.1375(a), the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician’s final score for the 2019 MIPS payment year and each MIPS payment year thereafter, unless we assign a different scoring weight. We proposed to revise §414.1375(a) (83 FR 35913) to specify the various sections of the statute (sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), and 1848(q)(5)(F) of the Act) under which a different scoring weight may be assigned for the Promoting Interoperability performance category. We established the reporting criteria to earn a performance category score for the Promoting Interoperability performance category under §414.1375(b). We proposed to revise §414.1375(b)(2)(i) to replace the reference to “each required measure” with “each base score measure” to improve the precision of the text. Under §414.1380(b)(4), the Promoting Interoperability performance category score is comprised of a score for participation and reporting, known as the “base score,” and a score for performance at varying levels above the
base score requirements, known as the “performance score,” as well as any applicable bonus scores. We proposed several editorial changes to §414.1380(b)(4) in an effort to more clearly and concisely capture the previously established policies. For further explanation of our scoring policies for performance periods in 2017 and 2018 for the Promoting Interoperability performance category, we refer readers to 81 FR 77216 through 77227 and 82 FR 53663 through 53664.

A general summary overview of the scoring methodology for the performance period in 2018 is provided in the Table 38.
<table>
<thead>
<tr>
<th>2018 Promoting Interoperability Objective</th>
<th>2018 Promoting Interoperability Measure</th>
<th>Required/Not Required for Base Score (50%)</th>
<th>Performance Score (up to 90%)</th>
<th>Reporting Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect Patient Health Information</td>
<td>Security Risk Analysis</td>
<td>Required</td>
<td>0</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td>Electronic Prescribing</td>
<td>e-Prescribing **</td>
<td>Required</td>
<td>0</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td>Patient Electronic Access</td>
<td>Provide Patient Access</td>
<td>Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td></td>
<td>Patient-Specific Education</td>
<td>Not Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td>Coordination of Care Through Patient Engagement</td>
<td>View, Download, or Transmit (VDT)</td>
<td>Not Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td></td>
<td>Secure Messaging</td>
<td>Not Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td></td>
<td>Patient-Generated Health Data</td>
<td>Not Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Send a Summary of Care **</td>
<td>Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td></td>
<td>Request/Accept Summary of Care **</td>
<td>Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td></td>
<td>Clinical Information Reconciliation</td>
<td>Not Required</td>
<td>Up to 10%</td>
<td>Numerator/Denominator</td>
</tr>
<tr>
<td>Public Health and Clinical Data Registry Reporting</td>
<td>Immunization Registry Reporting</td>
<td>Not Required</td>
<td>0 or 10%*</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td></td>
<td>Syndromic Surveillance Reporting</td>
<td>Not Required</td>
<td>0 or 10%*</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td></td>
<td>Electronic Case Reporting</td>
<td>Not Required</td>
<td>0 or 10%*</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td></td>
<td>Public Health Registry Reporting</td>
<td>Not Required</td>
<td>0 or 10%*</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td></td>
<td>Clinical Data Registry Reporting</td>
<td>Not Required</td>
<td>0 or 10%*</td>
<td>Yes/No Statement</td>
</tr>
<tr>
<td><strong>Bonus (up to 25%)</strong></td>
<td>Report to one or more additional public health agencies or clinical data registries beyond the one identified for the performance score</td>
<td>5% bonus</td>
<td>Yes/No Statement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Report improvement activities using CEHRT</td>
<td>10% bonus</td>
<td>Yes/No Statement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Report using only 2015 Edition CEHRT</td>
<td>10% bonus</td>
<td>Based on measures submitted</td>
<td></td>
</tr>
</tbody>
</table>

* A MIPS eligible clinician may earn 10 percent for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10 percent under the performance score.

** Exclusions are available for these measures.
We did not receive any comments on the proposed revisions to the regulation text at §§414.1375(a) and (b)(2)(i), and §414.1380(b)(4). We are finalizing these revisions as proposed.

We heard from many stakeholders that the current scoring methodology is complicated and difficult to understand. By providing flexibility and offering clinicians multiple measures to choose from within the performance score, it appears some clinicians may have been confused by the options. Other MIPS eligible clinicians have indicated that they dislike the base score because it is a required set of measures and provides no flexibility because the scoring is all or nothing. If a MIPS eligible clinician cannot fulfill the base score, they cannot earn a performance and/or bonus score. We have also received feedback from clinicians and specialty societies that the current requirements detract from their ability to provide care to their patients. In addition, stakeholders have indicated that the requirements of the Promoting Interoperability performance category for clinicians do not align with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) and that this creates a burden for the medical staff who are tasked with overseeing the participation of both clinicians and hospitals in these programs.

Based on the concerns expressed by stakeholders, we proposed a new scoring methodology (83 FR 35913-395918) and moved away from the base, performance and bonus score methodology that we currently use. We stated our belief that this change would provide a simpler, more flexible, less burdensome structure, allowing MIPS eligible clinicians to put their focus back on patients. The introduction of this new scoring methodology would continue to encourage MIPS eligible clinicians to push themselves on measures that are most applicable to how they deliver care to patients, instead of focusing on measures that may not be as applicable to them. Our goal was to provide increased flexibility to MIPS eligible clinicians and enable
them to focus more on patient care and health data exchange through interoperability. Additionally, we wanted to align the requirements of the Promoting Interoperability performance category with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and CAHs as we had proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515 through 20537). As the distinction between ambulatory and inpatient CEHRT has diminished and more clinicians are sharing hospitals’ CEHRT, we stated our belief that aligning the requirements between programs would lessen the burden on health care providers and facilitate their participation in both programs.

(ii) Proposed scoring methodology beginning with the MIPS performance period in 2019

In the CY 2019 PFS proposed rule (83 FR 35914 through 35918), we proposed a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. We stated our belief that this would be an overhaul of the existing program requirements as it would eliminate the concept of base and performance scores. We proposed a smaller set of objectives that consisted of e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. We proposed these objectives to promote specific HHS priorities and satisfy the requirements of section 1848(o)(2) of the Act. We included the e-Prescribing and Health Information Exchange objectives in part to capture what we believe are core goals for the 2015 Edition of CEHRT and also to satisfy the statutory requirements. These core goals promote interoperability between health care providers and health IT systems to support safer, more coordinated care. The Provider to Patient Exchange objective promotes patient awareness and involvement in their health care through the use of APIs, and ensures
patients have access to their medical data. Finally, the Public Health and Clinical Data Exchange objective supports the ongoing systematic collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior. The integration of health IT systems into the national network of health data tracking and promotion improves the efficiency, timeliness, and effectiveness of public health surveillance. We stated our belief that it is important to keep these core goals, primarily because these objectives promote interoperability between health care providers and health IT systems to support safer, more coordinated care while ensuring patients have access to their medical data.

Under the proposed scoring methodology, MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure would be scored based on the MIPS eligible clinician’s performance for that measure, based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require “yes or no” submissions. Each measure would contribute to the MIPS eligible clinician’s total Promoting Interoperability performance category score. The scores for each of the individual measures would be added together to calculate the Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. In general, the Promoting Interoperability performance category score makes up 25 percent of the MIPS final score. If a MIPS eligible clinician fails to report on a required measure or claim an exclusion for a required measure if applicable, the clinician would receive a total score of zero for the Promoting Interoperability performance category.

We also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to
report on only one measure from each objective to earn a score for that objective. Under this scoring methodology, instead of six required measures, the MIPS eligible clinician total Promoting Interoperability performance category score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in our proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the required four. We solicited public comment on this alternative approach, and whether additional flexibilities should be considered, such as allowing MIPS eligible clinicians to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.

In our proposed scoring methodology, the e-Prescribing objective would contain three measures each weighted differently to reflect their potential availability and applicability to the clinician community. In addition to the existing e-Prescribing measure, we proposed to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP); and Verify Opioid Treatment Agreement. For more information about these two proposed measures, we refer readers to section III.H.3.h.(5)(f) of the proposed rule (83 FR 35922 through 35925). The e-Prescribing measure would be required for reporting and weighted at 10 points because we believed it would be applicable to most MIPS eligible clinicians. In the event that a MIPS eligible clinician meets the criteria and claims the exclusion for the e-Prescribing measure in 2019, the 10 points available for that measure would be redistributed equally among the two measures under the Health Information Exchange objective:

- Support Electronic Referral Loops By Sending Health Information Measure (25 points)
Support Electronic Referral Loops By Receiving and Incorporating Health Information (25 points)

We solicited public comment on whether this redistribution is appropriate for 2019, or whether the points should be distributed differently.

The Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the MIPS performance period in 2019. These new measures may not be available to all MIPS eligible clinicians for the MIPS performance period in 2019 as they may not have been fully developed by their health IT vendor, or not fully implemented in time for data capture and reporting. Therefore, we did not propose to require these two new measures in 2019, although MIPS eligible clinicians may choose to report them and earn up to 5 bonus points for each measure. We proposed to require these measures beginning with the MIPS performance period in 2020, and we solicited public comment on this proposal.

Due to varying state requirements, not all MIPS eligible clinicians would be able to e-prescribe controlled substances, and thus, these measures would not be available to them. For these reasons, in the CY 2019 PFS proposed rule (83 FR 35915 through 35916) we proposed an exclusion for these two measures beginning with the MIPS performance period in 2020. The exclusion would provide that any MIPS eligible clinician who is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure.

As the two new opioid measures become more broadly available in CEHRT, we proposed each of the three measures within the e-Prescribing objective would be worth 5 points beginning with the MIPS performance period in 2020. Requiring these two measures would add 10 points to the maximum total score for the Promoting Interoperability performance category as these
measures would no longer be eligible for optional bonus points. To maintain a maximum total score of 100 points, beginning with the MIPS performance period in 2020, we proposed to reweight the e-Prescribing measure from 10 points down to 5 points, and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 points down to 35 points as illustrated in Table 38. We proposed that if the MIPS eligible clinician qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures associated with the e-Prescribing objective as described in section III.H.3.h.(5)(f) of the proposed rule, (83 FR 35921) the 15 points for the e-Prescribing objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to their Health Information measure by adding 5 points to each measure.

We refer readers to section III.I.3.h.(5)(f) of this final rule, where we discuss the Promoting Interoperability performance category measures, for a discussion of the comments we received regarding the above-referenced proposed scoring methodology for the e-Prescribing objective and associated measures. After consideration of the public comments we received, we are finalizing our proposed scoring for the E-Prescribing objective as proposed but with the modifications discussed at the end of this section III.I.3.h.(5)(f) of the preamble of this final rule. The e-Prescribing measure is finalized with modification, the Query of PDMP measure is finalized with modification, and the Verify Opioid Treatment Agreement measure is finalized with modification. In addition, we refer readers to section III.I.3.h.(5)(f)(ii) of the preamble of this final rule where we discuss our reasons for adopting the Query of PDMP measure with modification and the Verify Opioid Treatment Agreement measure with modification.

For the Health Information Exchange objective, we proposed to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending
Health Information measure, and proposed a new measure which combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. For more information about the proposed measure and measure changes, we refer readers to section III.I.3.h.(5)(f) of the proposed final rule (83 FR 35925 through 35928). MIPS eligible clinicians would be required to report both of these measures, each worth 20 points toward their total Promoting Interoperability performance category score. These measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange in an effort to promote care coordination and better patient outcomes. Similar to the two new measures in the e-Prescribing objective, the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure may not be available to all MIPS eligible clinicians as it may not have been fully developed by their health IT vendor, or not fully implemented in time for a MIPS performance period in 2019. For these reasons, we proposed two exclusions for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure:

1. Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure.

2. Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure.

We note that these two exclusions for the measure were proposed in different sections of the proposed rule (83 FR 35916, 35927).
In the event that a MIPS eligible clinician claims an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure, and that measure would then be worth 40 points. We solicited public comment on whether this redistribution is appropriate, or whether the points should be redistributed to other measures instead.

We refer readers to section III.I.3.h.(5)(f) of this final rule, where we discuss the Promoting Interoperability performance category measures, for a discussion of the comments we received regarding the above-referenced proposed scoring methodology for the Health Information Exchange objective and associated measures. We did not receive any comments regarding the redistribution of points if an exclusion is claimed for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. After consideration of the comments that we received, we are finalizing our proposals for the Health Information Exchange objective as proposed. In addition, measure specification details can be found in section III.I.3.h.(5)(f) of the preamble of this final rule.

In the CY 2019 PFS proposed rule (83 FR 359186), we proposed to weight the one measure in the Provider to Patient Exchange objective, Provide Patients Electronic Access to Their Health Information, at 40 points toward the total Promoting Interoperability performance category score in 2019 and 35 points beginning in 2020. We proposed that this measure would be weighted at 35 points beginning in 2020 to account for the two new opioid measures, which would be worth 5 points each beginning in 2020 as proposed. We stated our belief that this objective and its associated measure get to the core of improved access and exchange of patient data in Promoting Interoperability and are the crux of the Promoting Interoperability
performance category. This exchange of data between health care provider and patient is imperative in order to continue to improve interoperability, data exchange and improved health outcomes. We stated that it is important for patients to have control over their own health information, and through this highly weighted objective we are aiming to show our dedication to this effort.

We solicited comment on these proposals and our summary and response are below.

**Comment**: A few commenters supported CMS’ proposed weighting of the Provide Patients Electronic Access to Their Health Information measure.

**Response**: We appreciate the support regarding the proposed weight of this measure. We believe that it is important to give patients access to their data and therefore the measure deserves to be highly weighted.

**Comment**: A few commenters stated that an allocation of 40 points to a single measure (Provide Patient Electronic Access to Their Health Information) is too high. Commenters stated that if the points are redistributed to other measures because exclusions are claimed, especially if an exclusion is claimed on more than one measure, the emphasis on the remaining measures will increase.

**Response**: We believe that it is essential for patients to have access to their health information and the assignment of 40 points to this measure reflects the importance we place on patient’s access to their health information.

After consideration of the comments, we are finalizing with modification the proposals for the Provider to Patient Exchange objective. The Provide Patients Electronic Access to Their Health Information measure will be worth up to 40 points beginning in CY 2019. We had proposed that the measure would be worth up to 35 points beginning in CY 2020, but we are not
finalizing that proposal because we are not requiring the Verify Opioid Treatment Agreement measure beginning in CY 2020 as proposed, which would have been worth up to 5 points. For additional measure information, we refer readers to section III.I.3.h.(5)(f) of the preamble of this final rule.

The measures under the Public Health and Clinical Data Exchange objective are reported using “yes or no” responses and thus we proposed to score those measures on a pass/fail basis in which the MIPS eligible clinician would receive the full 10 points for reporting two “yes” responses, or for submitting a “yes” for one measure and claiming an exclusion for another. If there are no “yes” responses and two exclusions are claimed, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. A MIPS eligible clinician would receive zero points for reporting “no” responses for the measures in this objective if they do not submit a “yes” or claim an exclusion for at least two measures under this objective. We proposed that for this objective, the MIPS eligible clinician would be required to report on two measures of their choice from the following list of measures: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting. To account for the possibility that not all of the measures under the Public Health and Clinical Data Exchange objective may be applicable to all MIPS eligible clinicians, we proposed to establish exclusions for these measures as described in section III.H.3.h.(5)(f) of the proposed rule (83 FR 35929 through 35930). If a MIPS eligible clinician claims two exclusions, the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure under the Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020. Reporting more than two measures for
this objective would not earn the MIPS eligible clinician any additional points. We refer readers
to section III.H.3.h.(5)(f) of the proposed rule (83 FR 35929 through 35930) in regard to the
proposals for the Public Health and Clinical Data Exchange objective and its associated
measures.

We solicited comment on these proposals and our summary and response are below.

Comment: A commenter suggested that MIPS eligible clinicians should be eligible to
earn more points for reporting on more than two public health and clinical data exchange
measures.

Response: We appreciate the suggestion but decline to implement it at this time. We are
limiting bonus point opportunities to brand new measures, such as those associated with the e-
Prescribing objective, in an effort to maintain simplicity and avoid confusion in our scoring
methodology.

Comment: Some commenters questioned whether they could receive credit for reporting
to more than one registry for a measure.

Response: We believe that a clinician who is in active engagement with two different
public health agencies or clinical data registries for purposes of the same measure would
accomplish the same policy goal as our proposal to report on two measures. It is also consistent
with the policy we established in the CY 2018 Quality Payment Program final rule for reporting
on the measures associated with the Public Health and Clinical Data Registry Reporting
Objective for the performance score and bonus score (82 FR 53663-53664). In addition,
allowing MIPS eligible clinicians to report to two different public health agencies or clinical data
registries of their choice promotes flexibility in reporting and allows them to focus on the public
health measures that are most relevant to them and their patient populations. Therefore, we will
be adopting our proposal with modification to allow clinicians the flexibility to report to two different public health agencies or clinical data registries for purposes of the same measure.

After consideration of the public comments we received, we are finalizing our proposals for the Public Health and Clinical Data Exchange objective with modifications. MIPS eligible clinicians must report to two different public health agencies or clinical data registries for any of the following measures: Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. MIPS eligible clinicians may report to two different public health agencies or clinical data registries for purposes of the same measure if they choose. For additional measure information, we refer readers to section III.l.3.h.(5)(f) of this final rule.

In the CY 2019 PFS proposed rule (83 FR 359186), we proposed that the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, would remain part of the requirements for the Promoting Interoperability performance category, but would no longer be scored as a measure and would not contribute to the MIPS eligible clinician’s Promoting Interoperability performance category score. To earn any score in the Promoting Interoperability performance category, we proposed a MIPS eligible clinician would have to report that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the performance period occurs. We stated our belief that the Security Risk Analysis measure involves critical tasks and noted that the HIPAA Security Rule requires covered entities to conduct a risk assessment of their health care organization. This risk assessment will help MIPS eligible clinicians comply with HIPAA’s administrative, physical, and technical safeguards. Therefore, we stated that every MIPS eligible clinician should already be meeting the requirements for this objective and measure as it is a requirement
of HIPAA. We indicated that we still believe this objective and its associated measure are imperative in ensuring the safe delivery of patient health data. As a result, we would maintain the Security Risk Analysis measure as part of the Promoting Interoperability performance category, but we would not score the measure.

The following is a summary of the public comments received on the proposals for the Protect Patient Health Information objective and its associated measure, Security Risk Analysis and our responses.

**Comment:** A commenter stated that the Security Risk Analysis measure has historically been challenging for physicians. The commenter did not support the annual reporting of this measure to be required to achieve any score in the Promoting Interoperability category. To overcome what the commenter described as the burdensome nature of this measure, the commenter indicated that MIPS eligible clinicians need additional support and resources to aid in their understanding of how to conduct a security risk analysis that is compliant with CMS’s standards.

**Response:** The Security Risk Analysis measure has been a required measure since the beginning of the EHR Incentive programs in 2011 through the transition to MIPS starting in 2017. The requirement remains that the actions included in the measure must be performed once during the calendar year in which the performance period occurs. We appreciate the commenter’s interest in additional educational materials for clinicians on how they can improve the privacy and security of their health information. We refer them to https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_SecurityRiskAnalysis.pdf. HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk analysis in
accordance with the HIPAA Security Rule
(http://www.hhs.gov/hipaa/forprofessionals/security/guidance/guidance-risk-analysis/index.html). Additional free tools and resources available to assist MIPS eligible clinicians include a Security Risk Assessment (SRA) Tool developed by the Office of National Coordinator for Health Information Technology (ONC) and OCR at http://www.healthit.gov/providersprofessionals/security-risk-assessment-tool. We believe that performing an annual security risk assessment will help identify security weaknesses and may provide opportunities to improve the security of the MIPS eligible clinician’s electronic systems.

**Comment:** Several commenters stated that if the Security Risk Analysis measure is required, then MIPS eligible clinicians should receive credit for doing it. The commenters recommended that the technological, encryption, and other cybersecurity components of the security risk analysis should be shifted to the health IT vendor and should not be a burden placed on MIPS eligible clinicians.

**Response:** As we discussed in the proposed rule (83 FR 35916), we do not believe that the Security Risk Analysis measure should be scored because it includes actions already required under HIPAA and will help MIPS eligible clinicians comply with HIPAA’s administrative, physical, and technical safeguards. We do not believe points should be awarded because MIPS eligible clinicians should have already been performing these actions. In addition, while a health IT vendor’s products must possess the relevant privacy and security capabilities be certified, we believe that MIPS eligible clinicians must also conduct security risk assessments to make sure that vulnerabilities are identified and remediated. In addition, successful completion of a security risk analysis is required to earn a score in the Promoting Interoperability performance category.
Comment: The majority of commenters supported CMS’ proposal to require MIPS eligible clinicians to attest to the completion of the actions of the Security Risk Analysis measure with no associated score in order to be eligible to receive an overall score in the Promoting Interoperability performance category. They stated that this measure is essential to safely transmitting their patient data and successfully participating in the Promoting Interoperability performance category.

Response: As discussed in the preceding response, we agree that this measure should not be scored.

After consideration of the public comments, we are finalizing our proposal to require MIPS eligible clinicians to attest that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the MIPS performance period occurs. MIPS eligible clinicians who fail to complete these actions or fail to attest will not earn any score for the Promoting Interoperability performance category, regardless of whether they report on other measures for this category.

As we proposed at 83 FR 35916, similar to how MIPS eligible clinicians currently submit data, the MIPS eligible clinician would submit their numerator and denominator data for each measure, and a “yes or no” response for each of the two reported measures under the Public Health and Clinical Data Exchange objective. The numerator and denominator for each measure would then translate to a performance rate for that measure and would be applied to the total possible points for that measure. For example, the e-Prescribing measure was proposed to be worth 10 points. A numerator of 200 and denominator of 250 would yield a performance rate of \((200/250) = 80\) percent. This 80 percent would be applied to the 10 total points available for the e-Prescribing measure to determine the measure score. A performance rate of 80 percent for the
e-Prescribing measure would equate to a measure score of 8 points (performance rate * total possible measure points = points awarded toward the total Promoting Interoperability performance category score; 80 percent*10= 8 points). To calculate the Promoting Interoperability performance category score, the measure scores would be added together, and the total sum would be divided by the total possible points (100). The total sum cannot exceed the total possible points. This calculation results in a fraction from zero to 1, which can be formatted as a percent. For further clarification we refer readers to the scoring example that we included in the proposed rule (83 FR 35917).

When calculating the performance rates, measure and objective scores, and the Promoting Interoperability performance category score, we would generally round to the nearest whole number. For example if a MIPS eligible clinician received a score of 8.53 the nearest whole number would be 9. Similarly, if the MIPS eligible clinician received a score of 8.33 the nearest whole number would be 8. In the event that the MIPS eligible clinician receives a performance rate or measure score of less than 0.5, as long as the MIPS eligible clinician reported on at least one patient for a given measure, a score of 1 would be awarded for that measure. We stated that we believed this is the best method for the issues that might arise with the decimal points and is the easiest for computations.

In order to meet statutory requirements and HHS priorities, the MIPS eligible clinician would need to report on all of the required measures across all objectives in order to earn any score at all for the Promoting Interoperability performance category. Failure to report any required measure, or reporting a “no” response on a “yes or no” response measure, unless an exclusion applies would result in a score of zero. We solicited public comment on the proposed
Tables 39 and 40 illustrate our proposal for the new scoring methodology.

**TABLE 39: Proposed Scoring Methodology for the MIPS Performance Period in 2019**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measures</th>
<th>Maximum Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>e-Prescribing</td>
<td>e-Prescribing</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td><em>Bonus:</em> Query of Prescription Drug Monitoring Program (PDMP)</td>
<td>5 points bonus</td>
</tr>
<tr>
<td></td>
<td><em>Bonus:</em> Verify Opioid Treatment Agreement</td>
<td>5 points bonus</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Support Electronic Referral Loops by Sending Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td></td>
<td>Support Electronic Referral Loops by Receiving and Incorporating Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td>Provider to Patient Exchange</td>
<td>Provide Patients Electronic Access to Their Health Information</td>
<td>40 points</td>
</tr>
<tr>
<td>Public Health and Clinical Data Exchange</td>
<td>Choose two of the following: Immunization Registry Reporting</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td>Electronic Case Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public Health Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Data Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Syndromic Surveillance Reporting</td>
<td></td>
</tr>
</tbody>
</table>
TABLE 40: Proposed Scoring Methodology  
Beginning with MIPS Performance Period in 2020

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measures</th>
<th>Maximum Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>e-Prescribing</td>
<td>e-Prescribing</td>
<td>5 points</td>
</tr>
<tr>
<td></td>
<td>Query of Prescription Drug Monitoring Program (PDMP)</td>
<td>5 points</td>
</tr>
<tr>
<td></td>
<td>Verify Opioid Treatment Agreement</td>
<td>5 points</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Support Electronic Referral Loops by Sending Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td></td>
<td>Support Electronic Referral Loops by Receiving and Incorporating Health Information</td>
<td>20 points</td>
</tr>
<tr>
<td>Provider to Patient Exchange</td>
<td>Provide Patients Electronic Access to Their Health Information</td>
<td>35 points</td>
</tr>
<tr>
<td>Public Health and Clinical Data Exchange</td>
<td>Choose two of the following: Immunization Registry Reporting</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td>Electronic Case Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public Health Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Data Registry Reporting</td>
<td></td>
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<tr>
<td></td>
<td>Syndromic Surveillance Reporting</td>
<td></td>
</tr>
</tbody>
</table>

In the proposed rule (83 FR 35917), we sought public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology. We also sought public comment on other scoring methodologies such as the alternative we considered and described earlier in this section.

We solicited comment on these proposals and our summary of these comments and responses are below.

Comment: Some commenters expressed concern that CMS has gone back to an “all or nothing” approach, which existed in the original meaningful use program. Commenters indicated that under CMS’ proposal, clinicians would be required to report on all required measures within each of the four objectives. Failure to report on one measure without claiming an exclusion would result in a score of zero. Other commenters stated that the proposed new structure is still essentially an “all or nothing” approach, which they do not support. Instead, they suggested that
MIPS eligible clinicians who do not or cannot attest to a measure should not receive points for that particular measure, but they should still earn points for all of the other measures that they are able to submit data for.

**Response:** We tried to reduce confusion and clinician burden by proposing to reduce the number of measures that MIPS eligible clinicians are required to report and provide an opportunity for MIPS eligible clinicians to earn points by redistributing the points to other measures when an exclusion is claimed. We do not agree that this scoring structure is an all or nothing approach due to the reduction of measures, the requirement of a one in the numerator for numerator/denominator measures or a “yes” for yes/no measures, and the redistribution of points when an exclusion is claimed. We do not agree with the suggestion that MIPS eligible clinicians that do not or cannot attest to measures should not receive points since the measures have been reduced to six required measures which will reduce administrative burden and allow MIPS eligible clinicians to focus more on their patients. We believe it would disadvantage clinicians if we did not redistribute the points for measures when an exclusion is claimed. We believe the proposed scoring methodology promotes the goals of the performance category to focus on interoperability, improving patient access to health information and aligning the performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

**Comment:** One commenter agreed with the CMS proposal to give a MIPS eligible clinician a Promoting Interoperability performance category score of "zero" for failure to report on any one required measure, but recommended that CMS create an exclusion process with identified circumstances where partial credit for the measure may be applied, but such partial credit should be the exception and not the norm and should be evaluated on a case-by-case basis.

**Response:** We appreciate the suggestion but believe it would further complicate scoring
when we are trying to simplify it to the greatest extent possible. Our intention with our proposals for the scoring methodology was to reduce clinician burden. We do not believe that a process to address individual scenarios is feasible for us to implement at this time, but will take this comment into consideration for future rulemaking.

Comment: One commenter requested clarification of our proposal to require MIPS eligible clinicians to report on all of the required measures across all objectives in order to earn any score at all for the Promoting Interoperability performance category. The commenter questioned if failure to report any required measure would result in a zero for that measure or a zero for the Promoting Interoperability performance category.

Response: The clinician would earn a score of zero for the entire Promoting Interoperability performance category.

Comment: Some commenters expressed concern with the time required to incorporate new measures into CEHRT (an average of 1000 hours per measure per product) and requested that measures changes be done judiciously to minimize the burden to developers and to MIPS eligible clinicians who must implement the new measures.

Response: The proposed scoring methodology primarily would eliminate or revise existing measures, which should only require consolidation of existing workflows and actions. In addition, the certification criteria and standards for EHR technology would remain the same as finalized in the October 16, 2015 final rule titled “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 62602 through 62759).

Comment: One commenter stated that we should not require a minimum numerator of 1 for any of the performance measures, but instead we should require all program participants to
report on all of the performance measures, with an exclusion available for each measure in case their CEHRT does not support the measure. If the exclusion is claimed, the participant would receive a 0 on that measure, and the exclusion status would be published on Physician Compare.

**Response:** We disagree with the commenter’s suggested approach. CEHRT presently has the capability to support all of the proposed measures with the exception of the Query of Prescription Drug Monitoring measure and the Verify Opioid Treatment Agreement measure, which would be optional in the 2019 MIPS performance period. For more information on what will be posted on Physician Compare, see section III.I.3.1. of this final rule.

**Comment:** One commenter suggested an alternative intermediate solution where each measure would be worth up to 10 points for a total of 110 points (90 for the existing performance measures plus e-Prescribing plus a second registry measure).

**Response:** We appreciate this suggestion, but we believe that removing several of the existing performance score measures will help to reduce burden for MIPS eligible clinicians.

**Comment:** Many commenters supported CMS’ proposal to reduce the number of measures to be reported as part of the Promoting Interoperability performance category.

**Response:** We believe the reduction in reporting will relieve health care provider burden through a more flexible, performance-based approach.

**Comment:** Some commenters supported the CMS effort to reduce the complexity of the scoring methodology. Some commenters stated that the proposed scoring methodology reduces clinician burden by eliminating confusing base and performance scores in favor of scoring at the individual measure level, with relevant measure exclusions. Some commenters supported the overall reduction of measures in this category through the elimination of burdensome measures. Another commenter indicated that the proposed scoring methodology and measure set is a huge
improvement and does a lot to streamline the requirements of the Promoting Interoperability performance category. Commenters supported the move to a single set of measures because it will help alleviate confusion by MIPS eligible clinicians. Many commenters supported CMS’ proposed scoring methodology in which MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level.

Response: We appreciate the many commenters who supported the proposed scoring methodology and agree it will reduce burden.

Comment: A few commenters stated they favored a system that provides the flexibility for MIPS eligible clinicians to select the measures most relevant to their practice and patient population and are the least burdensome to implement.

Response: We believe the proposed scoring methodology approach, including the reduction of measures to reduce reporting burden and our goal to provide patients with access to their health information promotes the goals of the Promoting Interoperability performance category. Providing flexibility to choose measures that do not promote increased focus on interoperability or improving patient access to health information will deemphasize the goals of the Promoting Interoperability performance category. We received many comments indicating that there were too many measures so to address that we have reduced and combined measures to reduce MIPS eligible clinician burden.

Comment: One commenter supported this specific proposal to streamline and simplify the Promoting Interoperability performance category, but cautioned CMS against further implementation of major category overhauls. Significant changes, even those intended to reduce physician reporting burden, can increase burden when they require yet another round of health
care provider and staff education to understand how to maximize performance under a redesigned category scoring methodology. Solo practitioners and small group practices in particular have indicated that substantial category changes are significant burdens for their practices.

**Response:** We appreciate the commenter’s support for our proposal and will take the recommendation against further implementation of major category overhaul into consideration in future rulemaking. We note that in the CY 2018 Quality Payment Program final rule (82 FR 53682-53683), we finalized a significant hardship exception for the Promoting Interoperability performance category for MIPS eligible clinicians who are in small practices.

**Comment:** A few commenters disagreed with our proposal to combine the Request/Accept Summary of Care measure with the Clinical Information Reconciliation measure and they proposed that each measure remain separate and be worth 10 points, rather than having them combined and worth 20 points.

**Response:** We thank commenters for their suggestion but we decline to adopt it. For the reasons discussed in section III.I.3.h.(5)(f) of this final rule, we believe it is appropriate to combine these measures and have the point value reflect the combination.

**Comment:** Many commenters recommended that we establish a threshold of 50 points to align with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

**Response:** Although our proposed scoring methodology did not include a point threshold, we appreciate this comment and will take it into consideration as we develop future proposals.

**Comment:** A commenter supported the proposed weighting of the measures but recommended that CMS consider adding additional measures that would promote the integration
of clinical and administrative data toward the goal of creating substantive longitudinal patient records.

Response: We appreciate the support and appreciate the suggestion. In the proposed rule we did request comments (83 FR 35931 through 35932) on potential new measures as well as ways to link the quality, improvement activities, and the Promoting Interoperability performance categories. We plan to use the comments we received to inform future proposals that focus on integration.

Comment: Some commenters thanked CMS for aligning the measures in the inpatient and outpatient settings because it will reduce burden.

Response: We appreciate commenter’s support of our proposal to align the MIPS Promoting Interoperability performance category measures with the Medicare Promoting Interoperability Program measures for eligible hospitals and CAHs.

Comment: Some commenters stated that CMS should not implement the alternative scoring approach that was considered and discussed in the proposed rule because it would allow MIPS eligible clinicians to report on fewer measures and still earn the same credit which is a lowering of the bar for achieving interoperability. Many commenters suggested that the Public Health and Clinical Data Exchange objective would be deemphasized by reducing the reporting requirement to only one measure.

Response: We agree and will not be implementing the alternative that we considered. Our primary proposal focuses on interoperability and improving patient access to health information and we believe that the objectives and measures we have chosen will help to fulfill these goals. We agree that reporting to two different public health agencies or clinical data registries for any of the measures from the Public Health and Clinical Data Exchange objective
will help to build bi-directional data exchange between clinicians and public health agencies and clinical data registries. We believe that our proposal will enable MIPS eligible clinicians to push themselves on measures that are the most applicable to how they deliver care to patients.

Comment: Many commenters supported CMS’ alternative approach to scoring in which scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective.

Some commenters stated that requiring MIPS eligible clinicians to report on every single measure or claim an exclusion creates an unfair burden. Other commenters supported the alternative approach because they believe it is less rigid and provides MIPS eligible clinicians with more flexibility to report measures that are part of their workflow.

Response: We have taken commenters’ feedback into consideration as we have constructed our final policy as outlined in section III.1.3.h.(5)(d) of this final rule. We decline to finalize the alternative approach to scoring. In addition, the other objectives containing more than one measure are the Electronic Prescribing objective and the Health Information Exchange objective. For the Electronic Prescribing objective, we note that both the Query of PDMP and Verify Opioid Treatment Agreement measures are optional for reporting for CY 2019; therefore we believe this objective could require reporting on only one measure as opposed to multiple measures. We continue to believe that the objective and measure set that we selected will enable MIPS eligible clinicians to focus on interoperability and improving patient access to health information.
Comment: A commenter recommended that CMS only require that MIPS eligible clinicians attest to satisfying each measure for at least 1 patient instead of using a performance rate.

Response: We disagree. We believe that a performance-based scoring mechanism will enable MIPS eligible clinicians who perform well on measures to differentiate themselves from other MIPS eligible clinicians who submitted data with lower results for the Promoting Interoperability performance category.

Comment: One commenter suggested that if a MIPS eligible clinician cannot fulfill a measure that an exclusion process be created where partial credit can be earned. They recommended that partial credit be granted on a case-by-case basis.

Response: We do not believe that finalizing a process to address individual scenarios is feasible for us to implement at this time. We may take this comment into consideration in our development of future rulemaking.

Comment: One commenter supported all of the proposed measures as long as there is no minimum threshold requirement and no performance measurement.

Response: The Promoting Interoperability performance category sets a very low minimum threshold requirement for measures. We believe that the minimum reporting requirements we set (a one in the numerator for numerator/denominator measures, a “yes” for yes/no measures, unless an exclusion is claimed) are appropriate. We believe that a performance based scoring system as we are implementing for the Promoting Interoperability performance category will enable high performing MIPS eligible clinicians to distinguish themselves from others and potentially earn a higher upward adjustment,

Comment: One commenter urged CMS to allow MIPS eligible clinicians to “pick and
choose” measures from a “menu” of objectives and measures. Other commenters recommended that the Promoting Interoperability performance category not be limited to a small set of measures. The commenters recommended more flexibility by allowing MIPS eligible clinicians to select from a larger list of measures.

Response: We disagree because we allowed considerable choice for years one and two and received significant feedback about how complicated it was for clinicians to understand the requirements for the base and performance scores. We continue to believe that a reduced set of measures will reduce burden for clinicians and will enable them to focus more on patient care.

As we have received significant commenters support on our proposal to align the Promoting Interoperability requirements and measures with the Medicare Promoting Interoperability Program measures for eligible hospitals and CAHs, we decline to retain measures so that MIPS eligible clinicians have flexibility in selecting measures.

Comment: A commenter stated that if CMS does not remove the “all or nothing” scoring requirement, we recommend that the proposals related to re-weighting measures when a MIPS eligible clinician claims an exclusion be modified because they are confusing.

Response: While we understand that concern, we believe that if a MIPS eligible clinician meets the requirements of an exclusion, then the points for the excluded measure should be redistributed to another measure. We will develop educational tools to assist MIPS eligible clinicians to understand our redistribution policy.

Comment: A commenter stated that MIPS eligible clinicians rely on their EHR systems to help them with program participation. They warned that if these proposed changes are finalized in November 2018 for the 2019 performance period, the systems will not be updated until mid-2019 at the earliest. They requested a full calendar year’s notice before any changes
would become applicable.

Response: We disagree that a full calendar year’s notice is necessary. The proposed new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, includes two exclusions in CY 2019, as described in section III.I.3.h.(5)(f) of the preamble of this final rule. For the Electronic Prescribing objective, we note that both the Query of PDMP and Verify Opioid Treatment Agreement measures are optional for reporting for CY 2019. The criteria for all of the remaining measures (numerator/denominator or yes/no measures) would remain the same and are supported by 2015 Edition CEHRT.

Summary of Final Scoring Methodology: As discussed above, after consideration of the comments we received, we are finalizing our proposed performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in CY 2019, with modifications, as described below.

For additional measure-specific information, we refer readers to section III.I.3.h.(5)(f) the preamble of this final rule.

Promoting Interoperability Score: We are finalizing that MIPS eligible clinicians are required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure is scored based on the MIPS eligible clinician’s performance for that measure, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require a yes/no attestation. Each measure will contribute to the MIPS eligible clinician’s total Promoting Interoperability performance category score. The scores for each of the individual measures are added together to calculate the total Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. To calculate the Promoting Interoperability
performance category score, the measure scores are added together, and the total sum is divided by the total possible points (100). The total sum cannot exceed the total possible points. This calculation results in a fraction from zero to 1, which can be formatted as a percent. For a MIPS eligible clinician to earn a score greater than zero for the Promoting Interoperability performance category, in addition to completing the actions included in the Security Risk Analysis measure, the MIPS eligible clinician must submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure will translate to a performance rate for that measure and will be applied to the total possible points for that measure. The MIPS eligible clinician must report on all of the required measures across all of the objectives in order to earn any score at all. Failure to report any required measure, or reporting a “no” response on a yes/no response measure, unless an exclusion is claimed will result in a Promoting Interoperability performance category score of zero.

Security Risk Analysis Measure: We are finalizing our proposal that MIPS eligible clinicians must attest to having completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the MIPS performance period occurs. The Security Risk Analysis measure is not scored and does not contribute any points to the MIPS eligible clinician’s total score for the objectives and measures.

Electronic Prescribing Objective Scoring: We are finalizing the Electronic Prescribing objective as proposed with the following modifications. The e-Prescribing measure is worth up to 10 points in CYs 2019 and 2020. We are modifying the points for CY 2020 to reflect the modification to our proposal for the Query of Prescription Drug Monitoring Program (PDMP) measure in CY 2020. The Query of PDMP measure is optional in CY 2019 and worth 5 bonus points. We are not establishing a policy for the Query of PDMP measure for CY 2020 in this
final rule and intend to address this measure in future rulemaking. The Verify Opioid Treatment Agreement measure is optional in CY 2019 and 2020, and worth five bonus points. We intend to reevaluate the status of the Verify Opioid Treatment Agreement measure for subsequent years in future rulemaking. An exclusion is available for the e-Prescribing measure as described in section III.I.3.h.(5)(f) of the preamble of this final rule. If an exclusion is claimed for the e-Prescribing measure for CY 2019, the 10 points for the e-Prescribing measure will be redistributed equally among the measures associated with the Health Information Exchange objective. Since the Query of PDMP and Verify Opioid Treatment Agreement measures are optional and eligible for bonus points, no exclusions are available.

**Health Information Exchange Objective Scoring:** We are finalizing the Health Information Exchange objective as proposed. The Support Electronic Referral Loops by Sending Health Information measure is worth up to 20 points. An exclusion is available for this measure, as described in section III.I.3.h.(5)(f) of the preamble of this final rule, although we did not address in the proposed rule how the points would be redistributed in the event the exclusion is claimed. We intend to propose in next year’s rulemaking how the points will be redistributed if an exclusion is claimed. The new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, is worth up to 20 points. Exclusions are available for this measure, as described in section III.I.3.h.(5)(f) of this final rule. If an exclusion is claimed, the 20 points would be redistributed to the other measure within this objective, the Support Electronic Referral Loops by Sending Health Information measure, which would be worth up to 40 points. We will address in future rulemaking how the points will be redistributed if exclusions are claimed for both the Support Electronic Referral Loops by Sending Health Information
measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

Provider to Patient Exchange Objective Scoring: We are finalizing the Provider to Patient Exchange objective with modifications. The Provide Patients Electronic Access to Their Health Information measure is worth up to 40 points beginning with the MIPS performance period in CY 2019. No exclusions are available for this measure.

Public Health and Clinical Data Exchange Objective Scoring: We are finalizing the Public Health and Clinical Data Exchange objective as proposed with the following modifications. MIPS eligible clinicians must submit a yes/no response for two different public health agencies or clinical data registries for any of the measures associated with the Public Health and Clinical Data Exchange objective to earn 10 points for the objective. Failure to report on two different public health agencies or clinical data registries or submitting a “no” response for a measure will earn a score of zero. Exclusions available for this objective are discussed in section III.I.3.h.(5)(f) of the preamble of this final rule. If an exclusion is claimed for one measure, but the MIPS eligible clinicians submits a “yes” response for another measure, they would earn the 10 points for the Public Health and Clinical Data Exchange objective. If a MIPS eligible clinician claims exclusions for both measures they select to report on, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

Tables 41 and 42 reflect the final policy for the objectives, measures, and maximum points available for the MIPS performance periods in CY 2019 and CY 2020. Please note, the maximum points available do not include points that would be redistributed in the event an exclusion is claimed:
Tables 41 and 42 illustrate our final performance-based scoring methodology.

**TABLE 41: Scoring Methodology for the MIPS Performance Period in 2019**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measures</th>
<th>Maximum Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>e-Prescribing</td>
<td>e-Prescribing**</td>
<td>10 points</td>
</tr>
<tr>
<td></td>
<td>Bonus: Query of Prescription Drug Monitoring Program (PDMP)</td>
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<td>Bonus: Verify Opioid Treatment Agreement</td>
<td>5 point bonus</td>
</tr>
<tr>
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<td>20 points</td>
</tr>
<tr>
<td></td>
<td>Support Electronic Referral Loops by Receiving and Incorporating Health Information**</td>
<td>20 points</td>
</tr>
<tr>
<td>Provider to Patient Exchange</td>
<td>Provide Patients Electronic Access to Their Health Information</td>
<td>40 points</td>
</tr>
<tr>
<td>Public Health and Clinical Data Exchange</td>
<td>Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting**</td>
<td>10 points</td>
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<tr>
<td></td>
<td>Electronic Case Reporting**</td>
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<td></td>
<td>Clinical Data Registry Reporting**</td>
<td></td>
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<tr>
<td></td>
<td>Syndromic Surveillance Reporting**</td>
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</table>

**Exclusion available.**

**TABLE 42: Scoring Methodology for the MIPS Performance Period in 2020**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measures</th>
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</tr>
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<tbody>
<tr>
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<td></td>
<td>Syndromic Surveillance Reporting**</td>
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**Exclusion available.**
We proposed to codify the proposed new scoring methodology in new paragraphs (b)(4)(ii) and (iii) under §414.1380 and we are finalizing the proposed regulation text with modification.

(e) Promoting Interoperability/Advancing Care Information Objectives and Measures Specifications for the 2018 Performance Period

The Advancing Care Information (now Promoting Interoperability) performance category Objectives and Measures for the 2018 performance period are as follows. For more information, we refer readers to the CY 2017 Quality Payment Program and CY 2018 Quality Payment Program final rules (81 FR 77227 through 77229, and 82 FR 53674 through 53680, respectively).

**Objective**: Protect Patient Health Information

**Objective**: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

**Security Risk Analysis Measure**: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in §§164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician’s risk management process.

**Objective**: Electronic Prescribing

**Objective**: Generate and transmit permissible prescriptions electronically.

**e-Prescribing Measure**: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.
**Denominator:** Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.

**Numerator:** The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

**Exclusion:** Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

**Objective:** Patient Electronic Access

**Objective:** The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

**Patient Access Measure:** For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician’s CEHRT.

**Denominator:** The number of unique patients seen by the MIPS eligible clinician during the performance period.

**Numerator:** The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download,
and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician’s CEHRT.

*Patient-Specific Education Measure*: The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

*Denominator*: The number of unique patients seen by the MIPS eligible clinician during the performance period.

*Numerator*: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the performance period.

*Objective*: Coordination of Care Through Patient Engagement

*Objective*: Use CEHRT to engage with patients or their authorized representatives about the patient’s care.

*View, Download, Transmit (VDT) Measure*: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician by either: (1) viewing, downloading or transmitting to a third party their health information; or (2) accessing their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician’s CEHRT; or (3) a combination of (1) and (2).

*Denominator*: Number of unique patients seen by the MIPS eligible clinician during the performance period.
Numerator: The number of unique patients (or their authorized representatives) in the
denominator who have viewed online, downloaded, or transmitted to a third party the patient’s
health information during the performance period and the number of unique patients (or their
authorized representatives) in the denominator who have accessed their health information
through the use of an API during the performance period.

Secure Messaging Measure: For at least one unique patient seen by the MIPS eligible
clinician during the performance period, a secure message was sent using the electronic
messaging function of CEHRT to the patient (or the patient-authorized representative), or in
response to a secure message sent by the patient (or the patient-authorized representative).

Denominator: Number of unique patients seen by the MIPS eligible clinician during the
performance period.

Numerator: The number of patients in the denominator for whom a secure electronic
message is sent to the patient (or patient-authorized representative) or in response to a secure
message sent by the patient (or patient-authorized representative), during the performance
period.

Patient-Generated Health Data Measure: Patient-generated health data or data from a
non-clinical setting is incorporated into the CEHRT for at least one unique patient seen by the
MIPS eligible clinician during the performance period.

Denominator: Number of unique patients seen by the MIPS eligible clinician during the
performance period.

Numerator: The number of patients in the denominator for whom data from non-clinical
settings, which may include patient-generated health data, is captured through the CEHRT into
the patient record during the performance period.
Objective: Health Information Exchange

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.

Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Request/Accept Summary of Care Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient’s record an electronic summary of care document.

Denominator: Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
**Numerator:** Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the CEHRT.

**Exclusion:** Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.

**Clinical Information Reconciliation Measure:** For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The MIPS eligible clinician must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient’s medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient’s known medication allergies; and (3) Current Problem list. Review of the patient’s current and active diagnoses.

**Denominator:** Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.

**Numerator:** The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

**Objective:** Public Health and Clinical Data Registry Reporting

**Objective:** The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.
**Immunization Registry Reporting Measure:** The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

**Syndromic Surveillance Reporting Measure:** The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care setting.

**Electronic Case Reporting Measure:** The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

**Public Health Registry Reporting Measure:** The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

**Clinical Data Registry Reporting Measure:** The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

(f) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Measure Summary Overview

In the CY 2019 PFS proposed rule (83 FR 35920 through 35932), we proposed to adopt beginning with the performance period in 2019 the existing Promoting Interoperability objectives and measures as finalized in the CY 2018 Quality Payment Program final rule (82 FR 53674 through 53680) with several proposed changes as discussed herein, including the addition of new measures, removal of some of the existing measures, and modifications to the specifications of some of the existing measures. We did not propose to continue the Promoting Interoperability transition objectives and measures (see 82 FR 53674 through 53676) beyond the 2018 MIPS performance period because the 2015 Edition of CEHRT will be required beginning
with the MIPS performance period in 2019. Our intent for these proposed changes is to ensure the measures better focus on the effective use of health IT, particularly for interoperability, and to address concerns stakeholders have raised through public forums and in public comments related to the perceived burden associated with the current measures in the program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77216) our priority is to finalize reporting requirements for the Promoting Interoperability performance category that incentivizes performance and reporting with minimal complexity and reporting burden. In addition, we acknowledged that while we believe all of the measures of the Promoting Interoperability performance category are important, we must also balance the need for these data with data collection and reporting burden (81 FR 77221).

In CY 2017, we initiated an informal process outside of rulemaking for submission of new Promoting Interoperability performance category measures for potential inclusion in the Year 3 Quality Payment Program proposed rule. We prioritized measures that build on interoperability and health information exchange, the advanced use of CEHRT using 2015 Edition Standards and Certification Criteria, improve program efficiency and flexibility, measure patient outcomes, emphasize patient safety, and support improvement activities and quality performance categories of MIPS. In addition, and as we indicated in the CY 2018 Quality Payment Program proposed rule (82 FR 30079), we sought new measures that may be more broadly applicable to MIPS eligible clinicians who are Nurse Practitioners (NPs), Physician Assistants (PAs), Certified Registered Nurse Anesthetists (CRNAs) and Clinical Nurse Specialists (CNSs).

During this initial submission period, various MIPS eligible clinicians, stakeholders and health IT developers submitted new measures for consideration via an application posted on the
Through our review process, which included representation from the ONC, as well as various stakeholder listening sessions, we identified measure submissions that met our criteria and aligned with the Promoting Interoperability performance category goals and priorities, as well as broader HHS initiatives related to the opioid crisis.\(^{20}\) As a result of this process, we proposed two measures, Query of PDMP and Verify Opioid Treatment Agreement.

We proposed to remove six measures from the Promoting Interoperability objectives and measures beginning with the performance period in 2019. Two of the measures we proposed to remove – Request/Accept Summary of Care and Clinical Information Reconciliation – would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two measures it is replacing. Four of the measures – Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data – would be removed because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians’ progress on current program priorities. We stated that although the measures proposed for removal would no longer need to be submitted if we finalize the proposal to remove them, MIPS eligible clinicians may still continue to use the standards and functions of those measures based on the preferences of their patients and their practice needs. We stated our belief that this burden reduction would enable MIPS eligible clinicians to focus on new measures that further interoperability, advances of innovation in the use of CEHRT and the exchange of health care information.

As discussed in the proposed scoring methodology in section III.H.3.h.(5)(f) of the proposed rule, we proposed to add three new measures to the Promoting Interoperability objectives and measures beginning with the performance period in 2019. For the e-Prescribing objective, we proposed the two new measures referenced earlier, Query of PDMP and Verify Opioid Treatment Agreement, both of which support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers and focusing on the advanced use of CEHRT. For the Health Information Exchange objective, we proposed a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, which builds upon and replaces the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures, while furthering interoperability and the exchange of health information.

We also proposed to modify some of the existing Promoting Interoperability performance category objectives and measures beginning with the performance period in 2019. We proposed to rename the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. In addition, we proposed to rename the Patient Electronic Access objective to Provider to Patient Exchange, and proposed to rename the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information. We proposed to eliminate the Coordination of Care Through Patient Engagement objective and all of its associated measures as described earlier. Finally, we proposed to rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange and require reporting on at least two measures of the MIPS eligible clinician’s choice from the following: Immunization Registry Reporting; Syndromic Surveillance Reporting, Electronic
Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. In addition, we proposed exclusion criteria for each of these measures.

Finally, we solicited comment on a potential new measure Health Information Exchange Across the Care Continuum under the Health Information Exchange objective in which a MIPS eligible clinician would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a health care provider other than a MIPS eligible clinician. The measure would include health care providers in care settings including but not limited to long term care facilities and post-acute care providers such as skilled nursing facilities, home health, and behavioral health settings.

As we stated in the proposed rule (83 FR 35921) we understand from previous listening sessions that EHR vendors and developers will need time to develop, test and implement new measures, and MIPS eligible clinicians will need time to implement as well as establish and test their processes and workflows. As indicated above and in the discussion of the proposed scoring methodology in section III.H.3.h.(5)(d) of the proposed rule, we proposed three new measures (Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information). We proposed that the Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the performance period in 2019 and bonus points may be earned for reporting on them. We proposed that the Support Electronic Referral Loops by Receiving and Incorporating Health Information would be required beginning with the performance period in 2019 with exclusions available. We proposed to require the Query of PDMP and Verify Opioid Treatment Agreement measures beginning with the performance period in 2020, and we solicited public comment on this proposal.
We noted that the proposals under the Health Information Exchange objective require only consolidation of existing workflows and actions, while certification criteria and standards remain the same as in the CY 2018 Quality Payment Program final rule (82 FR 53677 through 53678). Therefore, we stated our belief that MIPS eligible clinicians could potentially implement this new measure for the performance period in 2019.

The following is a summary of the comments we received on our proposals.

Comment: One commenter stated that for some measures MIPS eligible clinicians and group practices should be able to get credit for actions that are taken outside of the 90-day performance period.

Response: Since the inception of the Quality Payment Program, we have limited the ability to increment the numerator and denominator of measures to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure for which the relevant actions may occur any time during the calendar year. The MIPS eligible clinician may select a MIPS performance period that exceeds the 90-day minimum up to a maximum of the full calendar year if they choose. (82 FR 53670).

(ii) Measure Proposals for the e-Prescribing Objective

In the CY 2019 PFS proposed rule (83 FR 35921 through 35925), we proposed two new measures under the e-Prescribing objective. In the CY 2017 Quality Payment Program final rule, we stated that MIPS eligible clinicians will have the option to include or not include controlled substances in the definition of “permissible prescriptions” at their discretion where feasible and allowable by law in the jurisdiction where they provide care (81 FR 77227). We believe it is important to consider other requirements specific to electronic prescribing of controlled substances for health care providers to take into account and how this may interact with the
proposals under this rulemaking. We are committed to combatting the opioid epidemic by making it a top priority for the agency and aligning its efforts with the HHS opioid initiative to combat misuse and promote programs that support treatment and recovery support services.

We proposed to add two new measures to the e-Prescribing objective that are based on electronic prescriptions for controlled substances (EPCS): Query of PDMP; and Verify Opioid Treatment Agreement. These measures build upon the meaningful use of CEHRT as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we proposed to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. We also proposed to apply the same policies for the existing e-Prescribing measure to both the Query of PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. We stated that MIPS eligible clinicians have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law. However, because the intent of these two new measures is to improve prescribing practices for controlled substances, MIPS eligible clinicians would have to include Schedule II opioid prescriptions in the numerator and denominator or claim the applicable exclusion. Additionally, we noted the intent of the proposed measures is not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice. We solicited comment on the impact that implementing this measure could have on patients who receive opioids due to medical diagnoses such as cancer or receiving
hospice care as well as treatment of patients under a program involving substance abuse education, treatment, or prevention under 42 CFR part 2.

Additionally, we solicited comment on the federal and state statutory and regulatory requirements that may impact implementation of the Query of PDMP and Verify Opioid Treatment Agreement measures.

We stated that in the event we finalize the new scoring methodology that we proposed in section III.H.3.h.(5)(d) of the proposed rule, MIPS eligible clinicians who claim the exclusion under the existing e-Prescribing measure would automatically receive an exclusion for all three of the measures under the e-Prescribing objective; they would not have to also claim exclusions for the other two measures, Query of PDMP and Verify Opioid Treatment Agreement. We are not finalizing this proposal because we are finalizing the two new measures (Query of PDMP and Verify Opioid Treatment Agreement) are optional, so exclusions would not be necessary for them.

(A) Query of Prescription Drug Monitoring Program (PDMP) Measure

As we stated in the proposed rule (83 FR 35922 through 35923), a PDMP is an electronic database that tracks prescriptions of controlled substances at the State level. PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking the prescribed controlled substances and improving prescribing practices. The ONC, Centers for Disease Control and Prevention (CDC), Department of Justice (DOJ) and Substance Abuse and Mental Health Services Administration (SAMHSA) have had integral roles in the integration and expansion of PMDPs with health information technology systems. For example, the ONC and SAMHSA collaboratively led the “Enhancing Access”
project to improve health care provider access to PDMP data utilizing health IT.\textsuperscript{21} Likewise, the CDC conducted a process and outcome evaluation of the PDMP EHR Integration and Interoperability Expansion (PEHRIIE) program funded by SAMHSA for nine states between FY 2012 and 2016. The PEHRIIE program goals were to integrate PDMPs into health IT and improve the comprehensiveness of PDMPs through initiating and/or improving interstate data exchange.\textsuperscript{22} In addition, the Bureau of Justice Assistance’s Harold Rogers Prescription Monitoring Program supports Prescription Drug Monitoring Program Information Exchange (PMIX) through funding, the goal of PMIX is to help states implement a cost-effective solution to facilitate interstate data sharing among PDMPs.\textsuperscript{23} Integration of the PDMP with health information technology systems supports improves access to PDMP data, minimizes changes to current workflow and overall burden and optimizes prescribing practices. The intent of the Query of the PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids.

**Proposed Measure Description:** For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

We stated that we recognize both the utility and value of addressing PDMP EHR integration and further recognizes the majority of states mandate use of State prescription monitoring programs (PMPs) requiring prescribers/dispensers to access PMP.\textsuperscript{24} According to the CDC, State-level policies that enhance PDMPs or regulate pain clinics helped several states drive

\textsuperscript{23} https://www.bja.gov/funding/Category-5-awards.pdf.
\textsuperscript{24} http://www.namsdl.org/library/14D3122C-96F5-F53E-E8F23E906B4DE09D/.
down opioid prescriptions and overdose deaths.\textsuperscript{25} We stated that we are also further aware of the varying integration approaches underway including efforts to integrate a state PDMP into a health information exchange or EHR or other efforts to enhance a user interface of some type, such as risk assessment tools or red flags. We noted federal evaluation resources available to inform integration efforts\textsuperscript{26} and believe integration is critical for enhancing health care provider workflow, access to critical PDMP data, and improving clinical care including prescription management.

We proposed that the query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. MIPS eligible clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law.

Although the query of the PDMP may currently be burdensome for some MIPS eligible clinicians as part of their current workflow practice, we stated our belief that querying the PDMP is beneficial to optimal prescribing practices and foresee progression toward fully automated queries of the PDMP building upon the current initiatives at the State level.

We proposed to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. We requested comment on these policy proposals, including whether additional queries should be performed and under which circumstances. In addition we

\textsuperscript{25} https://www.cdc.gov/drugoverdose/policy/successes.html
\textsuperscript{26} https://www.cdc.gov/drugoverdose/pdf/pehrie_report-a.pdf
solicited comment on whether the query should have additional constraints concerning when it should be performed.

**Denominator:** Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

**Numerator:** The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

*Exclusion (beginning in 2020):* Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. We proposed that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions. We also requested comment on the proposed exclusion criteria and whether there are circumstances which may justify other exclusions for the Query of PDMP measure and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We noted that we also understand that PDMP integration is not currently in widespread use for CEHRT, and many MIPS eligible clinicians may require additional time and workflow changes at the point of care before they can meet this measure without experiencing significant burden. For instance, many MIPS eligible clinicians will likely need to manually enter the data into CEHRT to document the completion of the query of the PDMP action. In addition, some MIPS eligible clinicians may also need to conduct manual calculation of the measure. Even for those MIPS eligible clinicians that have achieved successful integration of a PDMP with their
EHR, this measure may not be machine calculable, for instance, in cases where the MIPS eligible clinician follows a link within the EHR to a separate PDMP system. For the purposes of meeting this measure, we noted there is no existing certification criteria for the query of a PDMP. However, we stated our belief that the use of structured data captured in the CEHRT can support querying a PDMP through the broader use of health IT. We solicited public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

We noted the NCPDP SCRIPT 2017071 standard for e-prescribing is now available and can help to support PDMP and EHR integration. We solicited public comment, especially from health care providers and health IT developers on whether they believe use of this standard can support MIPS eligible clinicians seeking to report on this measure, and whether HHS should encourage use of this standard through separate rulemaking.

We solicited comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden.

In including EPCS as a component of the measure as proposed, we acknowledged and sought input on perceived and real technological barriers as part of its effective implementation including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient and health care provider relationships subsequent to in-person visit(s) and for prescribing purposes.
We also proposed that in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(a)(10)(ii) and (b)(3).

The following is a summary of the comments we received on these proposals.

**Comment:** One commenter stated that the measure is overly burdensome because view-only data is not sufficient for clinicians and data should be in a format that is acceptable by the receiving EHR system.

**Response:** We agree that if data exchanged is not supported in a computable format, it may create increased burden to the MIPS eligible clinician. Although we believe the Query of PDMP measure is a necessary step to combat the opioid crisis by taking advantage of health IT capabilities, we agree that the lack of EHR integration with PDMPs is an obstacle to widespread adoption of this measure. We will continue to work with our colleagues across HHS and with stakeholders to develop necessary standards and complementary resources to promote the advancement of PDMP functionality. Over time, we believe the continued advancement of this measure will help further patient safety and reduce provider burden. We are providing bonus points for this measure in CY 2019 and will propose our policy for CY 2020 in future rulemaking.

**Comment:** Some commenters supported this new measure but stated that there is little or no time for health IT developers to update their products, receive certification and roll these products out to users. Commenters requested that CMS give more lead-time for these type of changes and have the Query of PDMP measure be optional in the 2019 and 2020 MIPS performance periods.

Other commenters stated that while PDMPs play an important role in identifying high-risk patients, and recommended that CMS move more slowly with requiring the measure until
PDMPs are more fully integrated into EHRs and clinician workflows.

Response: We acknowledge that there is currently no certified functionality within CEHRT specific to connecting to a PDMP and that support for integration between PDMP systems and EHRs varies widely across States due to variations in laws and technical approaches. We believe that functionality currently in CEHRT may support integration with PDMP systems. While we understand the concern that there is not specific certified functionality to meet this measure, we stated in the proposed rule (83 FR 35923) that MIPS eligible clinicians have the flexibility to query the PDMP in any manner allowed under their State law. We also stated (83 FR 35923) that in order to meet the measure, MIPS eligible clinicians must use the capabilities of their CEHRT defined at §170.315(a)(10)(ii) and (b)(3).

The certification criteria defined at §170.315(b)(3) supports this measure because it allows a MIPS eligible clinician to create a new prescription, change a prescription, cancel a prescription, refill a prescription, request fill status notifications and request and receive medication history information to and from pharmacies. PDMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. Additionally, the CEHRT criteria defined at §170.315(a)(10)(ii) defines drug formulary checks, which are the most useful when utilized with e-Prescribing. These criteria ensure the availability of structured data to support PDMPs through the broader use of health IT and may increase the efficiency and safety of opioid prescribing, while potentially reducing the cost of care.

We are aware of the need for additional time to implement this measure and thus we are making it optional in CY 2019 and will propose our policy for this measure for CY 2020 in future rulemaking.
Comment: One commenter stated that CMS must recognize that the Query of PDMP measure may not provide a complete picture of the patient’s medication history.

Response: We agree that the Query of PDMP measure may not provide a complete picture of the patient’s medication history; however, it can provide the clinician with information to make a more informed clinical decision, and we believe it is a valuable tool to consider in caring for patients.

Comment: One commenter recommended that CMS and ONC work together to develop a set of national standards for PDMPs, so that the information can be exchanged across a variety of States. Another commenter recommended CMS and ONC develop standards to allow access to a PDMP through a HIE.

Response: We understand States have varying technical approaches for PDMPs and that some states are pursuing strategies that utilize HIEs to help clinicians access PDMPs. We believe these strategies are an important way to increase interoperability and support clinicians’ ability to connect with PDMP systems.

We will continue to work with ONC and other stakeholders to encourage the development of standards, which facilitate increased interoperability between PDMPs and other systems, including HIEs and clinician health IT systems.

Comment: A commenter stated that a State lacks a state-wide PDMP and requested an exclusion for MIPS eligible clinicians who do not have a State PDMP to query. Another commenter requested an exclusion for MIPS eligible clinicians who do not prescribe any Schedule II opioids during a 90-day performance period, because the lack of such exclusion could result in MIPS eligible clinicians prescribing an unnecessary Schedule II opioid just to avoid earning a zero for the Promoting Interoperability performance category. One commenter
requested that in addition to the proposed exclusion CMS should add an exclusion for MIPS eligible clinicians in states that do not support PDMP integration using the NCPDP SCRIPT or SMART on FHIR standard.

**Response:** We decline to add any exclusions to the Query of PDMP measure at this time. For CY 2019, exclusions are not available, as the measure is optional.

**Comment:** Some commenters stated the development of interfaces to connect EHRs to a PDMP vendor solution is underway, but there is a cost to access the PDMP gateway. Other commenters noted that some states charge clinicians fees to use a PDMP and a mandatory measure using PDMPs could add considerable financial burden.

**Response:** Our goal of burden reduction includes consideration of costs associated with meeting the Promoting Interoperability performance category requirements. We will continue to listen to feedback related to costs and mitigate burden wherever possible and as practicable within the MIPS programs. We will also continue to work with HHS partners and other stakeholder in the creation, harmonization, and promotion of free and open source interoperability standards for EHRs and PDMPs, and we encourage PDMPs across the country to connect to the free and open source RxCheck, a fully operational national hub that enables states to securely and efficiently share PDMP data.

**Comment:** A few commenters stated that this measure should be Yes/No reporting instead of reporting a numerator and denominator since some states require health care providers to download current PDMP results that are not incorporated into CEHRT. The commenter further stated that having this measure as a numerator/denominator will create significant challenges to capture and calculate the performance of this measure.

**Response:** We decline to change the format of the measure to a Yes/No metric as we
believe that a numerator/denominator reporting format captures the intent of the measure, which is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. We believe MIPS eligible clinicians need to demonstrate their performance in meeting these opioid measures.

Comment: A commenter questioned what documentation is required to indicate that they fulfilled the Query of PDMP measure. The commenter stated that in the 2020 MIPS performance period, when the measure is required, MIPS eligible clinicians will need time to figure out how to generate the appropriate documentation.

Response: We understand that many clinicians may be required to manually calculate this measure, and we plan to issue guidance regarding the documentation to retain. This may include MIPS eligible clinicians with EHR-integrated PDMPs, who still have to manually calculate the measure due to the lack of automated functionality. Due to challenges with reporting on this new measure, we will determine through future rulemaking the status of this measure for the 2020 MIPS performance period and beyond.

Comment: A commenter requested that the denominator of the measure be changed from “electronically prescribed” to all prescribed Schedule II opioids because entities that are barred from e-prescribing controlled substances would still benefit from incorporating PDMP queries into their workflows.

Response: As we stated in the proposed rule (83 FR 35922), intent of the Query of the PDMP measure is to build upon current PDMP initiatives from federal partners focusing on prescriptions generated and dispensing of opioids. The objectives and measures for the Promoting Interoperability performance category focus on the use of CEHRT. Therefore we
decline to expand the denominator of the measure to include Schedule II opioids that are not electronically prescribed.

**Comment:** One commenter requested clarification as to whether the numerator is intended to capture PMDP queries or user acknowledgement of conducting a PDMP query.

**Response:** The numerator captures instances were a MIPS eligible clinician conducts a query of a PDMP for prescription medication history, except where prohibited and in accordance with the applicable law. We understand that many clinician systems may not have the ability to capture the number of PDMP queries in an automated fashion, and that these clinicians may need to capture the data and calculate the measure manually. The intent of the measure is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities.

**Comment:** A commenter stated that many state PDMPs are not ready to implement direct integration of the PDMP with the EHR. Many commenters stated that this functionality needs to be a part of CEHRT, so that prescribers do not need to leave their EHR and log into a separate system to conduct the query of the PDMP. Commenters suggested that CMS redesign the measure so that only direct integration is included.

**Response:** We agree that there are issues associated with the integration of the PDMP with CEHRT and that is why we will establish our policies for the measure for CY 2020 and beyond in future rulemaking.

**Comment:** One commenter recommended that CMS allow MIPS eligible clinicians to use a health information exchange to access the Schedule II opioid prescription drug history and earn extra points.

**Response:** We have stated that clinicians may query the PDMP in any fashion allowed
under applicable state law, which would include the use of HIEs to access PDMP data.

Comment: A commenter recommended CMS and ONC work together with PDMPs, PDMP health IT vendors, and key standards development organizations (NCPDP and HL7 in particular) to address the interoperability and integration issues when using PDMPs. We note that, while NCPDP provides medication history query specifications that CEHRT support as part of their electronic prescribing capabilities, none of the PDMPs currently support these. The commenter suggested that consideration should be given whether comprehensive interoperability with PDMPs to support both clinicians and patients would benefit from the use of HL7 FHIR© standards.

Response: We recognize that interoperability and integration efforts are in various stages. CMS and ONC continue to work in tandem and with our stakeholders toward our shared goal of interoperability. We encourage work by PDMPs, pharmacies, and health IT developers to use existing and emerging open source standards to ensure greater interoperability between PDMPs and health IT systems and within efficient clinician workflows. The adoption and implementation of these open source standards is important not only for PDMP query functionality but for also other relevant tools, such as automated clinical decision support, that facilitate more informed prescribing practices and improved patient outcomes.

Comment: The commenter stated their state does not let the PDMP be fully integrated with the electronic medical record. The commenter also questioned how CMS envisions clinicians attesting to querying of the PDMP, and it would be helpful to have more guidance from CMS.

Response: If you choose to submit data for CY 2019 for the Query of PDMP measure, you will submit your numerator and denominator. We plan to provide additional information in
future rulemaking regarding this measure in CY 2020 and beyond.

Comment: A commenter stated that some states are not planning for EHR systems to interface with a PDMP and even those that are planning for this functionality may face a lengthy process to develop the ability for an EHR to integrate with a PDMP.

Response: We will use this input to help inform our future work and ongoing collaborative efforts with our HHS colleagues, and with other public- and private-sector partners, as appropriate. We will seek comment and suggestions in future rulemaking to ascertain if additional exclusions are needed for MIPS eligible clinicians located in one of the States where PDMPs are not integrated with EHRs.

Comment: Some commenters supported the intent of this measure but did not support the measure as written because it lacks standards. Commenters suggested that CMS work with ONC to develop a national standard for PDMPs.

Response: We will continue to collaborate with our colleagues across HHS, and with other public-and private-sector partners as appropriate.

Comment: A commenter addressed the impact the Query of PDMP measure may have on patients who receive opioids due to medical diagnoses such as cancer or receiving hospice. The commenter stated that patients with cancer, in hospice care and/or end of life patients should be excluded from this measure. The commenter also stated that CMS needed to do more work to define “cancer patient,” and whether this included cancer survivors or those with an active cancer diagnosis.

Response: We decline to add an exclusion for this for the 2019 MIPS performance period because the measure is optional and not required. If we propose to require this measure in future years, we may consider this suggestion for an exclusion.
After consideration of the comments we received, we are finalizing the Query of PDMP measure with modification:

Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

For the purposes of this measure, we are defining opioids as Schedule II controlled substances under 21 CFR 1308.12. We are finalizing the proposal to apply the same policies for the existing e-Prescribing measure to the Query of PDMP measure, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. The query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. MIPS eligible clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law. This measure includes all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. To meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§170.315(a)(10)(ii) and (b)(3).

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history
except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

As this measure is optional in CY 2019, we are not finalizing exclusions for it. We will propose our policy for the Query of a PDMP measure for CY 2020 in future rulemaking.

(B) Verify Opioid Treatment Agreement Measure

As we stated in the proposed rule at 83 FR 35923, the intent of this measure is for MIPS eligible clinicians to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient’s Schedule II opioid prescriptions is at least 30 cumulative days. We stated that we believe seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy. The intent of the treatment agreement is to clearly outline the responsibilities of both patient and MIPS eligible clinician in the treatment plan. Such a treatment plan can be integrated into care coordination and care plan activities and documents as discussed and agreed upon by the patient and MIPS eligible clinician. An opioid treatment agreement is intended to support and to enable further coordination and the sharing of substance use disorder (SUD) data with consent, as may be required of the individual.

We stated that we understand from stakeholder feedback during listening sessions that there are varied opinions regarding opioid treatment agreements amongst health care providers. Some are supportive of their use, indicating that treatment agreements are an important part of the prescription of opioids for pain management, and help patients understand their role and responsibilities for maintaining compliance with terms of the treatment. Other health care providers object to their use citing ethical concerns, and creation of division and trust issues in
the health care provider–patient relationship. Other concerns stem from possible disconnect between the language and terminology used in the agreement and the level of comprehension on the part of the patient. Because of the debate among practitioners, we requested comment on the challenges this proposed measure may create for MIPS eligible clinicians, how those challenges might be mitigated, and whether this measure should be included as part of the Promoting Interoperability performance category. We also acknowledged challenges related to prescribing practices and multiple State laws which may present barriers to the uniform implementation of this proposed measure. We solicited public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

*Proposed Measure Description:* For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient’s Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient’s electronic health record using CEHRT.

We proposed this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the MIPS eligible clinician during the performance period, as well as any Schedule II opioid prescriptions identified in the patient’s medication history request and response transactions during a 6-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

We stated that there also may be MIPS eligible clinician burdens specific to identifying the existence of a treatment agreement which could require additional time and changes to existing workflows, determining what constitutes a treatment agreement due to a lack of a
definition, standard or electronic format and manual calculation of the measure. We note that there is no certified capability specific to verification and incorporation of an opioid treatment agreement, however, clinicians must use the capabilities and standards defined for CEHRT at §§170.315(a)(10) and (b)(3) and 170.205(b)(2) to meet the measure. In addition, limitations in the completeness of care team information may limit the ability of a MIPS eligible clinician to identify all potential sources for querying and obtaining information on a treatment agreement for a specific patient. There are currently pilots in development focused on increasing connectivity and data exchange among health care providers to better integrate behavioral health information, for instance, pilots taking place as part of the federal Demonstration Program for Certified Community Behavioral Health Clinics (CCBHC)27 includes criteria on how CCBHCs should use health IT to coordinate services and track data on quality measures. Participants in such pilots would potentially have the means necessary to leverage health IT connectivity to query behavioral health data resources and health care providers within their region to identify the existence of an opioid treatment agreement and to successfully integrate patient information from the hospital stay into the care plan for the patient. We solicited comment on other similar pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.

We proposed the 6-month look-back period would begin on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT and provided an illustrative example of this policy in the proposed rule.

We proposed a 6-month look-back period to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the performance period. In addition, we proposed that the 6-month look-back period would utilize at a minimum the

industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at §170.205(b)(2)). As ONC has stated (80 FR 62642), adoption of the requirements for NCDCP SCRIPT v10.6 does not preclude developers from incorporating and using technology standards or services not required by regulation in their health IT products.

We did not propose to define an opioid treatment agreement as a standardized electronic document; nor did we propose to define the data elements, content structure, or clinical purpose for a specific document to be considered a “treatment agreement.” For this measure, we solicited comment on what characteristics should be part of an opioid treatment agreement including data, content and clinical purpose into CEHRT, including which functionalities could be utilized to accomplish this. We noted that a variety of standards available in CEHRT might support the electronic exchange of opioid abuse related treatment data, such as use of the Consolidated Clinical Document Architecture (C-CDA) care plan template that is currently optional in CEHRT.

We also solicited comment on methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could be utilized to accomplish this task.

We solicited comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the “patient health data capture” functionality (§170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

**Denominator:** Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as
identified in the patient's medication history request and response transactions during a 6-month look-back period.

**Numerator:** The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.

**Exclusion (beginning in 2020):** Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period.

We proposed that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to electronic prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions.

We requested comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We solicited comment on whether these types of agreements could create a burden on clinicians and patients, particularly clinicians who serve patients with cancer or those practicing in hospice, as well as the patients they serve.

We also proposed that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§170.315(a)(10) and (b)(3) and 170.205(b)(2).
As discussed earlier, we recognize that many health care providers are only beginning to adopt electronic prescriptions for controlled substances (EPCS) at this time. Although we have proposed two new measures which combine EPCS with other actions, we requested comment on whether stakeholders would be interested in a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed.

We solicited comment about the feasibility of such a measure, and whether stakeholders believe this would help to encourage broader adoption of EPCS.

The following is a summary of the comments we received on these proposals.

Comment: A few commenters supported the new Verify Opioid Treatment Agreement measure, but stated concern about the amount of time available for EHR vendors to update systems to meet the requirements of the measure and request CMS give more lead-time for these type of changes. Another commenter requested that CMS remove the requirement to use the capabilities and standards of CEHRT to verify if an opioid treatment agreement exists.

Response: We recognize the measure is technically complex and may require updates to a MIPS eligible clinician’s EHR systems in order to effectively perform the functionality associated with this measure. However, we believe there are MIPS eligible clinicians who are already using health IT to verify whether there is an opioid treatment agreement in place before electronically prescribing opioids. We also believe it is important to continue to improve prescribing practices for controlled substances using currently available methods as part of existing workflow practices, and that this particular measure can help lead to improvement in prescribing practices.

As discussed in the proposed rule, we believe there are some ways in which certified
health IT may be able to support the electronic exchange of opioid related treatment data, such as use of the C-CDA care plan template that is currently optional in CEHRT. This template contains information on health concerns, goals, interventions, health status evaluation & outcomes sections that could support the development of an opioid treatment agreement. In addition, the “patient health data capture” functionality which is part of the 2015 Edition certification criteria (§170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

We note that there is no capability within certified health IT to support verification of an opioid treatment agreement. We stated (83 FR 35925) that in order to meet the measure, MIPS eligible clinicians must use the capabilities and standards defined for CEHRT at §§170.315(a)(10) and (b)(3) and 170.205(b)(2). The certification criteria defined at §170.315(a)(10) defines drug formulary checks and preferred drug check lists for a given patient and medication, which are the most useful when utilized with e-Prescribing. These criteria may enable health IT to provide structured data to support querying and may increase the efficiency and safety of opioid prescribing, while potentially reducing the cost of care and confronting the opioid crisis.

The certification criteria defined at §170.315(b)(3) supports this measure because it allows a health care provider to create a new prescription, change a prescription, cancel a prescription, refill a prescription, request fill status notifications and request and receive medication history information. Additionally, certification criteria defined at §170.205(b)(2) adopts the NCPDP SCRIPT Standard v10.6 standards and associated implementation specifications for electronic prescribing.

While we understand the above regulations do not specifically define certification criteria
and standards for the Verify Opioid Treatment Agreement measure, we believe they may help provide a framework for MIPS eligible clinicians who would like to implement the measure.

Comment: Several commenters expressed concern regarding the calculation of the denominator and potential data inaccuracies because the data is from third party systems and the ability of the EHR to calculate the performance rate is reliant on the quality of the data received. The commenters stated there are no standards regarding the type or format of data that is received. Therefore, the EHR system may be incomplete, making the calculation inaccurate. The commenters recommended that the Verify Opioid Treatment Agreement measure be revised to acknowledge that the EHR will be able to calculate prescription duration only with data supplied.

In addition, a commenter stated the measure is highly problematic and prone to error calculation because the denominator is based on patients who are receiving an electronic prescription for a Schedule II opioid medication and have a total of 30 or more cumulative prescription days on the Schedule II opioid being prescribed in a 6-month look back period. The commenter stated that neither the NCPDP 10.6 Medication History Query nor the NCPDP 2017071 Medication History Query has a required, discrete data field to capture the prescription days. The commenter requested CMS not finalize the measure and not proceed with making the measure optional until it can be better defined. The commenter also stated that if the measure is finalized, that CMS should change its denominator proposal to be based on doses prescribed, as opposed to prescription days.

Response: We understand the measure would be technically complex and potentially burdensome for MIPS eligible clinicians to implement and that the results of the measure may be affected by data quality and availability issues. We may consider modifications to the
In addition, as opioid treatment agreements become more widely adopted, we believe this measure may help to encourage health IT vendors to develop innovative solutions to capture data and reduce workflow complexities.

Comment: A commenter requested clarification of the meaning of “incorporates the agreement” in CEHRT, as there are no standards about what data elements are included in opioid treatment agreements. The commenter also requested the numerator be changed to the number of unique patients in the denominator for whom the MIPS eligible clinician has a signed opioid treatment agreement in CEHRT.

Response: As we did not define standards, data elements, content structure or clinical purpose for a specific document to be considered an “opioid treatment agreement,” we also did not define what needs to be incorporated into the CEHRT to meet the measure. Rather the intent of an opioid treatment agreement is to support and enable further care coordination and shared decision making. Therefore, we leave it to the discretion of the MIPS eligible clinician to determine what is considered an opioid treatment agreement and how to capture this in their CEHRT.

We decline to change the numerator to those patients for whom the MIPS eligible clinician has a signed opioid treatment agreement in CEHRT. The goal of this measure is to encourage MIPS eligible clinicians to seek to identify an existing opioid treatment agreement for those patients for whom they have prescribed Schedule II opioids, rather than those patients for whom they have successfully identified and incorporated an opioid treatment agreement.

Comment: Many commenters suggested CMS align the requirements of this measure with the similar measure for eligible hospitals and CAHs under the Medicare Promoting
Interoperability Program, so that the Verify Opioid Treatment Agreement measure would be optional in the 2019 and 2020 MIPS performance periods.

Response: We appreciate the suggestion to align the requirements of the Verify Opioid Treatment Agreement measure in the Promoting Interoperability performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

CMS received many similar concerns and feedback on the Verify Opioid Treatment Agreement measure proposal for eligible hospitals and CAHs, which we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20528 through 20530). The concerns noted by commenters on both the FY 2019 IPPS/LTCH PPS proposed rule and the CY 2019 PFS proposed rule included the varied opinions on the effectiveness of opioid treatment agreements, lack of specified certification standards and criteria, and the complexities of implementing such a measure.

We understand these concerns and believe additional time is necessary to implement this measure before we make it required. Therefore, we are aligning with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and making the Verify Opioid Treatment Agreement measure optional for the 2019 and 2020 MIPS performance periods. We will include proposals for this measure for future years in future rulemaking.

Comment: Several commenters questioned whether MIPS eligible clinicians who do not prescribe opioids are allowed to claim an exclusion, or is the exclusion limited to those who cannot prescribe opioids because of applicable law.

Response: We are not finalizing the Verify Opioid Treatment Agreement measure as proposed and therefore are not finalizing the exclusion we proposed at 83 FR 35925, which would have allowed any MIPS eligible clinician who is unable to electronically prescribe
Schedule II opioids in accordance with applicable law during the performance period to claim an exclusion.

Because we are finalizing the measure as optional for both the 2019 and 2020 performance periods, we decline to offer any additional exclusions for this measure.

Comment: One commenter suggested that this measure overlaps with existing quality and improvement activities and thus CMS should work to allow MIPS eligible clinicians who report on measures and activities under the quality and improvement activities performance categories to automatically receive credit in the Promoting Interoperability performance category.

Response: We appreciate the suggestion and are currently considering possible ways that points could be earned across multiple performance categories. We refer readers to our request for comment (83 FR 35932) where we requested input on ways to link these three performance categories.

Comment: A commenter appreciated that the measure is intended to verify whether an opioid treatment agreement exists, rather than mandating the creation of an opioid treatment agreement.

Response: We believe it is important for MIPS eligible clinicians to be able to use an existing opioid treatment agreement if one exists, rather than creating a potentially duplicative agreement.

After consideration of the comments received, we are adopting our proposal for the addition of the Verify Opioid Treatment Agreement measure with modification:

Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period to claim an exclusion.
period, if the total duration of the patient’s Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient’s electronic health record using CEHRT.

We define opioids as Schedule II controlled substances under 21 CFR 1308.12. We are finalizing the proposal to apply the same policies for the existing e-Prescribing measure to the Verify Opioid Treatment Agreement measure, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. This measure includes all Schedule II opioids prescribed for a patient electronically using CEHRT by the MIPS eligible clinician during the performance period, as well as any Schedule II opioid prescriptions identified in the patient’s medication history request and response transactions during a 6-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

The 6-month look-back period begins on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT. The 6-month look-back period must utilize at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at §170.205(b)(2)).

To meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§170.315(a)(10) and (b)(3) and 170.205(b)(2).

**Denominator:** Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as
identified in the patient’s medication history request and response transactions during a 6-month look-back period.

*Numerator:* The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.

This measure will be optional in the CY 2019 and 2020 performance periods, so we are not finalizing the proposed exclusion for CY 2020.

(iii) Measures for the Health Information Exchange Objective

As we stated in the proposed rule (83 FR 35925) the Health Information Exchange measures for MIPS eligible clinicians hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. However, through our review of the existing measures, we determined that we could potentially improve the measures to further reduce burden and better focus the measures on interoperability in health care provider to health care provider exchange. Such modifications would address a number of concerns raised by stakeholders including:

- Supporting the implementation of effective health IT supported workflows based on a specific organization’s needs;

- Reducing complexity and burden associated with the manual tracking of workflows to support health IT measures; and

- Emphasizing within these measures the importance of using health IT to support closing the referral loop to improve care coordination.
We stated that we believe we can potentially improve the existing Health Information Exchange measures to streamline measurement, remove redundancy, reduce complexity and burden, and address stakeholders’ concerns about the focus and impact of the measures on the interoperable use of health IT.

In the CY 2019 PFS proposed rule (83 FR 35925 through 35928), we proposed several changes to the current measures under the Health Information Exchange objective. First, we proposed to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. We also proposed to remove the Clinical Information Reconciliation measure and combine it with the Request/Accept Summary of Care measure to create a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. This proposed new measure would include actions from both the Request/Accept Summary of Care measure and Clinical Information Reconciliation measure.

(A) Modifications to the Send a Summary of Care Measure

We proposed to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure (83 FR 35925 through 35926), to better reflect the emphasis on completing the referral loop and improving care coordination.

Through public comment and stakeholder correspondence, we have become aware that in the health care industry there is some misunderstanding of the scope of transitions and referrals which must be included in the denominator of this measure. In the event that a MIPS eligible clinician is the recipient of a transition of care or referral, and subsequent to providing care the MIPS eligible clinician transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the MIPS eligible
clinician. We expect this will help build upon the current provider to provider communication via electronic exchange of summary of care records created by CEHRT required under this measure, further promote interoperability and care coordination with additional health care providers, and prevent redundancy in creation of a separate measure.

In the past, stakeholders have raised concerns that the summary care records shared according to the C-CDA standard included excessive information not relevant to immediate care needs, which increased burden on health care providers. Under the ONC Health IT Certification Program 2015 Edition, CEHRT must have the capability to exchange all of the information in the CCDS as part of a summary care record structured according to the C-CDA standard. We previously finalized in the final rule titled “Medicare and Medicaid Programs Electronic Health Record Incentive Program - Stage 2: Health Information Technology, Standards Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (hereafter referred to as the “Stage 2 final rule”) (77 FR 53991 through 53993) that health care providers must transmit all of the CCDS information as part of this summary care record, if known, and that health care providers must always transmit information about the problem list, medications, and medication allergies, or validate that this information is not known.

As finalized in the final rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule” (hereafter referred to as the “2015 EHR Incentive Programs final rule”) (80 FR 62852 through 62861), our policy allows health care providers to constrain the information in the summary care record to support transitions of care. For instance, we encouraged health care providers to send a list of items that he or she believes to be pertinent and relevant to the patient's
care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. Although a current problem list must always be included, the health care provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

We also wish to encourage MIPS eligible clinicians to use the document template available within the C-CDA which contains the most clinically relevant information required by the receiver. Accordingly, we proposed that MIPS eligible clinicians may use any document template within the C-CDA standard for purposes of the measures under the Health Information Exchange objective. Although a MIPS eligible clinician’s CEHRT must be capable of sending the full C-CDA upon request, we believe this additional flexibility will help support clinicians’ efforts to ensure the information supporting a transition is relevant.

For instance, when the MIPS eligible clinician is referring to another health care provider the recommended document is the "Referral Note" which is designed to communicate pertinent information from a MIPS eligible clinician who is requesting services of another health care provider of clinical or non-clinical services. When the receiving health care provider sends back the information, the most relevant C-CDA document template may be the “Consultation Note,” which is generated by a request from a clinician for an opinion or advice from another clinician. Although the 2015 Edition transition of care certification criterion only requires testing to the Continuity of Care Document and Referral Note document templates, we proposed to allow MIPS eligible clinicians the flexibility to use additional C-CDA templates most appropriate to their clinical workflows. Clinicians would need to work with their health IT developer to determine appropriate technical workflows and implementation. For more information about the
The following is a summary of the comments we received on these proposals.

**Comment:** A commenter stated that renaming the measure creates too much confusion and inconvenience because there are too many MIPS eligible clinicians and locations per clinician to keep track of, which undermines the quality of care provided to patients. Other commenters stated that MIPS eligible clinicians are accustomed to the current name and changing the name will only contribute to confusion.

**Response:** We respectfully decline to retain the current name as we believe that the proposed new name, Support Electronic Referral Loops by Sending Health Information measure, better reflects the emphasis on completing the referral loop and improving care coordination. We also believe that it is important to align measure names across the Medicare Promoting Interoperability Program and the Promoting Interoperability performance category to reduce confusion and burden for health care providers.

**Comment:** A commenter requested that this measure be modified or removed from the Promoting Interoperability performance category because there is a limited number of specialists that are able to receive the summary of care.

**Response:** While we understand that there may be challenges associated with this measure, we believe that the sharing of health information with other health care providers treating patients is imperative to improving the quality of care. While we understand that some specialists may be lagging behind in their adoption of CEHRT, the numbers of specialists using CEHRT continues to rise over time. We continue to believe that the use of paper records will
continue to diminish and that use of CEHRT will continue to increase. Including this measure as a requirement of the Promoting Interoperability performance category will incentivize clinicians to electronically share the summary of care.

**Comment:** One commenter addressed our proposal to allow MIPS eligible clinicians to use any document template within the C-CDA for the measures associated with this objective and requested that CMS not expect clinicians to manually select C-CDA templates or portions of templates when sending documents because it adds workflow steps and interferes with solutions that automate sending of information. The commenter recommended that CMS investigate the Integrated Healthcare Enterprise (IHE) summary sections profile for potential future adoption. Other commenters supported allowing MIPS eligible clinicians and groups to determine which data is most appropriate to be shared.

**Response:** We believe that this additional flexibility allowing MIPS eligible clinicians to use any document template within the C-CDA will help support MIPS eligible clinicians efforts to ensure the information supporting a transition of care is relevant and note that the use of any additional template would be optional for MIPS eligible clinicians. Although MIPS eligible clinicians must have the capability to send the full CCDA upon request, they may choose to send just the items that are pertinent and relevant to the patient’s care. The ability to select the most appropriate template will enable the most clinically relevant information to be transmitted. We will work with ONC to consider other suggestions regarding the adoption of other health IT standards and may consider the suggestion to include the IHE summary sections profile in future rulemaking.
Comment: A few commenters requested that CMS allow for flexibility to use any C-CDA formats available to meet the HIE measures to create and electronically send summary of care records.

Response: We believe the proposal to allow MIPS eligible clinicians to use any document template within the C-CDA will provide further flexibility for health care providers to focus on clinically relevant information. We note that CEHRT supports the ability to send and receive C-CDA documents according to Releases 1.1 and 2.1 to support interoperability and exchange. The 2015 Edition transitions of care certification criterion at §170.315(b)(1) requires Health IT Modules to support the Continuity of Care Document, Referral Note, and (inpatient settings only) Discharge Summary document templates.

While MIPS eligible clinicians’ CEHRT must be capable of sending the full C-CDA upon request, we believe this additional flexibility to utilize different functionality within the C-CDA will help support clinicians efforts to ensure the information supporting a transition is relevant. We note that in the use of a document template the clinician would need to work with their developer to determine appropriate technical workflows and implementation.

Comment: Some commenters supported allowing MIPS eligible clinicians and groups to determine which data is most appropriate to be shared. A few commenters agreed with use of any C-CDA document templates available within the C-CDA which contains the most clinically relevant information that may be required by the recipient of the transition or referral. The commenters stated this proposal supports increased flexibility, enables increased information sharing between care providers, and will help providers better understand their patient’s history.
Response: We appreciate the feedback by the commenter and agree that this proposal will provide further flexibility for health care providers to focus on clinically relevant information and decrease burden associated with reporting requirements.

Comment: Commenters questioned whether there was an exclusion for the Support Electronic Referral Loops by Sending Health Information measure. A few commenters stated that the lack of an exclusion will unfairly disadvantage MIPS eligible clinicians and practices that are unable to send at least one received summary of care.

Response: While we proposed to change the name of the Send a Summary of Care measure, we did not propose changes to the numerator, denominator or exclusion for the measure. The exclusion remains for this measure. Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

After consideration of the comments received, we are finalizing the proposal to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure. We are also finalizing the proposal that MIPS eligible clinicians may use any document template within the C-CDA standard for purposes of the measures under the Health Information Exchange objective.

(B) Removal of the Request/Accept Summary of Care Measure

We proposed to remove the Request/Accept Summary of Care measure (83 FR 35926) based on our analysis of the existing measure and in response to stakeholder input.

We stated that, through review of implementation practices based on stakeholder feedback, we believe that the existing Request/Accept Summary of Care measure is not feasible for machine calculation in the majority of cases. The intent of the measure is to identify when
MIPS eligible clinicians are engaging with other providers of care or care team members to obtain up-to-date patient health information and to subsequently incorporate relevant data into the patient record. However, stakeholders have noted the measure specification does not effectively further this purpose. Specifically, the existing measure specification results in unintended consequences where health care providers implement either:

(1) A burdensome workflow to document the manual action to request or obtain an electronic record, for example, clicking a check box to document each phone call or similar manual administrative task, or

(2) A workflow which is limited to only querying internal resources for the existence of an electronic document.

Neither of these two implementation options is desirable when the intent of the measure is to incentivize and encourage health care providers to implement effective workflows to identify, receive, and incorporate patient health information from other health care providers into the patient record.

In addition, our analysis identified that the definition of incorporate within the Request/Accept Summary of Care measure is insufficient to ensure an interoperable result. When this measure was initially finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62860, we did not define “incorporate” as we believed it would vary amongst health care provider’s workflows, patient population and the referring health care provider. In addition, we noted that the information could be included as an attachment, as a link within the EHR, as imported structured data or reconciled within the record and not exclusively performed through use of CEHRT. Further, stakeholder feedback highlights the fact that the requirement to incorporate data is insufficiently clear regarding what data must be incorporated.
Our intention was that “incorporate” would relate to the workflows undertaken in the process of clinical information reconciliation further defined in the Clinical Information Reconciliation measure (80 FR 62852 through 62862). Taken together, the three measures under the Health Information Exchange objective were intended to support the referral loop through sending, receiving, and incorporating patient health data into the patient record. However, stakeholder feedback on the measures suggests that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows. Further, stakeholders noted, that when approached separately, the incorporate portion of the Request/Accept Summary of Care measure is both inconsistent with and redundant to the Clinical Information Reconciliation measure which causes unnecessary burden and duplicative measure calculation.

The following is a summary of the comments we received on these proposals.

**Comment:** Commenters supported the removal of this measure, and stated they appreciated CMS’ acknowledgement of the challenges of the current Request/Accept Summary of Care measure.

**Response:** We believe that removing the measure will reduce burden.

**Comment:** One commenter stated that it is confusing for CMS to state in the proposed rule that measures will be removed, when they are truly just re-named. The commenter stated that the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure would not be removed. Rather, they would be combined into a new measure named Support Electronic Referral Loops by Receiving and Incorporating Health Information.

**Response:** While we appreciate this comment, the result of our proposals would be to replace two measures with one measure, resulting in a reduction in the number of measures.
Comment: A commenter requested that CMS maintain the current separate Request/Accept Summary of Care and Clinical Information Reconciliation measures instead of replacing them with the combined measure because MIPS eligible clinicians understand the separate measures.

Response: We disagree and believe that reducing the number of measures reduces burden for MIPS eligible clinicians. Also the proposed measures, Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information, align with our focus on the exchange of health care information and aligns with the measures for the Medicare Promoting Interoperability Program.

After consideration of the comments received, we are removing the Request/Accept Summary of Care Measure as proposed.

(C) Removal of the Clinical Information Reconciliation Measure

We proposed to remove the Clinical Information Reconciliation measure (83 FR 35927) to reduce redundancy, complexity, and MIPS eligible clinician burden.

We stated that we believe the Clinical Information Reconciliation measure is redundant in regard to the requirement to “incorporate” electronic summaries of care in light of the requirements of the Request/Accept Summary of Care measure. In addition, the measure is not fully health IT based as the exchange of health care information is not required to complete the measure action and the measure specification is not limited to only the reconciliation of electronic information in health IT supported workflows. We stated in the 2015 EHR Incentive Programs final rule at 80 FR 62861 that the clinical information reconciliation process could involve both automated and manual reconciliation to allow the receiving health care provider to work with both electronic data received as well as the patient to reconcile their health
information. Further, stakeholder feedback from hospitals, clinicians, and health IT developers indicates that because the measure is not fully based on the use of health IT to meet the measurement requirements, health care providers must engage in burdensome tracking of manual workflows. While the overall activity of clinical information reconciliation supports quality patient care and should be a part of effective clinical workflows, the process to record and track each individual action places unnecessary burden on MIPS eligible clinicians.

The following is a summary of the comments we received on these proposals.

**Comment:** Commenters supported the removal of the Clinical Information Reconciliation measure and its incorporation with the Request/Accept Summary of Care measure. Some commenters stated that removal of the Clinical Information Reconciliation measure would reduce burden.

**Response:** We appreciate the support for our proposal and agree that it will reduce burden.

After consideration of the comments received, we are removing the Clinical Information Reconciliation measure as proposed.

(D) Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

We proposed to add the following new measure for inclusion in the Health Information Exchange objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information (FR 83 35927). This measure would build upon and replace the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

*Proposed name of measure and description:* Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care
record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.

We proposed to combine two existing measures, the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure, in this new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to focus on the exchange of health care information as the current Clinical Information Reconciliation measure is not reliant on the exchange of health care information to complete the measure action. We did not propose to change the actions associated with the existing measures; rather, we proposed to combine the two measures to focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

CMS and ONC worked together to define the following for this measure:

**Denominator:** Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.

**Numerator:** The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the
patient's known medication allergies; and (3) Current Problem List – Review of the patient’s current and active diagnoses.

**Exclusions:** (1) Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure. (2) Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure.

We note that these two exclusions for the measure were proposed in different sections of the proposed rule (83 FR 35916, 35927).

We requested comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be.

For the proposed measure, the denominator would increment on the receipt of an electronic summary of care record after the MIPS eligible clinician engages in workflows to obtain an electronic summary of care record for a transition, referral or patient encounter in which the MIPS eligible clinician has never before encountered the patient. The numerator would increment upon completion of clinical information reconciliation of the electronic summary of care record for medications, medication allergies, and current problems. The MIPS eligible clinician would no longer be required to manually count each individual non-health-IT-related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We stated that we believe this approach would
allow MIPS eligible clinicians to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level.

Finally, we proposed to apply our existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. We welcomed public comment on methods by which this specific action could potentially be electronically measured by the MIPS eligible clinician’s health IT system – such as incrementing on electronic signature or approval by an authorized health care provider – to mitigate the risk of burden associated with manual tracking of the action, such as having to click check boxes.

We welcomed public comment on these proposals. We solicited comment on methods and approaches to quantify the reduction in burden for MIPS eligible clinicians implementing streamlined workflows for this proposed health IT-based measure. We also solicited comment on the impact these proposed modifications may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, we solicited comment on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification, and on the appropriate timeline for such requirements factoring in the proposed continuous 90 day performance period within the calendar year for clinicians. Finally, we solicited comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing
Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

We stated that in the event we finalize the new scoring methodology we proposed in section III.H.3.h.(5)(d) of the proposed rule, an exclusion would be available for MIPS eligible clinicians who cannot implement the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for a performance period in CY 2019 and an exclusion for MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

We also proposed that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §170.315(b)(1) and (2).

We solicited comment on these proposals and our summary and response are below.

Comment: A commenter stated that the incorporation of clinical information within the C-CDA into the receiving clinician’s CEHRT is limited by the CEHRT and not the clinician. The commenter recommended that the measure be eliminated and requested that CMS work with ONC to strengthen interoperability requirements.

Response: We are working with ONC to explore and potentially implement many initiatives to strengthen interoperability. We understand that there may be limitations with 2015 CEHRT but we believe that EHR developers and vendors will update their products so the CEHRT will calculate the combined measure and not further burden the MIPS eligible clinician.

Comment: Many commenters supported the proposal to combine the Clinical Information Reconciliation measure with the Request/Accept Summary of Care measure into the proposed Support Electronic Referral Loops by Receiving and Incorporating Health Information
measure. Some commenters agreed that the proposed measure will allow MIPS eligible clinicians to focus on the exchange of health care information and reconcile the data in patients’ medical records.

Response: We appreciate the commenter’s support for efforts to improve processes and technology solutions around closing referral loops. We believe that the combined measure focuses on the exchange of health care information and reduces administrative burden. We also believe that this measure will help incentivize further innovation around interoperable exchange of information to support these processes.

Comment: Some commenters disagreed with our proposal to combine the Clinical Information Reconciliation measure with the Request/Accept Summary of Care measure stating that clinical information reconciliation is important and it should remain a stand-alone measure. They indicated that combining the Clinical Information Reconciliation measure with another measure diminishes its importance. Other commenters stated that combining these measures into one is onerous for both front line staff responsible for running reports, as well as EHR developers and clinicians hoping to improve scores, since they will not fully know which measure to target. Some commenters stated that the name change is extremely confusing. Other commenters stated that this new measure is more burdensome and it will be harder to specifically target issues within the measure because two workflows will be combined.

Response: We believe that the current separation of the measures is burdensome and redundant in the action of incorporation of the summary of care record. In addition, we listened to stakeholder’s concerns regarding the separate Request/Accept Summary of Care and Clinical Information Reconciliation measures, which indicated that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination
workflows and the incorporation aspect is redundant to both measures. We agree the process of clinical information reconciliation includes both automated and manual reconciliation to allow the receiving health care provider to work with both the electronic data provided with any necessary review, and to work directly with the patient to reconcile their health information. In addition, we believe that combining the measures of Request/Accept Summary of Care and Clinical Information Reconciliation retains the focus on interoperability and exchange of health information as opposed to the separation of the measures where health information exchange and interoperability was not a focus for clinical information reconciliation.

Comment: One commenter noted the measure exclusion (Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period) is causing greater hardship for those clinicians that refer out more than 100 times and therefore must report this measure. While most primary care clinicians refer out more than 100 times in a 90-day period, many specialists do not. If a specialist can claim an exclusion, and therefore, not set up direct messaging capabilities, it may affect the performance on the measure of clinicians that are referring to those specialists if they cannot find someone they refer to that has the capability.

Response: The use of direct messaging is not required to fulfill this measure. Our intent has been to promote and facilitate a wide range of options for the transmission of an electronic summary of care document. Examples of acceptable transmission methods include secure email, Health Information Service Provider (HISP), query-based exchange or use of third party HIE.

Comment: Commenters supported the exclusions for Support Electronic Referrals Loops by Receiving and Incorporating Health Information.
Response: We appreciate the support and believe the exclusions will benefit MIPS eligible clinicians who are unable to implement the measure because they do not refer or transition patients or because they cannot implement the measure for the 2019 MIPS performance period.

After consideration of the public comments we received, we are finalizing the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as proposed. We are finalizing the proposal to apply the existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record.

We are finalizing a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §170.315(b)(1) and (b)(2).

We are adopting the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as follows:

- **Measure Description:** Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.
**Denominator:** Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.

**Numerator:** The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient’s current and active diagnoses.

**Exclusions:** (1) Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure.

(2) Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

(iv) Measures for the Provider to Patient Exchange Objective

The Provider to Patient Exchange objective for MIPS eligible clinicians builds upon the goal of improved access and exchange of patient data, patient centered communication and coordination of care using CEHRT. We proposed a new scoring methodology in section III.H.3.h.(5)(d) of the proposed rule, under which we proposed to rename the Patient Electronic Access objective to Provider to Patient Exchange, remove the Patient-Specific Education measure and rename the Provide Patient Access measure to Provide Patients Electronic Access.
to Their Health Information. In addition, we proposed to remove the Coordination of Care through Patient Engagement objective and all associated measures. The existing Promoting Interoperability performance category Patient Electronic Access objective includes two measures and the existing Coordination of Care through Patient Engagement objective includes three measures.

We reviewed the Promoting Interoperability performance category requirements and determined that these proposals could reduce program complexity and burden and better focus on leveraging the most current health IT functions and standards for patient flexibility of access and exchange of information.

In the CY 2019 PFS proposed rule (83 FR 35928 through 35929), we proposed the Provider to Patient Exchange objective would include one measure, the existing Provide Patient Access measure, which we proposed to rename to Provide Patients Electronic Access to Their Health Information.

(A) Modifications to Provide Patient Access Measure

We proposed to change the name of the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information measure (83 FR 35928) to better reflect the emphasis on patient engagement in their health care and patient’s electronic access of their health information through use of APIs.

We proposed to change the measure name to emphasize electronic access of patient health information as opposed to use of paper-based actions and limit the focus to only health IT solutions to encourage adoption and innovation in use of CEHRT (80 FR 62783 through 62784). In addition, we are committed to promoting patient engagement with their healthcare information and ensuring access in an electronic format.
We solicited comment on these proposals and our summary and response are below.

Comment: A commenter supported the new name for the measure but recommended that CMS not require widespread use of APIs for at least 3 years after the final standard for the measure has been published.

Response: We decline to provide additional time to implement this measure. In the 2015 Edition final rule, ONC finalized certification criteria that will enable clinicians using 2015 Edition CEHRT to share information through an API consistent with the requirements of this measure (80 FR 62675). As discussed, we believe that eligible clinicians have already implemented, or are prepared to implement, this functionality as part of the 2015 Edition of CEHRT for 2019 and will be able to fulfill this measure.

Comment: One commenter recommended that CMS establish an exclusion for this measure if the MIPS eligible clinician cannot successfully identify an application that meets their security needs. Another requested an exclusion if the MIPS eligible clinician’s EHR does not have the ability to have a portal. A commenter cautioned that CMS must address the risks that this measure poses for systems security and the confidentiality of health information because of its use of APIs and recommended that CMS provide an exclusion for this measure for MIPS eligible clinicians that cannot successfully identify an application that meets their security needs. The commenter also recommended that CMS work with the OCR and the FTC to develop an extensive education program so that consumers can be aware of how application companies may use their data.

Response: We decline to implement exclusion criteria for the Provide Patients Electronic Access to Their Health Information measure as we believe MIPS eligible clinicians should work with their health IT vendors to identify applications that meet their security needs. While we
appreciate stakeholder concerns regarding security issues, we believe there are already applications available to consumers that could satisfy security requirements. The 2015 Edition of CEHRT enables clinicians to provide patients with timely access to their health information and make the patient’s health information available for the patient (or patient authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (API) in the MIPS eligible clinician’s CEHRT.

We appreciate commenters’ interest in additional educational materials for patients on how they can improve the privacy and security of their health information. We will take this comment into consideration as we consider what other consumer-facing materials are helpful, and we direct commenters to resources currently available from HHS (for example, content and materials such as those available at https://www.hhs.gov/hipaa/for-individuals/right-to-access/index.html) and FTC (for example, content and materials such as those available at https://www.consumer.ftc.gov/topics/online-security) websites.

Comment: A few commenters requested that CMS confirm that this measure focuses on MIPS eligible clinicians making the information available to patients and does not account for patient use.

Response: The Provide Patients Electronic Access to Their Health Information measure does not require that patients actually access their information. Patients should be able to access their health information on demand, and we encourage MIPS eligible clinicians to maintain the appropriate functionalities for patient access to their health information at all times unless the system is undergoing scheduled maintenance, which should be limited.
Comment: A commenter stated that changing the names of measures with essentially the same meaning is confusing to MIPS eligible clinicians. The Provide Patients Electronic Access to Their Health Information measure should simply be called the Provide Patients Electronic Access measure.

Response: We did not intend to confuse MIPS eligible clinicians. We believe that the name change effectively focuses the electronic aspect of the measure and our focus on leveraging advanced use of HIT. We also believe it is important to align the names of the measures of the Promoting Interoperability performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. Many health care providers have noted frustration with the differing requirements between the two programs and we believe that through alignment we can reduce much of that frustration.

After consideration of the comments we received, we finalizing the new name, Provide Patients Electronic Access to Their Health Information, as proposed.

(B) Removal of the Patient-Generated Health Data Measure

We proposed to remove the Patient-Generated Health Data (PGHD) measure (83 FR 35928) to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62851, the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received. Instead, we finalized that health care providers could work with their EHR developers to establish the methods and processes that work best for their practice and needs. We indicated that this could include incorporation of the information using a structured format (such as an existing field in the EHR or maintaining an isolation between the
data and the patient record such as incorporation as an attachment, link or text reference which would not require the advanced use of CEHRT). Although we continue to believe that incorporating this data is valuable, we prioritized only those actions which are completed electronically using certified health IT.

We solicited comment on these proposals and our summary and response are below.

Comment: Several commenters disagreed with our proposal to remove this measure as it is essential for encouraging the collection and use of patient-reported outcomes. The commenters urged CMS to retain this measure to encourage MIPS eligible clinicians to establish workflows to collect and integrate these critical data into their medical records, thereby promoting interoperability and patient-centered care. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination. Another stated that the measure is crucial for healthcare to be truly interoperable and person-centered.

Response: Functions and standards related to measures that are no longer required for the Promoting Interoperability performance category may still hold value for some health care providers and may be utilized as best suits their practice and the preferences of their patient population. The removal of measures is not intended to discourage the use of the standards, the implementation of best practices, or conducting and tracking the information for providers’ own quality improvement goals.

Comment: Another commenter stated that the measure did not accomplish its intended goal since we did not specify the manner in which health care providers would incorporate the data received.
Response: We agree that it is important to encourage providers to obtain data generated by patients, for instance, through the use of consumer-facing devices, and utilize this data to inform decision-making and provide more effective patient-centered care. While we are finalizing removal of the Patient-Generated Health Data measure for the reasons discussed in the proposed rule, we will continue to consider ways to encourage this activity.

Comment: Many commenters supported the removal of this measure. A commenter supported the removal of this measure because it is burdensome and takes valuable time away from patient care. Another commenter supported the removal of this measure but mentioned that allowing the transmission of key health data such as home blood pressure readings, finger-stick glucose levels, and other vitals is still beneficial to the patient. This functionality should thus remain available in CEHRT. Another suggested that CMS promote the use of patient-generated health data collected via remote monitoring by encouraging the development of open APIs across CEHRT developers.

Response: While we are removing the measure from the Promoting Interoperability performance category, the functionality is not being removed from 2015 Edition CEHRT. We will continue to work with ONC to encourage the development of innovative API functionality that supports exchange of patient-generated health data.

After consideration of the public comments we received, we are removing the Patient-Generated Health Data measure as proposed.

(C) Removal of the Patient-Specific Education Measure

We proposed to remove the Patient-Specific Education measure (83 FR 35928) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.
The Patient-Specific Education measure was finalized as a performance score measure for MIPS eligible clinicians in the CY 2017 Quality Payment Program final rule with the intent of improving patient health, increasing transparency and engaging patients in their care (81 FR 77228 through 77237).

We stated that we believe that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability, or reduce burden for MIPS eligible clinicians. In addition to not including interoperability as a core focus, stakeholders have indicated that this measure does not capture many of the innovative activities around providing patient education, for instance new approaches to integrating patient education within clinical decision support modules. As a result of this lack of alignment, this measure could potentially increase clinician burden.

We solicited comment on this proposal and our summary and response are below.

Comment: Many commenters supported the removal of this measure. A commenter supported the removal of this measure because it is burdensome. Other commenters stated that reporting on this measure takes valuable time away from patient care and leads to clinician frustration and ultimately contributes to burnout. Another commenter agreed with the removal of the measure because it does not align with promoting interoperability.

Response: We appreciate the commenters’ support for the removal of this measure.

Comment: Several commenters disagreed with the removal of this measure. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination. Another commenter stated that the measure is vital to improved health literacy that empowers patient self-care which reduces unnecessary utilization and decreases costs. One commenter stated the measure should be used
to provide patients with information about relevant clinical trials, medication adherence tools, and opioid management strategies. A few commenters stated that providing patients with relevant education materials raises their health literacy and enables them to be more active in managing their own health. Several commenters recommended that the measure be available for bonus points.

Response: We disagree that the Patient-Specific Education measure should be retained as a required measure. While we believe that there are merits to the Patient-Specific Education measure as identified by the commenters, we affirm our position that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category which aims to increase interoperability, leverage the most current health IT functions and standards and reduce burden for MIPS eligible clinicians. We also decline to offer bonus points for this measure. We note that bonus points should be reserved for brand new measures to help to ease the transition to becoming a required measure.

After consideration of the public comments we received, we are removing of the Patient-Specific Education measure as proposed.

(D) Removal of the Secure Messaging Measure

We proposed to remove the Secure Messaging measure (82 FR 35929) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from MIPS eligible clinicians’ progress on current program priorities.

The Secure Messaging measure was finalized in the CY 2017 Quality Payment Program final rule with the intent to build upon the policy goals of Stage 2 under the EHR Incentive Programs of using CEHRT for health care provider-patient communication (81 FR 77227 through 77236). We stated that we believe that the Secure Messaging measure does not align
with the current emphasis of the Promoting Interoperability performance category to increase interoperability or reduce burden for MIPS eligible clinicians. In addition, we stated that we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness.

We solicited comment on this proposal and our summary and response are below.

Comment: Some commenters opposed the removal of this measure because it supports meaningful improvements in interoperability. Other commenter noted that it must remain a required measure because it ensures that patients can communicate confidentially with their health care providers. Some commenters stated that some health care providers rely on secure messaging to communicate with patients in an effective and timely manner.

Response: We believe that there is a significant burden associated with tracking secure messages. Although we are not requiring the measure, the functionality remains in 2015 Edition CEHRT so MIPS eligible clinicians may continue to utilize the functionality if they choose.

Comment: Many commenters supported the removal of this measure. Some commenters stated that they supported the removal of this measure because it is burdensome, and reporting on this measure takes valuable time away from patient care and leads to clinician frustration and ultimately contributes to burnout.

Response: We agree that this measure may detract from MIPS eligible clinicians’ progress on current program priorities such as increasing interoperability and reducing burden.

After consideration of the public comments we received, we are removing the Secure Messaging measure as proposed.

(E) Removal of the View, Download or Transmit Measure
We proposed to remove the View, Download or Transmit measure (83 FR 35929) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

We stated that we have received MIPS eligible clinician and stakeholder feedback through correspondence, public forums, and listening sessions indicating there is ongoing concern with measures which require patient action for successful submission. We have noted that data analysis on the patient action measures supports stakeholder concerns that barriers exist which impact a clinician’s ability to meet them. Stakeholders have indicated that successful submission of the measure is reliant upon the patient, who may face barriers to access which are outside a clinician’s control.

After additional review, we noted that successful performance predicated solely on a patient’s action has inadvertently created burdens to MIPS eligible clinicians and detracts from progress on Promoting Interoperability measure goals of focusing on patient care, interoperability and leveraging advanced used of health IT. Therefore, we proposed to remove the View, Download or Transmit measure.

We solicited comment on this proposal and our summary and response are below.

**Comment:** Commenters supported the removal of this measure. One commenter stated that the View, Download, and Transmit measure is challenging because many practices that care for a much older population of patients are at a disadvantage for this measure because many of those patients do not own a computer or even have an email address and in some cases, do not own a cell phone. Another commenter appreciated the proposal to remove this measure and noted that CMS should not hold MIPS eligible clinicians accountable for actions beyond their control.
Response: Previous stakeholder feedback through correspondence, public forums, and listening sessions indicated there is ongoing concern with measures which require health care providers to be accountable for patient actions such as viewing, downloading, or transmitting. We further understand that there are barriers which could negatively impact a MIPS eligible clinician’s ability to successfully meet a measure requiring patient action, such as location in remote, rural areas and access to technology including computers, Internet and/or email. We believe that removing the patient action measures will allow for focus on program goals of increasing interoperability and patient access to their health information.

Comment: One commenter expressed concern about the removal of this measure and noted that it will limit the effectiveness of driving meaningful improvements in interoperability. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination.

Response: We disagree that the removal of this measure devalues patient and caregiver engagement as we are weighting the Provide Patients Electronic Access to their Health Information measure at 40 points, the highest of any measure in the Promoting Interoperability performance category in recognition of the value of patients having electronic access to their health information. We are removing the View, Download, Transmit measure because of the burden it places on MIPS eligible clinicians to be accountable for patient action.

After consideration of the public comments we received, we are removing the View, Download or Transmit measure as proposed.

In summary, we are removing the Coordination of Care Through Patient Engagement objective and its associated measures: View, Download or Transmit; Secure Messaging; and Patient-Generated Health Data. We are renaming the Patient Electronic Access objective to
Provider to Patient Exchange objective and removing the Patient-Specific Education measure. We are renaming the Provide Patient Access measure to Provide Patients Electronic Access to their Health Information.

(v) Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In connection with the scoring methodology proposed in section III.H.3.h.(5)(d) of the proposed rule, in the CY 2019 PFS proposed rule (83 FR 35929 through 35931), we proposed changes to the Public Health and Clinical Data Registry Reporting objective and five associated measures.

We stated that we believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry.

We proposed to change the name of the objective to Public Health and Clinical Data Exchange and proposed exclusions for each of the associated measures.

Under the new scoring methodology proposed in section III.H.3.h.(5)(d) of the proposed rule, we proposed that a MIPS eligible clinician would be required to submit two of the measures of the clinician’s choice from the five measures associated with the objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.

In prior rulemaking, we recognized the goal of increasing interoperability through public health registry exchange of data (80 FR 62771). We stated that we continue to believe that public health reporting is valuable in terms of health information exchange between MIPS eligible clinicians and public health and clinical data registries. For example, when
immunization information is directly exchanged between EHRs and registries, patient information may be accessed by all of a patient’s health care providers for improved continuity of care and reduced health care provider burden, as well as supporting population health monitoring.

We also proposed exclusion criteria for each of the Public Health and Clinical Data Exchange measures beginning with the performance period in 2019. Under the scoring methodology for the Promoting Interoperability performance category for the performance period in 2018 (82 FR 53676 through 53677), the measures associated with the Public Health and Clinical Data Registry Reporting objective are not required for the base score, and thus we did not establish exclusion criteria for them. However, we understand that some MIPS eligible clinicians may not be able to report to public health agencies or clinical data registries due to their scope of practice. Therefore, we proposed the following measure exclusions based on the exclusions finalized in previous rulemaking under the EHR Incentive Programs (80 FR 62862 through 62871).

Measure: Immunization Registry Reporting

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Immunization Registry Reporting measure if the MIPS eligible clinician:

1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period.
2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.

*Measure*: Syndromic Surveillance Reporting

*Proposed Exclusions*: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Syndromic Surveillance Reporting measure if the MIPS eligible clinician:

1. Is not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.

*Measure*: Electronic Case Reporting

*Proposed Exclusions*: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Electronic Case Reporting measure if the MIPS eligible clinician:
1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period.

2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.

Measure: Public Health Registry Reporting

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Public Health Reporting measure if the MIPS eligible clinician;

1. Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician’s jurisdiction during the performance period.

2. Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

Measure: Clinical Data Registry Reporting

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Clinical Data Registry Reporting measure if the MIPS eligible clinician;
1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period.

2. Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

We solicited comment on the proposed exclusions and whether there are circumstances that would require additional exclusion criteria for the measures.

In addition, we stated that we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and solicited public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed, as well as other policy levers outside of the Promoting Interoperability performance category that could be adopted for continued reporting to public health and clinical data registries, if necessary. As noted above, although we believe that these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation, we are also focused on reducing burden and identifying other appropriate venues in which reporting to public health and clinical data registries could be reported. We solicited public comment on the role that each of the public health and clinical data registries should have in the future of the Promoting Interoperability performance category and whether the submission of this data should still be required.
Lastly, we solicited public comment on whether the Promoting Interoperability performance category is the best means for promoting sharing of clinical data with public health entities.

We solicited comment on these proposals and our summary and response are below.

**Comment:** One commenter stated that these measures should be optional as they continue to remain difficult for MIPS eligible clinicians due to the lack of availability of interoperable public health registries. Another commenter noted that the measures should be a bonus and not required as they note that the path for participation is convoluted and will require an onerous amount of effort on the part of the clinician. Commenters also noted issues with AHRQ’s Registry of Patient Registries such as difficulty searching for registries that would fulfill the Promoting Interoperability performance category’s requirement.

**Response:** We disagree as we are trying to simplify scoring by limiting bonus opportunities to brand new measures. Hence we are offering bonus points for reporting the two new measures under the e-Prescribing objective but not the “new” measure under the Health Information Exchange objective because it is simply the combination of two existing measures. We know that there are some improvements that need to be made to AHRQ’s Registry of Patient Registries and we are working with AHRQ and CDC to improve the search capabilities so that available registries can be easily located.

**Comment:** Many commenters opposed CMS’ intent to remove the Public Health and Clinical Data Exchange objective and measures in the future and noted that interoperability of public health data is still evolving and incentivizes MIPS eligible clinicians to share data with public health agencies. One commenter encouraged CMS to reconsider removing the objective and measures for the following reasons: many states do not have other policy levers outside the
Promoting Interoperability programs and performance category to encourage or enforce public health reporting; CMS and States have spent many years now, using HITECH Act funding, supporting improvements to public health systems and HIEs to encourage health care providers to submit public health data, and thus, the reporting should continue; and in some states public health reporting is one of the driving use cases for participants to connect to their statewide HIE and removing these measures would remove an incentive to encourage health care providers to participate in HIEs. Another commenter expressed concerns about CMS’ intention to remove the Public Health and Clinical Data Exchange objectives and measures noting that it is a significant policy lever for those who have yet to engage in this aspect of the program.

**Response:** We understand the importance of reporting to public health and clinical data registries. We are continuing to focus on burden reduction, as well as other platforms and venues for reporting data to public health and clinical data registries outside of the Promoting Interoperability performance category. We will continue to monitor the data we compile specific to the public health reporting requirements and take the commenters’ concerns into consideration in future rulemaking.

**Comment:** One commenter requested clarification of whether a MIPS eligible clinician can submit to two different registries for purposes of the same measure and get credit for submitting to two registries, or must they report to different registries for purposes of two different measures to receive full credit for the objective.

**Response:** Although we proposed that a MIPS eligible clinician must report on two measures of their choice to fulfill the Public Health and Clinical Data Registry Reporting objective, we agree that a MIPS eligible clinician should be able to report to two different public health agencies or clinical data registries for purposes of the same measure. Therefore, as
previously discussed in section III.H.3.(5)(d) of this final rule, we are finalizing the proposal with modification so that a MIPS eligible clinician may earn full credit for this objective by reporting to two different public health agencies or clinical data registries for purposes of the same measure.

Comment: Some commenters agreed with the Public Health and Clinical Data Exchange reporting requirements proposed, stating they would continue to advance interoperability and improve early detection of outbreaks as well as promote population health strategies.

Response: We appreciate the support for our proposal and believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes and increase the timeliness and efficiency of reporting.

Comment: A few commenters supported the proposed exclusions for the Public Health and Clinical Data Exchange measures. One commenter suggested that the first exclusion for the Immunization Registry Reporting measure be modified to 100 or less immunizations in a performance period.

Response: We decline to expand the first exclusion for the Immunization Registry Reporting measure because if the MIPS eligible clinician is performing any immunizations we believe that the information should be reported to an immunization registry.

Comment: One commenter recommended that CMS specify that exclusions may only be claimed if a MIPS eligible clinician meets exclusions for all of the measures associated with the Public Health and Clinical Data Exchange objective and has made all possible efforts to report on the measures for this objective. The commenter suggested that participation in this objective should be encouraged instead of claiming exclusions, which would not improve interoperability or support improvements to population health. Commenters also stated that public health
reporting also supports added value for individuals and reporters by enabling bidirectional information exchange between clinical care and public health.

Response: We agree that MIPS eligible clinicians should try to find public health registries with which they can be in active engagement. We understand the concerns of the commenters and are committed to reducing provider burden while increasing flexibility. As previously discussed in section III.H.3.(5)(d) of this final rule, we believe the ability to report to two different public health agencies or clinical data registries will promote flexibility in reporting and enables MIPS eligible clinicians to focus on the measures that are most relevant to them and their patient population.

After consideration of the comments we received, we are finalizing our proposals with modification. We are changing the name of the objective to Public Health and Clinical Data Exchange and adopting exclusions for each of the associated measures. As previously discussed in section III.H.3.(5)(d) of this final rule, we are adopting a final policy to allow MIPS eligible clinicians to earn full credit for this objective by reporting to two different public health agencies or clinical data registries for any of the measures associated with the objective.

We may use the comments that we received on the removal of the Public Health and Clinical Data Exchange objectives and measures to inform future rulemaking.

To assist readers in identifying the requirements of CEHRT for the Promoting Interoperability performance category objectives and measures under the scoring methodology we are finalizing in section III.I.3.h.(5)(d) of this final rule, we include Table 43, which includes the 2015 Edition certification criteria required to meet the objectives and measures.
### TABLE 43: Promoting Interoperability Objectives and Measures and Certification Criteria for the 2015 Edition

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>2015 Edition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect Patient Health Information</td>
<td>Security Risk Analysis</td>
<td>The requirements are a part of CEHRT specific to each certification criterion.</td>
</tr>
<tr>
<td>e-Prescribing</td>
<td>e-Prescribing</td>
<td>§170.315(b)(3) (Electronic Prescribing).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks and (b)(3) (Electronic Prescribing)</td>
</tr>
<tr>
<td></td>
<td>Query of PDMP</td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.205(b)(2) (Electronic Prescribing Standard)</td>
</tr>
<tr>
<td></td>
<td>Verify Opioid Treatment Agreement</td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.205(b)(2) (Electronic Prescribing Standard)</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Support Electronic Referral Loops by Sending Health Information</td>
<td>§170.315(b)(1) (Transitions of Care)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(b)(1) (Transitions of Care)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(b)(2) (Clinical Information Reconciliation and Incorporation)</td>
</tr>
<tr>
<td>Provider to Patient Exchange</td>
<td>Provide Patients Electronic Access to Their Health Information</td>
<td>§170.315(e)(1) (View, Download, and Transmit to 3rd Party)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(g)(7) (Application Access—Patient Selection)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(g)(8) (Application Access—Data Category Request)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(g)(9) (Application Access—All Data Request)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The three criteria combined are the “API” certification criteria.</td>
</tr>
<tr>
<td>Public Health and Clinical Data Exchange</td>
<td>Immunization Registry Reporting</td>
<td>§170.315(f)(1) (Transmission to Immunization Registries)</td>
</tr>
<tr>
<td></td>
<td>Syndromic Surveillance Reporting</td>
<td>§170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance)</td>
</tr>
<tr>
<td></td>
<td>Electronic Case Reporting</td>
<td>§170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting)</td>
</tr>
<tr>
<td></td>
<td>Public Health Registry Reporting</td>
<td>EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys)</td>
</tr>
<tr>
<td></td>
<td>Clinical Data Registry Reporting</td>
<td>No 2015 Edition health IT certification criteria at this time.</td>
</tr>
</tbody>
</table>

(vi) Request for Comment - Potential New Measures Health Information Exchange Across the Care Continuum

We are working to introduce additional flexibility to allow MIPS eligible clinicians a wider range of options in selecting measures that are most appropriate to their setting, patient population, and clinical practice improvement goals. For this reason, in the CY 2019 PFS proposed rule (83 FR 35931) we solicited comment on a potential concept for future rulemaking.

28 References from Title 45
to add two additional measure options related to health information exchange for MIPS eligible clinicians.

We received many comments in response to our request, and we will consider them as we develop future policy regarding the potential new measures that focus on health information exchange across the care continuum.

(g) Improvement Activities Bonus Score under the Promoting Interoperability Performance Category and Future Reporting Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77202), we discussed our approach to the measurement of the use of CEHRT to allow MIPS eligible clinicians and groups the flexibility to implement CEHRT in a way that supports their clinical needs. Toward that end, we adopted a policy for the 2017 and 2018 performance periods (81 FR 77202-77209 and 82 FR 53664-53670) and codified it at §414.1380(b)(4)(i)(C)(2) to award a bonus score to MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category based on our belief that the use of CEHRT in carrying out these activities could further the outcomes of clinical practice improvement.

In the CY 2019 PFS proposed rule (83 FR 35932 through 35935), we proposed significant changes to the scoring methodology and measures beginning with the performance period in 2019. In connection with these changes, we did not propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods. As discussed in section III.H.3.h.(5)(b) of the proposed rule, we shifted the focus of this performance category to put a greater emphasis on interoperability and patient access to health information, and we stated that we do not believe awarding a bonus for performing an improvement activity using CEHRT would directly support those goals. While
we continued to believe that the use of CEHRT in completing improvement activities is extremely valuable and vital to the role of CEHRT in practice improvement, awarding a bonus in the Promoting Interoperability performance category would not be appropriate in light of the new direction we wanted to take, and we solicited comment on other ways to promote the use of CEHRT.

We invited comments on our decision not to propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods, and our responses are below.

Comment: Commenters supported our decision not to continue the bonus points for completing improvement activities using CEHRT.

Response: We appreciate the support and although we are discontinuing the bonus points, we will continue to seek other opportunities to promote the use of CEHRT.

Comment: Some commenters stated that they opposed our decision not to continue the bonus points for completing improvement activities using CEHRT stating that providing bonus points in the Promoting Interoperability performance category represented CMS’ understanding that health IT can play an invaluable role in improving outcomes and incentivized MIPS eligible clinicians to incorporate health IT into their practice workflows and clinical activities. The commenters requested that CMS continue to incentivize—but not require—clinicians to use health IT as they accomplish improvement activities.

Response: We are limiting bonus points to brand new measures in the Promoting Interoperability performance category such as the Verify Opioid Treatment Agreement measure. We are exploring opportunities that would allow MIPS eligible clinicians to earn credit across multiple MIPS performance categories. We continue to believe that the use of health IT,
telehealth, and connection of patients to community-based services is important. We encourage the use of health IT as we understand it is an important aspect of the care delivery processes described in many of the established improvement activities found at https://qpp.cms.gov/. In addition, we encourage stakeholders to submit new improvement activities through the Annual Call for Activities that encourage the use of health IT.

After consideration of the comments received, we are not continuing the bonus points for completing improvement activities using CEHRT.

We acknowledged that the omission of this bonus could be viewed as increasing burden, and sought to counteract that concern by evaluating other methods to reduce burden to offset this potential increase. We have also considered various ways to align and streamline the different performance categories under the MIPS. In lieu of the improvement activities bonus score, we have looked extensively at ways to link three of the performance categories -- quality, improvement activities and Promoting Interoperability -- to reduce burden and create a more cohesive and closely linked MIPS program. One possibility we have identified is to establish several sets of new multi-category measures that would cut across the different performance categories and allow MIPS eligible clinicians to report once for credit in all three performance categories. Our goal would be to establish several of combined measures so MIPS eligible clinicians could report once for credit across all three performance categories. We only solicited comment on this concept, as we are still evaluating the appropriate measure combinations and feasibility of a multi-category model.

Furthermore, we stated that to promote measurement that provides clinicians with measures that are meaningful to their practices, we intend to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (quality,
improvement activities, Promoting Interoperability, and cost), and solicited comments on this topic.

We thank commenters for their views and we will consider their views as we develop future policy proposals.

(h) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (82 FR 30079), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information (now known as Promoting Interoperability) performance category. We established a policy for the performance periods in 2017 and 2018 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the advancing care information performance category, but if they choose to report, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period
(2017) to further evaluate the participation of these MIPS eligible clinicians in the advancing care information performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. In the CY 2019 PFS proposed rule (83 FR 35933), we stated that as we have not yet analyzed the data for the first MIPS performance period, it would be premature to propose to alter our treatment of these MIPS eligible clinicians in year 3.

Accordingly, we proposed to continue this policy for the performance period in 2019 and to codify the policy at §414.1380(c)(2)(i)(A)(5). We requested public comments on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter suggested that PAs and NPs not have their Promoting Interoperability performance category reweighted with possible exceptions for small PA and NP-owned practices. The commenter indicated that PAs have been using CEHRT for years and should be held to the same standards and expectations as physicians.

Response: We agree that the goal is to have all MIPS eligible clinicians use CEHRT. However, we believe that at this point in time it is premature to determine whether there are sufficient measures applicable and available to NPs, PAs, CNSs, and CRNAs. We plan to analyze performance data as it becomes available to inform future rulemaking. We note that if NPs and PAs choose to report data for the Promoting Interoperability performance category, they will be scored like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score.

After consideration of the comments we received, we will continue the policy for NPs,
PAs, CRNAs, and CNSs for the performance period in 2019 as proposed. We are codifying the policy at §414.1380(c)(2)(i)(A)(5) as proposed.

(ii) Physical therapists, Occupational therapists, Clinical social workers, and Clinical psychologists

As discussed in section III.H.3.a. of the proposed rule, in accordance with section 1848(q)(1)(C)(i)(II) of the Act, we proposed to add the following clinician types to the definition of a MIPS eligible clinician, beginning with the performance period in 2019: physical therapists; occupational therapists; clinical social workers; and clinical psychologists (83 FR 35883 through 35884). For the reasons discussed in prior rulemaking and in the preceding section III.H.3.h.(5)(f) of the proposed rule, we proposed (83 FR 35933) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 and 2018 to these new types of MIPS eligible clinicians for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we stated that we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. Thus, we proposed to rely on section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category if there are not sufficient measures applicable and available to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, clinical social workers, and clinical psychologists). We encouraged all of these new types of MIPS eligible clinicians to report on these measures to the extent they are applicable and available; however, we understand that some of them may choose to accept a weight of zero for this performance category if they are unable to fully report the Promoting Interoperability measures. We stated that we believe this approach is appropriate for
their first performance period (in 2019) based on the payment consequences associated with reporting, the fact that many of these types of MIPS eligible clinicians may lack experience with EHR use, and our current uncertainty as to whether we have proposed sufficient measures that are applicable and available to these types of MIPS eligible clinicians. We would use their first performance period to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and would consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We stated that these MIPS eligible clinicians may choose to submit Promoting Interoperability performance category measures if they determine that these measures are applicable and available to them; however, if they choose to report, they would be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category would be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score.

We proposed to codify this policy at §414.1380(c)(2)(i)(A)(4).

The following is a summary of the comments we received on this proposal.

Comment: A few commenters stated that they are very pleased that CMS proposed to assign a weight of zero to the Promoting Interoperability performance category for physical and occupational therapists. The commenters stated that this is appropriate because the four included objectives have minimal relevance to therapy. Additionally, commenters noted that PTs and OTs have not received any financial incentives or support for implementing CEHRT, and therefore, it would be inappropriate to require them to report on measures for the Promoting Interoperability performance category.
Response: We will continue to monitor participation of physical therapists, occupational therapists, and clinical psychologists to evaluate whether there are sufficient measures applicable and available to them. Our intention is not to continue the proposed policy in perpetuity. We believe that for increased interoperability and health information exchange it is important for all types of MIPS eligible clinicians to use CEHRT, and we aim to adopt measures for the Promoting Interoperability performance category that are available and applicable to all types of MIPS eligible clinicians.

Comment: A commenter recommended that these types of clinicians not be automatically reweighted and instead recommended the creation of some sort of methodology to encourage health IT utilization and interoperability goals for these clinician types.

Response: We disagree. We believe these specialties may not have sufficient measures applicable and available to them. We believe that through enabling these specialties to report if they are able or be reweighted if they are not, will give these specialties more time if they need it as they may not be familiar with the use of CEHRT. The reweighting will not be forever, but will be in place until we can determine through data analysis that these specialties are reporting in sufficient numbers to require their participation in the Promoting Interoperability performance category.

After consideration of the comments that we received, we are adopting our proposal with modification. In section III.I.3.a. of this final rule, we are adopting a final policy to add the following types of clinicians to the definition of MIPS eligible clinician: physical therapist, occupational therapist, qualified speech-language pathologist, qualified audiologist, clinical psychologist, and registered dietitian or nutritional professional. For the reasons discussed in the proposed rule, we will apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for
the performance periods in 2017 and 2018 to each of these new types of MIPS eligible clinicians for the performance period in 2019. We are not adopting a policy related to clinical social workers because they are not being added as MIPS eligible clinicians at this time. We are finalizing the proposed regulation text at §414.1380(c)(2)(i)(A)(4) to reflect these modifications.

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

(a) Overview

As codified at §414.1370, MIPS eligible clinicians, including those participating in MIPS APMs, are subject to MIPS reporting requirements and payment adjustments, unless excluded on another basis.

In the CY 2017 Quality Payment Program rule, we finalized the APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and the MIPS.

We established at §414.1370(c) that the MIPS performance period under §414.1320 applies for the APM scoring standard. We finalized under §414.1370(f) that, under the APM scoring standard, MIPS eligible clinicians will be scored at the APM entity group level and each MIPS eligible clinician will receive the APM Entity’s final MIPS score. In the CY 2019 PFS proposed rule, we proposed to amend §414.1370(f)(2) to state that if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

The MIPS final score under the APM scoring standard is comprised of the four MIPS performance categories as finalized at §414.1370(g): quality; cost; improvement activities; and
advancing care information. In 2018, these performance categories are scored at 50 percent, 0 percent, 30 percent, and 20 percent, respectively.

(b) Summary of Proposals

In the CY 2019 PFS proposed rule, we discussed the following proposed policies:

- We proposed to revise §414.1370(b)(3) to clarify the requirement for MIPS APMs to assess performance on quality measures and cost/utilization.

- We proposed to modify the Shared Savings Program quality reporting requirements by expanding the reporting exception for solo practitioners such that, beginning in 2019, in the case of a Shared Savings Program ACO’s failure to report quality measures as required by the Shared Saving Program, we will allow a solo practitioner to report on any available MIPS measures, including individual measures.

- We proposed to clarify that, beginning in 2019, the complete reporting requirement for Web Interface reporters be modified to specify that if an APM Entity fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we will score the CAHPS for ACOs survey and apply it towards the APM Entity’s quality performance category score. In this scenario, the Shared Savings Program TIN-level reporting exception will not be triggered and all MIPS eligible clinicians within the ACO will receive the APM Entity score.

- We clarified that we will consider each distinct track of an APM and whether it meets the criteria necessary to be a MIPS APM under §414.1370(b)(1). We further clarified the term “track” to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity’s participation in another “track” within the same APM.
• We clarified our interpretation of the rule at §414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period, and indicated that we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

• We proposed to remove the Promoting Interoperability (formerly advancing care information) full-TIN reporting requirement for participants in the Shared Savings Program to allow individual TIN/NPIs to report for the Promoting Interoperability performance category.

• We explained how performance feedback may be accessed by ACO participant TINs in the Shared Savings Program.

• We proposed to update the MIPS APM measure sets that apply for purposes of the APM scoring standard.

(c) MIPS APM Criteria

In the CY 2017 Quality Payment Program final rule, we established at §414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: APM Entities must participate in the APM under an agreement with CMS or by law or regulation, the APM must require that APM Entities include at least one MIPS eligible clinician on a participation list, the APM must base payment incentives on performance (either at the APM entity or eligible clinician level) on cost/utilization and quality measures, and the APM must be neither a new APM for which the first performance period begins after the first day of the MIPS performance year, nor an APM in the final year of operation for which the APM scoring standard is impracticable.
As stated in the CY 2019 PFS proposed rule (83 FR 35934), it has come to our attention that there may have been some ambiguity in the third criterion at §414.1370(b)(3). We have received questions as to whether the criterion requires MIPS APMs to base payment incentives on performance on cost/utilization “measures”, or whether it requires more generally that MIPS APMs base payment incentives on “cost/utilization.” Because we did not address this exact point in prior rulemaking and our intended policy is not strictly clear from the regulation text, we clarified in the CY 2019 PFS proposed rule that we intended the word “measures” at §414.1370(b)(3) to modify only “quality” and not “cost/utilization.” To make this criterion clear, we proposed to modify the regulation to specify that a MIPS APM must be designed in such a way that participating APM Entities are incentivized to reduce costs of care or utilization of services, or both. This proposed change to §414.1370(b)(3) would make it clear that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

**Comment:** We received several comments supporting our proposal to modify the criterion at §414.1370(b)(3) to clarify that the word “measures” only modifies the word “quality” and not “cost/utilization.” Commenters stated that as proposed, this revision would mean that a MIPS APM could take into account performance in terms of cost/utilization using a cost/utilization measure and/or through other model design features. One commenter noted appreciation of this clarification and stated that this update to §414.1370(b)(3) will allow participating APM Entities more flexibility when reporting cost/utilization information. Further,
this commenter stated that our proposed clarification is consistent with CMS’s intent and the implied intent of MACRA. Another commenter expressed appreciation for this clarification and noted that this may increase participation in MIPS.

**Response:** We agree with commenters that the policy as intended and clarified allows for flexibility in how reporting cost/utilization information is reported. We continue to believe that accounting for cost/utilization performance can be accomplished by taking model design features into account and it is unnecessary to rely solely on cost/utilization measures. Therefore, we are finalizing our proposal to modify §414.1370(b)(3) to specify that a MIPS APM must be designed in a way that participating APM Entities are incentivized to reduce costs of care or utilization of services, or both. We continue to believe that this change to the regulation text will clarify our intent that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures. We are revising §414.1370(b)(3), as proposed, to state that the APM bases payment on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

We also proposed to clarify that we will consider each distinct track of an APM and whether it meets the criteria, in this final rule, to be a MIPS APM, and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. However, we specified that we will not further consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the MIPS APM criteria.

For purposes of this clarification, we understand the term “track” to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity’s participation in another “track” within the same APM. For example, we consider the three risk arrangements under OCM to be three separate “tracks.”
The following is a summary of the public comments received on this clarification and our responses:

**Comment:** Some commenters supported our clarification. One commenter noted that this clarification allows for maximum flexibility, and allows APM the ability to offer different risk levels, which would, in turn, expand the pool of participants able to join APMs.

**Response:** We appreciate the support, and agree with the commenter that identifying MIPS APMs by considering each distinct track of an APM against our criteria to be a MIPS APM would be likely to increase the potential number of eligible participants to join MIPS APMs.

We will continue to evaluate whether each distinct track of an APM meets our criteria to be a MIPS APM. We note that this may result in an APM having tracks that are MIPS APMs and tracks that are not MIPS APMs.

We also clarified our interpretation of the regulation at §414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), but require participants to report quality data for quality measures tied to payment for the full MIPS performance period, beginning January 1. Under these circumstances where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

The following is a summary of the public comments received on this clarification and our responses:
**Comment**: Commenters noted that this clarification will provide flexibility to those eligible clinicians and APM entities participating in an APM that begins after January 1. Commenters also stated that this clarification would prevent duplicative reporting of quality measures for both the APM and for MIPS, and would be consistent with CMS’s efforts to reduce administrative burden.

**Response**: We appreciate the commenters’ support of our clarification. We agree that our interpretation of §414.1370(b)(4)(i) will prevent duplicative reporting of quality measures and is consistent with our other efforts to reduce administrative burden.

We are clarifying our interpretation of the regulation at §414.1370(b)(4)(i). Therefore, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM. We believe that this interpretation will eliminate possibly conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS and will reduce the likelihood of duplicative reporting of quality information.

Based on the MIPS APM criteria we expect that the following 10 APMs likely will satisfy the requirements to be MIPS APMs for the 2019 performance year:

- Comprehensive ESRD Care Model (all Tracks).
- Comprehensive Primary Care Plus Model (all Tracks).
- Next Generation ACO Model.
- Oncology Care Model (all Tracks).
- Medicare Shared Savings Program (all Tracks).
- Medicare ACO Track 1+ Model.
- Bundled Payments for Care Improvement Advanced.
Independence at Home Demonstration.

Maryland Total Cost of Care Model (Maryland Primary Care Program).

Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

Final CMS determinations of MIPS APMs for the 2019 MIPS performance year will be announced via the Quality Payment Program website at https://qpp.cms.gov/. Further, we make these determinations based on the established MIPS APM criteria as specified in §414.1370(b) of our regulation, taking into account the clarifications made in this final rule.

(d) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

For the quality performance category, MIPS eligible clinicians in APM Entities will continue to be scored only on the quality measures that are required under the terms of their respective APMs, and available for scoring as specified in §414.1370(g)(1) and explained in the CY 2017 Quality Payment Program final rule (82 FR 53698, 53692).

(A) Web Interface Reporters

In the CY 2018 Quality Payment Program final rule, we discussed the requirements for MIPS eligible clinicians participating in a MIPS APM that requires use of the CMS Web Interface for quality reporting, subsequently referred to as “Web Interface Reporters” (82 FR 53954). In that rule we finalized a policy to use quality measure data that participating APM Entities submit using the CMS Web Interface and CAHPS surveys as required under the terms of the APM (82 FR 53568, 53692). We also codified at §414.1370(f)(1) a policy under which, in the event a Shared Savings Program ACO does not report quality measures as required by the Shared Savings Program under §425.508, each ACO participant TIN will be treated as a unique
APM entity for purposes of the APM scoring standard, and may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

For the 2019 MIPS performance year, we anticipate that there will be four Web Interface Reporter APMs: the Shared Savings Program; the Medicare ACO Track 1+ Model; Next Generation ACO Model; and the Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

(aa) Complete reporting requirement

Under §414.1370(f)(1), if a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under §425.508, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard and the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements. In the CY 2019 PFS proposed rule (83 FR 35935), we stated that we would like to clarify that any “partial” reporting through the CMS Web Interface that does not satisfy the requirements of the Shared Savings Program will be considered a failure to report. Should a Shared Savings Program ACO fail to report, the exception under §414.1370(f)(1) is triggered. In this scenario, each ACO participant TIN has the opportunity to report quality data to MIPS according to MIPS group reporting requirements to avoid a score of zero for the quality performance category (81 FR 77256).

We recognized that, under this policy, successfully reporting to MIPS according to group reporting requirements may be difficult for solo practitioners, for whom case thresholds and other requirements may make many group reporting measures unavailable. Therefore, we proposed to modify the exception such that beginning in 2019, in the case of a Shared Savings Program ACO’s failure to report quality measures as required by the Shared Saving Program, we
will also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures, in the event that their ACO fails to complete reporting for all Web Interface measures.

The following is a summary of the public comments received on this clarification and our responses:

**Comment:** One commenter noted that this modification will increase Shared Savings Program ACO participants’ flexibility in the unlikely event that the ACO does not submit quality measures.

**Response:** We agree with the commenter that allowing solo practitioners to report any available MIPS measures, including individual measures, will allow additional flexibility when reporting to MIPS in the event their ACO fails to complete the reporting of all Web Interface measures.

After consideration of all public comments, we are clarifying that beginning in 2019, in the case of a Shared Savings Program ACO’s failure to completely report all Web Interface measures as required by the Shared Savings Program, we will allow a solo practitioner to report on any available MIPS measures, including individual measures.

We also proposed, beginning with the 2019 performance period, to modify the complete reporting requirement for Web Interface reporters to specify that if an APM Entity (in this case, an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we will score the CAHPS for ACOs survey and apply it towards the APM Entity’s quality performance category score. In this scenario the Shared Savings Program TIN-level reporting exception will not be triggered and all MIPS eligible clinicians within the ACO will receive the APM Entity score.
We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Some commenters supported our proposal. Other commenters expressed concern about applying the CAHPS score for ACOs to the APM Entity’s quality performance score.

Response: Upon further consideration, we believe that the proposed change could unduly limit the ACO participant TINs’ opportunity to achieve the highest possible quality performance category score: by scoring the ACO entity’s CAHPS score in this scenario, the entity’s total possible quality score would be capped at the total possible CAHPS score. Therefore, in the case where an ACO entity fails to successfully report Web Interface measures but does successfully report CAHPS, we will continue to treat ACO participant TINs as unique APM Entities under the APM scoring standard and will score each TIN only on the MIPS measures it has reported, up to a score of 100 percent for the performance category.

After taking all comments into account, we are not finalizing our proposal to modify the complete reporting requirement for Web Interface reporters to apply the CAHPS for ACOs survey score toward an APM Entity’s quality performance category score if an ACO fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey.

(B) Other MIPS APMs

Under §414.1370(g)(1)(ii), the MIPS quality performance category score for a MIPS performance period is calculated for the APM Entity using the data submitted by the APM Entity based on measures specified by us through notice and comment rulemaking and available for
scoring for each Other MIPS APM from among those used under the terms of the Other MIPS APM.

In the 2019 MIPS performance year, we anticipate that there will be up to six Other MIPS APMs for which we will use this scoring methodology, based on their respective measure sets and reporting requirements:

- The Oncology Care Model.
- Comprehensive ESRD Care Model.
- Comprehensive Primary Care Plus Model.
- Bundled Payments for Care Improvement Advanced.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Independence at Home Demonstration.

(ii) Promoting Interoperability Performance Category

In the CY 2017 Quality Payment Program final rule (81 FR 77262 through 77264; 81 FR 77266 through 77269), we established a policy at §414.1370(g)(4)(ii) for MIPS APMs other than the Shared Savings Program, under which we attribute one Promoting Interoperability performance category score to each MIPS eligible clinician in an APM Entity group based on the higher of either individual or group-level data submitted for the MIPS eligible. We will then use these scores to create an APM Entity group score equal to the average of the highest scores available for each MIPS eligible clinician in the APM Entity group.

For the Shared Savings Program, we also finalized at §414.1370(g)(4)(i) that ACO participant TINs are required to report on the Promoting Interoperability performance category, and we will weight and aggregate the ACO participant TIN scores to determine an APM Entity group score (81 FR 77258 through 77260). This policy was meant to align requirements between
the MIPS Promoting Interoperability measures and the Shared Savings Program ACO-11 measure, which is used to assess Shared Savings Program ACOs based on the MIPS Promoting Interoperability measures. However, we have found that limiting reporting to the ACO participant TIN creates unnecessary confusion, and restricts Promoting Interoperability reporting options for MIPS eligible clinicians who participate in the Shared Savings Program. Therefore, beginning in the 2019 MIPS performance period, we proposed (83 FR 35935) to no longer apply the requirement as finalized at §414.1370(g)(4)(i) and instead to apply the existing policy at §414.1370(g)(4)(ii) to MIPS eligible clinicians who participate in the Shared Savings Program so that they may report on the Promoting Interoperability performance category at either the individual or group level like all other MIPS eligible clinicians under the APM scoring standard.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters supported our proposed policy. One commenter recommended that CMS allow reporting at the individual level only when group-level information is not reported.

Response: We believe that by aligning Shared Savings Program Promoting Interoperability scoring rules with those for the rest of MIPS and MIPS APMs we will reduce confusion while creating opportunities for individual MIPS eligible clinicians to contribute positively to the total ACO Entity score in the event that a participant TIN fails to report on this performance category.

Comment: One commenter requested that CMS maintain the current requirement for ACO participant TIN-level reporting for Promoting Interoperability performance category
measures. The commenter noted that although the proposed change increases flexibility, larger ACOs may encounter difficulty managing the Promoting Interoperability reporting for all of the individual MIPS eligible clinicians that bill through TINs of ACO participants, risking a payment consequences for failing to report.

Response: The Promoting Interoperability performance category may be reported at either the individual or group level, not the APM Entity (ACO) level; therefore, this policy change will increase MIPS eligible clinicians’ opportunities to report in the event that an ACO participant TIN does not, but should not give rise to a scenario where an ACO’s performance category score would be negatively impacted. If the participant TIN reports for the PI performance category, there would be no need for the ACO to manage reporting for individual MIPS eligible clinicians; if the TIN fails to report, the individual MIPS eligible clinicians within that TIN would have an opportunity to reduce the negative impact of that failure by reporting individually.

After consideration of the comments received, we are finalizing the proposal to allow MIPS eligible clinicians participating in the Shared Savings Program to report on the Promoting Interoperability performance category at either the individual or group level.

(e) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, we should note that whereas split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity or
individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which is a full-TIN APM, will be able to access their performance feedback at the ACO participant TIN level.

(f) Summary of Finalized Policies

In this section, we are finalizing the following policies:

**MIPS APM Criteria:**

- We are modifying the MIPS APM criterion at §414.1370(b)(3) to state that the APM bases payment on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

- We are finalizing our clarification that we separately evaluate each distinct track of an APM to determine whether it meets our criteria to be a MIPS APM. We note that this may result in an APM having some tracks that are MIPS APMs and other tracks that are not MIPS APMs.

- We are finalizing our clarification of our interpretation of the regulation at §414.1370(b)(4)(i). Therefore, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM. We believe that this will eliminate possibly conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS and will reduce the likelihood of duplicative reporting of quality information.

- Final determinations of MIPS APMs for the 2019 MIPS performance year will be made by CMS and announced on the QPP website at [https://qpp.cms.gov/](https://qpp.cms.gov/). Further, in making
these final determinations for 2019, we will use the MIPS APM criteria established in §414.1370(b), taking into account the clarifications we are finalizing in this final rule.

Complete Reporting Requirements:

● We are finalizing our policy as proposed so that beginning in 2019, if a Shared Savings Program ACO fails to report quality measures as required by the Shared Savings Program we would also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures.

● We are not finalizing our proposal to modify the complete reporting requirement for Web Interface reporters so that, in the case where a Shared Savings Program ACO fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we would apply the CAHPS for ACOs survey toward and APM Entity’s quality performance category score. Therefore, in the case where a Shared Savings Program ACO fails to successfully report Web Interface measures but does successfully report the CAHPS for ACOs survey, we will continue to treat the ACO participant TINs as unique APM Entities under the APM scoring standard and will score each TIN only on the MIPS measures it has reported.

Promoting Interoperability Performance Category:

● We are finalizing the proposal to allow MIPS eligible clinicians participating in the Shared Savings Program to report on the Promoting Interoperability performance category at either the individual or group level.

(g) Measure Sets
### TABLE 44: MIPS APM Measure List-- Comprehensive ESRD Care Model

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>NQF/Quality ID #</th>
<th>National Quality Strategy Domain</th>
<th>Measure Description</th>
<th>Primary Measure Steward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Care: Eye Exam</td>
<td>0055</td>
<td>Effective Clinical Care</td>
<td>Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Diabetes Care: Foot Exam</td>
<td>0056</td>
<td>Effective Clinical Care</td>
<td>Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Advance Care Plan</td>
<td>0326</td>
<td>Communication and Care Coordination</td>
<td>Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Medication Reconciliation Post-Discharge</td>
<td>0554</td>
<td>Communication and Care Coordination</td>
<td>The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following the discharge in the office by the physicians, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. National Committee for Quality Assurance. This measure is reported as three rates stratified by age group:  ● Reporting Criteria 1: 18–64 years of age.  ● Reporting Criteria 2: 65 years and older.  ● Total Rate: All patients 18 years of age and older.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Influenza Immunization for the ESRD Population</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Percentage of patients aged 6 months and older seen for a visit between July 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.</td>
<td>KCQA</td>
</tr>
<tr>
<td>Pneumococcal Vaccination Status</td>
<td>0043</td>
<td>Community/Population Health</td>
<td>Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Screening for Clinical Depression and Follow-Up Plan</td>
<td>0418</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 12 and older screened for depression on the date of the encounter and using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.</td>
<td>CMS</td>
</tr>
<tr>
<td>Tobacco Use: Screening and Cessation</td>
<td>0028</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Measure Name</td>
<td>NQF/Quality ID #</td>
<td>National Quality Strategy Domain</td>
<td>Measure Description</td>
<td>Primary Measure Steward</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>----------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td>cessation counseling intervention if identified as a tobacco user.</td>
<td></td>
</tr>
</tbody>
</table>
| Falls: Screening, Risk Assessment, and Plan of Care to Prevent Future Falls  | 0101            | Patient Safety                   | (A) Screening for Future Fall Risk: Patients who were screened for future fall risk at last once within 12 months.  
(B) Multifactorial Falls Risk Assessment: Patients at risk of future fall who had a multifactorial risk assessment for falls completed within 12 months.  
(C) Plan of Care to Prevent Future Falls: Patients at risk of future fall with a plan of care or falls prevention documented within 12 months. | NCQA                    |
| ICH CAHPS: Nephrologists' Communication and Caring                           | 0258            | N/A                              | Summary/Survey Measures may include:  
● Getting timely care, appointments, and information.  
● How well providers communicate.  
● Patients’ rating of provider.  
● Access to specialists.  
● Health promotion and education.  
● Shared Decision-making.  
● Health status and functional status.  
● Courteous and helpful office staff.  
● Care coordination.  
● Between visit communication.  
● Helping you to take medications as directed, and  
● Stewardship of patient resources. | CMS                      |
<p>| ICH CAHPS: Quality of Dialysis Center Care and Operations                    | 0258            | N/A                              | Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease. | CMS                      |
| ICH CAHPS: Providing Information to Patients                                 | 0258            | N/A                              | Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease. | CMS                      |
| ICH CAHPS: Rating of the Nephrologist                                         | 0258            | N/A                              | Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease. | CMS                      |
| ICH CAHPS: Rating of Dialysis                                                | 0258            | N/A                              | Comparison of services and quality of care that dialysis facilities provide from the perspective of | CMS                      |</p>
<table>
<thead>
<tr>
<th>Measure Name</th>
<th>NQF/Quality ID #</th>
<th>National Quality Strategy Domain</th>
<th>Measure Description</th>
<th>Primary Measure Steward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center Staff</td>
<td></td>
<td></td>
<td>ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</td>
<td></td>
</tr>
<tr>
<td>ICH CAHPS: Rating of the Dialysis Facility</td>
<td>0258</td>
<td>N/A</td>
<td>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</td>
<td>CMS</td>
</tr>
<tr>
<td>Standardized Mortality Ratio</td>
<td>0369</td>
<td>N/A</td>
<td>This measure is calculated as a ratio but expressed as a rate.</td>
<td>CMS</td>
</tr>
<tr>
<td>Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>The standardized ratio of the observed to expected number of incident patients under age 75 listed on the kidney or kidney-pancreas transplant waitlist or who received a living donor transplant within the first year of initiating dialysis based on the national rate.</td>
<td>CMS</td>
</tr>
<tr>
<td>Percentage of Prevalent Patients Waitlisted (PPPW)</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>The percentage of patients who were on the kidney or kidney-pancreas transplant waitlist.</td>
<td>CMS</td>
</tr>
</tbody>
</table>
## TABLE 45: MIPS APM Measure List-- Comprehensive Primary Care Plus (CPC+) Model

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>NQF/Quality ID</th>
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<th>Primary Measures Steward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlling High Blood Pressure</td>
<td>0018</td>
<td>Effective Treatment/Clinical Care</td>
<td>Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (&lt;140/90 mmHg) during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Diabetes: Hemoglobin A1c (HbA1c) Poor Control (&gt;9 percent)</td>
<td>0059</td>
<td>Effective Treatment/Clinical Care</td>
<td>Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c &gt;9.0 percent during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Dementia: Cognitive Assessment</td>
<td>2872</td>
<td>Effective Treatment/Clinical Care</td>
<td>Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Falls: Screening for Future Fall Risk</td>
<td>0101</td>
<td>Patient Safety</td>
<td>Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
</tbody>
</table>
| Initiation and Engagement of Alcohol and Other Drug Dependence Treatment | 0004           | Effective Treatment/Clinical Care | Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported:  
a. Percentage of patients who initiated treatment within 14 days of the diagnosis.  
b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit. | National Committee for Quality Assurance   |
| Closing the Referral Loop: Receipt of Specialist Report | Not Endorsed   | Communication and Care Coordination | Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.                                                        | CMS                                       |
| Cervical Cancer Screening                         | 0032           | Effective Treatment/Clinical Care | Percentage of women 21–64 years of age, who were screened for cervical cancer using either of the following criteria:  
  ● Women age 21–64 who had cervical cytology performed every 3 years.  
  ● Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years. | National Committee for Quality Assurance   |
<p>| Colorectal Cancer Screening                       | 0034           | Effective Treatment/Clinical Care | Percentage of patients 50–75 years of age who had appropriate screening for colorectal cancer.                                                                                                                   | National Committee for Quality Assurance   |
| Diabetes: Eye Exam                                | 0055           | Effective Treatment/Clinical Care | Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam.                                 | National Committee for Quality Assurance   |</p>
<table>
<thead>
<tr>
<th>Measure Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention</td>
<td>0028</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months and who received cessation counseling intervention if identified as a tobacco user.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Breast Cancer Screening</td>
<td>2372</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>CG–CAHPS® Survey 3.0 - modified for CPC+</td>
<td>Not Endorsed</td>
<td>Person and Caregiver-Centered Experience and Outcomes</td>
<td>CG–CAHPS® Survey 3.0</td>
<td>AHRQ</td>
</tr>
<tr>
<td>Inpatient Hospital Utilization</td>
<td>Not Endorsed</td>
<td>Communication and Care Coordination</td>
<td>For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Emergency Department Utilization</td>
<td>Not Endorsed</td>
<td>Communication and Care Coordination</td>
<td>For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Diabetes: Medical Attention for Nephropathy</td>
<td>0062</td>
<td>Effective Treatment/ Clinical Care</td>
<td>The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Preventive Care and Screening: Depression and Follow-Up Plan</td>
<td>0418</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Depression Utilization of the PHQ-9 Tool</td>
<td>0712</td>
<td>Effective Treatment/ Clinical Care</td>
<td>The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying visit.</td>
<td>MN Community Measurement</td>
</tr>
<tr>
<td>Preventive Care and Screening: Influenza Immunization</td>
<td>0041</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.</td>
<td>American Medical Association-convened Physician Consortium for Performance Improvement(R) (AMA-PCPI)</td>
</tr>
<tr>
<td>Pneumococcal Vaccination Status for Older</td>
<td>Not Endorsed</td>
<td>Community/Population Health</td>
<td>Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.</td>
<td>National Committee for Quality</td>
</tr>
</tbody>
</table>

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*CG–CAHPS®* Survey 3.0 - modified for CPC+ is not endorsed.

*American Medical Association-convened Physician Consortium for Performance Improvement(R)* (AMA-PCPI) is not endorsed.
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<tr>
<td>Adults</td>
<td></td>
<td></td>
<td>Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
</tbody>
</table>
| Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet    | 0068            | Effective Treatment/Clinical Care | Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:  
- Adults aged >=21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR  
- Adults aged >=21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR  
- Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70–189 mg/dL. | CMS                       |
<p>| Statin Therapy for the Prevention and Treatment of Cardiovascular Disease  | Not Endorsed    | Effective Treatment/Clinical Care | Percentage of patients 65 years of age and older who were ordered high-risk medications.                                                                                                                                                                                                                                                                   | National Committee for Quality Assurance |
| Use of High-Risk Medications in the Elderly                                | 0022            | Patient Safety                   | Percentage of patients aged 18 years and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period. | CMS                       |
| Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented | Not Endorsed    | Community/Population Health       | Percentage of patients aged 18 years and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period. | CMS                       |
| Documentation of Current Medications in the Medical Record                | 0419            | Patient Safety                   | Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter.                                                                                                                                                                                                 | CMS                       |
| Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan | 0421            | Community/Population Health       | Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months. | CMS                       |</p>
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</thead>
<tbody>
<tr>
<td>Diabetes: Foot Exam</td>
<td>0056</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)</td>
<td>0081</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) &lt; 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)</td>
<td>0083</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) &lt; 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF &lt;40 percent)</td>
<td>0070</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF &lt;40 percent who were prescribed beta-blocker therapy.</td>
<td>PCPI Foundation</td>
</tr>
<tr>
<td>Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture</td>
<td>Not Endorsed</td>
<td>Effective Treatment/ Clinical Care</td>
<td>Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.</td>
<td>CMS</td>
</tr>
<tr>
<td>HIV Screening</td>
<td>Not Endorsed</td>
<td>Community/Population Health</td>
<td>Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).</td>
<td>Centers for Disease Control and Prevention (CDC)</td>
</tr>
<tr>
<td>Measure Name</td>
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<td>National Quality Strategy Domain</td>
<td>Measure Description</td>
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</tr>
<tr>
<td>--------------------------------------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Total Resource Use Population-based PMPM Index (RUI)</td>
<td>1598</td>
<td>N/A</td>
<td>This measure is used to assess the total resource use index population-based per member per month (PMPM). The Resource Use Index (RUI) is a risk adjusted measure of the frequency and intensity of services utilized to manage a provider group’s patients. Resource use includes all resources associated with treating members including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary and behavioral health services.</td>
<td>Minneapolis (MN): Health Partners</td>
</tr>
<tr>
<td>Measure Name</td>
<td>NQF/Quality ID</td>
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<td>Measure Description</td>
<td>Primary Measure Steward</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
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<td>--------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer</td>
<td>0223</td>
<td>Communication and Care Coordination</td>
<td>Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.</td>
<td>Commission on Cancer, American College of Surgeons</td>
</tr>
<tr>
<td>Breast Cancer: Hormonal Therapy for Stage I (T1b-IIIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer</td>
<td>0387</td>
<td>Communication and Care Coordination</td>
<td>Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC. ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.</td>
<td>AMA-convened Physician Consortium for Performance Improvement</td>
</tr>
<tr>
<td>Oncology: Medical and Radiation – Plan of Care for Pain</td>
<td>0384</td>
<td>Person and Caregiver-Centered Experience and Outcomes</td>
<td>Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB - III hormone receptor negative breast cancer</td>
<td>0559</td>
<td>Communication and Care Coordination</td>
<td>Percentage of female patients, age &gt;18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB-III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.</td>
<td>Commission on Cancer, American College of Surgeons</td>
</tr>
<tr>
<td>Documentation of Current Medications in the Medical Record</td>
<td>0419</td>
<td>Patient Safety</td>
<td>Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over the counters, herbs, and vitamin/mineral/ dietary AND must contain the medications’ name, dosage, frequency and route of administration.</td>
<td>CMS</td>
</tr>
<tr>
<td>Oncology: Medical and Radiation -Pain Intensity Quantified</td>
<td>0383</td>
<td>Person and Caregiver-Centered Experience</td>
<td>Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.</td>
<td>Physician Consortium for Performance Improvement Foundation</td>
</tr>
<tr>
<td>Patient-Reported Experience of Care</td>
<td>N/A</td>
<td>Person and Caregiver-Centered Experience</td>
<td>Summary/Survey Measures may include:</td>
<td>CMS</td>
</tr>
<tr>
<td>Measure Name</td>
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</tr>
<tr>
<td>Preventive Care and Screening: Screening for Depression and Follow-Up Plan</td>
<td>0418</td>
<td>Community/Population Health</td>
<td>Percentage of patients aged 12 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool and if positive, a follow-up plan is documented on the date of the positive screen.</td>
<td>CMS</td>
</tr>
<tr>
<td>Proportion of patients who died who were admitted to hospice for 3 days or more</td>
<td>N/A</td>
<td>N/A</td>
<td>Percentage of OCM-attributed FFS beneficiaries who died and spent at least 3 days in hospice during the measurement time period.</td>
<td>CMS</td>
</tr>
<tr>
<td>Risk-adjusted proportion of patients with all-cause ED visits that did not result in a hospital admission within the 6-month episode</td>
<td>N/A</td>
<td>N/A</td>
<td>Percentage of OCM-attributed FFS beneficiaries who had an ER visit that did not result in a hospital stay during the measurement period.</td>
<td>CMS</td>
</tr>
<tr>
<td>Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode</td>
<td>N/A</td>
<td>N/A</td>
<td>Percentage of OCM-attributed FFS beneficiaries who were had an acute-care hospital stay during the measurement period.</td>
<td>CMS</td>
</tr>
<tr>
<td>Trastuzumab administered to patients with AJCC stage I (T1c) - III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy</td>
<td>1858</td>
<td>Efficiency and Cost reduction</td>
<td>Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c)–III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant Chemotherapy.</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>Measure Name</td>
<td>NQF/Quality ID #</td>
<td>National Quality Strategy Domain</td>
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<tr>
<td>-------------------------------------------------</td>
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<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>All-Cause Hospital Readmission</td>
<td>1789</td>
<td>Communication and Care Coordination</td>
<td>This measure estimates a hospital-level risk-standardized readmission rate (RSRR) of unplanned, all cause readmission after admission for any eligible condition within 30 days of hospital discharge.</td>
<td>CMS</td>
</tr>
<tr>
<td>Advanced Care Plan</td>
<td>0326 (adapted)</td>
<td>Communication and Care Coordination</td>
<td>Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.</td>
<td>NCQA</td>
</tr>
<tr>
<td>Perioperative Care: Selection of Prophylactic Antibiotic: First or Second Generation Cephalosporin</td>
<td>0268</td>
<td>Patient Safety</td>
<td>Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic who had an order for first OR second generation cephalosporin for antimicrobial prophylaxis.</td>
<td>American Society of Plastic Surgeons</td>
</tr>
<tr>
<td>Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Elective Coronary Artery Bypass Graft (CABG) Surgery</td>
<td>2558</td>
<td>Patient Safety</td>
<td>The measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.</td>
<td>CMS</td>
</tr>
<tr>
<td>Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction</td>
<td>2881</td>
<td>Patient Safety</td>
<td>This measure assesses days spent in acute care within 30 days of discharge from an inpatient hospitalization for acute myocardial infarction (AMI) to provide a patient-centered assessment of the post-discharge period. This measure is intended to capture the quality of care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: emergency department (ED) visits, observation stays, and unplanned readmissions at any time during the 30 days post-discharge. To aggregate all three events, we measure each in terms of days. In 2016, CMS will begin annual reporting of the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and are hospitalized in</td>
<td>CMS</td>
</tr>
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<td>--------------------------</td>
</tr>
<tr>
<td>AHRQ Patient Safety Measures</td>
<td>0531</td>
<td>Patient Safety</td>
<td>The modified PSI-90 Composite measure (name changed to Patient Safety and Adverse Events Composite) consists of ten component indicators: PSI-3 Pressure ulcer rate; PSI-6 Iatrogenic pneumothorax rate; PSI-8 Postoperative hip fracture rate; PSI-9 Perioperative hemorrhage or hematoma rate; PSI-10 Hysiologic and metabolic derangement rate; PSI-11 Postoperative respiratory failure rate; PSI-12 Perioperative pulmonary embolism or Deep vein thrombosis rate; PSI-13 Postoperative sepsis rate; PSI-14 Postoperative wound dehiscence rate; and PSI-15 Accidental puncture or laceration rate.</td>
<td>AHRQ</td>
</tr>
<tr>
<td>Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty</td>
<td>1550</td>
<td>Patient Safety</td>
<td>The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort).</td>
<td>CMS</td>
</tr>
</tbody>
</table>

1 The specifications used for the Advanced Care Plan quality measure in BPCI Advanced are not NQF endorsed, but have been created specifically for BPCI Advanced.
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<td>0018</td>
<td>Effective / Clinical Care</td>
<td>Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (&lt;140/90 mmHg) during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Diabetes: HbA1c Poor Control (&gt;9 percent)</td>
<td>0059</td>
<td>Effective Clinical Care</td>
<td>Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c &gt; 9.0 percent during the measurement period.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Initiation and Engagement of Alcohol and Other Drug Dependence Treatment</td>
<td>0004</td>
<td>Effective / Clinical Care</td>
<td>Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported:</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>a. Percentage of patients who initiated treatment within 14 days of the diagnosis.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.</td>
<td></td>
</tr>
<tr>
<td>CG -CAHPS Survey 3.0 - modified for CPC+</td>
<td>Not Endorsed</td>
<td>Person and Family Engagement/ Patient and Caregiver Experience</td>
<td>CG–CAHPS Survey 3.0</td>
<td>AHRQ</td>
</tr>
<tr>
<td>Inpatient Hospital Utilization</td>
<td>Not Endorsed</td>
<td>Communication and Care Coordination</td>
<td>For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>Emergency Department Utilization</td>
<td>Not Endorsed</td>
<td>Communication and Care Coordination</td>
<td>For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.</td>
<td>National Committee for Quality Assurance</td>
</tr>
</tbody>
</table>
TABLE 49: MIPS APM Measure List--Independence at Home Demonstration

<table>
<thead>
<tr>
<th>Measure Name</th>
<th>NQF/Quality ID</th>
<th>National Quality Strategy Domain</th>
<th>Measure Description</th>
<th>Primary Measure Steward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months.</td>
<td>CMS</td>
</tr>
<tr>
<td>Number of readmissions within 30 days per 100 inpatient discharges</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Risk adjusted readmissions to a hospital within 30 days following discharge from the hospital for an index admission.</td>
<td>CMS</td>
</tr>
<tr>
<td>Emergency Department Visits for Ambulatory Care Sensitive Conditions</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Risk adjusted emergency department visits for three ambulatory care sensitive conditions: diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD).</td>
<td>CMS</td>
</tr>
<tr>
<td>Contact with beneficiaries within 48 hours upon admission to the hospital and discharge from the hospital and/or ED</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Percent of hospital admissions, hospital discharges, and emergency department (ED) visits for beneficiaries enrolled in IAH with a follow-up contact within 48 hours.</td>
<td>CMS</td>
</tr>
<tr>
<td>Medication reconciliation in the home</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Percent of hospital discharges and emergency department (ED) visits for beneficiaries enrolled in IAH with medication reconciliation in the home within 48 hours.</td>
<td>CMS</td>
</tr>
<tr>
<td>Percentage with Documented Patient Preferences</td>
<td>Not Endorsed</td>
<td>N/A</td>
<td>Percent of beneficiaries enrolled in IAH with patient preferences documented in the medical record for a demonstration year.</td>
<td>CMS</td>
</tr>
</tbody>
</table>

We proposed to update the MIPS APM measure sets that apply for purposes of the APM scoring standard (83 FR 35933 through 35934). The following is a summary of the public comments received on these measure sets and our responses:

Comment: Several commenters supported the measure sets set forth in the proposed rule. Other commenters recommended additional measures to be used in future years or suggested modifications to the measures themselves.

Response: We thank the commenters for their support and note that, consistent with §414.1370(g)(1)(i)(A) and (ii)(A), we are using only measures that are included or that CMS
intends to include in each APM measures set at the time of publication of this final rule. Should those measures be removed or revised from that measure set before the end of the performance year, we will not score APM Entities on their performance on those measures, but will include updated measures in future rulemaking.

Per our policy expressed in last year’s final rule (82 FR 53695 and 53696), the measure sets on the MIPS APM measure list for the year will represent all possible measures which may contribute to an APM Entity’s MIPS score for the MIPS quality performance category, and may include measures that are the same as or similar to those used by MIPS. However, a given measure ultimately might not be used for scoring, for example if its data becomes inappropriate or unavailable for scoring.

After consideration of the comments received, we are finalizing our proposal to update the MIPS APM measure sets that apply for purposes of the APM scoring standard and will score only measures that already have been included in the measure sets of their given APM, according to the terms of participation in that APM. We note that Table 48 has been updated to reflect the most current APM measure sets.

i. MIPS Final Score Methodology

(1) Converting Measures and Activities into Performance Category Scores

(a) Background

For the 2021 MIPS payment year, we intend to build on the scoring methodology we finalized for the transition years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts.
As we continue to move forward in implementing the MIPS program, we strive to balance the statutory requirements and programmatic goals with the ease of use, stability, and meaningfulness for MIPS eligible clinicians. We do so while also emphasizing simplicity and the continued development of a scoring methodology that is understandable for MIPS eligible clinicians.

In the CY 2017 Quality Payment Program final rule, we finalized a unified scoring system to determine a final score across the 4 performance categories (81 FR 77273 through 77276). For the 2019 MIPS performance period, we proposed to build on the scoring methodology we previously finalized, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements (83 FR 35948 through 35949). For quality performance category scoring, we proposed to extend some of the transition year policies to the 2019 MIPS performance period, and we also proposed several modifications to existing policies (83 FR 35947 through 35949). In the CY 2018 Quality Payment Program final rule (82 FR 53712 through 53714), we established a methodology for scoring improvement in the cost performance category. However, as required by section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018, we proposed that the cost performance category score would not take into account improvement until the 2024 MIPS payment year (83 FR 35956). In the CY 2018 Quality Payment Program final rule (82 FR 53753 through 53767), we finalized the availability of a facility-based measurement option for clinicians who met certain requirements, beginning with the 2019 MIPS performance period. As discussed in section III.I.3.i.(1)(d) of this final rule, we are finalizing our proposal to change the determination of facility-based measurement to include consideration of presence in the on-campus outpatient hospital. The policies for scoring the 4 performance categories are described in detail in section III.I.3.i.(1) of this final rule.
These policies will help eligible clinicians as they participate in the 2019 MIPS performance period/2021 MIPS payment year, and as we move beyond the transition years of the program. Section 51003 of the Bipartisan Budget Act of 2018 provides flexibility to continue the gradual ramp up of the Quality Payment Program and enables us to extend some of the transition year policies to the 2019 performance period.

Unless otherwise noted, for purposes of this section III.I.3.i. of this final rule, the term “MIPS eligible clinician” will refer to MIPS eligible clinicians who collect and submit data and are scored at either the individual or group level, including virtual groups; it will not refer to MIPS eligible clinicians who are scored by facility-based measurement, as discussed in section III.I.3.i.(1)(d) of this final rule. We also note that the APM scoring standard applies to MIPS eligible clinicians in APM Entities in MIPS APMs, and those policies take precedence where applicable. Where those policies do not apply, scoring for MIPS eligible clinicians as described in section III.I.3.h.(6) of this final rule will apply. We refer readers to section III.I.4. of this final rule for additional information about the APM scoring standard.

(b) Scoring the Quality Performance Category for the Following Collection Types: Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Although we did not propose changing the basic scoring system that we finalized in the CY 2018 Quality Payment Program final rule for the 2021 MIPS payment year (82 FR 53712 through 53748), we proposed several modifications to scoring the quality performance category, including removing high-priority measure bonus points for CMS Web Interface measures and extending the bonus point caps, and adding a small practice bonus to the quality performance
category score. The following section describes these previously finalized policies and our proposals (83 FR 35950 through 35952).

We also proposed updates to §414.1380(b)(1) in an effort to more clearly and concisely capture previously established policies (83 FR 35946 through 35955). These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We will make note of the updated regulatory citations in their relevant sections below.

(i) Scoring Terminology

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 through 77831 and 82 FR 53568 through 54229, respectively), we used the term “submission mechanisms” in reference to the various ways in which a MIPS eligible clinician or group can submit data to CMS. As discussed in section III.I.3.h.(1)(b) of this final rule, it has come to our attention that the way we have described the various ways in which MIPS eligible clinicians, groups and third-party intermediaries can submit data to our systems does not accurately reflect the experience users have when submitting data to us. We refer readers to section III.I.3.h.(1)(b) of this final rule for further discussion on our finalized changes to the scoring terminology related to measure specification and data collection and submission. For additional discussion on the impact of the proposed terminology change on our benchmarking methodology, validation process, and end-to-end reporting bonus, we refer readers to sections III.I.3.i.(1)(b)(ii), (v), and (x) of this final rule.

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77282 and 82 FR 53718, respectively) for our previously established benchmarking policies. As part of our proposed technical updates to §414.1380(b)(1) discussed in section
III.I.3.i.(1)(a)(i) of this final rule, our previously established benchmarking policies at §414.1380(b)(1)(i) through (iii) would now be referenced at §414.1380(b)(1)(i) through (ii).

When we developed the quality measure benchmarks, we sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements (81 FR 28249 through 28250). The feedback we have received thus far from stakeholders on our benchmarks is helping to inform our approach to the benchmarking methodology, especially as we look for possible ways of aligning with Physician Compare benchmarks. As described in section III.I.3.i.(1)(b)(xii) of this final rule, we solicited comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes.

We anticipate changes in scoring would be paired with potential modifications to measure selection and criteria discussed in section III.I.3.h.(2)(b) of this final rule. In the CY 2019 PFS proposed rule (83 FR 35947), we sought input on opportunities to further reduce confusion about our benchmarking methodology described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77278), which includes further clarification of our benchmarking process and potential areas of alignment between the MIPS and Physician Compare benchmarking methodologies.

We thank commenters for their input and may take this input into consideration in future years.

(A) Revised Terminology for MIPS Benchmarks

We previously established at §414.1380(b)(1)(iii) separate benchmarks for the following submission mechanisms: EHR; QCDR/registry, claims; CMS Web Interface; CMS-approved
survey vendor; and administrative claims. In the CY 2019 PFS proposed rule, we did not propose to change our basic approach to our benchmarking methodology; however, we proposed to amend §414.1380(b)(1)(ii) consistent with the proposed data submission terminology changes discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35947). Specifically, beginning with the 2021 MIPS payment year, we proposed to establish separate benchmarks for the following collection types: eCQMs; QCDR measures (as described at §414.1400(e)); MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. We would apply benchmarks based on collection type rather than submission mechanism. For example, for an eCQM, we would apply the eCQM benchmark regardless of submitter type (MIPS eligible clinician, group, third party intermediary). In addition, we would establish separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications. In addition, we note that our proposed benchmarking policy allows for the addition of future collection types as the universe of measures continues to evolve and as new technology is introduced. Specifically, we proposed to amend §414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

The following is a summary of the public comments on these proposals and our responses:

**Comment:** A few commenters expressed support for our proposal to establish separate benchmarks by collection types, citing the difference in measure performance across collection
types. One commenter stated this update would maintain consistency when migrating between current MIPS terminology to proposed MIPS terminology.

Response: We thank commenters for their support as we continue to clarify and improve our benchmarking policies.

Comment: One commenter expressed concern about the proposal to update our regulatory text to state that benchmarks are based on collection types from all available sources, including APMs. Specifically, the commenter noted that incorporating APM data into benchmark calculations will set the benchmarks too high since APM participants tend to be high performers.

Response: We recognize commenter’s concern; however, this is not a new policy, and we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77279) for additional discussion on the inclusion of APMs in the MIPS benchmarks. As measures and technology evolve, we are constantly reviewing and evaluating what data sources are appropriate for benchmarks.

Comment: One commenter requested clarification on whether QCDR measures that have an e-specified collection type and a manual collection type will also be considered separate collection types with distinct benchmarks.

Response: We expect that a QCDR measure for which data is abstracted through EHRs or manually (that is, paper records) would have to be approved as two separate measures. As a result, each measure would only be compared to its own benchmark.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to amend §414.1380(b)(1)(ii) to establish separate benchmarks based on collection type and to remove the mention of each individual benchmark and state that
benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(iii) Assigning Points Based on Achievement

In the CY 2017 Quality Payment Program final rule, we established the policies for scoring quality measures performance (81 FR 77286). We refer readers to §414.1380(b)(1) for more on these policies.

(A) Floor for Scored Quality Measures

For the 2019 and 2020 MIPS payment years, we finalized at §414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). In this way, MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements (81 FR 77286 through 77287; 82 FR 53719). For measures with a benchmark based on the performance period (rather than on the baseline period), we stated that we would continue to assign between 3 and 10 measure achievement points for performance periods after the first transition year (81 FR 77282, 77287; 82 FR 53719). For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years (81 FR 77286 through 77287; 82 FR 53719).

For the 2021 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend §414.1380(b)(1)(i) accordingly (83 FR 35947). We will revisit the 3-point floor for such measures again in future rulemaking.
We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters expressed support for the three-point floor for measures that can be reliably scored against a benchmark based on the baseline period because it would reduce confusion, help reduce burden, maintain stability, and encourage physicians to continue to participate in MIPS.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing our proposal, for the 2021 MIPS payment year, to apply a 3-point floor for each measure that can be reliably scored against a benchmark, and to amend §414.1380(b)(1)(i) accordingly.

(B) Additional Policies for the CAHPS for MIPS Measure Score

Although participating in the CAHPS for MIPS survey is optional for all groups, some groups will be unable to participate in the CAHPS for MIPS survey because they do not meet the minimum beneficiary sampling requirements. CMS has sampling requirements for groups of 100 or more eligible clinicians, 25 to 99 eligible clinicians, and 2 to 24 eligible clinicians to ensure an adequate number of survey responses and the ability to reliably report data. Our sampling timeframes necessitate notifying groups of their inability to meet the sampling requirements late in the performance period (see 82 FR 53630 through 53632). As a result, we are concerned that some groups that expect and plan to meet the quality performance category requirements using the CAHPS for MIPS survey may find out late in the performance period that they are unable to meet the sampling requirements and, therefore, are unable to have their performance assessed on this measure. These groups may need to report on another measure to meet the requirements of the quality performance category.
We want to encourage the reporting of the CAHPS for MIPS survey and do not want the uncertainty regarding sampling requirements to be a barrier to selecting the CAHPS for MIPS survey. To mitigate this concern, beginning with the 2021 MIPS payment year, we proposed to reduce the denominator (that is, the total available measure achievement points) for the quality performance category by 10 points for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements (83 FR 35948). By reducing the denominator instead of only assigning the group a score of zero measure achievement points (because the group would be unable to submit any CAHPS for MIPS survey data), we are effectively removing the impact of the group’s inability to submit the CAHPS for MIPS survey. We believe this reduction in denominator would remove any need for groups to find another measure if they are unable to submit the CAHPS for MIPS survey. Therefore, we proposed to amend §414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that registered for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters supported our proposed policy. One commenter believes this will encourage more groups to conduct the survey.

Response: We appreciate the commenters’ support.

Comment: One commenter requested clarification on when groups would be notified that they did not meet the beneficiary sampling requirement. The commenter also requested clarification on what protections the agency will institute for groups who must cancel their...
contracts with survey vendors “late in the performance period” when they are notified that they did not meet the beneficiary sampling requirement. The commenter stated that CMS should not hold groups accountable for vendor costs that result from the agency’s late notification process.

Response: We do not anticipate the notification process for minimum beneficiary sample requirements will change. CMS provides information on sample design and sample size requirements in the QPP Resource Library to aid groups in deciding whether or not to elect CAHPS for MIPS. CMS sends communication about sample size eligibility to the point of contact provided by each group during the registration process for CAHPS for MIPS. Providing more than one point of contact will help to promote timely delivery of the information on sample size eligibility to the group. Groups should coordinate with their vendors to address any questions regarding costs in the event the group does not meet the beneficiary sampling requirement. For any additional questions please visit the Quality Payment Program website at qpp.cms.gov.

Comment: One commenter sought clarification whether CMS would automatically apply the scoring policy or first provide groups with the option to report on an alternate quality measure or improvement activity.

Response: We will not automatically apply the scoring policy. Notifications will be sent twice to groups that have registered for the CAHPS for MIPS survey and who have an insufficient sample size, with the second notification usually occurring in September. These notifications also encourage groups to select other relevant measures that can be completed. We believe that this policy is necessary because the notification late in the performance period might not allow sufficient time for groups to collect and report a different quality measure, however, some practices may have other quality measures (beyond the 6 minimum) that they have been
reporting on that could be submitted within the performance period. For groups that submitted 5 or fewer quality measures and do not meet the CAHPS for MIPS sampling requirements, the quality denominator will be reduced by 10 points. For groups that submitted 6 or more quality measures and do not meet the CAHPS for MIPS sampling requirements, we will score the 6 measures with the highest achievement points.

The notification will also encourage groups to select other relevant improvement activities that can be completed within the performance period. We refer readers to section III.I.3.h.(4)(b) of this final rule for further information on submission criteria for the improvement activities performance category.

After consideration of public comments, we are finalizing our proposal to amend §414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

We do not want groups to register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement, so we solicited comments on whether we should limit this proposed policy to groups for only one MIPS performance period. For example, for the performance period following the application of this proposed policy, a notice could be provided to groups during registration indicating that if the sampling requirement is not met for a second consecutive performance period, the proposed policy will not be applied. This would provide notice to the group that they may not meet the sampling requirement needed for the CAHPS for MIPS survey and may need to look for alternate measures but does not preclude the group from registering for the CAHPS for MIPS
survey if they expect to meet the minimum beneficiary sampling requirements in the second MIPS performance period.

We thank commenters for their suggestions and may consider them for future rulemaking.

(iv) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to CY 2017 Quality Payment Program final rule (82 FR 53721 through 53727) for our established policies for scoring topped out measures.

Under §414.1380(b)(1)(xiii)(A), for the 2020 MIPS payment year, 6 measures will receive a maximum of 7 measure achievement points, provided that the applicable measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. Under §414.1380(b)(1)(xiii)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727). As part of our technical updates to §414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, our previously finalized topped out scoring policies are now referenced at §414.1380(b)(1)(iv).

We refer readers to the 2018 MIPS Quality Benchmarks’ file that is located on the Quality Payment Program resource library (https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html) to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks’ file. We note that the final determination of which measure benchmarks
are subject to the topped out cap will not be available until the 2019 MIPS Quality Benchmarks’ file is released in late 2018.

We did not propose to apply our previously finalized topped out scoring policy to the CAHPS for MIPS survey (82 FR 53726). Because the CAHPS for MIPS survey was revised in 2018 (82 FR 53632), we do not have historical benchmarks for the 2018 performance period, so the topped out policy would not be applied for the 2019 performance period. Last year, we received limited feedback when we sought comment on how the topped out scoring policy should be applied to CAHPS for MIPS survey. In CY 2019 PFS proposed rule, we sought feedback on potential ways we can score CAHPS for MIPS Summary Survey Measures (SSM) (83 FR 35948). For example, we could score all SSMs, which means there would effectively be no topped out scoring for CAHPS for MIPS SSMs, or we could cap the SSMs that are topped out and score all other SSMs. We sought comment on these approaches and additional approaches to the topped out scoring policy for CAHPS for MIPS SSMs. We noted that we encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

We thank commenters for their suggestions and will consider them for future rulemaking.

(v) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77288 through 77289), we established scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. As part of our technical updates to §414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously finalized scoring policies are now referenced at §414.1380(b)(1)(i)(A) and (B).
A summary of the current and proposed policies is provided in Table 50. For more of the statutory background and details on current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77288 through 77289 and 82 FR 53727 through 53730, respectively).

**TABLE 50: Quality Performance Category: Scoring Measures**

<table>
<thead>
<tr>
<th>Measure type</th>
<th>Description</th>
<th>Scoring rules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class 1</strong></td>
<td>For the 2018 and 2019 MIPS performance period: Measures that can be scored based on performance. Measures that were submitted or calculated that met the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 60 percent.)</td>
<td>For the 2018 and 2019 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.</td>
</tr>
<tr>
<td><strong>Class 2</strong></td>
<td>For the 2018 and 2019 MIPS performance period: Measures that were submitted and meet data completeness, but do not have both of the following: (1) a benchmark (2) at least 20 cases.</td>
<td>For the 2018 and 2019 MIPS performance period: 3 points * This Class 2 measure policy does not apply to CMS Web Interface measures and administrative claims based measures</td>
</tr>
<tr>
<td><strong>Class 3</strong></td>
<td>For the 2018 and 2019 MIPS performance period: Measures that were submitted, but do not meet data completeness criteria, regardless of whether they have a benchmark or meet the case minimum.</td>
<td>For the 2018 and 2019 MIPS performance period: 1 point except for small practices, which would receive 3 measure achievement points. Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points. **This Class 3 measure policy would not apply to CMS Web Interface measures and administrative claims based measures</td>
</tr>
</tbody>
</table>

As the MIPS program continues to mature, we are looking to find ways to improve our policies, including what to do with measures that do not meet the case minimum. Although many MIPS eligible clinicians can meet the 20-case minimum requirement, we recognize that small practices and individual MIPS eligible clinicians may have difficulty meeting this standard. Although we process data from the CY 2017 MIPS performance period to determine how often submitted measures do not meet case minimums, we invited public comment on ways
we can improve our case-minimum policy. In determining future improvements to our case minimum policy, our goal is to balance the concerns of MIPS eligible clinicians who are unable to meet the case minimum requirement and for whom we cannot capture enough data to reliably measure performance, while not creating incentives for MIPS eligible clinicians to choose measures that do not meet case minimum even though other more relevant measures are available.

We thank commenters for their suggestions and will consider them for future rulemaking.

In the CY 2019 PFS proposed rule (83 FR 35949), we proposed to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and to amend §414.1380(b)(1)(i) accordingly.

We also proposed to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend §414.1380(b)(1)(i)(B)(1) accordingly (83 FR 35949). This policy is part of our effort to move toward complete and accurate reporting that reflects meaningful effort to improve the quality of care that patients receive. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although we may revisit this policy through future rulemaking.

We requested comments on the proposals above. These comments and our responses are discussed below.

Comment: Several commenters supported the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case
minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period.

Response: We thank commenters for their support. However, we want to stress that these policies were not meant to be permanent and as clinicians continue to gain experience with the program we will revisit the appropriateness of these policies in future rulemaking.

Comment: A few commenters did not support our proposal to reduce points for measures that do not meet data completeness to zero starting with the CY 2020 MIPS performance period because of concerns that it would add complexity and burden as clinicians are continuing to learn the program. A few commenters suggested that CMS should return to assigning these measures 3 points or, at a minimum, continue to assign them 1 point or provide special scoring for MIPS eligible clinicians with significant administrative burdens. A few commenters recommended that clinicians should at least get some credit for attempting to report and, through no fault of their own, fail to meet the data completeness threshold, citing the difficulty of getting all the necessary data from hospitals and/or their billing companies to report on 60 percent of all applicable patients.

Response: We understand and recognize commenters’ concerns. However, as the program is being fully implemented, we want to ensure that our policies align with our goal of improving quality. This scoring policy was intended to be temporary, and we believe that data completeness is something that is within the direct control of clinicians. Although we understand that many clinicians have administrative burdens and we continuously strive to reduce paperwork, we also believe that it is important to develop policies that align with the program’s goal to improve quality of care. By the fourth year of implementation, we believe this policy is no longer needed and that removing this policy helps streamline our scoring policies.
After consideration of public comments, we are finalizing the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and the amending of §414.1380(b)(1)(i) accordingly.

After consideration of public comments, we are finalizing our proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend §414.1380(b)(1)(i)(B)(1) accordingly. Measures submitted by small practices will continue to receive 3 points for all future MIPS performance periods.

(vi) Scoring Flexibility for Measures with Clinical Guideline Changes During the Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD-10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018, through September 30, 2018, for the 2018 MIPS performance period). We noted that performance on measures that are not significantly impacted by changes to ICD-10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31). Lastly, we finalized that we will publish the list of measures requiring a 9-month assessment process on the CMS website by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period (for example, January 2, 2019, for the 2018 MIPS performance period). As part of our technical updates to §414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, these previously finalized policies are now referenced at §414.1380(b)(1)(viii).
We remain concerned about instances where clinical guideline changes or other changes to evidence supporting a measure occur during the performance period that may significantly impact a measure. Clinical guidelines and protocols developed by clinical experts and specialty medical societies often underpin quality measures. At times, measure stewards must amend quality measures to reflect new research and changed clinical guidelines, and sometimes, as a result of the change in these guidelines, adherence to guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. We sought comment in the CY 2018 Quality Payment Program final rule regarding whether we should apply scoring flexibility to measures significantly impacted by clinical guideline changes (82 FR 53716). We refer readers to the CY 2019 PFS proposed rule for a summary of the comments we received (83 FR 35949 through 35950).

We remain concerned that findings of evidence-based research, providing the basis for sound clinical practice guidelines and recommendations that are the foundation of a quality measure, may change outside of the rulemaking cycle. As the clinical evidence and guidelines change, approved measures may no longer reflect the most up-to-date clinical evidence and could be contrary to patient well-being. There may be instances in which changes to clinical guidelines are so significant, that an expedited review is needed outside of the rulemaking cycle because measures may result in a practice that is harmful to patients. To further align with policies adopted within other value based programs such as the Hospital VBP Program (83 FR 20409), we proposed to suppress a measure without rulemaking, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950). We would rely on measure stewards for notification in changes to clinical guidelines. We will publish on the CMS Web site
suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

In the CY 2019 PFS proposed rule (83 FR 35950), we proposed policies to provide scoring flexibility in the event that we need to suppress a measure during a performance period. Scoring for a suppressed measure would result in a zero achievement points for the measure and a reduction of the total available measure achievement points by 10 points. We believe that this approach effectively removes the impact of the eligible clinician’s inability to receive measure achievement points for the measure, if a submitted measure is later suppressed.

We also proposed to add a new paragraph at §414.1380(b)(1)(vii) that, beginning with the 2019 MIPS performance period, CMS will reduce the total available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians that submit a measure significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950).

We requested comments on the proposal above. These comments and our responses are discussed below.

**Comment:** A few commenters supported the proposal because it holds the clinician harmless from clinical guideline changes that impact quality measures. One commenter noted that it is important that clinicians are protected from any adverse impacts on their scoring when they are following updated clinical guidelines to ensure proper patient care and safety.

**Response:** We appreciate the support of the proposal.

**Comment:** Several commenters did not support the proposal. Commenters questioned whether there would be an expectation that the clinician would continue collecting data on the measure, or whether they would be allowed to submit the measure with less than 12 months’ data
for the suppressed measure. A few commenters stated the policy should only be applied if the clinical guideline change relates to patient harm or patient safety, in which case data collection on the quality measure should cease immediately. A few commenters indicated that clinicians invest significant time and resources to assess and improve their performance over the course of the performance period, and thus suppressing the scoring of a quality measure, unless patient harm is involved, does not appropriately recognize these efforts. One commenter suggested that CMS establish an attestation process through the EIDM system to allow clinicians the option to attest their intent to report the measure, and CMS should adjust their scoring accordingly.

**Response:** We appreciate the commenters’ suggestions. There are rare instances in which changes to clinical knowledge and guidelines can significantly impact measure specifications and the intent of the measure, which we believe requires suppression of scoring so as to encourage the clinicians to follow the guidelines that are best for the patient, rather than tracking the guidelines that were finalized in the measure set, which may negatively impact patient care. Clinical guideline changes that occur between rulemaking cycles would need to be significant enough that the change in the most up-to-date clinical evidence could result in patient harm if the clinician does not follow these new guidelines or otherwise provide misleading results as to what is measured as good quality care. We believe there are rare instances in which we should not delay our support of the use of the most current clinical evidence by continuing to require the collection of data and scoring the measure until the next rulemaking cycle. For example, a guideline may be updated because clinical evidence indicates that a new medication should replace a medication specified in a quality measure. If this occurs between rulemaking cycles, we would not want the scoring policy to disadvantage the clinicians adopting the updated guideline and using the recommended medication. We envision that this policy would be
applied in two circumstances. First, there is a newly issued or updated guideline where there is wide consensus that would result in a significant change to a quality measure. In these cases, it would be expected that clinicians would adopt clinical processes to support the new guideline which may not be compatible with the existing measures and could provide misleading results or patient harm. In this case, we anticipate the quality measure would be reviewed and updated during the next rulemaking process. Second, we envision using this policy in rare cases where there is a new or revised guideline, even if there is no broad consensus within the specialty, because some clinicians will begin to adopt the new guideline which would not be consistent with the quality measures and scoring the measure could cause misleading results for those clinicians. We believe it important to suppress the measure until guideline and quality measure are reviewed by the Measures Application Partnership (MAP) and other processes to support the Annual List of Measures, including rulemaking. We do not envision using this policy solely based on indications that guideline revisions are anticipated but not completed. Until the guideline is updated, clinicians would be expected to follow the existing guideline and it would not be prudent to use the scoring policy. Nor would we activate the policy if the guideline change does not significantly impact the measure results.

In the event of the need for the special scoring policy, we would communicate to clinicians through multiple channels regarding the changes. We appreciate that clinicians invest significant time and resources to select measures, we also believe it is critical that the measure results do not cause patient harm or otherwise harm clinician performance by scoring potentially misleading data. We believe suppressing the measure and reducing the total possible achievement points by 10 would recognize this effort by not forcing clinicians in the middle of a performance to select a new measure to report.
We appreciate the time and resources clinicians expend to collect data for a quality measure; however, we believe the policy will only be used in rare occasions, which will limit disruption to clinicians. We also believe that the policy will not disadvantage the clinician and will “hold harmless” any clinician submitting data on the measure. Scoring would be suppressed for any clinician that submitted data on the measure prior to the announcement. Similarly, given how rarely we anticipate we will need to use this policy, we do not believe we require a process for attestation regarding which measures will be selected prior to the performance period.

**Comment:** A few commenters recommended regular communication between CMS and measure stewards and supported the proposal that it would be the responsibility of the measure steward to notify CMS of changes to the clinical guidelines that may impact existing quality measures. One commenter requested that CMS allow multiple sources, rather than just measure stewards, to identify potential significant changes to clinical guidelines that may pose patient safety risks. Another commenter stated that only measure stewards should notify CMS of significant changes to clinical guidelines.

**Response:** We regularly monitor changes to quality measures and work closely with clinical organizations that maintain clinical guidelines and measure stewards to identify quality measures impacted by significant changes to clinical guidelines during the performance period. We will mainly rely on measure stewards to identify significant changes, especially those relating to potential patient harm. We clarify that measure stewards are not necessarily the owner and/or developer of the clinical guidelines. In many instances measure stewards defer to the clinical organizations or stakeholders who own, maintain and update the clinical guideline when changes are warranted. We intend to continue to work collaboratively with measure stewards, clinical organizations, measure owners and other key stakeholders responsible for the
maintenance of these guidelines prior to deciding to suppress the scoring of a measure. As noted above, if we decide to suppress these measures, we would notify clinicians through multiple means.

After consideration of public comments, we are finalizing a modification of our proposal and adding a new paragraph at §414.1380(b)(1)(vii) stating that, beginning with the 2021 MIPS payment year, we will reduce the denominator of available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. To clarify, we regularly monitor changes to quality measures and clinical guidelines and we will rely mainly on measure stewards, who often defer to the clinical organizations or other stakeholders who own, maintain and update the clinical guideline when a guideline change is warranted, for notification in changes to clinical guidelines. We will publish on the CMS Web site suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

(vii) Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2021 MIPS payment year, we will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that
the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

As discussed in section III.I.3.h.(1)(b) of this final rule, we proposed to revise our terminology regarding data submission. This updated terminology will more accurately reflect our current submissions and validation policies. In the CY 2019 PFS proposed rule (83 FR 35950), we proposed to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry.

We note that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician’s score according to the reweighting policies described in sections III.I.3.i.(2)(b)(ii) and III.I.3.i.(2)(b)(iii) of this final rule.

We did not receive any comments on this proposal.

We are finalizing our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

(viii) Small Practice Bonus

In the CY 2018 Quality Payment Program final rule (82 FR 53788), we finalized at §414.1380(c)(4) to add a small practice bonus of 5 points to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice as defined at §414.1305 and submit data on at least one performance category in the 2018 MIPS performance period.
We continue to believe an adjustment for small practices is generally appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap we have observed (based on historical PQRS data) for small practices in comparison to larger practices. We believe a small practice bonus specific to the quality performance category is preferable for the 2021 MIPS payment year and future years. We believe it is appropriate to apply a small practice bonus points to the quality performance category based on observations using historical data, which indicates that small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web Interface, and more likely to have lower performance rates in the quality performance category than other practices. We want the final score to reflect performance, rather than the ability and infrastructure to support submitting quality performance category data.

We considered whether we should continue to apply the small practice bonus through bonus points in all 4 performance categories, but believe the need for doing so is less compelling. The improvement activities performance category already includes special scoring for small practices (please refer to §414.1380(b)(3) and see section III.I.3.i.(1)(e) of this final rule for more information). In addition, for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR (see section III.I.3.h.(5) of this final rule). Finally, the cost performance category does not require submission of any data; therefore, there is less concern about a small practice being burdened by those requirements. For these reasons, we proposed to transition the small practice bonus to the quality performance category.

Starting with the 2021 MIPS payment year, we proposed at §414.1380(b)(1)(v)(C) to add a small practice bonus of 3 points in the numerator of the quality performance category for MIPS
eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure (83 FR 35950). Because MIPS eligible clinicians in small practices are not measured on the readmission measure and are not able to participate in the CMS Web Interface, they generally have a quality performance category denominator of 60 total possible measure achievement points. Thus, our proposal of 3 measure bonus points generally represents 5 percent of the quality performance category score. As described in section III.I.3.i.(2)(b)(iii) of this final rule, for clinicians in many small practices, the quality performance category weight may be up to 85 percent of the final score. (For example, if a small practice applies for the Promoting Interoperability significant hardship application and does not meet the sufficient case minimum for cost measures, then the weights of Promoting Interoperability and cost performance categories are redistributed to quality and the quality performance category weight would be 85 percent.)

With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices. We believe this is appropriate because it is similar to the impact of the small practice bonus we finalized for the 2020 MIPS payment year (5 points added to the final score). Although we recognize that the impact of the small practice bonus for MIPS eligible clinicians in small practices who do not receive reweighting for the cost and/or Promoting Interoperability performance categories will be less than 4.25 points added to the final score, we believe a consistent approach is preferable for simplicity, and we do not believe that a larger bonus is appropriate as that could potentially inflate the quality performance category score and the final score and mask poor performance.

29 We get 4.25 points using the following calculation: (3 measure bonus point/60 total measure points) * 85 percent * 100 = 4.25.
We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Some commenters supported the proposal and recommended that CMS continue to evaluate the least complicated method to apply the small practice bonus in future years. One commenter indicated that a small practice bonus should be retained as long as possible to support small practices. A few commenters recommended stability over several performance periods for the small practice bonus, with incentives maintained over time with no changes from year-to-year. One commenter recommended that CMS codify the small practice bonus for at least 3 years.

Response: We will evaluate MIPS data to determine whether any future adjustment is still needed based on analysis of the performance of small group practices compared to larger practices. While we appreciate commenters’ recommendations for stability in the bonus over time, we believe that we must be guided by the annual analysis of small practices’ experience with the Quality Payment Program to determine if the adjustment is still warranted. Any extension to the small practice bonus would be proposed through future rulemaking.

Comment: One commenter recommended bonus points be applied evenly across the following performance categories: quality; improvement activities; and Promoting Interoperability. Another commenter indicated that it did not support a bonus based on the size or location of the practice and recommended aligning the four performance categories and awarding bonuses for activities that apply across the performance categories. One commenter recommended that the clinician be allowed the option to have bonus points added to a performance category of his or her choice. A few commenters stated that small practices are consistently disadvantaged compared to large health systems for not only quality reporting, but
also requirements of other performance categories including Promoting Interoperability and improvement activities.

Response: We considered dividing the small practice bonus between the performance categories; however, we believe that spreading the bonus across performance categories may not be appropriate, and the other performance categories already take small practices into account.

As stated earlier, the improvement activities performance category already includes special scoring for small practices. The Promoting Interoperability performance category has a hardship exception for small practices. The cost performance category does not require submission of any data. For these reasons, we believe that it is appropriate for the small practice bonus to be in the quality performance category.

Comment: Many commenters did not support reducing the small practice bonus from 5 points in the final score to 3 measure bonus points in the quality performance category because of concerns that small practices will receive less points, which may not support small practices sufficiently. Several commenters stated that the bonus needs to be significant enough so that adjustments provide more equitable scoring to small practices. One commenter recommended that if the bonus is applied in the quality performance category, 5 points should be awarded.

Response: We understand commenters’ concerns. We recently estimated quality performance category scores for the 2019 MIPS performance period using data from the 2017 MIPS performance period. This new data was not available before the publication of the proposed rule. In this new analysis, we found that the number of eligible clinicians whose quality performance category was reweighted to 85 percent of the final score was lower than we anticipated. We found that for approximately three-fourths of the clinicians in small practices (and those not subject to the APM scoring standard), quality was weighted between 45 and 60
percent when we applying our proposed CY 2019 performance period policies to MIPS year 1 data. Thus, the 3 bonus points proposed (which generally represents 5 percent of the quality performance category score for small practices) would represent a lower overall bonus when added to the final score than we had originally anticipated. While we still believe that the small practice bonus should be applied to the quality category performance score, it was not our intention to lower the overall impact on the final score.

With our updated impact analysis in this final rule, we discovered that trends identified when we originally established the small practice bonus still exist. For example, in the CY 2018 Quality Payment Program proposed rule (82 FR 30139 through 30140), we noted that clinicians in practices with more than 100 clinicians may perform better in the Quality Payment Program on average compared to clinicians in smaller practices. We believed this trend was due primarily to two factors: participation rates and Web Interface reporting. While we estimate more clinicians in small practices are participating in MIPS in our updated model in this final rule compared to our estimates in the 2019 PFS proposed rule, we still see a gap in quality participation when comparing clinicians in small practices to clinicians in large practices (89.8 percent compared to 100.0 percent respectively). We also noticed a discrepancy in performance among those who submitted data for the quality performance category. Prior to applying a small practice bonus, the average quality score for submitters in small practices was 62 percent compared to 82 percent for clinicians in large groups. It is unclear whether the cause of the discrepancy is related to Web Interface reporting, to performance, or to factors related to data collection. While we continue to analyze the implications of these results, we believe increasing the small practice bonus from 3 to 6 measure bonus points for 1 year would be appropriate to ensure that we are correctly incentivizing participation during the transition years without
lowering the impact of the small practice bonus. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score. For those clinicians who have six measures and for whom the quality performance category weight is 45 percent, then the small practice bonus would equate to 4.5 final score points. For those with a quality performance category weight of 60 percent, the small practice bonus would equate to 6 final score points. We recognize that for some practices whose quality score is reweighted to 85 percent of their final score, this may account for a large part of the final score; however, based on the new CY 2017 MIPS performance period data, we do not believe this will be the case for a large proportion of small practices. On average, we estimate this change to the small practice bonus will add 4.4 points to the final score for clinicians in small practices who submit quality information to MIPS.

We want to remind readers that the small practice bonus was only meant to be temporary and as we further analyze CY 2017 MIPS performance period data we expect that the bonus will likely be reduced or removed in future rulemaking. While we currently believe that it is appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap for small practices in comparison to larger practices, we believe that upon further analysis of CY 2017 MIPS performance period data the small practice bonus may not address the underlying reasons for the disparate performance between small practices and other clinicians. As a result, we intend to revisit this bonus during next year’s rulemaking cycle.
Comment: Many commenters stated that the small practice bonus should not be embedded in the quality performance category and should be a standalone bonus at the final score level to reduce complication in scoring, provide greater flexibility, and reduce burden on small practices. Several commenters stated that the quality performance category is contributing less to the final score, since it is being reduced from 50 percent to 45 percent, and may be reduced in the future, which would continually reduce the small practice bonus. A few commenters noted that moving the bonus to the quality performance category provides additional scoring complexity and will not be equitable, since the bonus will be applied to small practices regardless of the number of measures submitted for the quality performance category. For example, the bonus of 3 points for a clinician being scored on one quality measure would translate to a higher contribution to the final score than applying a bonus of 3 points for a clinician being scored on 6 measures. One commenter was concerned that moving the small practices bonus to the quality performance category will remove the opportunity for a bonus from clinicians who do not, or cannot, report quality measures.

Response: We believe it is more appropriate for the small practice bonus to reside in the quality performance category because small practices have different reporting options than larger practices (for example, only small practices are able to submit data via Medicare Part B claims, but they cannot do so via the Web Interface), and burdens associated with submitting data could affect the quality performance category score. We also believe there is at least one quality measure that is relevant to the vast majority of clinicians in the Quality Payment Program. The small practice bonus is available to any small practice submitting at least one quality measure. We reiterate that we have special policies to assist small practices in the improvement activities and Promoting Interoperability performance categories, which limit the need for a small practice
bonus in those performance categories. The cost performance category does not require additional burden to submit information and does not have the same reporting restrictions as the quality performance category. Over time, we will monitor the weight of the quality performance category and the small practice contribution to the final score to determine if the amount of the small practice bonus needs to be adjusted. We acknowledge that moving the small practice bonus may add to the complexity of scoring, but, on balance, we believe it is appropriate to encourage the submission of quality measures. Also, we note that previously the small practice bonus was added to the final score regardless of the number of quality measures that were submitted. Although the bonus is now in the quality category, the equity of the bonus does not change with this policy. In addition, we will continue to monitor data to evaluate the performance of small practices in the quality performance category to determine differences between small and large practices and propose any necessary changed in future rulemaking.

**Comment:** One commenter requested clarification on how CMS will extend the small practice bonus to MIPS APMs.

**Response:** The small practice bonus will be applied to the final quality performance category score for MIPS APMs at the MIPS APM entity-level. For further discussion on our MIPS APM scoring policies, we refer readers to section III.I.3.h.(6) of this final rule.

**Comment:** One commenter indicated that the bonus score changes based on the reweighting of certain performance categories for clinicians, which they believe gives an advantage to clinicians who have a higher percentage of the score weighed to the quality performance category. One commenter did not support moving the bonus to the quality performance category, because the potential to reweight performance categories results in a
bonus that is not predictable during the performance period for clinicians, who do not know which performance categories will be reweighted.

Response: We appreciate that there might be differences in the reweighting of performance categories for small practices. As stated previously, we believe the quality performance category is an important component of the Quality Payment Program. While it was our intention to apply a bonus to the quality performance category with a cap approximately equal to the final score small practice bonus for the 2018 MIPS performance period/2020 MIPS payment year, we recognize that due to reweighting, the magnitude of the bonus will vary; however, in order to reduce complexity, we believe that a uniform bonus of 6 measure bonus points added to the numerator for quality is appropriate. As discussed in our response above, the policy is consistent with our other quality performance category bonuses because, for most clinicians, 6 measure bonus points is 10 percent of the 60-point denominator within the quality performance category. In addition, clinicians can predict whether their scores will be reweighted based on eligibility and special status information in the lookup tool. We will monitor the extent to which reweighting the quality performance category contribution to the final score affects quality measure bonus points awarded and so that we may keep the bonuses as equitable as possible.

Comment: A few commenters indicated that the small practice bonus should be extended to rural practices and different practice sizes. One commenter recommended extending the bonus to all rural practices, regardless of practice size, because of the belief that all rural practices struggle with access to resources. One commenter indicated a belief that the program offers few bonus points and opportunities for high scores for small and rural practices, which may result in a skewed scoring system that rewards large groups with resources to support
participation. One commenter recommended that the small practice bonus be available to groups with 10 or less participants, to align the definition with virtual group requirements. One commenter indicated that groups with more than 15 clinicians should be considered a small practice for purposes of the bonus.

Response: As discussed in the CY 2018 Quality Program final rule (82 FR 53778), we observed that performance for rural MIPS eligible clinicians is very similar to performance for non-rural MIPS clinicians once we account for practice size, so we do not believe a bonus for MIPS clinicians practicing in a rural setting is appropriate at this time. Additionally, we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53777) that we believe it is important to maintain a consistent definition of small practices within the Quality Payment Program. In addition, we have not seen discrepancies between simulated MIPS final scores for practices of 16 to 24 clinicians and for practices of 15 or fewer clinicians. However, we will continue to monitor this issue and assess whether there are scoring differences between small rural and small urban practices and, if so, address it in future rulemaking.

Comment: One commenter requested that CMS articulate how the policies proposed align with other CMS efforts to support the long-term, sustainable transformation of small practices and those serving rural and underserved communities.

Response: We recognize the unique challenges that eligible clinicians in small practices face and have established a unique set of policies to reduce their participation burden and ease their transition into the program. The special policies include the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies
available for small practices that do not have CEHRT (2018 Quality Payment Program final rule (82 FR 53683)); special scoring provisions available for the improvement activities performance category (82 FR 53656), and the provisions related to the low-volume threshold at section III.I.3.c. of this final rule. We are also continuing the Small, Underserved, and Rural Support initiative, which provides no-cost technical assistance to MIPS eligible clinicians in small practices. The initiative offers customized, one-on-one support to help MIPS eligible clinicians in small practices familiarize themselves with the program requirements, develop a strategy to successfully participate, and continue improving outcomes for beneficiaries. See: https://qpp.cms.gov/about/small-underserved-rural-practices for further information.

As discussed in the response above, we have estimated quality performance category scores using data from the 2017 MIPS performance period. As a result of this new data that was not available before the publication of the proposed rule we believe increasing the small practice bonus from 3 to 6 measure bonus points would be appropriate to ensure that we are correctly incentivizing participation without lowering the final score of small practices. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score.

After consideration of public comments, we are not finalizing as proposed the proposal to amend §414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 3 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to
MIPS on at least 1 quality measure. Instead, based on the rationale discussed previously, we are finalizing the amendment of §414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 6 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure.

(ix) Incentives to Report High-Priority Measures

In the CY 2017 Quality Payment Program final rule, we established a cap on high-priority measure bonus points for the first 2 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category (81 FR 77294). As part of our proposed technical updates to §414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policy on incentives to report high-priority measures is now referenced at §414.1380(b)(1)(v)(A). In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend §414.1380(b)(1)(v)(A)(1)(ii), accordingly (83 FR 35951).

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: One commenter supported the proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2019 performance period/2021 MIPS payment year.

Response: We thank the commenter for its support of our proposal.
After consideration of public comments, we are finalizing our proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend §414.1380(b)(1)(v)(A)(1)(ii), accordingly.

We established the scoring policies for high-priority measure bonus points in the CY 2017 Quality Payment Program final rule (81 FR 77293). We noted that, in addition to the required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure (81 FR 77293). We refer readers to §414.1380(b)(1)(v)(A) for more details on the high-priority measure bonus points scoring policies.

For the 2021 MIPS payment year, we proposed to modify the policies finalized in the CY 2017 Quality Payment Program final rule (and amend §414.1380(b)(1)(v)(A) accordingly) to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures (83 FR 35951). As we continue to move forward in implementing the MIPS program, we no longer believe that it is appropriate to award CMS Web Interface reporters measure bonus points to be consistent with other policies regarding selection of measures. Based on additional data analyses since the first-year policy was implemented, we have found that practices that elect to report via CMS Web Interface generally perform better than other practices that select other collection types. Therefore, the benefit of the bonus points is limited and instead we believe will create higher than normal scores. Bonus points were created as transition policies which were not meant to continue through the life of the program. Measure bonus points are also used to encourage the selection of additional high-priority measures. As the program matures, we have established other policies related to measures selection, such as applying a cap of 7 measure achievement points if a clinician selects and submits a measure that
has been topped out for 2 or more years; however, we have excluded CMS Web Interface
reporters from the topped out policies because reporters have no choice in measures. By the
same logic, since CMS Web Interface reporters have no choice in measures, we do not believe it
is appropriate to continue to provide additional high-priority measure bonuses for reporting CMS
Web Interface measures. We note the CMS Web Interface users may still elect to report the
CAHPS for MIPS survey in addition to the CMS Web Interface, and if they do, they would
receive the high priority bonus points for reporting the survey.

We requested comments on the proposal above. These comments and our responses are
discussed below.

Comment: A few commenters supported the proposal to discontinue awarding high-
priority measure bonus points to CMS Web Interface reporters because it strengthens the
incentive to report high-priority measures for those who actively elect to report these measures
and reduces the advantage for the large practices that are able to report through CMS Web
Interface. One commenter expressed support for the proposal because groups who report via
Web Interface perform better than groups who use alternative data collection types, have an
increased probability of earning higher quality performance category and overall higher MIPS
scores, and can still earn bonus points for reporting CAHPS for MIPS survey measures.

Response: We thank the commenters for their support as we look for ways to improve
our scoring policy.

Comment: Several commenters did not support the proposal to remove high-priority
bonus points for CMS Web Interface reporters. One commenter stated it would disincentivize
clinicians and groups from participating in APMs and stated that ACOs do not have an
alternative submission method. Another commenter suggested that the bonus points should
continue for non-MIPS APM participants because these submitters voluntarily choose a larger and more difficult and complex set of measures than are required. A few commenters stated that there is not an option to submit additional high-priority measures to earn these bonus points and that this proposal disadvantages ACOs which have demonstrated a high commitment to quality as evidenced by recent MIPS performance feedback reports. One commenter recommended that CMS should not remove all bonus points until it proposes to do the same for the other collection types. A few commenters suggested delaying removal of the bonus points to allow clinicians sufficient notice and until further information and insight is gained about performance in these measures. One commenter stated that the policy penalizes Web Interface reporters for their commitment to measures that truly reflects their practices.

Response: The high priority measure bonus points were intended to encourage the selection of certain measures. As we work towards improving our scoring policy to align with our goals of improving quality of care, we no longer believe we should award bonus points to CMS Web Interface reporters because they do not select individual measures to report, rather the Web Interface is a measurement set. This bonus policy was meant to be temporary, and we believe that as the MIPS program goes into its third year it is an appropriate time to begin to limit the assignment of high priority bonus points. While we recognize the commenters’ concerns, the removal of the bonus was not intended to penalize Web Interface reporters and we still have several special policies available for Web Interface reporters. We have excluded CMS Web Interface reporters from the topped out measure cap (82 FR 53576), so although they are no longer able to receive this bonus, they are still able to receive maximum achievement points for all measures, even though some of the CMS Web Interface measures may be considered topped
Additionally, CMS Web Interface reporters are still able to receive measure bonus points for reporting the CAHPS for MIPS survey and for end-to-end reporting.

We will consider commenters’ concerns in future rulemaking.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures and to amend 414.1380(b)(1)(v)(A) accordingly.

As part of our move towards fully implementing the high value measures as discussed in section III.I.3.h.(2)(b)(iv) of this final rule, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intend to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year (83 FR 35951).

We thank commenters for suggestions and may consider them for future rulemaking.

(x) Incentives to Use CEHRT to Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. Under §414.1380(b)(1)(xv), 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria. In order to receive the bonus for end-to-end reporting, eligible clinicians must use the 2015 Edition CEHRT. We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77297) and section III.I.3.h.(2)(b)(i) of this final rule for further discussion on our certification requirements for the end-to-end reporting bonus. As part of our proposed technical updates to §414.1380(b)(1) discussed in section
III.I.3.i.(1)(b) of this final rule, our previously established electronic end-to-end reporting bonus point scoring policy is now referenced at §414.1380(b)(1)(v)(B).

In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year (83 FR 35951). We also proposed to continue to assign bonus points for end-to-end electronic reporting for the 2021 MIPS payment year, as we have seen that this policy encourages electronic reporting. We proposed to amend §414.1380(b)(1)(v)(B) accordingly.

We requested comments on the proposal above. These comments and our responses are discussed below.

**Comment:** Several commenters supported maintaining the bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and requested that CMS continue to assign them in future years. One commenter noted that continuing the bonus points beyond the 2021 MIPS payment year will allow clinicians in smaller practices who are not yet capable of end-to-end electronic reporting an opportunity to do so. Another commenter supported the bonus only if those that are not able to submit using end-to-end electronic reporting have access to CEHRT at no cost to the clinician. One commenter suggested that CMS continue the bonus points until the program is more mature and additional data on performance and reporting is gathered. A few commenters who supported maintaining the bonus points beyond the 2021 MIPS payment year, stated that the removal of the bonus points would result in increased administrative burden to CMS and clinicians, and would adversely affect the ability for clinicians with limited quality measures available to earn bonus points.

**Response:** While we signaled our intent to discontinue bonus points for end-to-end electronic reporting in the future (83 FR 35951), we are taking into consideration the suggestions
we received on additional ways we can incentivize and encourage these reporting methods for future rulemaking.

After consideration of public comments, we are finalizing our proposals to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and to amend §414.1380(b)(1)(v)(B) accordingly.

We also proposed to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35951). We proposed that the end-to-end reporting bonus can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298). However, the end-to-end reporting bonus would not be applied to the claims submission type because it does not meet the criteria discussed above. This is not a policy change but rather a clarification of our current process in light of the proposed terminology changes.

We did not receive any comments on this proposal.

After consideration of public comments, we are finalizing our proposals to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology and only apply the bonus to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298).

As discussed in section III.I.3.i.(1)(b)(x) of this final rule, we believe that in the future, bonus points for end-to-end reporting for all submission types will no longer be needed as we move towards fully implementing the program, and as a result we intend to consider in future rulemaking modifying our scoring policy to no longer offer end-to-end reporting bonus points
after the 2021 MIPS payment year (83 FR 35951). Consistent with the section 1848(q)(5)(B)(ii) of the Act, which requires the Secretary to encourage the use of CEHRT for quality reporting, we will continue to be committed to ways that we can incentivize and encourage these reporting methods. We invited comment on other ways that we can encourage the use of CEHRT for quality reporting.

We thank commenters for suggestions and will consider them for future rulemaking.

(xi) Calculating Total Measure Achievement and Measure Bonus Points

(A) Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77300, and 82 FR 53733 through 53736, respectively), we established the policy for calculating total measure achievement and measure bonus points for Non-CMS Web Interface reporters. We refer readers to §414.1380(b)(1) for more details on these policies.

We did not propose any changes to the policy for scoring submitted measures collected across multiple collection types; however, we provided a summary of how this policy will be scored using our new terminology (83 FR 35952). We noted that CMS Web Interface and facility-based measurement each have a comprehensive set of measures that meet the proposed MIPS category requirements. As a result, we did not combine CMS Web Interface measures or facility-based measurement with other ways groups can be scored for data submitted for MIPS (other than CAHPS for MIPS, which can be submitted in conjunction with the CMS Web Interface). We refer readers to section III.I.3.i.(1)(d) of this final rule for a description of our policies on facility-based measurement (83 FR 35956 through 35963).
Although we have established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, we anticipate that this will be a rare circumstance and do not encourage clinicians to submit the same measure collected via multiple collection types. Table 51 is included in this final rule for illustrative purposes and clarity due to the changes in terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35893 through 35895). For further discussion of this example, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53734).
### TABLE 51: Example Assigning Total Measure Achievement and Bonus Points for an Individual MIPS Eligible Clinician Who Submits Measures Collected Across Multiple Collection Types

<table>
<thead>
<tr>
<th>Measure Achievement Points</th>
<th>Six Scored Measures</th>
<th>High-Priority Measure Bonus Points</th>
<th>Incentive for CEHRT Measure Bonus Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIPS CQMs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure A (Outcome)</td>
<td>7.1</td>
<td>7.1</td>
<td>(required outcome measure does not receive bonus points)</td>
</tr>
<tr>
<td>Measure B</td>
<td>6.2</td>
<td>(points not considered because it is lower than the 8.2 points for the same claims measure)</td>
<td></td>
</tr>
<tr>
<td>Measure C (high priority patient safety measure that meets requirements for additional bonus points)</td>
<td>5.1</td>
<td>(points not considered because it is lower than the 6.0 points for the same claims measure)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Claims</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure A (Outcome)</td>
<td>4.1</td>
<td>(points not considered because it is lower than the 7.1 points for the same MIPS CQM)</td>
<td>No bonus points because the MIPS CQM of the same measure satisfies requirement for outcome measure.</td>
</tr>
<tr>
<td>Measure B</td>
<td>8.2</td>
<td>8.2</td>
<td></td>
</tr>
<tr>
<td>Measure C (High priority patient safety measure that meets requirements for additional bonus points)</td>
<td>6.0</td>
<td>6.0</td>
<td>No bonus (Bonus applied to the MIPS CQMs)</td>
</tr>
<tr>
<td>Measure D (outcome measure &lt;50% of data submitted)</td>
<td>1.0</td>
<td>(no high priority bonus points because below data completeness)</td>
<td></td>
</tr>
<tr>
<td><strong>EHR (direct submission using end-to-end)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure E</td>
<td>5.1</td>
<td>5.1</td>
<td>1</td>
</tr>
<tr>
<td>Measure F</td>
<td>5.0</td>
<td>5.0</td>
<td>1</td>
</tr>
<tr>
<td>Measure G</td>
<td>4.1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Measure H</td>
<td>4.2</td>
<td>4.2</td>
<td>1</td>
</tr>
<tr>
<td>Measure I (high priority patient safety measure that is below case minimum)</td>
<td>3.0</td>
<td>(no high priority bonus points because below</td>
<td>1</td>
</tr>
</tbody>
</table>

**Reporting that meets CEHRT/bonus point criteria**
<table>
<thead>
<tr>
<th>Measure Achievement Points</th>
<th>Six Scored Measures</th>
<th>High-Priority Measure Bonus Points</th>
<th>Incentive for CEHRT Measure Bonus Points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>35.6</td>
<td>1 (below 10% cap&lt;sup&gt;1&lt;/sup&gt;)</td>
<td>5 (below 10% cap)</td>
</tr>
</tbody>
</table>

Quality Performance Category Percent Score Prior to Improvement Scoring

(35.6 + 1 + 5) / 60 = 69.33%

<sup>1</sup> In this example, the cap would be 6 points, which is 10 percent of the total available measure achievement points of 60.

We did not propose any changes to our policy regarding scoring measure achievement points and bonus points when using multiple collection types for non-Web Interface MIPS eligible clinicians in the quality performance category for the 2019 MIPS performance period.

(B) Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77302 through 77306, and 82 FR 53736 through 82 FR 53737, respectively), we finalized the scoring policies for CMS Web Interface reporters. As part of our technical updates to §414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policies for CMS Web Interface reporters are now referenced at §414.1380(b)(1)(i)(A)(2)(i) and (b)(1)(v)(A).

(xii) Future Approaches to Scoring the Quality Performance Category

As we discuss in section III.I.3.h.(2)(b)(iv) of this final rule, we anticipate making changes to the quality performance category to reduce burden and increase the value of the measures we are collecting. We discussed that existing measures have differing levels of value and our approaches for implementing a system where points are awarded based on the value of the measure. Should we adopt these approaches, we anticipate needing to modify our scoring approaches accordingly. In addition, we have received stakeholder feedback requesting that we
simplify scoring for the quality performance category. Therefore, we solicited comment on the following approaches to scoring that we may consider in future rulemaking and whether these approaches move the clinicians towards reporting high value measures and more accurate performance measurement (83 FR 35954 through 35955).

One option for simplification is restructuring the quality requirements with a predetermined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. Further, we would categorize MIPS and QCDR measures by value, because we recognize that not all measures are created equal. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collection of information. A system to classify measures as a particular value (for example, gold, silver, or bronze) is discussed in section III.I.3.h.(2)(b)(iv) of this final rule. In this approach, the highest tier would include measures that are considered “gold” standard, such as outcome measures, composite measure, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high-value measure. Measures considered in the second tier, or at a “silver” standard, would be process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement, or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures, would have scoring caps in place that would reflect the measure’s status as a “bronze measure.” In this scenario, we could envision awarding points for achievement as follows: up to 15 to 20 points in the top tier; up to 10 points in the next tier; and up to 5 points in the lowest tier. Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as
many measures to MIPS. We would still want to ensure the submission of high value measures and might include requirements that restrict the number of lower tier measures that could be submitted; alternatively, we could add a requirement that a certain number of higher tier measures would need to be submitted. With this approach, we could still incentivize reporting on high-priority measures by classifying them as “gold” standard measures which would be eligible for up to 15 to 20 achievement points.

Alternatively, we could keep our current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator but change the minimum number of measure achievement points available to vary by the measure tier. For example, high-tier measures could qualify for high priority bonus and/or have a higher potential floor (for example, 5 measure achievement points instead of the floor of 3 measure achievement points for “gold” standard measures, which would be eligible for up to 10 measure achievement points.); whereas low-tier measures could have a lower floor (for example, 1 measure achievement point instead of the floor of 3 measure achievement points for “bronze standard’ measures).

Taking into consideration the potential future quality performance category change, we also believe that removing the validation process to determine whether the eligible clinician has measures that are available and applicable would simplify the quality performance category significantly. Several stakeholders have expressed their confusion with the validation process. A move to sets of measures in the quality performance category, potentially with some criteria to define the clinicians for whom these measures are applicable, would eliminate the need for a validation process for measures that are available and applicable. Moving to sets of measures would also enable us to develop more robust benchmarks. We also believe that in the next few
years, we could remove the validation process for measures that are available and applicable if we set the denominator at a pre-determined level (as outlined in the example above at 50 points) and let clinicians determine the best method to achieve 50 points. For the 2019 and 2020 MIPS payment years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points (small practices receive 3 points regardless of whether they meet data completeness). Through stakeholder engagement, particularly feedback provided by QCDRs who have developed their own measures, we have heard that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks. Eligible clinicians have voiced concern on reporting on QCDR measures without benchmarks because they are not certain that a benchmark could be calculated and established for the MIPS performance period, and they would therefore be limited to a 3-point score for that QCDR measure. In addition, QCDRs have inquired about the possibility of creating QCDR benchmarks. To encourage reporting of QCDR measures, we sought comment on an approach to develop QCDR measure benchmarks based off historical measure data. This may require QDCRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. We anticipate that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. Detailed discussion of the self-nomination period timeline and requirements can be found in section III.I.3.k of this final rule. Our concern with utilizing historical data provided by QCDRs to develop benchmarks is whether QCDRs have the capability to filter through their historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical data to CMS for QCDR measure benchmarking consideration.
Furthermore, once the historical data is submitted by the QCDR, CMS would analyze the data to ensure that it met benchmarking standards prior to it being accepted to form a benchmark. However, to perform this analysis CMS may need additional data elements such as the sources of the data, data completeness, and the collection period. In addition to seeking comment on developing QCDR measure benchmarks from historical data, we also solicited comment as to how our aforementioned concerns may be addressed in future rulemaking.

We also recognize that improving the electronic capture, calculation, and reporting of quality measures is also an important component of reducing provider burden. We invited comment on how we can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described under this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.

We solicited comment on these approaches and other approaches to simplify scoring, provide incentives to submit more impactful measures that assess outcomes rather than processes, and develop data that can show differences in performance and determine clinicians that provide high value care (83 FR 35954 through 35955).

We thank commenters for suggestions and will consider them for future rulemaking.

(xiii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

Section 1848(q)(5)(D)(i) of the Act stipulates that, beginning with the second year to which the MIPS applies, if data sufficient to measure improvement is available, the improvement of the quality performance category score for eligible clinicians should be measured. To measure improvement, we require a direct comparison of data from one Quality Payment Program year to another (82 FR 52740). For more descriptions of our current policies, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53737 to 53747). As part of our technical
updates to §414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established improvement scoring policies are now referenced at §414.1380(b)(1)(vi).

In the CY 2018 Quality Payment Program final rule, we adopted a policy that MIPS eligible clinicians must fully participate to receive a quality performance category improvement percent score greater than zero (82 FR 53743 through 53745). In §414.1380(b)(1)(vi)(F), we determined “participation” to mean compliance with §414.1330 and §414.1340 in the current performance period. We issued a technical correction for the CY 2018 Quality Payment Year final rule, replacing §414.1330 with §414.1335 since §414.1335 is more specific because it discusses the quality performance category requirements.

We finalized at §414.1380(b)(1)(vi)(C)(4) that we would compare the 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year (82 FR 53744 through 53745). In the CY 2019 PFS proposed rule, we proposed to continue this policy for the 2019 MIPS performance period and amend §414.1380(b)(1)(vi)(C)(4), accordingly (83 FR 35955). We proposed to compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent.

The following is a summary of the public comments on the proposal and our responses:

Comment: One commenter supported the proposal.

Response: We thank the commenter for its support.

After consideration of public comments, we are finalizing the proposal to continue our previously established policy for the 2019 MIPS performance period and amend §414.1380(b)(1)(vi)(C)(4), accordingly. Specifically, we will compare the 2019 performance to
an assumed 2018 quality performance category achievement percent score of 30 percent if a
MIPS eligible clinician earned a quality performance category score less than or equal to 30
percent in the previous year.

(xiv) Calculating the Quality Performance Category Percent Score Including Achievement and
Improvement Points

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77300 and 82
FR 53747 through 53748, respectively), we finalized the policies on incorporating the
improvement percent score into the quality performance category percent score. As part of our
technical updates to §414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our
previously established policies are now referenced at §414.1380(b)(1)(vii).

(c) Scoring the Cost Performance Category

(i) Scoring Achievement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring achievement
in the cost performance category, we refer readers to the CY 2017 Quality Payment Program
final rule (81 FR 77308 through 77311) and the CY 2018 Quality Payment Program final rule
(82 FR 53748 through 53749). In the CY 2017 Quality Payment Program final rule (81 FR
77308 through 77309), we established that we will determine cost measure benchmarks based on
cost measure performance during the performance period. We also established that at least 20
MIPS eligible clinicians or groups must meet the minimum case volume that we specify for a
cost measure in order for a benchmark to be determined for the measure, and that if a benchmark
is not determined for a cost measure, the measure will not be scored. We proposed to codify
these final policies at §414.1380(b)(2)(i) (83 FR 35955 through 35956).
While we did not receive any public comments for this proposal, we are finalizing our proposal to codify these final policies at §414.1380(b)(2)(i).

(ii) Scoring Improvement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring improvement in the cost performance category, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53749 through 53752). Section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take into account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. We do not believe this change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category percent score for each of the 2020 through 2023 MIPS payment years. Therefore, we proposed to revise §414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points (83 FR 35955). Under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under our proposal, the maximum cost improvement score for the 2020 MIPS payment year would be zero percentage points. We also proposed at §414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year (83 FR 35956). The following is a summary of the public comments received on these proposals and our responses:
Comment: A few commenters supported the proposals to set the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years at zero percentage points.

Response: We thank the commenter for their support.

Comment: Several commenters requested that the cost performance category score be determined in a different manner because of the proposed inclusion of episode-based measures. A few commenters recommended that the new measures have a lower weight in determining the cost performance category score than the previously-established MSPB and total per capita cost measures. A few commenters recommend that similar to the quality performance category, only the 6 measures with the highest scores among those for which the clinician or group met the case minimum should be included in calculating the cost performance category score. Likewise, a few commenters recommended that similar to the quality performance category, scores for cost measures should not be below 3 out of 10 points. One commenter recommended that a cost performance category score not be calculated if a clinician or group only meets the case minimum for a single cost measure.

Response: We do not believe that the inclusion of new measures in the cost performance category necessitates a change in the determination of the cost performance category score. Measures in the cost performance category differ from quality measures because they do not require reporting on the part of the clinicians outside of the usual claims submission process. Therefore, there is no choice of measures for clinicians nor burden of reporting. We believe that this is an important consideration in maintaining a simpler scoring mechanism in the cost performance category and scoring all measures for which an individual or group meets the case minimum. Some groups due to their size and comprehensiveness will meet the case minimum for
all cost measures. Other individuals and groups will meet the case minimum for fewer measures. A scoring policy that would only score the top 6 measures in the cost performance category would provide an advantage for those groups with more than 6 measures because it would disregard those measures on which performance was poorest. For example, a group that met the case minimum for 10 measures and scored in the lowest decile for the total per capita cost score and the highest decile for all other measures, would have the score for the total per capita measure dropped and would receive the highest possible score in the cost performance category. A group that met the case minimum for only 6 measures, and also performed in the lowest decile for the total per capita cost score and the highest decile for the other 5 cost measures for which it met the case minimum, would not have performance on this measure disregarded and receive a lower score.

We believe that not scoring clinicians and groups that meet the case minimum for only a single measure would fail to recognize that a single measure, such as total per capita cost, could reflect care provided to a large number of patients.

After consideration of the public comments, we are finalizing as proposed our proposal to revise §414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. We are also finalizing as proposed our proposal at §414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year.

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

(i) Background
In the CY 2018 Quality Payment Program final rule, we established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53752 through 53767). We originally proposed a facility-based measurement scoring option for the 2018 MIPS performance period. We did not finalize the policy because we were concerned that we would not have the operational ability to inform clinicians early enough in the 2018 MIPS performance period to allow them to consider the consequences and benefits of participation (82 FR 53755).

(ii) Facility-Based Measurement Applicability

(A) General

In the CY 2018 Quality Payment Program final rule, we limited facility-based reporting to the inpatient hospital in the first year for several reasons, including because a more diverse group of clinicians (and specialty types) provide services in an inpatient setting than in other settings, and because the Hospital Value-Based Purchasing (VBP) Program adjusts payment to hospitals for inpatient services in connection with their performance under that program (82 FR 53753 through 53755). We also limited measures applicable for facility-based measurement to those used in the Hospital VBP Program because the Hospital VBP Program compares hospital performance on a series of different measures intended to capture the breadth of inpatient care in the facility (82 FR 53753). We noted that we were open to the consideration of additional facility types in the future but recognized that adding a facility type would be dependent upon whether CMS has established a value-based purchasing program for that facility type, the applicability of measures, and our ability to appropriately attribute a clinician to a facility (82 FR 53754). Please note that when we use the term value-based purchasing, we are referring in
general to value-based purchasing programs or scores, and not specifically the Hospital VBP Program, unless specifically stated.

We did not propose to add additional facility types for facility-based measurement, but we are interested in potentially expanding to other settings in future rulemaking. Therefore, in section III.I.3.i.(1)(d)(vii) of this final rule, we outline several issues on which we requested feedback and would need to be resolved in order to expand this option to a wider group of facility-based clinicians in future years.

(B) Facility-Based Measurement by Individual Clinicians

In the CY 2018 Quality Payment Program final rule, we established individual eligibility criteria for facility-based measurement at §414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS (82 FR 53756 through 53757) is eligible as an individual for facility-based measurement. We had noted, as a part of our proposal summary, that we would use the definition of professional services in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). For purposes of determining eligibility for facility-based measurement, we discussed CMS using data from the period between September 1 of the calendar year, 2 years preceding the MIPS performance period, through August 31 of the calendar year preceding the MIPS performance period, with a 30-day claims run out but did not finalize that as part of the applicable regulation (82 FR 53756 through 53757). Because we are using the quality measures associated with the inpatient hospital to determine the MIPS quality and cost performance
category score, we wanted to ensure that eligible clinicians contributed to care in that setting during that time period.

We indicated that CMS will use POS code 21 (inpatient) and POS code 23 (emergency department) for this purpose (82 FR 53756). Commenters on our proposal (as summarized in the CY 2018 Quality Payment Program final rule (82 FR 53756 through 53757)) expressed concern that adopting the definition that we did for facility-based clinicians would limit the number of clinicians who would be eligible.

In the CY 2019 PFS proposed rule, we proposed to modify our determination of a facility-based individual at §414.1380(e)(2)(i) in four ways (83 FR 35957). First, we proposed to add on-campus outpatient hospital (as identified in the POS code in the HIPAA standard transaction, that is, POS code 22) to the settings that determine whether a clinician is facility-based. Second, we proposed that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. Third, we proposed that, if we are unable to identify a facility with a value-based purchasing score to attribute as a clinician’s performance, that clinician is not eligible for facility-based measurement. Fourth, we proposed to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed in section III.I.3.b. of this final rule. We explain these four proposals from the proposed rule in this section. In the CY 2019 PFS proposed rule, we stated our belief that these proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting.

First, we proposed to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement (83 FR 35957). We
agree with commenters that limiting the eligibility to our current definition may prevent some clinicians who are largely hospital-based from being eligible. However, expanding eligibility without taking into account the relationship between the clinician and the facility and facility’s performance could result in unfairly attributing to a clinician performance for which the clinician is not responsible or has little to no role in improving. We do believe that a significant provision of services in the on-campus outpatient hospital are reflected in the quality captured by the Hospital VBP Program. For example, patients in observation status are typically treated by the same staff and clinicians as those who meet the requirements for inpatient status. Although there are some clinical differences that may result in a patient having observation status, we believe that the quality of care provided to these patients in this same setting would be comparable, reflecting the overall healthcare system at that particular location. In the CY 2019 PFS proposed rule, we stated our conviction, based on this that a sufficient nexus exists for attributing the hospital’s VBP Total Performance Score to clinicians that provide services in on-campus outpatient hospital settings.

Second, we proposed to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement (83 FR 35957). Although we generally believe that clinicians who provide services in the outpatient hospital can affect the quality of care for inpatients, we noted in the CY 2019 PFS proposed rule our belief that a clinician who is measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. We explained our concern about attributing inpatient facility performance to clinicians who provide at least 75 percent of their services at on-campus outpatient hospitals (with POS code 22) when such clinicians exclusively provide outpatient services that are unrelated to inpatient
hospital service by describing an example: a dermatologist who provides office-based services in a hospital-owned clinic but who never admits or treats patients within the inpatient or emergency room setting does not meaningfully contribute to the quality of care for patients measured under the Hospital VBP Program.

We stated in the CY 2019 PFS proposed rule how we had considered different ways to best identify those who contribute to the quality of care in the inpatient setting while keeping the facility-based scoring option as simple as possible. We provided one explanation of an alternative we had considered: separately measuring the HCPCS codes for observation services; however, as also noted in the proposed rule, we believe that such a measurement may not fairly consider services provided by clinicians for whom observations services may be embedded in a global code for a procedure rather than billed as a separate observation service. We also considered requiring a clinician to provide a certain percentage of services with the inpatient hospital POS. We described how we had not identified a threshold (other the one claim threshold we proposed) that would more meaningfully differentiate clinicians who provide services with the outpatient hospital POS code versus those who do not contribute to the services that would be measured under the Hospital VBP Program. We identified our goal of ensuring that the program rules are clear and easily applied to clinicians, so as to both avoid confusion on program participation requirements and to meet overall agency goals to increase transparency in the agency’s activities. Our proposal of using a single service as the threshold would provide a simple, bright-line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services as well as outpatient services. We explained in the proposed rule that this would limit the chance of clinicians who exclusively practice in the outpatient setting being measured on the Hospital VBP Program’s performance of an unrelated hospital. We
recognized this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility and solicited comment on whether a better threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating unnecessary or inappropriate barriers to eligibility for facility-based measurement.

We explained in the proposed rule our rationale and reasoning for these first two proposals as being based in large part on our analysis of the previously finalized policy for eligibility for the facility-based measurement scoring option. Using claims data, we had identified all clinicians that would be MIPS eligible as either an individual or group, and identified the POS codes submitted for PFS services provided by those clinicians. We then modeled the existing final policy based on inpatient and ER services. Although almost all ER physicians would be scored under facility-based measurement, a relatively small percentage of clinicians in other specialties, even those which we expected to have significant presence in the hospital, would be eligible for the facility-based measurement scoring option. For example, only 13.45 percent of anesthesiologists would be eligible for the facility-based measurement scoring option under the policy finalized in the CY 2018 Quality Payment Program final rule. Adding the on-campus outpatient hospital POS code substantially increased eligibility for the facility-based measurement scoring option in our modeling, even after we adjusted for requiring one service with the inpatient or emergency department POS. Under our proposal, our model illustrated that 72.55 percent of anesthesiologists would be eligible. However, the model did not show that the proposal would substantially increase the number of clinicians eligible for the facility-based measurement scoring option who, based on specialty identification, may not have a significant presence in the hospital. For example, the modeling of the proposed policy projected
an increase in the percentage of family physicians eligible for the facility-based measurement scoring option from 11.34 percent to 13.86 percent, which is still a very small percentage of those clinicians.

Third, we proposed to add a new criterion (to be codified at §414.1380(e)(2)(i)(C)) that stated to be eligible for facility-based measurement, we must be able to attribute a clinician to a particular facility that has a value-based purchasing score (83 FR 35957 through 35958). We explained in the proposed rule how, for facility-based measurement to be applicable, we must be able to attribute a clinician to a facility with a value-based purchasing score. Based on our definition of facility-based measurement, we stated that this means a clinician must be associated with a hospital with a Hospital VBP Program Total Performance Score. We explained our concern that the proposed expansion of eligibility for facility-based measurement would increase the number of clinicians eligible for facility-based measurement but to whom we would be unable to attribute the performance of a particular facility that has a value-based purchasing score. As we noted in the CY 2018 Quality Payment Program final rule (82 FR 53766), some hospitals do not have a Hospital VBP Program Total Performance Score that could be used to determine a MIPS quality and cost performance category score, such as hospitals in the state of Maryland. Hence, clinicians associated with those hospitals would not be able to use facility-based measurement but could report quality measures through another method and have cost measures calculated if applicable. We explained that, under our proposal, a similar result, although relatively rare, would happen if we could not attribute a clinician identified as facility-based to a specific facility; those clinicians who are identified as facility-based but whom we cannot attribute to a hospital would have to participate in MIPS quality reporting through another method, or they would receive a score of zero in the quality performance category. Therefore,
we proposed to add the requirement to §414.1380(e)(2)(i)(C) that a clinician must be able to be attributed to a particular facility with a value-based purchasing score under the methodology specified in §414.1380(e)(5) to be eligible for facility-based measurement. The cross-reference to paragraph (e)(5) is to the methodology we also proposed for determining the applicable facility score to be used. Our proposed new regulatory text at §414.1380(e)(2)(i)(C) addresses both attribution to a facility and the need for that facility to have a value-based purchasing score by conditioning eligibility for facility-based scoring for an individual clinician on the clinician being attributed under the methodology in paragraph (e)(5) to a facility with a value-based purchasing score.

Fourth, we proposed to change the dates of determining eligibility for facility-based measurement (83 FR 35958). In section III.M.3.b. of the proposed rule, we proposed to modify the dates of the MIPS determination period that would provide eligibility determination for small practice size, non-patient facing, low-volume threshold, ASC, hospital-based, and facility-based determination periods. To align this regulation controlling facility-based scoring with these other determination periods, we proposed that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out, in determining eligibility for facility-based measurement.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported the four proposed changes to the determination of a facility-based individual.

Response: We appreciate the commenters’ support.
Comment: One commenter recommended that CMS include the place of service code used for the off-campus outpatient hospital (POS code 19) in determining individual eligibility for facility-based measurement, noting that many clinicians work in both on-campus and off-campus outpatient hospital settings. The commenter further suggested the inclusion of the measures from the Hospital Outpatient Quality Reporting Program.

Response: While we are finalizing our proposal to add on the on-campus outpatient code (POS code 22), we disagree that the off-campus outpatient hospital setting (POS code 19) indicates that a clinician has a significant impact on the quality and cost within an inpatient hospital setting in the way that POS code 22 might. A clinician may work at an off-campus outpatient hospital setting that is miles from the hospital and not have any involvement with patients that are hospitalized. We do not believe the Hospital VBP Program measures, which reflect the quality of care furnished to patients in hospitals in inpatient settings, are applicable to (or relate to the performance of) those clinicians who primarily bill within the off-campus outpatient hospital setting; therefore, we do not believe such clinicians should be eligible for facility-based measurement.

While the measures used in the Hospital Outpatient Quality Reporting Program do reflect quality for the off-campus outpatient hospital, section 1848(q)(2)(C)(ii) of the Act provides that we may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. Our determination of facility-based measurement does not consider the specialty of clinicians, so we therefore do not believe it is appropriate or consistent with the statutory authority to add this setting or these measures at this time.
Comment: One commenter recommended that the threshold of services required to be provided in facilities to be eligible for facility-based measurement be reduced from 75 percent to more than 50 percent of services, because clinicians often work in multiple settings.

Response: As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53757), we believe the 75 percent threshold is appropriate to use because it is similar to our determination of hospital-based eligible clinicians in the Promoting Interoperability performance category. In the context of our proposal to change the eligibility criteria for facility-based measurement, we still believe that a 75 percent threshold indicates that a clinician is spending much of their clinical time working in a hospital and the quality of their work is reflected in that setting. Clinicians who work in more varied settings may be better measured through another method of participating in MIPS.

Comment: One commenter recommended that CMS not include the requirement to bill at least a single service with the POS code used for the inpatient hospital or emergency room as this requirement could easily be gamed.

Response: We continue to believe that using a single service as the threshold provides a simple, bright line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services, as well as outpatient services. We will monitor this requirement and may consider changing it in future rulemaking if we find evidence or examples of gaming, such as that clinicians are providing services in the inpatient setting primarily so they may meet the requirements of facility-based measurement.

Comment: Several commenters supported the facility-based measurement and the proposed policies because this option would reduce burden and recognize the joint accountability for measures in the hospital environment.
Response: We appreciate the commenters’ support as we begin to implement facility-based measurement in the 2019 MIPS performance period/2021 MIPS payment year.

Comment: Several commenters requested that CMS provide more data analysis on the implementation of facility-based measurement. A few commenters noted concerns with how the facility-based scoring option could contribute to an uneven playing field. Commenters’ concerns highlighted that automatically applying a quality and cost score eliminates incentives to coordinate care which may place these clinicians at an unfair advantage over those who must report on measures and take steps to perform well on those measures. Hence, commenters encouraged CMS to closely monitor the impact of the facility-based scoring option policy. One commenter suggested that CMS provide more data on how MIPS eligible clinicians might score in the facility-based scoring option. Another commenter suggested that CMS provide data on the percentage of certain specialists who would be eligible. A few commenters suggested that CMS should closely monitor how facility-based measurement impacts total MIPS scores between specialties and groups working within the same hospital, as well as the effect of facility-based measurement on those who are not eligible. One commenter suggested that CMS provide more information via educational resources; another commenter requested that CMS explain how the Hospital VBP Program Total Performance Score is converted into MIPS scoring and requirements for group reporting options.

Response: We recognize the value of data analysis when developing additional scoring options for MIPS eligible clinicians. We continue to believe that the facility-based scoring option will reduce administrative burden by streamlining reporting and allowing clinicians to focus on quality improvement. We disagree that clinicians have an advantage under facility-based scoring option given that we have established an eligibility threshold to identify those
clinicians that have a significant impact on the care delivered within the facility and the facility’s performance under the Hospital VBP Program. The scoring methodology developed for facility-based measurement translates scores in the Hospital VBP Program to scores in the Quality and Cost performance category. Because that translation takes into account the distribution of scores in the Hospital VBP program, which is analogous to the distribution of scores in MIPS, clinicians who are scored using facility-based measurement will have a similar range of scores as those who are not eligible for facility-based measurement. We will continue to monitor the impact of the finalized facility-based scoring policies in efforts to avoid unfair advantages within the MIPS program.

**Comment:** Several commenters expressed concern about the availability of facility-based measurement beginning in the 2019 MIPS performance period/2021 MIPS payment year. The commenters expressed concern that the measures included in the Hospital VBP Program were not representative of the care provided by clinicians and would distract from efforts to focus on measures on which these clinicians could have an effect. A few commenters supported facility-based measurement as a short-term solution to reducing administrative burden for clinicians who primarily work within an inpatient setting but encouraged movement towards measures that are more meaningful for certain specialists who also predominantly work within an inpatient setting.

**Response:** We recognize that the Hospital VBP Program was not designed to measure clinicians’ performance but rather hospitals’ performance. However, we believe that by using the established 75 percent threshold to identify clinicians as eligible for facility-based scoring, we are distinguishing between those clinicians who ultimately have a significant impact on the hospital’s performance score for the care and cost rendered within that facility versus those who do not. We therefore believe that the Hospital VBP Program measures do reflect the
performance of the clinicians in a team-based environment. We note that there may be more opportunities for clinicians, particularly specialists who wish to report on more clinically meaningful measures, to participate in MIPS using qualified registries or QCDRs that may be related to care provided to those specific patients in a facility setting, and we encourage clinicians who find the MIPS measures more meaningful in the context of their patient population to report in that manner.

After consideration of the public comments, we are finalizing our proposals to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement and to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement as reflected in the regulation text at §414.1380(e)(2)(i)(A) and (B). We are also finalizing our proposal that we must be able to attribute a clinician to a particular facility that has a value-based purchasing score under the methodology specified in §414.1380(e)(5) to meet eligibility for facility-based measurement as codified at §414.1380(e)(2)(i)(C). We are also finalizing our proposed policy that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out to determine eligibility for facility-based measurement.

(C) Facility-Based Measurement by Group

In the CY 2018 Quality Payment Program final rule (82 FR 53757), we finalized at §414.1380(e)(2)(ii) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined to be facility-based as part of a group. We established at
§414.1380(e)(2)(ii) that a facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group’s TIN meet the requirements at §414.1380(e)(2)(i) (82 FR 53758). We did not propose any changes to the determination of a facility-based group but acknowledged that our proposal to change how individual clinicians are determined to be eligible for facility-based measurement will necessarily have a practical impact for practice groups. For more of the statutory background and descriptions of our current policies on determining a facility-based group, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53757 through 53758).

(iii) Facility Attribution for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53759), we finalized at §414.1380(e)(5) a method to identify the hospital whose scores would be associated with a MIPS eligible clinician or group for purposes of facility-based measurement scoring. However, because of a discrepancy in the preamble and the proposed regulation text in the CY 2018 Quality Payment Program proposed rule (82 FR 53759), we indicated we would address this issue as part of the next Quality Payment Program rulemaking cycle. Under the current regulation text §414.1380(e)(5), a facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the clinician or group provided services to the most Medicare beneficiaries during the year claims are drawn (that is, the 12-month period described in paragraph (e)(2)). Although we did not propose any changes, we are revising this section to replace the word “segment” with “period” for clarity purposes.

If an equal number of Medicare beneficiaries are treated at more than one facility, then we will use the value-based purchasing score for the highest-scoring facility (82 FR 53759.
through 53760). For more of the statutory background and descriptions of our current policies for attributing a facility to a MIPS eligible clinician, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53759 through 53760).

In considering the issue of facility attribution for a facility-based group, we stated in the CY 2019 PFS proposed rule that we believe that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group at §414.1380(e)(2)(ii). A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group’s TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the value-based purchasing score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. We proposed to revise §414.1380(e)(5) to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group (83 FR 35958).

We proposed to remove “or group” from §414.1380(e)(5) and redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians (83 FR 35958). Under our proposal, newly redesignated paragraph (e)(5)(i) would retain the rule for facility attribution for an individual MIPS eligible clinician as finalized in the CY 2018 Quality Payment Program final rule; we also proposed a few minor edits to the paragraph for grammar and to improve the sentence flow. We also proposed to add a new paragraph (e)(5)(ii) to provide that a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in §414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as
individuals (83 FR 35958). We made this proposal because of our wish to emphasize the connection between an individual clinician and a facility. We explained in the CY 2019 PFS proposed rule that using the plurality of clinicians reinforces the connection between an individual clinician and facility and is more easily understandable for larger groups.

The following is a summary of the public comments received on these proposals and our responses:

**Comment:** A few commenters suggested that CMS consider additional rules or standards for attribution of a clinician or group to a facility for purposes of using that facility’s Total Performance Score. One commenter requested that CMS consider using an eligible clinician’s/group’s second most utilized facility in cases where the top utilized facility does not have a Hospital VBP Program Total Performance Score. Another commenter encouraged CMS develop a group level attribution methodology to account for groups that practice in multiple sites and the commenter believed that an accountability model will be more meaningful and actionable for these groups.

**Response:** We are finalizing our proposal that if we are unable to identify a particular facility with a value-based purchasing score under the methodology specified in §414.1380(e)(5), such as those facilities in the state of Maryland, to attribute for use as an individual clinician’s performance, then that clinician is not eligible for facility-based measurement. We are concerned that using a hospital other than the most utilized could result in assigning a score based on a hospital at which the clinician rarely works. For example, in the case of using the second most utilized facility, an individual clinician may have primarily worked in the facility without a Hospital VBP Program Total Performance Score and then only have seen a single patient at the second most utilized hospital with a Hospital VBP Total
Performance Score. However, we will consider looking into this issue in future rulemaking, including whether it may be appropriate to allow for the score to be based upon a facility other than the one at which a clinician provides services to the most patients.

We understand that some groups that may be facility-based include clinicians that practice in a number of different facilities. However, we believe this issue is similar to that experienced in other clinician groups that may have a diversity of clinicians and settings. In section III.I.3.e of the proposed rule (83 FR 35891), we requested comments on developing an opportunity for clinicians to participate in MIPS as subgroups. We believe that our consideration of that issue could inform the determination of members of a group that practice in a single TIN but who serve patients in many different facilities.

After consideration of the public comments, we are finalizing our proposals to remove “or group” from §414.1380(e)(5); redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians; and add a new paragraph (e)(5)(ii) to §414.1380(e)(5) regarding group scoring methodologies in which a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in §414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals.

(iv) No Election of Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we did not finalize our proposal for how individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility’s performance would elect to do so through an attestation. We did finalize, and reflect in the introductory text at
§414.1380(e), that an individual clinician or group would elect to use a facility-based score. In the CY 2019 PFS proposed rule (82 FR 53760), we specified that such clinicians or groups would be required to submit their election during the data submission period through the attestation submission mechanism established for the improvement activities and the Promoting Interoperability performance categories. An alternative approach, which likewise was not finalized, did not require an election process, but instead would have automatically applied a facility-based measurement to MIPS eligible clinicians and groups who met the eligibility criteria for facility-based measurement, if such an application were technically feasible (82 FR 53760). We noted in the CY 2018 Quality Payment Program final rule (82 FR 53760) that we would examine both the attestation process and the opt-out process, and work with stakeholders to identify a new proposal in future rulemaking. We explained in the CY2018 Quality Payment Program final rule (82 FR 53760) our interest in a process that would impose less burden on clinicians than an attestation requirement and requested comment on automatically assigning a clinician or group a facility-based score, but with a notice and opportunity to opt-out of facility-based measurement. We summarized those comments in the CY 2019 PFS proposed rule (83 FR 35958).

After further considering the advantages and disadvantages of an opt-in or an opt-out process, we proposed a modified policy that would not require an election process. We proposed to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score (83 FR 35959). Under our proposal, if the MIPS eligible clinician or group is eligible for facility-based measurement, we would calculate a combined quality and cost performance category score. We proposed to use the facility-based
score to determine the MIPS quality and cost performance category scores, unless we received
another submission of quality data for or on behalf of that clinician or group and the combined
quality and cost performance category score for the other submission results in a higher
combined quality and cost performance score. If the other submission has a higher combined
quality and cost performance score, then we would not apply the facility-based performance
scores for either the quality or cost performance categories (83 FR 35959). Under our proposal,
the combined score for the quality and cost performance categories would determine the scores
to be used for both the quality and cost performance categories, for both individual clinicians and
for groups that meet the requirements of paragraph (e)(2). We did not propose to adopt a formal
opt-out process because, under our proposal, the higher of the combined quality and cost
performance scores for the clinician or clinician group would be used, which would only benefit
the clinician or group. We explained in the proposed rule our strong commitment to reducing
burden as part of the Quality Payment Program and that we believe that requiring a clinician or
group to elect a measurement process (or to opt-out of a measurement process) based on facility
performance would add unnecessary burden.

In MIPS, we score clinicians as individuals unless they submit data as a group. We stated
in the proposed rule that the same policy should apply to facility-based measurement, even
though there are no submission requirements for the quality performance category for individuals
under facility-based measurement. We proposed to revise §414.1380(e)(4) to state that there are
no submission requirements for individual clinicians in facility-based measurement, but a group
must submit data in the improvement activities or Promoting Interoperability performance
categories in order to be measured as a group under facility-based measurement. We explained
how, if a group does not submit improvement activities or Promoting Interoperability measures,
we would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group under our proposal. In the case of virtual groups, MIPS eligible clinicians will have formed virtual groups prior to the MIPS performance period; as a result, virtual groups eligible for facility-based measurement will always be measured as a virtual group (83 FR 35959). Although we can calculate a score for a TIN without the submission of data by the TIN, we would not be certain if the clinicians in that group actually wanted to be measured as a group without an active submission (in other words, if the group did not submit data as a group). As we explained in the proposed rule, we view submission of data on the improvement activities or Promoting Interoperability measures as an indication by the clinicians in that group that they want to be scored as a group; using the choice to submit data as a group to identify a group in the context of facility-based scoring would preserve and respect choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. We solicited comment specifically on this proposal and other means to achieve the same ends.

In the CY 2018 Quality Payment Program final rule, we established that if a clinician or group elects facility-based measurement but also submits MIPS quality data, then the clinician or group would be measured on the method that results in the higher quality score (82 FR 53767). We proposed to adopt this same scoring principle in conjunction with our proposal not to use (or require) an election process. Therefore, we proposed at §414.1380(e)(6)(vi) that the MIPS quality and cost score for clinicians and groups eligible for facility-based measurement would be based on the facility-based measurement scoring methodology described in §414.1380(e)(6) unless the clinician or group receives a higher combined score for the MIPS quality and cost performance categories through data submitted to CMS for MIPS (83 FR 35959). We stated in
the proposed rule that this policy is not applicable to any MIPS eligible clinicians scored under the APM scoring standard described at §414.1370; we further clarify here that this includes Shared Savings Program participant TINs in ACOs that have failed to complete web interface reporting, unless these measures are specifically required under the terms of the applicable APM.

We also proposed conforming changes in two other sections of regulatory text. We proposed to revise the introductory text at §414.1380(e) to remove “elect to,” and therefore, reflect that clinicians and groups who are determined to be facility-based will receive MIPS quality and cost performance categories under the methodology in paragraph (e) (83 FR 35959 through 35960). Because of our proposal to not require clinicians to opt-in into facility-based measurement, we acknowledged that there may be clinicians that will continue to submit data via other methods. We explained that these clinicians and groups are not prohibited from submitting quality measures to CMS for purposes of MIPS. However, under our proposal, if a higher combined quality and cost score is achieved using data submitted to CMS for purposes of MIPS, then we will use the MIPS scores based on the submission. We also proposed to revise §414.1380(e)(4) and (e)(6)(v)(A) to reflect that facility-based measurement does not require election and to replace the phrase “clinicians that elect facility-based measurement” with “clinicians and groups scored under facility-based measurement” (83 FR 35960) as part of this policy.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based
measurement and who would benefit by having a higher combined quality and cost performance category score.

**Response:** We thank the commenters for their support.

**Comment:** A few commenters opposed our proposal to require a group to submit information in the improvement activities or Promoting Interoperability performance categories to be measured as a facility-based group. A few of these commenters requested that rather than requiring the submission of information in these categories, CMS offer an election process. One commenter questioned how a group that was excluded from both the improvement activities and Promoting Interoperability performance categories could participate as a facility-based group. One commenter suggested that it would be difficult to complete an improvement activity if members of the group practice at more than one facility.

**Response:** We continue to believe that our proposal of a clinician receiving the higher of the quality and cost performance score available would only benefit the individual MIPS eligible clinician or group. If we do not require groups to submit data in the improvement activity or Promoting Interoperability performance categories, then we will be unable to tell whether the clinician should be measured as part of a group. We will consider whether there would be an opportunity for a facility-based group to elect to participate without submitting data on another performance category in the future as feasible. We do not believe that we would need to establish additional policies for groups that would have their improvement activities performance score re-weighted specifically because we generally expect reweighting to occur for the improvement activities performance category only in rare cases of extreme and uncontrollable events. We do note that the clinicians in a facility-based group who meet the requirements for facility-based measurement as individuals will have scores in the quality and cost performance
categories determined for them as individuals if there is no data submission from the group in the improvement activity or Promoting Interoperability performance categories.

**Comment:** Commenters encouraged CMS to provide as much information as possible to eligible clinicians including information on eligibility for facility-based measurement, clinician type, potential performance score under facility-based scoring, and to which facility the eligible clinician will be attributed. Several commenters noted that more information would give clinicians the opportunity to assess the advantages and disadvantages of various reporting options under MIPS. One commenter stated that more information will avoid confusion as to how the facility-based scoring option will work during the performance period. A few commenters noted concerns with the timing of receiving information about facility-based measurement. Some commenters noted the risk of a clinician assuming that he or she will meet the criteria for facility-based measurement when that may not be the case. Another commenter noted that the timing is important in making decisions as to whether to report as a group or an individual under the facility-based scoring option.

**Response:** We intend to provide as much information as possible as early as possible to clinicians about their eligibility and the hospital performance upon which a MIPS eligible clinician’s score would be based. We acknowledge that clinicians may want to consider this information to make financial and operational decisions, regardless of not having to be required to opt-in to facility-based scoring. We intend to provide additional information to clinicians regarding their status with facility-based measurement eligibility, facility attribution, and a preview score based on data from the previous performance period. We anticipate that this information will be released during the first quarter of the performance period, if technically
feasible, beginning with the 2019 performance period, and we aim to notify clinicians as soon as
this information is available.

Comment: Many commenters expressed concern with our proposal to not require an opt-
in or offer an opt-out for facility-based measurement. A few commenters noted that performing
this calculation automatically would reduce the control that clinicians have over their
participation in MIPS. A few commenters suggested that automatically calculating a score for
facility-based clinicians would reduce the incentive to participate in clinical data registries. A
few commenters suggested that not requiring an opt-in would provide a performance advantage
to facility-based clinicians over those who are not eligible for facility-based measurement. One
commenter expressed concern that clinicians could have measures displayed on Physician
Compare from facility-based measurement.

Response: Receiving the higher of the combined quality and cost performance scores
available would only benefit the applicable individual MIPS eligible clinician or group; however,
we are uncertain that facility-based clinicians would necessarily perform better than those who
submit MIPS data, because the opportunity to submit data via other methods provides individual
clinicians or groups the opportunity to select quality measures. We continue to believe that
adding a formal opt-in or opt-out process would add unnecessary burden for both individual
clinicians and groups. Additionally, we believe that those MIPS eligible clinicians who will not
be required to submit MIPS data will benefit from a reduction in administrative burden while
being measured in a facility in which their care has a significant impact on the facility’s
performance. We note that clinicians who wish to better control their performance in MIPS may
submit measures through another method. Hence, we are finalizing our proposal to not require
an opt-in or opt-out for facility-based measurement. Additionally, we did not propose any
policies for how facility-based measures, other than the scores derived from those measures and included as quality and cost performance category scores, will be displayed on Physician Compare, but we thank commenters for their input and will take this input into consideration in future years.

Comment: One commenter requested clarification on how CMS would score a facility-based clinician who submits data on the quality performance category but does not have a cost performance category score, and thus, the cost performance category weight would need to be redistributed to the quality performance category.

Response: The cost performance category can be reweighted to 0 percent if there are not sufficient cost measures applicable and available (for example, if the clinician does not meet the minimum case requirements for the cost measures). In cases in which a clinician or group does not have a score in the cost performance category, in general, the weight of the cost performance category would be redistributed to the quality performance category. In that case, the points assigned under §414.1380(b) for purposes of calculating/assigning the MIPS final score in the cost and quality categories will be compared to the points that contribute to the final score from the quality and cost scores established under facility-based measurement. For example, a clinician whose data was submitted on their behalf by a third-party intermediary and received a MIPS quality performance category percent score of 50 percent but did not meet the case minimum for cost measures, would have a total of 30 points as the combined score for the quality and cost performance categories. If that same clinician were eligible for facility-based measurement, the score based on that third party intermediary submission would be used unless the combination of the quality and cost scores established under facility-based measurement (as calculated under §414.1380(e)(6)) resulted in more than 30 points towards the final score.
Comment: One commenter requested guidance and language as to how to account for MIPS eligible clinicians who wish to use their facility’s Hospital VBP Program Total Performance Score for the quality and cost performance categories, yet still use a QCDR to report.

Response: Our proposed policy to not require an opt-in or offer an opt-out for facility-based measurement anticipates that there may be some clinicians and groups who will both receive a score based upon facility-based measurement and submit quality measures via various collection types. These clinicians may believe these quality measures better represent their performance or that they will perform better submitting these measures. In all cases, under the policy we are finalizing here, we will compare combined performance in these two categories and assign the clinician or group the higher combined score, whether based on the facility-based measurement or through another submission type. We note that facility-based measurement only applies to the quality and cost performance categories; the Promoting Interoperability and improvement activity performance categories would still require reporting on the part of the clinicians or group.

After consideration of the public comments, we are finalizing our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and those who have a higher combined quality and cost performance category score. Additionally, we are finalizing our proposal to revise §414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement and that a group must submit data in the improvement activities or Promoting Interoperability performance categories to be measured as a group under facility-based measurement. Additionally, we are also revising the proposed regulation text for
§414.1380(e)(4) by adding “to be” between “clinicians” and “scored” to clarify that this paragraph is establishing the data submissions necessary for facility-based scoring to be possible as opposed to a provision governing MIPS reporting as a whole for all categories. We are also finalizing the conforming changes at §414.1380(e)(4) and (e)(6) to revise text that referred to an election by the clinician or group to use facility-based scoring. Additionally, while we did not propose any changes, we are revising §414.1380(e) to state, for the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories under the methodology described in this paragraph (e). These technical changes are made to conform to our policy in this section to not require or offer an election and to improve readability.

(v) Facility-Based Measures

(A) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. In the CY 2018 Quality Payment Program proposed rule, we proposed to include for the 2020 MIPS payment year all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures for purposes of facility-based measurement (82 FR 30125). We noted how these measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act (82 FR 30125). In the CY 2018 Quality Payment Program final rule, we did not finalize our proposal that the facility-based measures available for the 2018
MIPS performance period would be the measures adopted for the FY 2019 Hospital VBP Program; nor did we finalize our proposal that, for the 2020 MIPS payment year, facility-based individual MIPS eligible clinicians or groups that were attributed to a facility would be scored on all measures on which the facility is scored via the Hospital VBP Program’s Total Performance Score methodology (82 FR 53762).

We did finalize a facility-based measurement scoring standard but not the specific instance of using the FY 2019 Hospital VBP Program Total Performance Score methodology (82 FR 53755). We expressed our belief that using all measures from the Hospital VBP Program is appropriate; nevertheless, because we did not finalize the facility-based measurement scoring option for the 2018 MIPS performance period/2020 MIPS payment year, it was not appropriate to adopt these policies at that time (82 FR 53762 through 53763). We noted that we intended to propose measures that would be available for facility-based measurement for the 2019 MIPS performance period/2021 MIPS payment year in future rulemaking (82 FR 53763).

(B) Measures in Facility-Based Scoring

As we noted in the proposed CY 2019 PFS rule, we continue to believe it is appropriate to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring; these Hospital VBP Program measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act. We also stated how it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that we use to determine eligibility for facility-based measurement.

Beginning with the 2019 MIPS performance period, we proposed at §414.1380(e)(1)(i) to adopt for facility-based measurement, the measure set that we finalize for the fiscal year Hospital VBP Program for which payment begins during the applicable MIPS performance period. For
the 2019 MIPS performance period (which runs on the 2019 calendar year), we proposed to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. The performance period for these measures varies but performance ends in 2018 for all measures.

We also proposed at §414.1380(e)(1)(ii) that, starting with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Additionally, we note a typographical error in the CY 2019 PFS proposed rule (83 FR 35960) in which we state FY 2019 instead of FY 2020, which we believe commenters have likely understood given the comments we have received on FY 2020 measures. However, we provide additional clarification in this final rule.

We noted in the proposed rule that this approach of adopting all the measures in the Hospital VBP Program can be applied to other value-based purchasing programs in the future, should we decide to expand facility-based measurement to settings other than hospitals.

In the CY 2018 Quality Payment Program final rule we also established at §414.1380(e)(6)(i) that the available quality and cost measures for facility-based measurement are those adopted under the value-based purchasing program of the facility for the year specified. We established at §414.1380(e)(6)(ii) that we will use the benchmarks adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53763 through 53764). We noted that we would determine the particular value-based purchasing program to be used for facility-based measurement in future rulemaking but would routinely use the benchmarks associated with that program (82 FR 53764). Likewise, at §414.1380(e)(6)(iii), we
established that the performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53755). We noted that these provisions referred to the general parameters of our method of facility-based measurement and that we would address specific programs and years in future rulemaking (82 FR 53763). For the CY 2019 performance period, we proposed regulation text for these three provisions to specify that the measures, performance period, and benchmark period for facility-based measurement are the measures, performance period, and benchmark period established for the value-based purchasing program used to determine the score as described in §414.1380(e)(1) (83 FR 35960). We provided an example in the proposed rule to illustrate this policy: for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 Hospital VBP Program along with the associated benchmarks and performance periods. As explained earlier, we intended this to mean that for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2020 Hospital VBP Program along with the associated benchmarks and performance periods.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters noted their appreciation of the facility-based scoring option but requested that CMS consider additional measures that are more relevant to specific specialties as that would capture clinically meaningful information. One commenter suggested CMS develop episode-based risk adjusted measures even if they are not used in the Hospital VBP Program. Another commenter suggested that CMS consider additional avenues to collect more meaningful information.
Response: Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. Based on this statutory requirement and because we want to align incentives between clinicians and hospitals, we proposed to use measures that are developed and implemented in other programs, as opposed to new measures that reflect a facility’s performance. Due to this limitation, we note that there may be additional avenues for clinicians to participate in MIPS using qualified registries or QCDRs that measure quality for services that may be provided in a facility setting, such as inpatient surgeries, without being measured in facility-based measurement.

After consideration of the public comments, we are finalizing the proposed regulation text at §414.1380(e)(1)(i) that the measures for facility-based measurement will be the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period. We are also finalizing the proposed regulation text at §414.1380(e)(1)(ii) that, beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program for the fiscal year for which payment begins during the applicable MIPS performance period. This means that for the 2021 MIPS payment year, the Total Performance Score for FY 2020 will be applied for the MIPS performance year 2019. Additionally, while we did not propose any changes, we are revising the regulation text at §414.1380(e)(1)(i) to stated that the measures used for facility-based measurement are the measure set finalized for the fiscal year VBP program for which payment begins during the applicable MIPS performance period. This update is not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We have also
made a technical revision in which we revise §414.1380(e)(6)(ii), (iv), and (v) to reference only (e)(1) rather than (e)(1)(i) for improvements in readability and clarity of the regulation.

(C) Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year

For informational purposes, we provided a list of measures included in the FY 2020 Hospital VBP Program that would be used in determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year. The FY 2020 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. We noted in the proposed rule that these measures are determined through separate rulemaking (83 FR 38244); the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement based on §414.1380(e)(1) as finalized here. We repeat the list of measures finalized for the FY 2020 Hospital VBP measure set and Total Performance Score in Table 52.
## TABLE 52: FY 2020 Hospital VBP Program Measures

<table>
<thead>
<tr>
<th>Short Name</th>
<th>Domain/Measure Name</th>
<th>NQF #</th>
<th>Performance Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCAHPS</td>
<td>Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)</td>
<td>0166 (0228)</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
<tr>
<td><strong>Person and Community Engagement Domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Outcomes Domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MORT-30-AMI</td>
<td>Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization</td>
<td>0230</td>
<td>July 1, 2015 – June 30, 2018</td>
</tr>
<tr>
<td>MORT-30-HF</td>
<td>Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization</td>
<td>0229</td>
<td>July 1, 2015 – June 30, 2018</td>
</tr>
<tr>
<td>MORT-30-PN</td>
<td>Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.</td>
<td>0468</td>
<td>July 1, 2015 – June 30, 2018</td>
</tr>
<tr>
<td>THA/TKA</td>
<td>Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)</td>
<td>1550</td>
<td>July 1, 2015 – June 30, 2018</td>
</tr>
<tr>
<td><strong>Safety Domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon and Abdominal Hysterectomy SSI</td>
<td>American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.</td>
<td>0753</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
<tr>
<td>MRSA Bacteremia</td>
<td>National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure</td>
<td>1716</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
<tr>
<td>CDI</td>
<td>National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure</td>
<td>1717</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
<tr>
<td>PC-01</td>
<td>Elective Delivery</td>
<td>0469</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
<tr>
<td><strong>Efficiency and Cost Reduction Domain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSPB</td>
<td>Payment-Standardized Medicare Spending Per Beneficiary (MSPB)</td>
<td>2158</td>
<td>January 1, 2018 – December 31, 2018</td>
</tr>
</tbody>
</table>
(vi) Scoring Facility-Based Measurement

(A) Scoring Achievement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we adopted certain scoring policies for clinicians and groups in facility-based measurement. We established at §414.1380(e)(6)(iv) and (v) that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the value-based purchasing program for the specified year, then awarding scores associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not scored using facility-based measurement for the MIPS payment year (82 FR 53764). We also finalized at §414.1380(e)(6)(v)(A) that clinicians scored under facility-based measurement would not be scored on other cost measures (82 FR 53767).

For detailed descriptions of the current policies related to scoring achievement in facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53763). Because we proposed to not require or allow an opt-in process for facility-based measurement, we proposed a change to the determination of the quality and cost performance category scores. We proposed that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year (83 FR 35961). Under our proposal, the determination of percentile performance would be independent of those clinicians who would not have their quality or cost scores determined until we make the determination of their status under facility-based measurement.
The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported our proposal that the quality and cost performance category percent scores for clinicians in facility-based measurement would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal to change the determination of the quality and cost performance category scores at §414.1380(e)(6)(iv) and (v) to establish both scores by determining the percentile performance of the facility in value-based purchasing program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year. Also, we have revised the last sentence in paragraphs (e)(6)(iv) and (v) to more clearly state that a clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality or cost categories.

(B) Scoring Improvement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we finalized that we would not give a clinician or group participating in facility-based measurement the opportunity to earn improvement points based on prior performance in the MIPS quality and cost performance
categories; we noted that the Hospital VBP Program already takes improvement into account in determining the Total Performance Score (82 FR 53764 through 53765). We proposed to add this previously finalized policy to regulatory text at §414.1380(e)(6)(iv) and (v) (83 FR 35961).

We did not address in the CY 2018 Quality Payment Program final rule a policy for a clinician or group who participates in facility-based measurement for one performance period, and then does not participate in facility-based measurement in a subsequent performance period (for example, a clinician who is scored using facility-based measurement in the 2019 MIPS performance period and is not eligible for facility-based measurement in the 2020 MIPS performance period). After further considering the issue, we stated in the CY 2019 PFS proposed rule our position that it is not possible to assess improvement in the quality performance category for those who are measured under facility-based measurement in 1 year and then through another method in the following year. Our method of assessing and rewarding improvement in the MIPS quality performance category separates points awarded for measure performance from those received for bonus points (82 FR 53745). Our method of determining the quality performance category score using facility-based measurement does not allow for the separation of achievement from bonus points. For this reason, we proposed at §414.1380(b)(1)(vi)(A)(4)\textsuperscript{30} to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year (83 FR 39561).

We did not receive any public comments on this proposal, so we will finalize our proposal to add regulatory text at §414.1380(e)(6)(iv) and (v) and our proposal at §414.1380(b)(1)(vi)(A)(4) to not assess improvement for MIPS-eligible clinicians who are

\textsuperscript{30}The codification was misidentified in the preamble of the proposed rule as §414.1380(b)(1)(xi)(A)(4) but the regulation text was proposed, at 83 FR 36081, to be codified at §414.1380(b)(1)(vi)(A)(4), where we are finalizing it.
scored in MIPS through facility-based measurement in 1 year but through another method in the following year.

(vii) Expansion of Facility-Based Measurement to Use in Other Settings

We initiated the process of facility-based measurement focusing on the inpatient hospital setting, but have noted in the past our policy goal of expanding the concept into other facilities and programs and future, in particular to use the post-acute care (PAC) and the end-stage renal disease (ESRD) settings as the basis for facility-based measurement and scoring. In the proposed rule, we summarized a number of issues and topics related to the use of PAC and ESRD facilities (83 FR 35962 through 35963). We solicited comment on these topics, including:

- How to attribute the quality and cost of care for patients in PAC settings to clinicians;
- Whether using a value-based purchasing program, that is, a similar approach to §414.1380(e)(1), could work for PAC given the number and variation of PAC settings and clinicians;
- The level of influence MIPS-eligible clinicians have in determining performance on quality measures for individual settings and programs in the PAC setting;
- Which PAC QRP measures may be best utilized to measure clinician performance;
- Methods to identify the appropriate measures for scoring, and what measures would be most influenced by clinicians;
- Whether all measures that are reported as part of the PAC QRPs should be included or whether we should identify a subset of measures;
- Whether we should limit facility-based measurement to specific PAC settings and programs such as the IRF QRP or LTCH QRP, or whether we should consider all PAC settings in the facility-based measurement discussion;
The extent to which the quality measures of dialysis centers reflect clinician performance; and

Practical and policy considerations related to whether we could to attribute the performance of a specific ESRD facility to an individual clinician.

We appreciate the comments received in response to these considerations and may consider these suggestions in policies that will be proposed as part of future rulemaking.

(e) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to §414.1380(b)(3) and the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769). We also refer readers to §414.1355 and the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662) and CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) for previously established policies regarding the improvement activities performance category generally.

(i) Regulatory Text Updates

In the CY 2019 PFS proposed rule, we proposed updates to both §§414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies (83 FR 35963). We also proposed one substantive change with respect to patient-centered medical homes and comparable specialty practices (83 FR 35963). These are discussed in more detail in this section.

(A) Improvement Activities Performance Category Score and Total Required Points

In an effort to more clearly and concisely capture previously established policies, we proposed updates to §414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963). We also clarified that the improvement activities performance category score cannot exceed 100 percent (83 FR 35963).
We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at §414.1380(b)(3) as proposed.

(B) Weighting of Improvement Activities

In an effort to more clearly and concisely capture previously established policies, we proposed updates to §414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at §414.1380(b)(3) as proposed.

(C) APM Improvement Activities Performance Category Score

In an effort to more clearly and concisely capture previously established policies, we proposed updates to §414.1380(b)(3)(i) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at §414.1380(b)(3)(i) as proposed.

(D) Patient-Centered Medical Homes and Comparable Specialty Practices

In the CY 2019 PFS proposed rule (83 FR 35963), we proposed to modify our regulations at §414.1380(b)(3)(ii) to more clearly and concisely capture our previously established policies for patient-centered medical homes and comparable specialty practices and refer readers to the CY 2019 PFS proposed rule for more details.

In addition, it had come to our attention that in the preamble of the CY 2017 Quality Payment Program final rule (81 FR 77186 and 77179), the terminology “automatic” was used in reference to patient-centered medical home or comparable specialty practice improvement activities scoring credit. In that rule (81 FR 77186), in response to one comment, we stated, “…
any MIPS eligible clinician or group that does not qualify by October 1st of the performance year as a certified patient-centered medical home or comparable specialty practice cannot receive automatic credit as such for the improvement activities performance category.” In response to another comment in that rule (81 FR 77179), we stated, “Other certifications that are not for patient-centered medical homes or comparable specialty practices would also not qualify automatically for the highest score.”

While we used the term “automatic” then, we have since come to realize it is inaccurate because an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive full credit for the improvement activities performance category. In the CY 2018 Quality Payment Program final rule (82 FR 53649), in response to comments we received regarding patient-centered medical homes or comparable specialty practices receiving full credit for the improvement activities performance category for MIPS, we stated that we would like to make clear that credit is not automatically granted; MIPS eligible clinicians and groups must attest in order to receive the credit.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35963), we proposed codifying at §414.1380(b)(3)(ii) to require that an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. Specifically, MIPS eligible clinicians who wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice for a continuous 90-day minimum during the performance period.

We solicited comments on the above proposal. We received the following comment on this proposal.
Comment: One commenter supported the proposal to modify current regulations to more clearly and concisely capture previously established policies for patient-centered Medical Homes and comparable specialty practices.

Response: We thank the commenter for your support.

After consideration of the comment we received, we are finalizing our changes to regulation text at §414.1380(b)(3)(ii) as proposed.

(E) Improvement Activities Performance Category Weighting for Final Scoring

In the CY 2019 PFS proposed rule (83 FR 35963), in an effort to more clearly and concisely capture previously established policies, we proposed to make technical changes to §414.1355(b) to state that unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises 15 percent of a MIPS eligible clinician’s final score for the 2019 MIPS payment year and for each MIPS payment year thereafter). We stated that we believe these changes would better align the regulation text with the text of the statute.

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at §414.1355(b) as proposed.

(ii) CEHRT Bonus

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209) and the CY 2018 Quality Payment Program final rule (82 FR 53664 through 53670), we established that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category if they are completed using CEHRT. This bonus is applied under the Promoting Interoperability performance category and not under the improvement activities performance category. In the CY 2019 PFS proposed rule (83 FR
35932), we proposed a new approach for scoring the Promoting Interoperability performance category that is aligned with our MIPS program goals of flexibility and simplicity. We refer readers to section III.I.3.h.(5)(g) of this final rule for a summary of the comments we received regarding this proposal and our responses.

(f) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.I.3.h.(5) of this final rule, where we discuss our proposals for scoring the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to §414.1380(c), the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), and the discussion in the CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785). In this final rule, we discuss our proposal to continue the complex patient bonus for the 2021 MIPS payment year, as well as a modification to the final score calculation for the 2021 MIPS payment year. Finally, we discuss refinements to reweighting policies.

(a) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals’ health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under
section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) and, as appropriate, other information, including information collected before completion of such studies and recommendations.

(i) Considerations for Social Risk

In the CY 2019 PFS proposed rule (83 FR 35964), we summarized our efforts related to social risk and the relevant studies conducted under section 2(d) of the IMPACT Act. We received several comments suggesting various approaches to adjust for social risk factors in the Quality Payment Program going forward. We thank commenters for their input and will take this input into consideration in future years. We also plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

(ii) Complex Patient Bonus for the 2021 MIPS Payment Year

In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we finalized at §414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was two-fold: (1) to protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We noted that we would assess on an annual basis whether to continue the
bonus and how the bonus should be structured (82 FR 53771). For a detailed description of the complex patient bonus finalized for the 2020 MIPS payment year, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776).

For the 2019 MIPS performance period/2021 MIPS payment year, we proposed in the CY 2019 PFS proposed rule to continue the complex patient bonus as finalized for the 2018 MIPS performance period/2020 MIPS payment year and to revise §414.1380(c)(3) to reflect this policy (83 FR 35964 through 35965). Although we intended to maintain the complex patient bonus as a short-term solution, we did not believe we had sufficient information available at the time of the proposed rule to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to propose a different approach for the 2019 MIPS performance period/2021 MIPS payment year. At the time of the proposed rule, we did not believe additional data sources were available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. In the CY 2019 PFS proposed rule, we noted our intention to analyze data when feasible from the 2017 MIPS performance period to identify differences in performance that are consistent across performance categories and that we may, in the future, shift the complex patient bonus to specific performance categories (83 FR 35965). In the absence of data analysis from the first year of MIPS, we did not believe that a change was appropriate at that time. Therefore, we stated that while we work with stakeholders to identify a long-term approach to account for patient risk factors in MIPS, we believed it was appropriate to continue the complex patient bonus for another year to support MIPS eligible clinicians who treat patients with risk factors, as well as to maintain consistency with the 2020 MIPS payment year and minimize confusion. We had received significant feedback from MIPS eligible clinicians that consistency in the MIPS program over
time is valued when possible in order to minimize confusion and to help MIPS eligible clinicians predict how they will be scored under MIPS. Therefore, we stated our belief that it is appropriate to maintain consistent policies for the complex patient bonus in the 2021 MIPS payment year until we have sufficient evidence and new data sources that support an updated approach to account for patient risk factors.

Although we did not propose changes to the complex patient bonus for the 2021 MIPS payment year, we stated that the dates used in the calculation of the complex patient bonus may change as a result of other proposals we made in the CY 2019 PFS proposed rule (83 FR 35885 through 35886). For the 2020 MIPS payment year, we finalized that we will use the second 12-month segment of the eligibility determination period to calculate average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians (82 FR 53771 through 53772). We proposed to change the dates of the eligibility determination period (now referred to as the MIPS determination period) beginning with the 2021 MIPS payment year (83 FR 35885 through 35886). Specifically, the second 12-month segment would begin on October 1 of the calendar year preceding the applicable performance period and end on September 30 of the calendar year in which the applicable performance period occurs. We indicated that if this proposed change to the MIPS determination period is finalized, then beginning with the 2021 MIPS payment year, the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) would be used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.
We solicited comments on the above proposals. These comments and our responses are discussed below.

**Comment:** Several commenters supported our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. Commenters stated that the bonus helps to create fairer scoring for MIPS eligible clinicians. Some commenters requested that we continue the bonus beyond the 2019 MIPS performance period/2021 MIPS payment year. A few commenters supported the complex patient bonus but requested that we increase the complex patient bonus above the proposed 5 points, stating that 5 points will have a minimal impact on the final score.

**Response:** We thank commenters for their support of our proposal to maintain the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. We plan to review available information, including any updated data, in future years to determine if it is appropriate to modify our approach to adjusting for social risk factors. As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53775), we believe a complex patient bonus of 5 points added to the final score is appropriate and is justified by information currently available at this time.

**Comment:** Several commenters did not support our approach for the complex patient bonus. Commenters pointed out limitations in the use of HCC and dual-eligibility to calculate the complex patient bonus. For instance, commenters stated that these indicators are not sufficient to adjust for differences in performance and suggested other indicators that might be more appropriate (such as income or education). Commenters urged us to continue to explore alternative methods to adjust for patient complexity in future years.
Response: We understand that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. However, we are not aware of data sources for indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient’s complexity. We have decided to pair the HCC risk score with the proportion of dual eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional options in future years based on any updated data or additional information in order to better account for social risk factors while minimizing unintended consequences.

Comment: One commenter recommended that we use the 12-month performance period to determine the complex patient bonus, stating that it is the most accurate representation of the patient population of a MIPS eligible clinician.

Response: We believe that aligning the time period for assigning beneficiaries for purposes of calculating the complex patient bonus with the MIPS determination period is preferable for simplicity. In addition, when we designed our systems, we incorporated user feedback that requested eligibility information be connected to data submission. In order to be able to provide this information on the complex patient bonus at or near the time of data submission, it is necessary to use the second 12-month segment of the MIPS determination period as proposed to identify beneficiaries for purposes of assigning HCC risk scores and full benefit or partial benefit dual eligible beneficiaries to MIPS eligible clinicians, rather than the performance period. We note that this second 12-month segment begins 3 months before the year in which the performance period occurs and ends 9 months into the year in which the performance period occurs, creating a considerable overlap between the MIPS determination period and the year in which the performance period occurs (9 months).
After consideration of public comments, we are finalizing our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year as proposed. We are also finalizing the changes to the regulation text at §414.1380(c)(3) as proposed. We are also modifying the timing used to calculate the complex patient bonus based on our changes to the MIPS determination period finalized in III.I.3.b. of this final rule. The second 12-month segment of the MIPS determination period will be used when calculating average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: in general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability (formerly advancing care information) performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 and 82 FR 53779, respectively). Under the proposals we are finalizing in sections III.I.3.h.(3)(a) and III.I.3.h.(2)(a)(ii) of this final rule, for the 2021 MIPS payment year, the cost performance category will make up 15 percent and the quality performance category will make up 45 percent of a MIPS eligible clinician’s final score. Table 53 summarizes the weights specified for each performance category.
(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported.

(A) Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted
In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77322 through 77325 and 82 FR 53779 through 53780, respectively), we explained our interpretation of what it means for there to be sufficient measures applicable and available for the quality and cost performance categories, and we finalized policies for the 2019 and 2020 MIPS payment years under which we would assign a scoring weight of zero percent to the quality or cost performance category and redistribute its weight to the other performance categories in the event there are not sufficient measures applicable and available, as authorized by section 1848(q)(5)(F) of the Act. For the quality performance category, we stated that having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician (82 FR 53780). For the cost performance category, we stated that having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician (82 FR 53780). We established that if a MIPS eligible clinician is not attributed enough cases for a cost measure (in other words, has not met the required case minimum for the measure), or if a cost measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated that if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score (82 FR 53780).

In the CY 2019 PFS proposed rule, we proposed to codify these policies for the quality and cost performance categories at §414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year (83 FR 35966).
For the Promoting Interoperability performance category, in the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77245) and the CY 2018 Quality Payment Program final rule (82 FR 53680 through 53687), we established policies for assigning a scoring weight of zero percent to the Promoting Interoperability performance category and redistributing its weight to the other performance categories in the final score. We proposed to codify those policies under §414.1380(c)(2)(i) and (iii) (83 FR 35966).

For the improvement activities performance category, we stated in the CY 2019 proposed rule (83 FR 35967 through 35968) that we continue to believe that all MIPS eligible clinicians will have sufficient activities applicable and available, except for limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities, and circumstances where a MIPS eligible clinician joins a practice in the final 3 months of the performance period as discussed in the CY 2019 PFS proposed rule (83 FR 35967 through 35968). We stated that, barring these circumstances, we believe that all MIPS eligible clinicians will have sufficient improvement activities applicable and available (82 FR 53780).

We solicited comments on the above proposals. These comments and our responses are discussed below.

**Comment:** One commenter supported our reweighting policies, stating that they provide flexibility for MIPS eligible clinicians who are unable to participate in specific performance categories.

**Response:** We thank this commenter for its support.

**Comment:** One commenter expressed concern with our reweighting policies, because the commenter believes MIPS eligible clinician may expend resources to submit data to us, and then
receive reweighting based on our determination that there are not sufficient measures or activities applicable and available.

Response: Our reweighting policies would not lead us to reweight a MIPS eligible clinician after they submit data for a given performance category. Rather, we would consider whether these policies are applicable in the event that we do not receive any data for a MIPS eligible clinician for a particular performance category. If we determine that the clinician is eligible for reweighting under our policies, then we would redistribute the weight of the performance category, rather than awarding a score of zero to the clinician for that performance category.

After consideration of public comments, we are finalizing our proposal to codify the reweighting policies for the quality and cost performance categories at §414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year, as proposed. We are also finalizing our proposal to codify the Promoting Interoperability reweighting policies under §414.1380(c)(2)(i) and (iii) as proposed.

(B) Reweighting the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances

For a summary of the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53780 through 53783). In the proposed rule (83 FR 35966), we proposed to codify this policy at §414.1380(c)(2)(i)(A)(5),
but we inadvertently referred to the wrong paragraph of the regulation text, and the citation should have read §414.1380(c)(2)(i)(A)(6).

We proposed a few minor modifications to our extreme and uncontrollable circumstances policy (83 FR 35967). First, beginning with the 2019 MIPS performance period/2021 MIPS payment year, we proposed at §414.1380(c)(2)(i)(A)(5) (which should have read §414.1380(c)(2)(i)(A)(6)) that, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with §414.1325, he or she would be scored on the submitted data like all other MIPS eligible clinicians, and the categories would not be reweighted (83 FR 35967). We proposed this modification to align with a similar policy for the Promoting Interoperability performance category (82 FR 53680 through 53682). We stated that if a MIPS eligible clinician reports on measures or activities specified for the quality or improvement activities performance categories, then we assume the clinician believes there are sufficient measures or activities applicable and available to the clinician.

For most quality measures and improvement activities, the data submission occurs after the end of the MIPS performance period, so clinicians would know about the extreme and uncontrollable circumstance prior to submission. However, for the quality performance category, measures submitted via the Medicare Part B claims collection type are submitted by adding quality data codes to a claim. As a result, it is possible that a MIPS eligible clinician could have submitted some Medicare Part B claims collection type data prior to the submission of a reweighting application for extreme and uncontrollable events. Under our proposal, we would score the quality performance category because we have received data. However, we
previously finalized at §414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). If a clinician experiences an extreme and uncontrollable event that affects all of the performance categories, then under our proposal, the clinician would only be scored on the quality performance category if they submit data for only that category. The clinician would also have to submit data for the improvement activities or the Promoting Interoperability performance categories in order to be scored on two or more performance categories and receive a final score different than the performance threshold.

This proposal did not include administrative claims data that we receive through the claims submission process and use to calculate the cost measures and certain quality measures. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at §414.1325(a)(2), there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category. Please see section III.I.3.h.(1)(b) of this final rule for a description of collection types, submission types, and submitter types. We calculate performance on these measures using administrative claims data, and clinicians are not required to submit any additional data for these measures. Therefore, we stated that we did not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We also proposed to apply the policy we finalized for virtual groups in the CY 2018 Quality Payment Program final rule (82 FR 53782 through 53783) to groups submitting reweighting applications for the quality, cost, or improvement activities performance categories.
based on extreme and uncontrollable circumstances (83 FR 35967). For groups, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances. In the CY 2019 PFS proposed rule (83 FR 35967), we stated that although we did not specifically propose to apply this policy to groups in the CY 2018 Quality Payment Program proposed rule, our intention was to apply the same policy for groups and virtual groups, and thus if we adopt this proposal, we would apply the policy to groups beginning with the 2018 performance period/2020 MIPS payment year.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: One commenter supported our proposal for groups, stating that all MIPS eligible clinicians in the group will likely be facing the same barriers and a group application will reduce administrative burden and redundancy.

Response: We thank the commenter for its support of our proposal to apply the same policy we established for virtual groups to groups. Under the proposed policy, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances.

Comment: One commenter expressed concern that MIPS eligible clinicians who submit an application for reweighting based on extreme and uncontrollable circumstances, but who also
report via Medicare Part B claims collection type may be unfairly penalized if claims data is received prior to the extreme and uncontrollable event. Another commenter suggested that we should score data received from MIPS eligible clinicians who submit a reweighting application only if they would receive a score that would result in a payment adjustment no lower than a neutral adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive an application for reweighting for the clinician based on extreme and uncontrollable circumstances, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at §414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). The clinician’s cost performance category score would not contribute to their final score because as we discuss above, there are no data submission requirements for the cost performance category, and we do not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We assume that if a MIPS eligible clinician submits data to us following the submission of an application for reweighting based on extreme and uncontrollable circumstances, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.
After consideration of public comments, we are finalizing our proposal to codify the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances. We are finalizing our proposal that, beginning with the 2019 performance period/2021 MIPS payment year, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with §414.1325, he or she will be scored on the submitted data like all other MIPS eligible clinicians, and the categories will not be reweighted. We are also finalizing our proposal, beginning with the 2018 performance period/2020 MIPS payment year, that, for groups, we will evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided. We are finalizing the regulation text at §414.1380(c)(2)(i)(A)(6) as proposed.

(C) Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for MIPS Eligible Clinicians Who Join a Practice in the Final 3 Months of the Performance Period Year

Beginning with the 2019 MIPS performance period, we proposed that a MIPS eligible clinician who joins an existing practice (existing TIN) during the final 3 months of the calendar year in which the MIPS performance period occurs (the performance period year) that is not participating in MIPS as a group would not have sufficient measures applicable and available (83 FR 35967 through 35968). We also proposed that a MIPS eligible clinician who joins a practice
that is newly formed (new TIN) during the final 3 months of the performance period year would not have sufficient measures applicable and available, regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group (83 FR 35967 through 35968).

In each of these scenarios, we proposed to reweight all four of the performance categories to zero percent for the MIPS eligible clinician and, because he or she would be scored on fewer than two performance categories, the MIPS eligible clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment under the policy at §414.1380(c) (83 FR 35967 through 35968). We proposed to codify these policies at §414.1380(c)(2)(i)(A)(3).

We proposed this policy because we are not currently able to identify these MIPS eligible clinicians (or groups if the group is formed in the final 3 months of the performance period year) at the start of the MIPS submission period. When we designed our systems, we incorporated user feedback that requested eligibility information be connected to the submission process. In order to submit data, an individual TIN/NPI or the group TIN must be in the files generated from the MIPS eligibility determination periods. As discussed in the CY 2019 PFS proposed rule (83 FR 35885 through 35886), we have two 12-month determination periods for eligibility. We proposed and are finalizing in section III.II.3.b. of this final rule that the second 12-month segment of the MIPS eligibility determination period will end on September 30 of the calendar year in which the applicable MIPS performance period occurs; therefore, we will have no eligibility information about clinicians who join a practice after September 30 of the performance period year. MIPS eligible clinicians who join an existing practice (existing TIN) in the final 3 months of the performance period year that is not participating in MIPS as a group will not be identified by our systems, and we will not have the ability to inform them that they
are eligible or to receive MIPS data from them. Similarly, practices that form (new TIN) in the final 3 months of the performance period year will not be in the MIPS determination files. Accordingly, we stated that the measures and activities would not be available because any data from these MIPS eligible clinicians would not be accessible to us.

If a MIPS eligible clinician joins a practice (existing TIN) in the final 3 months of the performance period year, and the practice is not newly formed and is reporting as a group for the performance period, the MIPS eligible clinician will be able to report as part of that group. In this case, we are able to accept data for the group because the TIN would be in our MIPS eligibility determination files. Therefore, we stated that we believe the measures and activities would be available in this scenario, and reweighting would not be necessary for the MIPS eligible clinician. We noted that, if a MIPS eligible clinician’s TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination will not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician’s TIN/NPI combination as soon as the information becomes available. Please see section III.I.3.j.(1) of this final rule for more information about assigning group scores to MIPS eligible clinicians.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposal to reweight MIPS eligible clinicians who form a new practice in the final 3 months of the performance period year or join an existing practice that does not participate in MIPS as a group.

Response: We thank commenters for their support of our proposal.
**Comment:** One commenter requested that we extend this policy to the 2018 performance period as well.

**Response:** We note that we did not propose to apply the policy to the 2018 performance period, and as such, we will not be extending it in this final rule.

**Comment:** One commenter did not support our proposal to treat MIPS eligible clinicians who join a new or existing practice in the final 3 months of the performance period year differently depending on whether the practice reports as a group. The commenter also requested that we reweight MIPS eligible clinicians who switch practices at any time during the performance period, because a MIPS eligible clinician's previous practice may not report on their behalf and because clinicians are impacted by training and other requirements associated with switching practices that may impact performance.

**Response:** A MIPS eligible clinician who joins an existing practice that is participating in MIPS as a group would have the opportunity to contribute to the group’s performance and final score. We refer readers to section III.I.3.j.(1) of this final rule for a discussion of which MIPS eligible clinicians may receive a group final score. We do not believe it would be appropriate to reweight the performance categories for MIPS eligible clinicians who change practices at any time during the performance period year because, consistent with our discussion in the CY 2019 PFS proposed rule (83 FR 35967 through 35968), we would be able to identify these clinicians at the beginning of the MIPS submission period if they change practices prior to the final 3 months of the performance period year. We also believe MIPS eligible clinicians who change practices prior to the final 3 months of the performance period year generally should have sufficient time to prepare for MIPS reporting, in the event that their prior practice does not submit data for them.
After consideration of public comments, we are finalizing as proposed our proposal to reweight the quality, cost, improvement activities, and Promoting Interoperability performance categories to zero percent for MIPS eligible clinicians who join an existing practice (existing TIN) during the final 3 months of the performance period year that is not participating in MIPS as a group, or a practice that is newly formed (new TIN) during the final 3 months of the performance period year regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group. We are finalizing the proposed regulation text at §414.1380(c)(2)(i)(A)(3) as proposed.

(D) Automatic Extreme and Uncontrollable Circumstances Policy Beginning with the 2020 MIPS Payment Year

In conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900).

In the CY 2019 PFS proposed rule (83 FR 35968), we stated that we believe that a similar automatic extreme and uncontrollable circumstances policy would be appropriate for any year of the MIPS program to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. As we discussed in the interim final rule (82 FR 53897), we believe such a policy would reduce burden on clinicians
who have been affected by widespread catastrophes and would align with existing policies for other Medicare programs. We proposed at §414.1380(c)(2)(i)(A)(7) and (c)(2)(i)(C)(3) to apply the automatic extreme and uncontrollable circumstances policy we adopted for the transition year to subsequent years of the MIPS program, beginning with the 2018 MIPS performance period and the 2020 MIPS payment year, with a few additions to address the cost performance category (83 FR 35968). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read §414.1380(c)(2)(i)(A)(8) instead of §414.1380(c)(2)(i)(A)(7). For a description of the policy we adopted for the MIPS transition year, we refer readers to the discussion in the interim final rule (82 FR 53895 through 53900).

In the interim final rule (82 FR 53897), we stated that we were not including the cost performance category in the automatic extreme and uncontrollable circumstances policy for the transition year because the cost performance category is weighted at zero percent in the final score for the 2017 MIPS performance period/2019 MIPS payment year. We finalized a 10 percent weight for the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year (82 FR 53643) and are finalizing a 15 percent weight for the 2019 performance period/2021 MIPS payment year (see section III.I.3.h.(3)(a) of this final rule). In the CY 2019 PFS proposed rule (83 FR 35968), we stated that for the reasons discussed in the CY 2018 Quality Payment Program final rule (82 FR 53781), we believe a MIPS eligible clinician’s performance on measures calculated based on administrative claims data, such as the measures specified for the cost performance category, could be adversely affected by a natural disaster or other extreme and uncontrollable circumstance, and that the cost measures may not be applicable to that MIPS eligible clinician. Therefore, we proposed to include the cost
performance category in the automatic extreme and uncontrollable circumstances policy beginning with the 2018 MIPS performance period/2020 MIPS payment year (83 FR 35968).

Under our policy for the transition year, if a MIPS eligible clinician in an affected area submits data for any of the MIPS performance categories by the applicable submission deadline for the 2017 MIPS performance period, he or she will be scored on each performance category for which he or she submits data, and the performance category will not be reweighted to zero percent in the final score (82 FR 53898). Our policy for the transition year did not include measures that are calculated based on administrative claims data (82 FR 53898). As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at §414.1325(a)(2), there are no data submission requirements for the cost performance category, and we will calculate performance on the measures specified for the cost performance category using administrative claims data. We proposed for the cost performance category, if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that would enable us to calculate the cost measures for that clinician (83 FR 35968).

In the interim final rule (82 FR 53897), we did not include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and we stated in the CY 2019 PFS proposed rule (83 FR 35968) that we continue to believe such a policy is not necessary. Unless we receive data from a TIN indicating that the TIN would like to be scored as a group for MIPS, performance by default is assessed at the individual MIPS eligible clinician level. Similarly, performance is not assessed at the virtual group level unless the member TINs submit an application in accordance with §414.1315. We stated that if we receive data from a group or
virtual group, we would score that data, even if individual MIPS eligible clinicians within the
group or virtual group are impacted by an event that would be included in our automatic extreme
and uncontrollable circumstances policy. Regardless of whether we receive data from a group or
virtual group, we would have no mechanism to determine whether the group or virtual group did
not submit data, or submitted data and performed poorly, because it had been affected by an
extreme and uncontrollable event unless the group notifies us of its circumstances. Instead of
establishing a threshold for groups or virtual groups to receive automatic reweighting based on
the number of clinicians in the group or virtual group impacted by extreme and uncontrollable
events, we stated that we believe it is preferable that these groups and virtual groups submit an
application for reweighting based on extreme and uncontrollable circumstances under our
existing policy (82 FR 53780 through 53783) where they may be eligible for reweighting if they
establish that the group or virtual group was sufficiently impacted by the extreme and
uncontrollable event.

We solicited comments on the above proposals. These comments and our responses are
discussed below.

Comment: Several commenters supported our proposed application of the automatic
extreme and uncontrollable policy starting with the 2018 MIPS performance period/2020 MIPS
payment year to reduce burden on impacted MIPS eligible clinicians. A few commenters
supported our proposal to extend the automatic extreme and uncontrollable policy to include the
cost performance category for the 2018 MIPS performance period/2020 MIPS payment year and
future years.

Response: We thank commenters for their support of our proposals.
Comment: One commenter suggested that we only score performance categories (including the cost performance category) for MIPS eligible clinicians impacted by the automatic extreme and uncontrollable policy if they would receive a positive or neutral payment adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive data for the clinician prior to a triggering event for the automatic extreme and uncontrollable circumstances policy, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at §414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). We assume that if a MIPS eligible clinician submits data to us following a triggering event, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.

Comment: One commenter disagreed with our decision to not propose an automatic extreme and uncontrollable circumstances policy for groups, because clinicians who choose to report as group for purposes of MIPS conduct all aspects of MIPS at a group level.

Response: We continue to believe that a group policy is not necessary and that there are barriers to implementing such a policy. For example, because group reporting is optional, we would have no mechanism to determine who would have been intending to report without
receiving a data submission. Additionally, some groups may be split between areas that are impacted by the triggering event and areas that are not. We do not believe that it would be appropriate to make a decision about how the group is impacted without additional information. We believe our application-based extreme and uncontrollable circumstances policy provides the mechanism for such an assessment. Finally, we note that if all the MIPS eligible clinicians in a group are located in an area affected by the extreme and uncontrollable circumstance, and the group is not able to submit for MIPS as a group, then all the MIPS eligible clinicians in the group would be considered as individuals and covered by the automatic extreme and uncontrollable circumstances policy.

After consideration of public comments received, we are finalizing these proposals and the regulation text at §414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3) as proposed.

iii. Extreme and Uncontrollable Circumstance Policy for the 2017 performance period/2019 MIPS payment year

As discussed in the preceding section III.I.3.i.(2)(b)(ii)(D), in conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900). In the CY 2019 PFS proposed rule (83 FR 35968), we proposed to codify this policy for the quality and improvement activities performance categories at §414.1380(c)(2)(i)(A)(6) and for the advancing care information (now
Promoting Interoperability) performance category at §414.1380(c)(2)(i)(C)(3). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read §414.1380(c)(2)(i)(A)(7) instead of §414.1380(c)(2)(i)(A)(6).

A summary of the comments we received on the IFC and our responses are included below.

**Comment**: Many commenters supported the automatic extreme and uncontrollable circumstance policy for the 2017 MIPS performance period. Several commenters stated that the policy is appropriate given the burden these events have had on impacted MIPS eligible clinicians. Several commenters supported the flexibility afforded by this policy and noted that the policy will allow impacted MIPS eligible clinicians to focus on providing patient care during natural disasters without having to focus on MIPS reporting. Several commenters supported our policy to allow clinicians impacted by extreme and uncontrollable events to report for MIPS if they choose because commenters believe some MIPS eligible clinicians may be less impacted by natural disasters and may have interest in reporting for MIPS. One commenter supported including events that have been designated by FEMA in the automatic extreme and uncontrollable circumstance policy. Another commenter supported using the practice location listed in PECOS to determine eligibility for the automatic extreme and uncontrollable policy.

**Response**: We believe that the automatic extreme and uncontrollable circumstance policy is appropriate to provide relief to MIPS eligible clinicians experiencing natural disasters and will help to ensure they are able to focus on providing patient care. In the CY 2018 Quality Payment Program final rule, we noted that we anticipate the types of events that could trigger this policy would be events designated as FEMA major disasters or a public health emergency.
declared by the Secretary, although we will review each situation on a case-by-case basis (82 FR 53897).

Comment: One commenter urged CMS to develop a clear communications plan for alerting MIPS eligible clinicians that they are eligible for the automatic extreme and uncontrollable circumstance policy.

Response: We agree that it will be important to effectively alert MIPS eligible clinicians who we determine are covered by the automatic extreme and uncontrollable circumstance policy. Similar to other CMS programs, we communicated applicability information through routine communication channels, including, but not limited to, issuing memos, emails, and notices on the QPP Web site, qpp.cms.gov.

Comment: One commenter stated that providing MIPS eligible clinicians who are impacted by extreme and uncontrollable events with a final score that is equal to the performance threshold if they report on only one performance category does not recognize their efforts for that performance category. Instead, commenter stated CMS should score the MIPS eligible clinician on that category.

Response: We continue to believe that the final score for MIPS should be a composite score. Therefore, for MIPS eligible clinicians who are subject to the automatic extreme and uncontrollable circumstance policy, we will continue to apply our general MIPS policy codified at §414.1380(c) that MIPS eligible clinicians who are scored on fewer than 2 performance categories receive a score equal to the performance threshold (82 FR 53958). MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances who submit data for the quality performance category would also have to submit data for the
Promoting Interoperability or improvement activities performance categories in order for the data submitted to contribute to their final score.

Comment: One commenter stated that scoring data that are submitted by impacted MIPS eligible clinicians is unfair because they are being assessed against MIPS eligible clinicians who were not impacted by natural disasters.

Response: Because the performance threshold is set very low (at 3 points) for the 2017 MIPS performance period, we believe that MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy but submit data will easily exceed the performance threshold and thus will not be negatively impacted. Furthermore, we assume that MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances but then submit data for more than one performance category believe there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score.

Comment: One commenter suggested that CMS should not score Medicare Part B claims measures that are submitted by MIPS eligible clinicians impacted by extreme and uncontrollable events.

Response: If a MIPS eligible clinician reports via Medicare Part B claims for the quality performance category and we receive data prior to the extreme and uncontrollable event, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or improvement activities performance categories. We previously finalized at §414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779).
Comment: One commenter suggested that CMS consider providing a positive payment adjustment for MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy instead of providing a neutral payment adjustment because this will help to incentivize MIPS eligible clinicians to return to affected areas.

Response: It is unclear to us how a positive payment adjustment would incentivize clinicians to return to affected areas, or how we would go about verifying whether and why they have returned, since many factors influence clinician choice in practice location.

After consideration of the public comments, we are adopting the IFC as a final rule without any modifications. We are finalizing the regulation text at §414.1380(c)(2)(i)(A)(7) and §414.1380(c)(2)(i)(C)(3) as proposed.

(iv) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules, we established policies for redistributing the weights of performance categories for the 2019 and 2020 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories (81 FR 77325 through 77329; 82 FR 53783 through 53785, 53895 through 53900). We proposed to codify these policies under §414.1380(c)(2)(ii) (83 FR 35969).

For the 2021 MIPS payment year, we proposed at §414.1380(c)(2)(ii)(B) to apply similar reweighting policies as finalized for the 2020 MIPS payment year (83 FR 35969). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read §414.1380(c)(2)(ii)(C) instead of §414.1380(c)(2)(ii)(B). In general, we would redistribute the weight of a performance category or categories to the quality performance category. We stated that redistributing
weight to the quality performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. We proposed to continue to redistribute the weight of the quality performance category to the improvement activities and Promoting Interoperability performance categories (83 FR 35969). However, for the 2021 MIPS payment year, based on our proposal to weight the cost performance category at 15 percent, we proposed to reweight the Promoting Interoperability performance category to 45 percent and the improvement activities performance category to 40 percent when the quality performance category is weighted at zero percent (83 FR 35969). We chose to weigh Promoting Interoperability higher in order to align with goals of interoperability and for simplicity because we generally have avoided assigning partial percentage points to performance category weights. Reweighting scenarios under the proposal are presented in Table 54.

**TABLE 54: Performance Category Redistribution Policies Proposed for the 2021 MIPS Payment Year**

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

We stated that we have heard from stakeholders in previous years that our reweighting policies place undue weight on the quality performance category, and, although we continue to believe the
policies are appropriate, we solicited comment on alternative redistribution policies in which we would also redistribute weight to the improvement activities performance category (see Table 55). Under the alternative redistribution policy we considered, we would redistribute the weight of the Promoting Interoperability performance category to the quality and improvement activities performance categories (83 FR 35969 through 35970). We would redistribute 15 percent of the Promoting Interoperability performance category weight to the quality performance category, and 10 percent to the improvement activities performance category. We stated that redistributing more of the weight of the Promoting Interoperability performance category to the quality performance category is appropriate because MIPS eligible clinicians have had more experience reporting on quality measures under other CMS programs than reporting on improvement activities. We would redistribute the cost performance category weight equally to the quality and improvement activities performance categories (5 percent to each) under this alternative policy.

**TABLE 55: Alternative Performance Category Redistribution Policies Considered for the 2021 MIPS Payment Year**

<table>
<thead>
<tr>
<th>Reweighting Scenario</th>
<th>Quality</th>
<th>Cost</th>
<th>Improvement Activities</th>
<th>Promoting Interoperability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Reweighting Needed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Scores for all four performance categories</td>
<td>45%</td>
<td>15%</td>
<td>15%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Reweight One Performance Category</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No Promoting Interoperability</td>
<td>60%</td>
<td>15%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>- No Cost</td>
<td>55%</td>
<td>0%</td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td>- No Quality</td>
<td>0%</td>
<td>15%</td>
<td>40%</td>
<td>45%</td>
</tr>
<tr>
<td>- No Improvement Activities</td>
<td>60%</td>
<td>15%</td>
<td>0%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Reweight Two Performance Categories</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No Cost and No Promoting Interoperability</td>
<td>70%</td>
<td>0%</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>- No Cost and No Quality</td>
<td>0%</td>
<td>0%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>- No Cost and No Improvement Activities</td>
<td>75%</td>
<td>0%</td>
<td>0%</td>
<td>25%</td>
</tr>
<tr>
<td>- No Promoting Interoperability and No Quality</td>
<td>0%</td>
<td>15%</td>
<td>85%</td>
<td>0%</td>
</tr>
<tr>
<td>- No Promoting Interoperability and No Improvement Activities</td>
<td>85%</td>
<td>15%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>- No Quality and No Improvement Activities</td>
<td>0%</td>
<td>15%</td>
<td>0%</td>
<td>85%</td>
</tr>
</tbody>
</table>

We solicited comments on the above proposals. These comments and our responses are
discussed below.

Comment: A few commenters supported our proposed reweighting policies for the 2019 MIPS performance period/2021 MIPS payment year.

Response: We thank commenters for their support of our proposal.

Comment: Several commenters supported the alternative policy we considered to reweight to both quality and improvement activities, and stated our primary proposal which generally reweights to quality, places undue weight on the quality performance category. Some commenters stated that reweighting to the improvement activities performance category is appropriate given the importance of practice improvement. A few commenters stated that the quality performance category is particularly challenging, and therefore, placing additional weight on this performance category would not be fair to MIPS eligible clinicians who receive reweighting for the cost or Promoting Interoperability performance categories. A few commenters also mentioned that our reweighting policies place undue burden on small and rural practices who have particular difficulty performing well on the quality performance category. A few commenters requested that we redistribute all of the weight of the Promoting Interoperability or cost performance categories to the improvement activities performance category, in order to avoid placing undue focus on quality and due to the importance of quality improvement.

Response: We continue to believe reweighting to the quality performance category is appropriate as the quality performance category is a critical component of value-based care, and therefore, we believe performance on quality measures is important. While there is variation in performance for the quality performance category, for the improvement activities we are only assessing whether the MIPS eligible clinician completed activities. We believe that reweighting to the quality performance category will encourage MIPS eligible clinicians to report on the
quality performance category due to the higher category weight (that is, a zero score for this performance category would have more significant impact), particularly those clinicians who may have only reported to the improvement activities performance category, and will minimize complexity. We believe it is important to encourage MIPS eligible clinicians to report on quality while the performance threshold is still relatively low. In regards to the concern on small and rural practice performance in the quality performance category, we note that small practices that report quality measures can receive the small practice bonus we are finalizing in section III.I.3.i.(1)(b)(viii) of this final rule and we have not seen differences in performance for rural practices. We plan to review available approaches to reweighting in future years including impact on small and rural practices and may revisit our policies to ensure they are fair and not overly complex.

Comment: One commenter disagreed with our proposal to reweight the quality performance category to the improvement activities and Promoting Interoperability performance categories, because the commenter noted concern with our discussion of available and applicable measures for the quality performance category and reweighting this category would place greater weight on other performance categories. Another commenter noted that reweighting the quality performance category may lead to MIPS eligible clinicians inaccurately receiving a positive, neutral, or negative payment adjustment.

Response: We believe reweighting to the improvement activities and Promoting Interoperability performance categories in the rare cases when the quality performance category is reweighted is appropriate because MIPS eligible clinicians have limited experience being scored on the cost performance category. We also expect the cases when a MIPS eligible clinician does not have any quality measures to be very rare.
After consideration of public comments, we are finalizing these proposals and the regulation text at §414.1380(c)(2)(ii)(A) through (C) as proposed.

Because the cost performance category was zero percent of a MIPS eligible clinician’s final score for the 2017 MIPS performance period, we stated in the CY 2019 PFS proposed rule (83 FR 35970) that it is not appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we were concerned that there would be limited measures in the cost performance category under our proposals for the 2019 MIPS performance period and stated that it may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also noted that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we solicited comment on redistributing weight to the cost performance category in future years.

We thank commenters for their input and will take this input into consideration in future years.

(c) Final Score Calculation

We proposed to revise the formula at §414.1380(c) for calculating the final score (83 FR 35970). We did not propose to continue to add the small practice bonus to the final score for the 2021 MIPS payment year and proposed to add a small practice bonus to the quality performance category score instead starting with the 2021 MIPS payment year (83 FR 35950 through 35951). Therefore, we proposed to revise the formula to omit the small practice bonus from the final
score calculation beginning with the 2021 MIPS payment year (83 FR 35970). We requested public comments on this proposal.

Although we received several comments on the small practice bonus, we did not receive any comments on our proposed revisions to the formula to calculate the final score. We discuss our policy for our revised small practice bonus in the quality performance category in section III.I.3.i.(1)(b)(viii) of this final rule.

After consideration of public comments, we are finalizing our proposed revisions to §414.1380(c) as proposed.

In the CY 2019 PFS proposed rule, we solicited comments on approaches to simplify calculation of the final score (83 FR 35970). We thank commenters for their input and will take this input into consideration in future years.

j. MIPS Payment Adjustments

(1) Final Score Used in Payment Adjustment Calculation

For our previously established policies regarding the final score used in payment adjustment calculations, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332) and the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787). Under our policies, for groups submitting data using the TIN identifier, we will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period (82 FR 53785). We proposed to modify this policy for the application of the group final score, beginning with the 2019 performance period/2021 MIPS payment year (83 FR 35971). We proposed a 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of
the calendar year of the performance period (October 1 through December 31 of the performance period year) (83 FR 35971). We proposed for groups submitting data using the TIN identifier, we would apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the proposed 15-month window (83 FR 35971). We stated that we believe that partially aligning with the second segment of the MIPS determination period creates consistency with our eligibility policies that informs a group or eligible clinician of who is eligible. We refer readers to the CY 2019 PFS proposed rule (83 FR 35884 through 35886) where we discuss our proposals related to MIPS determination periods.

We noted that, if a MIPS eligible clinician’s TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician’s TIN/NPI combination as soon as the information becomes available.

We solicited comments on the above proposal.

**Comment:** One commenter supported the concept of assigning a group score to clinicians who are in a group during the final 3 months of the calendar year of the performance period, stating that it is administratively burdensome for large organizations to track clinicians who join their practice during the last 3 months of the calendar year of the performance period and determine whether or not their previous practice intends to submit data on their behalf for the same calendar year of the performance period.

**Response:** We thank the commenter for their support.

**Comment:** One commenter expressed concern with the 15-month gap between the end of
the first segment of the MIPS determination period and the end of the calendar year of the MIPS performance period for clinicians in groups who qualify for a group final score. The commenter stated that many clinicians move from one TIN to another and recommended we allow groups to report both on behalf of individual clinicians or as a group for all clinicians who have assigned their billing rights to the TIN during the calendar year of the performance period.

Response: We realize that the first segment of the MIPS determination period, as codified in this final rule at §414.1305, ends 15 months before the end of the calendar year of the performance period; however, we believe the performance of a group should coincide, to the extent possible, with clinicians who are in the group during the performance period. Therefore, we believe it is appropriate to use the 15-month window which includes the second segment of the MIPS determination period and the last 3 months of the calendar year of the performance period. We note that group reporting is an option and practices may elect to submit for individual eligible clinicians, rather than as a group, as long as eligible clinicians are identified prior to end of the second segment of the MIPS determination period. As discussed in section III.I.3.i.(2)(b)(ii)(C) of this final rule, we do not have the ability to accept data for new group practices formed in the last 3 months of the calendar year of the performance period, or for individual MIPS eligible clinicians who switch practices in the last 3 months of the calendar year of the performance period if their new practice is not participating in MIPS as a group.

Comment: One commenter did not support the proposed 15-month window, citing the need for additional clarity and guidance to avoid complexity and confusion, and suggested that CMS provide examples of how this policy would apply in different scenarios. This commenter also recommended that CMS consider the implications of the proposal on clinician employment and how the proposal may negatively impact the ability of clinicians to switch practices.
Response: We do not agree that this proposal would cause confusion or add complexity. We believe the 15-month window aligns with our eligibility policies and better informs clinicians about their eligibility, streamlining the program. For example, for the 2019 MIPS performance period, if an eligible clinician joins a group practice in November of 2019 and that group practice existed prior to the last 3 months of the year (that is, prior to October 1, 2019) and submits MIPS data as a group, we would apply the group final score to that eligible clinician if the clinician bills under the group’s TIN during the proposed 15-month window. Another example is a MIPS eligible clinician who joins a group practice in October of 2018 and that group practice submits MIPS data as a group for the 2019 MIPS performance period; for the 2019 performance period, we would apply the group final score to that eligible clinician if the clinician bills under the group’s TIN during the proposed 15-month window. We appreciate the suggestion to consider the policy’s implications on clinician employment and will take this into consideration in future rulemaking.

After consideration of the comments we received, we are finalizing our proposed 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the calendar year of the performance period through September 30 of the calendar year of the performance period) and also includes the final 3 months of the calendar year of the performance period (October 1 through December 31 of the calendar year of the performance period). We are also finalizing that for groups submitting data using the TIN identifier, we will apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the 15-month window. We refer readers to section III.I.3.i.(2)(b)(ii)(C) of this final rule for a detailed discussion of the reweighting of the quality, cost, improvement activities and Promoting Interoperability performance categories for MIPS eligible clinicians who join a group practice in
the final 3 months of the calendar year of the performance period.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This
additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

To determine a performance threshold to propose for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year), in the CY 2019 PFS proposed rule (83 FR 35971), we again relied upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018. As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with newly added clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2021 MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35971), we noted that we considered using the final scores for the 2017 MIPS performance period/2019 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2018, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses. We noted that if technically feasible, we would consider using the actual data used to determine the final scores for the
2019 MIPS payment year to estimate a performance threshold for the 2024 MIPS payment year in the final rule.

Because the final scores for MIPS eligible clinicians were not yet available at the time of the CY 2019 PFS proposed rule, we reviewed the data relied upon for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536) as we believed it was the best data available to us to estimate the actual data for the 2017 MIPS performance period/2019 MIPS payment year (83 FR 35971). Please refer to the CY 2019 PFS proposed rule (83 FR 35971 through 35973) for more details about the data we used.

In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. In the CY 2019 PFS proposed rule (83 FR 35972), we stated that when we analyzed the estimated final scores for the first year of the program (the 2019 MIPS payment year), the mean final score was between 63.50 and 68.98 points and the median was between 77.83 and 82.5 points based on the different participation assumptions. For purposes of estimating the performance threshold for the 2024 MIPS payment year, we used the mean final score based on data used for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536), which resulted in an estimated performance threshold between 63.50 and 68.98 points for the 2024 MIPS payment year. We noted that this is only an estimation we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act, and we will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

We proposed a performance threshold of 30 points for the 2021 MIPS payment year to be codified at §414.1405(b)(6) (83 FR 35972). A performance threshold of 30 points would be
a modest increase over the performance threshold for the 2020 MIPS payment year (15 points), and we stated that we believe it would provide a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we have estimated would be between 63.50 and 68.98 points.

We stated that we want to encourage continued participation and the collection of meaningful data by MIPS eligible clinicians. A higher performance threshold would help MIPS eligible clinicians strive to achieve more complete reporting and better performance and prepare MIPS eligible clinicians for the 2024 MIPS payment year. However, a performance threshold set too high could also create a performance barrier, particularly for MIPS eligible clinicians who did not previously participate in PQRS or the EHR Incentive Programs. Additionally, we stated that we believe a modest increase from the performance threshold for the 2020 MIPS payment year would be particularly important to reduce the burden for MIPS eligible clinicians in small or solo practices. We stated that we believe that active participation of MIPS eligible clinicians in MIPS will improve the overall quality, cost, and care coordination of services provided to Medicare beneficiaries.

In the CY 2019 PFS proposed rule (83 FR 35972), we noted that we heard from stakeholders requesting that we continue a low performance threshold and from stakeholders that requested we ramp up the performance threshold to help MIPS eligible clinicians prepare for a future performance threshold of the mean or median of final scores and to meaningfully incentivize higher performance. We also noted that we heard from stakeholders who stated a higher performance threshold may incentivize higher performance by MIPS eligible clinicians through higher positive MIPS payment adjustments for those who exceed the performance threshold. We noted our belief that a performance threshold of 30 points for the 2021 MIPS
payment year would provide a gradual and incremental increase from the performance threshold of 15 points for the 2020 MIPS payment year and could incentivize higher performance by MIPS eligible clinicians.

We also noted our belief that a performance threshold of 30 points represents a meaningful increase compared to 15 points, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold, and we provided examples to support our belief in the CY 2019 PFS proposed rule (83 FR 35972). We invited public comment on the proposal to set the performance threshold for the 2021 MIPS payment year at 30 points (83 FR 35972). Alternatively, we considered whether the performance threshold should be set at a higher or lower number, for example, 25 points or 35 points, and also sought comment on alternative numerical values for the performance threshold for the 2021 MIPS payment year (83 FR 35972).

We solicited comments on the above proposal.

Comment: Many commenters supported the proposed performance threshold of 30 points, indicating that the increase is reasonable; is aligned with what they believe to be Congress’s intent to ensure that clinicians continue to be held accountable for quality and cost; is not a significant change from the prior year; encourages clinicians to increase their engagement and performance in MIPS; and is low enough to protect eligible clinicians who may not have experience reporting in MIPS from negative payment adjustments. One commenter stated that raising the performance threshold may help limit the flattening impact of the overall cost performance category score. One commenter stated the modest increase would not disadvantage small practices if the small practice bonus and other special scoring policies remain available to them and is reasonable considering that a fair portion of clinicians are excluded from MIPS
under the low-volume threshold.

**Response:** We thank the commenters for their support.

**Comment:** Many commenters did not support the proposed performance threshold of 30 points and stated it is too high, is not gradual enough, would be unduly taxing, and many eligible clinicians are still adapting to the complexities of the MIPS program. Several commenters did not support the performance threshold citing the number of policy changes to the MIPS program and stated that group practices and clinicians, including newly eligible clinicians, should gain experience with MIPS policy changes, including changes to episode-based cost measures and the restructuring of the Promoting Interoperability performance category, before the performance threshold is raised. Several commenters recommended a performance threshold of 20 points given the number of changes being proposed. Commenters also indicated 20 points would help newly eligible clinicians adjust to program reporting requirements and that it could be met or exceeded by reporting on 6 quality measures that receive at least 3 points per measure and one high weighted improvement activity or 2 medium weighted improvement activities to avoid a negative MIPS payment adjustment. A few commenters indicated that clinicians need more time to be educated about the MIPS program.

**Response:** We acknowledge the concerns submitted by many commenters. We recognize that many requirements and scoring policies in the MIPS program have changed since the 2017 MIPS performance period/2019 MIPS payment year, but we believe the proposed performance threshold of 30 points is an appropriate increase that encourages increased participation and engagement in the MIPS program and that incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care.

We also do not believe that increasing the performance threshold to 30 points is
unreasonable or too steep, but is rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. In the CY 2019 PFS proposed rule, we estimated the performance threshold we would establish for the 2024 MIPS payment year would be between 63.50 and 68.98 points. This information was based on year 1 estimates from the regulatory impact analysis (83 FR 35972; 81 FR 77514 through 77536). When we looked at the actual final scores for MIPS eligible clinicians for the 2017 MIPS performance period/2019 MIPS payment year, we found the mean final score was 74.01 points and the median final score was 88.97 points. As discussed in section VII.F.8.d. of the Regulatory Impact Analysis (RIA) of this final rule, we also estimated the potential final scores for the 2019 MIPS performance period/2021 MIPS payment year. In the RIA, we updated our estimates by using data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applying the scoring and eligibility policies for the third year of MIPS (the 2019 MIPS performance period/2021 MIPS payment year). In the RIA, we estimated the mean final score for the 2019 performance period/2021 MIPS payment year at 69.53 points and the median final score at 78.72 points. Based on these numbers, we estimate the performance threshold that we would establish for the 2024 MIPS payment year would likely be over 65 points. We believe that if we set the performance threshold at 20 points (or another number lower than 30 points) for the 2021 MIPS payment year, then the increases in the performance threshold for each of the 2022 and 2023 MIPS payment years would have to be steeper to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, in accordance with 1848(q)(6)(D)(iv) of the Act.

Additionally, we recognize that some policy changes, such as those finalized in this final rule for the Promoting Interoperability performance category, the impact of topped out measures
on the quality performance category, the increased weighting of the cost performance category, and the introduction of episode-based cost measures may dampen final scores because it will be more difficult to achieve a perfect performance category score of 100 percent. However, we believe there are also many options for a MIPS eligible clinician, including a newly eligible clinician, to earn a final score at or above a performance threshold of 30 points that do not require a perfect score in every performance category and that these policies do not preclude a MIPS eligible clinician from performing well. For example, a MIPS eligible clinician that submits the maximum number of improvement activities (achieving 40 points out of a possible 40 points) that is weighted at 15 percent of the final score (100 percent improvement activities performance category score x 15 percent x 100 equals 15 points toward the final score) and achieves a quality performance category score of 35 percent that could be achieved through a minimum of complete reporting of quality measures at varying levels of performance (35 percent quality performance category score x 45 percent x 100 equals 15.75 points toward the final score) would qualify for 30.75 points and exceed the performance threshold. When we also consider the cost and Promoting Interoperability performance categories scores, clinicians have even more options to exceed a 30-point performance threshold. While the performance threshold could be met or exceeded without clinician participation in the quality performance category, we encourage clinicians to participate in multiple performance categories, including the quality performance category, to help facilitate successful participation in MIPS when the performance threshold will be increased in future years and to align with the MIPS program’s focus on value-based care and the delivery of high quality care for Medicare beneficiaries.

31 The score for the quality performance category would be (6 measure achievement points x 1 measure plus 3 measure achievement points x 5 measures)/60 total possible achievement points or 35 percent. This assumes an outcome measure is submitted. That score could be higher if the clinician qualifies for bonuses in the quality performance category.
We agree with commenters about the need to educate clinicians, including newly eligible clinicians, about MIPS program policies and policy changes from year to year and encourage clinicians to utilize the resources available to educate clinicians about the MIPS program at the CMS Quality Payment Program Resource library at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html.

**Comment:** Several commenters recommended a lower performance threshold specifically for eligible clinicians in their first year of MIPS eligibility, citing that this flexibility is more equitable and allows for a greater chance of successful participation, is a reasonable approach, and that 30 points creates an unlevel playing field. A few commenters recommended 25 points and other scoring accommodations for newly eligible clinicians, including occupational therapists and physical therapists. A few commenters suggested alternative performance thresholds for newly eligible clinicians including 3 points and a modified “pick your pace” threshold for these clinicians. One commenter recommended a performance threshold of 20 points and stated a 30-point performance threshold is a very high standard for eligible clinicians in their first year of eligibility.

**Response:** As described in section III.I.3.j.(2) of this final rule, the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year (year 6). Therefore, a clinician who is a MIPS eligible clinician beginning with the 2021 MIPS payment year would have 4 years in the program to ramp up to year 6. Conversely, a clinician who first becomes a MIPS eligible clinician in a later year would be afforded less time to ramp up the closer the program gets to year 6. We refer readers to section III.I.3.a. of this final rule for our discussion of new eligible clinician types.
**Comment:** Many commenters stated that CMS should not increase the performance threshold until there is actual MIPS participation data available to analyze and share with clinicians, indicating that there is insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold, the program is still in its early stages, and that use of actual data would provide eligible clinicians a greater sense of how they performed in the program overall.

**Response:** We appreciate the commenters’ concerns with the proposed performance threshold and their request for a delay in increasing the performance threshold until we have more information about how clinicians are actually performing under MIPS. As discussed earlier in this section, we estimate that we would likely set the performance threshold for the 2024 MIPS payment year at over 65 points. We did analyze the actual final scores for the 2019 MIPS payment year and found the mean final score was 74.01 points and the median final score was 88.97 points for MIPS eligible clinicians. We believe that setting the performance threshold at 30 points for the 2019 performance period/2021 MIPS payment year is appropriate because it encourages increased participation and prepares clinicians for the additional participation requirements to meet or exceed the performance thresholds that will be set for later years. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year required by section 1848(q)(6)(D)(iv) of the Act.

We also note that eligible clinicians have received performance feedback based on their performance in year 1 of MIPS. As previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53801 through 53802), on an annual basis, beginning July 1, 2018,
performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories for the 2017 performance period, and if technically feasible, for the improvement activities and advancing care information (now known as Promoting Interoperability) performance categories. For details on the release of the feedback reports for the first year of MIPS, we refer readers to section III.I.3.g. of this final rule.

Comment: Several commenters did not support the proposed performance threshold of 30 points, stating their belief that it burdens smaller practices, especially individual clinicians who are unable to afford CEHRT. A few commenters recommended that CMS consider a bonus for solo practitioners.

Response: We acknowledge the concerns of commenters regarding the potential burden on small practices, particularly solo practitioners. We also recognize the unique challenges for solo practitioners who participate in MIPS and have established a set of policies for small practices that apply to solo practitioners as well. The special policies available for small practices include the small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies available for small practices (CY 2018 Quality Payment Program final rule (82 FR 53683)); and special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656. We also note that clinicians in small practices are more likely than clinicians in larger practices to fall below one of the low-volume criteria and would not be required to submit to MIPS; however, if they exceed at least one, but not all, of the low volume criteria, then they would be able to take advantage of the opt-in policy.
We refer readers to section III.I.3.c. of this final rule for more details.

**Comment:** A few commenters recommended a more modest increase to the performance threshold and asked us to consider specialty-specific performance thresholds, or special scoring policies for clinicians in specialty practices, stating this would allow for more fair comparisons among clinicians. One commenter stated concerns with ambulatory surgical center-based clinicians being able to meet a 30-point threshold and requested that CMS consider scoring relief for ambulatory surgical center-based clinicians and groups. One commenter stated concerns for certified registered nurse anesthetists (CRNAs) meeting the performance threshold, citing the lack of anesthesia-related measures, low achievable points due to quality measure benchmarking, the lack of applicable cost measures, and the inability of CRNAs to participate in the Promoting Interoperability performance category that places a significant amount of time, money and resources into achieving performance scores to meet the minimum performance threshold. One commenter did not support the proposed performance threshold and believed that clinicians who are not capable of submitting data for more than one MIPS performance category could not meet the performance threshold.

**Response:** We appreciate the unique challenges faced by MIPS eligible clinicians that are in specialty practices, including clinicians based in ambulatory surgical centers and CRNAs. However, we believe that different performance criteria for certain types of clinicians would create more confusion and burden than a cohesive set of criteria. We also do not believe the proposed increase in the performance threshold is overly aggressive or unfair to specialty practices and note that there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold. We also believe that except for a few circumstances, such as extreme and uncontrollable circumstances, rare cases where there are no quality
measures, or clinicians joining an existing practice (existing TIN) during the final 3 months of the calendar year in which the performance period occurs (the performance period year) that is not participating in MIPS as a group, most MIPS eligible clinicians would have sufficient measures and activities available and applicable to them for the quality and improvement activities performance categories and would be scored on these two categories. We also have policies in place, such as data validation process discussed in section III.I.3.i.(1)(b)(vii) of this final rule, to assess if clinicians have fewer than 6 measures available and applicable for the quality performance category. We refer the readers to the discussion of our reweighting policies for extreme and uncontrollable circumstances at section III.I.3.i.(2)(b)(ii) of this final rule.

Comment: A few commenters supported keeping a performance threshold of 15 points to minimize administrative burdens as part of the "Patients over Paperwork" initiative and to give clinicians adequate time to adjust their practice to meet the program's requirements.

Response: We are mindful of the efforts and requirements for eligible clinician participation in MIPS and agree that many clinicians need time to become familiar with the program’s policies and requirements and gain experience with increased participation under the MIPS program. However, we do not believe that maintaining the performance threshold at 15 points for the 2019 performance period/2021 MIPS payment year appropriately encourages clinicians to actively participate in MIPS and incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year that the statute requires. We believe a meaningful increase to a performance threshold of 30 points maintains appropriate flexibility for
clinicians to meet or exceed the performance threshold, while requiring increased participation over the level of engagement required to meet or exceed the 15-point threshold for year 2 of MIPS. We also believe the increased participation better prepares clinicians to succeed under MIPS in future years, will encourage a transition to the MIPS program’s focus on value-based care, and will improve the overall quality, cost, and care coordination of services to Medicare beneficiaries.

Comment: Several commenters recommended a higher performance threshold believing that the proposed performance threshold punishes eligible clinicians who have invested time and money to achieve high MIPS performance, compromises the ability of high performers to earn the maximum payment adjustment, and dilutes program effectiveness to drive quality improvement and reduce spending growth. A few commenters recommended a performance threshold between 30 points and 60 points. One commenter recommended a performance threshold of 50 points, stating it would better reward clinicians and groups who are engaged with the program and encourage the examination of alternative payment models.

Response: The MIPS statute requires budget neutrality, and clinicians will receive a positive, negative, or neutral payment adjustment factor that is determined by their performance and the distribution of final scores across all MIPS eligible clinicians; accordingly, high performers would likely receive higher payment adjustments if fewer MIPS eligible clinicians meet or exceed the performance threshold. While a higher performance threshold provides a greater financial reward for high performers, we believe the proposal of 30 points is warranted to encourage clinician participation in MIPS and to encourage a movement toward value-based care with a focus on the delivery of high quality care. We also believe that the additional performance threshold for exceptional performance discussed later in section III.I.3.j.(3) of this
final rule provides an additional financial incentive and financial reward for high performers and will continue to incentivize their exceptional performance. Moreover, we believe setting the performance threshold higher than 30 points would not provide a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, as required by the statute, but rather would result in a sharp increase over the performance threshold of 15 points for the 2020 MIPS payment year.

After consideration of the comments, we are finalizing our proposal to set the performance threshold at 30 points for the 2021 MIPS payment year as proposed. We are codifying the performance threshold for the 2021 MIPS payment year and finalizing the regulation text at §414.1405(b)(6) as proposed.

We also solicited comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which in the CY 2019 PFS proposed rule we based on the estimated mean final score for the 2019 MIPS payment year (83 FR 35972). We were particularly interested in whether we should use the median, instead of the mean, and whether in the future we should estimate the mean or median based on the final scores for another MIPS payment year. We also solicited comment on whether establishing a path forward to a performance threshold for the 2024 MIPS payment year that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year would be beneficial, and whether it would be beneficial for MIPS eligible clinicians to know in advance the performance threshold for the 2022 and 2023 MIPS payment years to encourage and facilitate increased clinician engagement and prepare clinicians for meeting the performance threshold for the 2024 MIPS payment year.
We thank commenters for their input on these topics and will take this input into consideration in future years.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) the threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act.

Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500,000,000 of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in the CY 2019 PFS proposed rule (83 FR 35971), we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act, as amended by section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018, to propose a performance threshold of 30 points for the 2021 MIPS payment year. The special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the
2021 MIPS payment year, we proposed to again decouple the additional performance threshold from the performance threshold (83 FR 35973 through 35974).

During the time period in which we were drafting the CY 2019 PFS proposed rule, we did not have actual MIPS final scores for a prior performance period. We noted in the CY 2019 PFS proposed rule (83 FR 35973 ) that if we did not decouple the additional performance threshold from the performance threshold, then we would have to set the additional performance threshold at the 25th percentile of possible final scores above the performance threshold. With a performance threshold set at 30 points, the range of total possible points above the performance threshold is 30.01 to 100 points and the 25th percentile of that range is 47.5, which is less than one-half of the possible 100 points in the MIPS final score. We stated that we do not believe it would be appropriate to lower the additional performance threshold to 47.5 points because we do not believe a final score of 47.5 points demonstrates exceptional performance by a MIPS eligible clinician, as these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act and proposed at §414.1405(d)(5) to set the additional performance threshold at 80 points for the 2021 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold (83 FR 35973).

As required by section 1848(q)(6)(D)(iii) of the Act, we took into account the data available and the modeling described in the CY 2019 PFS proposed rule to estimate final scores for the 2021 MIPS payment year (83 FR 35973). We stated that we believed 80 points was appropriate to incentivize clinicians who have made greater strides to meaningfully participate in the MIPS program to perform at even higher levels. An additional performance
threshold of 80 points would require a MIPS eligible clinician to perform well on at least two performance categories. We stated that, generally, a MIPS eligible clinician could receive a maximum score of 45 points for the quality performance category, which is below the 80-point additional performance threshold. In addition, 80 points is at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. We noted the additional performance threshold at 80 points could increase the incentive for excellent performance while keeping the focus on quality performance.

We also stated an increase would encourage increased engagement and further incentivize clinicians whose performance meets or exceeds the additional performance threshold, recognizing that a fixed amount is available for a year under section 1848(q)(6)(F)(iv) of the Act to fund the additional MIPS payment adjustments and that the more clinicians who receive an additional MIPS payment adjustment, the lower the average clinician’s additional MIPS payment adjustment will be.

For future years, we stated that we may consider additional increases to the additional performance threshold.

We solicited comments on these proposals.

Comment: Many commenters recommended the additional performance threshold remain at 70 points. Several commenters stated it would be more difficult to reach 80 points rather than 70 points because of proposed changes to the Promoting Interoperability performance category, changes to quality measures, more topped out measures, the increased weighting of the cost performance category, the introduction of episode-based cost measures, and the removal of bonus points. One commenter recommended that the additional performance threshold remain at 70 points for at least another year because clinicians are still learning to interpret their feedback
reports and make adjustments to their practices accordingly. One commenter stated that clinicians in specialty practices without a significant breadth of reportable measures would be adversely affected while those specialties that do have large numbers of measures with full scoring potential would benefit and that this was unfair and would discourage high performance for those clinicians and groups within specialties. One commenter indicated that the increase may cause more clinicians to report on measures that bring more points rather than the most value to their patients and practice. Another commenter stated the increase seemed arbitrary and that clinicians who earn 70 points should be considered exceptional. One commenter stated that keeping the additional performance threshold at 70 points would allow the payment adjustment to be spread more evenly rather than to only a select few and alleviate some of the lack of positive payment adjustment incentive due to the very low 30-point performance threshold.

A few commenters stated the additional performance threshold should not be increased until information is available and data shared with clinicians from the first 2 years of the program about the number of eligible clinicians who were able to earn the additional payment adjustment, including the number of psychiatrists who exceeded the additional performance threshold during the 2017 MIPS performance period.

Response: We note that many commenters recommended that we maintain 70 points for the additional performance threshold for the 2019 performance period/2021 MIPS payment year. However, we believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries. Based on our current data, our belief that raising the additional performance threshold will incentivize continued improved performance, and our concern that
policy changes may make it challenging for clinicians to reach an additional performance threshold of 80 points while they are becoming familiar and comfortable with the policy changes, we believe it is important to raise the additional performance threshold, but by less than the original amount proposed. Therefore, for year 3 of the MIPS program, we are finalizing the additional performance threshold at 75 points, which is halfway between our proposal of 80 points and the level recommended by many commenters of 70 points.

We appreciate commenters’ concerns about the proposed policy changes for MIPS impacting clinicians’ ability to exceed the additional performance threshold. While we recognize that some of the policy changes being finalized in this rule, including new scoring policies for the Promoting Interoperability performance category, changes to quality measures, the identification of more topped out measures, the increased weighting of the cost performance category, and the introduction of episode-based cost measures, may make it more challenging for clinicians to achieve higher scores while they are becoming more familiar and comfortable with these new policies, we also believe these policy changes help simplify and streamline the MIPS program and reduce overall burden after an initial adjustment period. Thus, we believe it is appropriate to slightly increase the additional performance threshold for year 3 and will consider raising it more in future years.

In addition, despite these changes, we believe that 75 points is achievable for many clinicians. Based on our most current data, we estimated for the 2019 performance period/2021 MIPS payment year a mean final score of 69.53 points and a median final score of 78.72 points as discussed elsewhere in this section and in section VII.F.8.d. of the RIA of this final rule. We also believe a modest increase above the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year would result in an additional performance
threshold that is attainable and that would allow for multiple pathways for clinicians, including clinicians in specialty practices whose choice of applicable and available measures will likely vary according to specialty, to perform exceptionally well and would encourage higher performance by clinicians for year 3 of the MIPS program.

We acknowledge that the number of quality measures available to clinicians can vary by specialty and practice. We believe our quality performance category scoring validation policy accounts for certain instances where clinicians have less than 6 measure available. We believe these adjustments allow us to develop a fair comparison across different MIPS eligible clinicians and would not preclude clinicians from reaching the final additional performance threshold.

We also note that we have shared performance feedback with clinicians and groups based on their performance in year 1 of MIPS and recognize that clinicians may make adjustments to their clinical practice in response to that feedback, and because we are trying to balance that year 3 is a transition year with the goal of encouraging clinicians to improve their performance and to deliver value-based, high quality care, we believe that a moderate increase to 75 points is appropriate.

Comment: Many commenters supported the proposal to increase the additional performance threshold for exceptional performance to 80 points for the 2021 MIPS payment year and stated it encourages strong performance from clinicians and health systems, supports continuous performance improvement, motivates and holds clinicians accountable to deliver quality care, creates a competitive playing field for high performers, rewards clinicians who have invested time and resources and have demonstrated success under MIPS performance standards, seems reasonable, and is an appropriate increase for year 3 of the program. One commenter supported the proposal because it ensures clinicians are considering both cost and quality. One
commenter stated that raising the threshold may help with flattening the overall cost performance score. One commenter supported the proposal because it is high enough to identify exceptional scores, but was uncertain if it would translate into improved patient outcomes or would meet CMS objectives. One commenter supported the proposal should CMS continue its policies that provide bonus points in the MIPS program and allow for claims-based reporting.

Response: We received many comments in support of our proposal for an additional performance threshold of 80 points. We agree with the commenters that raising the performance threshold encourages strong clinician performance, participation in multiple performance categories, and continuous performance improvement; provides an appropriate financial reward for high performers; and promotes a focus on the delivery of high quality, value-based care by clinicians.

We also note that there were many commenters recommending that the additional performance threshold remain at 70 points and other commenters recommending 75 points. We have considered the totality of the comments and are swayed by the comments requesting a more modest increase to the additional performance threshold. We have also considered the updated regulatory impact analysis which incorporates Quality Payment Program year 1 data to estimate performance for the 2019 performance period/2021 MIPS payment year in section VII.F.8.d. of this final rule and found a mean score of 69.53 points and a median final score of 78.72 points. Given these findings, we believe that a small decrease from the proposed additional performance threshold of 80 points that would fall between the mean and the median would help the additional performance threshold remain attainable and would allow for a larger number of clinicians to receive the additional payment adjustment.

We also believe an increase in the additional performance threshold would incentivize
Clinicians to increase their focus on value-based care with an emphasis on the delivery of high quality care for patients, but that an increase of 10 points is too steep, and thus, are finalizing an additional performance threshold of 75 points that is midway between our original proposal of 80 points and the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year of 70 points.

**Comment:** A few commenters stated an increase to 80 points would disproportionately impact small practices and make it difficult for them to participate successfully in the MIPS program. One commenter recommended CMS should not increase the additional performance threshold until data was available to consider the impact on small practices and then set a fair threshold.

**Response:** We recognize the unique challenges to eligible clinicians in small practices participating in MIPS and believe the special policies for small practices provide some relief for small practices seeking to perform well. We refer readers to special policies for small practices including: the small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the significant hardship exception for the Promoting Interoperability performance category available for small practices (CY 2018 Quality Payment Program final rule 82 FR 53683); the special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656); and the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule). We also note that small practices are more likely than larger practices to fall below one or more of the provisions related to the low-volume threshold and would be able to take advantage of the opt-in policy and refer readers to a discussion of the low-volume threshold at section III.I.3.c. of this final rule.
We also analyzed the data referenced in section VII.F.8.d. of the RIA of this final rule, and found that more small practices than larger practices may find it harder to meet or exceed the additional performance threshold. We agree with commenters referenced here and elsewhere in this section that an additional performance threshold of 80 points is too steep of an increase from 70 points, but we believe that an increase is appropriate for year 3 and that the current policies that provide flexibilities for small practice provide a pathway for a successful transition for clinicians who have made a commitment toward value and the delivery of high quality care in the MIPS program. Based on these competing concerns, as noted above, we are finalizing an additional performance threshold of 75 points.

We also note that the additional performance threshold rewards exceptional performance in the MIPS program and a clinician could successfully participate in MIPS by meeting or exceeding the performance threshold and receive a neutral or positive payment adjustment.

**Comment**: A few commenters recommended 75 points because it is a more modest, 5-point increase from the previous performance threshold of 70 points. One commenter supported 75 points believing the increase seems fair because the threshold is more attainable for many eligible clinicians who are specialists, such as those practicing interventional pain management, who may have difficulty identifying relevant measures that improve patient quality of care. One commenter supported 75 points should CMS finalize its proposal to remove claims-based reporting and finalize its proposal to remove bonus points for improvement activities completed using CEHRT.

**Response**: We agree with an additional performance threshold of 75 points. We believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their
focus on value-based care and promote the delivery of high quality care for patients. We also believe that a more modest increase of 5 points, rather than an increase of 10 points, over the additional performance threshold for year 2 is appropriate because year 3 is still a transition year and we want to encourage increased clinician engagement and increased performance in the MIPS program that drives toward the delivery of value-based, high quality care for Medicare beneficiaries. We also note that some commenters stated that the proposed 10-point increase may have unintended consequences especially because of the impact that proposed policy changes could have on final scores as clinicians are becoming familiar with these changes. We want to reward exceptional performance that, given the impact of the policy changes in this final rule, could be less than 80 points. As such, we are swayed by comments that an increase to 75 points is more modest and a reasonable half-way point that still would raise the bar on what is rewarded as exceptional performance for the 2019 MIPS performance period.

We note that a lower additional performance threshold could reduce the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the funds available (up to $500 million for the year) are distributed over more clinicians that score above the lower additional performance threshold. For the reasons discussed above, we believe 75 points is appropriate for year 3 and note that the additional performance threshold will be raised in future years.

**Comment:** A few commenters recommended a higher additional performance threshold for exceptional performers. One commenter recommended an additional performance threshold of 85 points to further efforts to engage clinicians and groups through financial incentives tied to metric performance. One commenter recommended a steeper scale for awarding exceptional performance for scores of 90 points or greater.
Response: We believe that a steeper increase in the additional performance threshold is not appropriate given that MIPS is still in a transition period and because of the MIPS policy changes we are making in this final rule that include scoring changes to the Promoting Interoperability performance category and the addition of episode-based cost measures to the cost performance category, that could impact final scores for year 3 of the MIPS program as eligible clinicians become more familiar and comfortable with these policy changes. We want to reward exceptional performance that, given the impact of our policy changes in this final rule, could include performance below 85 or 90 points, particularly for small practices which may not have sufficient case minimum to achieve maximum quality performance category score. We recognize a higher additional performance threshold will allow for a higher financial reward for high performers, but we want to encourage participation with wider availability of this funding.

Comment: One commenter recommended that CMS increase the thresholds in the CY 2020 performance period and going forward because higher thresholds will result in a wider array of payment adjustments, thereby encouraging more participation and rewarding those that invest in improving their quality of care.

Response: We thank the commenter for the input and will take this comment into consideration in future rule-making.

After consideration of the comments, we are not finalizing our proposal of 80 points for the additional performance threshold and instead are finalizing 75 points for the additional performance threshold for the 2021 MIPS payment year. We are codifying the additional performance threshold for the 2021 MIPS payment year and finalizing the proposed regulation text at §414.1405(d)(5) with modification to reflect 75 points instead of 80 points.

(4) Application of the MIPS Payment Adjustment Factors
(a) Application to the Medicare Paid Amount for Covered Professional Services

In the CY 2018 Quality Payment Program final rule (82 FR 53795), we finalized the application of the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year. Sections 51003(a)(1)(A)(i) and 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 amended sections 1848(q)(1)(B) and 1848(q)(6)(E) of the Act, respectively, by replacing the references to “items and services” with “covered professional services” (as defined in section 1848(k)(3)(A) of the Act). Covered professional services as defined in section 1848(k)(3)(A) of the Act are those services for which payment is made under, or is based on, the Medicare PFS and which are furnished by an eligible professional. As a result of these changes, the MIPS payment adjustment factor determined under section 1848(q)(6)(A), and as applicable, the additional MIPS payment adjustment factor determined under section 1848(q)(6)(C) of the Act, will be applied to Part B payments for covered professional services furnished by a MIPS eligible clinician during a year beginning with the 2019 MIPS payment year and not to Part B payments for other items and services.

To conform with these amendments to the statute, we proposed to revise §414.1405(e) to apply the MIPS payment adjustment factor and, if applicable, the additional MIPS payment adjustment factor, to the Medicare Part B paid amount for covered professional services furnished by a MIPS eligible clinician during a MIPS payment year (beginning with 2019) (83 FR 35973 through 35974). We also proposed to revise §414.1405(e) to specify the formula for applying these adjustment factors in a manner that more closely tracks the statutory formula under section 1848(q)(6)(E) of the Act (83 FR 35973 through 35974). Specifically, we
proposed the following formula: in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of: the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100 (83 FR 35974).

We did not receive any comments on this proposal.

We are finalizing our proposed changes to the regulation text at §414.1405(e) as proposed. We also refer readers to section III.I.3.a. of this final rule where we discuss the covered professional services to which the MIPS payment adjustment could be applied. We also refer readers to section III.I.3.c.(3) of this final rule where we discuss other conforming edits to the regulation text at §§414.1310(a), 414.1310(b), and 414.1310(d) that specify the circumstances when the MIPS payment adjustment would not apply to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

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

In the CY 2018 Quality Payment Program final rule, we did not address the application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53795), we responded to a comment requesting guidance on how the MIPS payment adjustment and the calculation of the Medicare limiting charge amount would be applied for non-participating clinicians, and we stated our intention to address these issues in future rulemaking. Beginning with the 2019 MIPS payment year, we proposed that the MIPS payment adjustment does not apply for non-assigned claims for non-participating clinicians (83 FR 35974). This approach is consistent with the policy for
application of the value modifier that was finalized in the CY 2015 PFS final rule (79 FR 67950 through 67951). Sections 1848(q)(6)(A) and 1848(q)(6)(C) of the Act require that we specify a MIPS payment adjustment factor, and if applicable, an additional MIPS payment adjustment factor for each MIPS eligible clinician, and section 1848(q)(6)(E) of the Act (as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018) requires that these payment adjustment factor(s) be applied to adjust the amount otherwise paid under Part B for covered professional services furnished by the MIPS eligible clinician during the MIPS payment year. When non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the clinician collects payment from the beneficiary. This is referred to as a non-assigned claim. Application of the MIPS payment adjustment to these non-assigned claims would not affect payment to the MIPS eligible clinician. Rather, it would only affect Medicare payment to the beneficiary. If the MIPS payment adjustment were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the MIPS payment adjustment is positive and decreased when the MIPS payment adjustment is negative. Although the statute does not directly address this situation, it does suggest that the MIPS payment adjustment is directed toward payment to the MIPS eligible clinician and the covered professional services they furnish. We continue to believe that it is important that beneficiary liability not be affected by the MIPS payment adjustment and that the MIPS payment adjustment should be applied to the amount that Medicare pays to MIPS eligible clinicians.

On that basis, we proposed to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year (83 FR 35974). We do not expect this proposal would be
likely to affect a clinician’s decision to participate in Medicare or to otherwise accept assignment for a particular claim, but we solicited comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.

We solicited comments on the above proposal.

**Comment:** A few commenters supported the proposal to apply the adjustment to claims that are billed and paid on an assignment-related basis and not to any non-assigned claims.

**Response:** We thank the commenters for their support.

**Comment:** One commenter recommended that this policy be revisited in the next year and evaluated for unintended consequences, including whether there are any adverse effects on Medicare beneficiaries who see a non-participating clinician who does not accept assignment for a claim.

**Response:** We thank the commenter for the input and will take this comment into consideration in future rulemaking.

After consideration of the comments, we are finalizing our proposal to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year.

(c) Waiver of the Requirement to Apply the MIPS Payment Adjustment Factors to Certain Payments in Models Tested under Section 1115A of the Act

(i) Overview

CMS tests models under section 1115A of the Act that may include model-specific payments made only to model participants under the terms of the model and not to any other providers of services or suppliers. Some of these model-specific payments may be considered payments for covered professional services furnished by a MIPS eligible clinician, meaning
that the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment
adjustment factor (collectively referred to as the MIPS payment adjustment factors) applied
under §414.1405(e) of our regulations would normally apply to those payments.

(ii) Summary of Proposals and Comments Received

Section 1115A(d)(1) of the Act authorizes the Secretary to waive requirements of Title
XVIII of the Act (and certain other requirements) as may be necessary solely for the purposes
of testing models under section 1115A. We stated in the proposed rule (83 FR 35974 through
35975) that we believe it is necessary to waive the requirement to apply the MIPS payment
adjustment factors to a model-specific payment or payments (to the extent such a payment or
payments are subject to the requirement to apply the MIPS payment adjustment factors) for
purposes of testing a section 1115A model under which such model-specific payment or
payments are made in a specified payment amount (for example, $160 per-beneficiary, per-
month); or paid according to a methodology for calculating a model-specific payment that is
applied in a consistent manner to all model participants. In both cases, applying the MIPS
payment adjustment factors to these model-specific payments would introduce variation in the
amounts of model-specific payments paid across model participants, which could compromise
the model test and the evaluation thereof.

We proposed to amend §414.1405 to add a new paragraph (f) to specify that the MIPS
payment adjustment factors applied under §414.1405(e) would not apply to certain model-
specific payments as described above for the duration of a section 1115A model’s testing
beginning in the 2019 MIPS payment year (83 FR 35974 through 35975). We proposed to use
the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS
payment adjustment factors under section 1848(q)(6)(E) of the Act and §414.1405(e)
specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments (83 FR 35974 through 35975). To illustrate how the proposed waiver would apply, and to provide notice regarding one model-specific payment to which this proposed waiver would apply, we included an example in the proposed rule involving the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM) (83 FR 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported our proposal to waive the application of the MIPS payment adjustment factors to certain model-specific payments. The commenters agreed that these waivers are necessary to test models that would involve these types of model-specific payments, and without such waivers the evaluation of certain models could be compromised.

Response: We appreciate the commenters’ support.

Comment: One commenter noted that the proposed amendment at §414.1405(f) is ambiguous as to whether paragraphs (1), (2), and (3) refer to three different classes of payments, or to one class of payments that meet all three conditions. The commenter suggested that we clarify our intended policy.

Response: We clarify that only payments meeting all three conditions set forth at §414.1405(f) will qualify for the waiver of the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and §414.1405(e). We have amended §414.1405(f) to specify that payments must meet all three conditions to reduce any potential ambiguity, and made further amendments to §414.1405(f) for greater clarity and readability and to more closely align with the
policy described in the preamble text of the proposed rule, including to clarify that the regulatory text in §414.1405(f)(3) refers to payments made in a consistent manner to all model participants, including those participants subject to the MIPS payment adjustment factors and participants not subject to the MIPS payment adjustment factors.

After considering public comments, we are finalizing our proposal to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and §414.1405(e) specifically for payments specified at §414.1405(f) with the clarifying amendments described herein. As discussed in the CY 2019 PFS proposed rule (83 FR 35975), one model-specific payment to which this finalized waiver will apply is the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM). The duration of this waiver will begin with the 2019 MIPS payment year and continue for the duration of OCM.

We proposed to provide the public with notice that this proposed new regulation applies to model-specific payments that the Innovation Center elects to test in the future in two ways: first, we would update the Quality Payment Program website (www.qpp.cms.gov) when new model-specific payments subject to this proposed waiver are announced; and second, we would provide a notice in the Federal Register to update the public on any new model-specific payments to which this waiver would apply (83 FR 35974 through 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:
Comment: One commenter urged CMS to denote which models and model specific payments are subject to this new policy on the Quality Payment Program website and Federal Register as soon as possible.

Response: We plan to provide the public with notice as soon as practicable for model-specific payments subject to this waiver via the Quality Payment Program website (www.qpp.cms.gov), and separate notice in the Federal Register.

After considering public comments, we are finalizing our policy as proposed to provide the public with notice in the following two ways: (1) we will update the Quality Payment Program website (www.qpp.cms.gov) when new model-specific payments subject to this waiver are announced; and (2) we will provide a notice in the Federal Register to update the public on any new model-specific payments to which this waiver will apply.

(d) CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

(i) Overview

In conjunction with releasing the CY 2019 PFS proposed rule, CMS announced the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration, established by CMS using our demonstration authority under section 402 of the Social Security Amendments of 1967 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustments will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care.
(ii) Summary of Proposals

We proposed to use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive requirements of section 1848(q)(6)(E) of the Act and the regulations implementing it in order to waive the payment consequences (positive, negative or neutral adjustments) of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We noted, relating to our proposal to waive payment consequences, that the Demonstration would have the effect of removing MIPS eligible clinicians from the population across which positive and negative payment adjustments are calculated under MIPS, and because of the requirement to ensure budget neutrality with regard to the MIPS payment adjustments under section 1848(q)(6)(F)(ii) of the Act, the Demonstration may affect the payment adjustments for other MIPS eligible clinicians.

We proposed that these waivers would be applicable for a MIPS eligible clinician participating in the Demonstration if they meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, and that these thresholds would match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program. We also proposed to calculate thresholds based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement. For purposes of the Demonstration, we proposed to make determinations about clinicians’ Qualifying Payment Arrangements with MAOs, consistent with the criteria used for Other Payer Advanced APMs under the Quality Payment Program and as set forth in
§414.1420. We proposed to begin the MAQI Demonstration in CY 2018, with the 2018 Performance Period, and operate the project for a total of 5 years.

We also noted in the proposed rule that, for eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, we would waive the provision in section 1848(q)(1)(A)(iii) of the Act requiring that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities. We clarify that, with this waiver, the Demonstration will prohibit voluntary reporting under the MIPS by eligible clinicians who participate in the Demonstration and are not subject to the MIPS reporting requirements and payment adjustment for a given year. This last waiver is intended to prevent potential gaming in the form of an eligible clinician intentionally submitting data showing poor performance for a year for which they are not subject to the MIPS reporting requirements and payment adjustment pursuant to the terms of the Demonstration in order to show improvement in their performance in future years when that improvement could result in higher MIPS scoring.

(iii) Applicable Waivers

Section 402(b) of the Social Security Amendments of 1967 (as amended) authorizes the Secretary to waive requirements of Title XVIII that relate to payment and reimbursement in order to carry out demonstrations under section 402(a). We proposed to use this authority to waive certain requirements of section 1848(q) of the Act and the regulations implementing it, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 (adopted to implement the payment consequences), subject to conditions outlined in the Demonstration.

We solicited comment on these proposals.
The following is a summary of the public comments, relating to proposed waivers, received in response to our request for comment and our responses:

**Comment:** Many commenters supported the proposal to use demonstration waiver authority (under section 402 of the Social Security Amendments of 1967 (as amended)) to test the MAQI Demonstration.

**Response:** We appreciate the commenters’ support of the MAQI Demonstration.

**Comment:** Many commenters urged CMS to use its waiver authority in the MAQI Demonstration to allow another path towards QP status and provide eligible clinicians with the 5 percent incentive payment offered to QPs.

**Response:** Demonstration projects under the authority of section 402(a)(1)(A) of the Social Security Amendments of 1967 are intended to test whether changes in payment or reimbursement will increase the efficiency or economy of health care services. Our actuarial analyses determined that a demonstration design that would grant QP status, including a 5 percent incentive payment, to eligible clinicians who met the thresholds would have introduced a significant level of new costs to CMS, without adequate evidence for realizing an equal amount of savings from the proposed interventions. Without a basis to believe that the economy or efficiency of health care services would be increased, we do not believe that it is appropriate to design a demonstration with such parameters. Considering that the proposed exclusions from MIPS reporting and payment consequences under the MAQI Demonstration are not anticipated to have a net cost to CMS, we plan to test whether these exclusions will increase or maintain clinician participation in payment arrangements with MAOs that are similar to Advanced APMs and change the manner in which clinicians deliver care. This test is consistent with the standards set forth in section 402(a)(1)(A) of the Social Security Amendments of 1967.
Comment: Some commenters urged CMS to monitor the impact of the Demonstration on MIPS payment adjustments, including one commenter that expressed concern that the MIPS-eligible population pool would be reduced and another commenter that expressed concern about whether the potential benefits being tested under the MAQI Demonstration outweigh any potential impacts on the level of MIPS payment adjustments.

Response: We agree that it will be important to monitor the impact of the Demonstration on payments received by MIPS eligible clinicians to whom the waivers do not apply, but we note that it may be challenging to draw significant conclusions from such monitoring as there are many variables that may impact and influence a clinician’s final MIPS payment adjustment. We plan to share information on participation levels in the MAQI Demonstration with the public as soon as this information is available.

Comment: A few commenters commended CMS on starting the MAQI Demonstration in 2018, while a few commenters advised CMS to clarify the timeline associated with a CY 2018 implementation of the Demonstration and when determinations would be made under the Demonstration to identify participating eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustments.

Response: We appreciate certain commenters’ support for beginning the Demonstration in CY 2018, and note that by doing so, clinicians that meet threshold levels of participation in Qualifying Payment Arrangements with MAOs in 2018 can be considered for exclusion from the MIPS reporting requirements and payment adjustment under the Demonstration a year before participation in such Qualifying Payment Arrangements could be considered under the All-Payer Combination Option. We anticipate collecting Qualifying Payment Arrangement and threshold information for eligible clinicians participating in the Demonstration starting in late fall of 2018,
and making final CMS determinations on whether eligible clinicians meet the criteria to be excluded from the MIPS reporting requirements and payment adjustment, based on this submitted information, by December 2018 or (January 2019 at the latest). We note that eligible clinicians participating in the MAQI Demonstration in 2018 will be evaluated to determine whether they meet the criteria to be excluded from MIPS reporting requirements for the 2018 MIPS performance year, and from the MIPS payment adjustment for the corresponding 2020 MIPS payment year.

**Comment:** Some commenters recommended that CMS make changes to the Demonstration criteria relating to clinician eligibility for the exclusion from the MIPS reporting requirements and payment adjustment, such as Qualifying Payment Arrangements and thresholds.

**Response:** As noted in the proposed rule, we intend to use criteria and requirements that are consistent with the Medicare and Other Payer Advanced APM Options under the Quality Payment Program. Changing the clinician eligibility for exclusion from the MIPS reporting requirements and payment adjustment would not be consistent with this intent.

We also received comments on other provisions associated with the Demonstration.

**Comment:** Some commenters advised CMS to make changes to the Demonstration application and data collection process.

**Response:** The application and data collection process are outside the scope of the proposals in the CY 2019 PFS proposed rule; however, we will seek to balance reporting burden with the need to solicit information necessary to ensure that the demonstration is being implemented, tested and evaluated appropriately.
Comment: A few commenters requested additional agency focus in helping physicians and practices better understand their options under Medicare, Medicare Advantage, the Quality Payment Program, the MAQI Demonstration and other value-based payment arrangements.

Response: We are committed to reaching our stakeholders, including clinicians, the technology community, private payers, and beneficiaries, to raise awareness that Medicare is evolving quickly to a value-based system. In addition to raising awareness that change is occurring, we will continue current efforts to engage in a learning process with stakeholders where they may voice opinions and suggestions to help collaboratively drive the goals of the Quality Payment Program. We will continue to set expectations that this will be an iterative process, and, while change will not happen overnight, we are committed to continuing our work to improve how Medicare pays for quality and value, instead of the quantity of services. We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to help clinicians understand program and model requirements, how to use available tools to enhance their practices, improve quality, reduce expenditures, and progress to participation in Advanced APMs if that is the best choice for their practice.

We are offering support in the form of fact sheets, webinars, online courses, and direct technical assistance to help clinicians successfully participate in the Quality Payment Program, the MIPS or the Advanced APM track. This range of support to help clinician practices actively participate in the Quality Payment Program that can be found at the following website at https://qpp.cms.gov/.

We also discussed that the Demonstration would waive the provision in section 1848(q)(1)(A)(iii) of the Act that the Secretary shall permit any eligible clinician to voluntarily
report on applicable measures and activities, so that the Demonstration would prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds to be excluded from the MIPS reporting requirements and payment adjustment for a given year. We did not receive any comments on this proposal. We explained that this waiver is necessary to prevent the potential gaming opportunity wherein participating clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive artificially inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences. We note here that by prohibiting reporting under MIPS we are also, in effect, disallowing MIPS performance feedback for those clinicians who participate in the Demonstration and meet the criteria to be excluded from the MIPS reporting requirements and payment adjustments. Eligible clinicians who participate in the Demonstration but are not excluded from the MIPS reporting requirements and payment adjustment (whether through participation in the Demonstration or otherwise) would continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

(iv) Summary of Finalized Policies

After considering public comments, we are finalizing our proposals to implement the MAQI Demonstration in CY 2018 and use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive certain requirements of section 1848(q)(6)(E) of the Act, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We are also finalizing that we will waive the provision in section 1848(q)(1)(A)(iii) of the Act that the
Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities, so that the Demonstration will prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds that will trigger application of the waivers from the MIPS reporting requirements and payment adjustment for a given year. Related to this waiver of the last sentence of section 1848(q)(1)(A)(iii) of the Act, MAQI Participants who are not subject to the MIPS reporting requirements and payment adjustments will therefore not receive MIPS performance feedback under section 1848(q)(12) of the Act.

In addition, we are also announcing our final policies that, under the waivers identified previously: (1) eligibility for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration will be determined using thresholds of combined participation in Qualifying Payment Arrangements and Advanced APMs that are the same as the QP thresholds under the Medicare Option of the Quality Payment Program codified at §414.1430(a); and (2) Qualifying Payment Arrangements under the MAQI Demonstration will be identified using criteria consistent with those used to identify Other Payer Advanced APMs codified at §414.1420. To qualify for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, a MAQI participating clinician must meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, using Demonstration thresholds that match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program, and based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement.

(e) Example of Adjustment Factors
In the CY 2019 PFS proposed rule (83 FR 35978 through 35981), we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year. We updated the figure and tables based on the policies we are adopting in this final rule, as follows.

Figure 3 provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies adopted in this final rule for the 2021 MIPS payment year. In Figure 3, the performance threshold is 30 points. The applicable percentage is 7 percent for the 2021 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 7 percent for the 2021 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 7.5 points based on the performance threshold of 30 points for the 2021 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 7 percent for the 2021 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.
If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 7 percent.

Only those MIPS eligible clinicians with a final score equal to 30 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 30 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 7 percent.

Figure 3 illustrates an example of the slope of the line for the linear adjustments and has been updated from prior rules, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.159. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.11 percent (7 percent \( \times 0.159 \)). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The additional performance threshold is 75 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500,000,000. In
Figure 3, the example scaling factor for the additional MIPS payment adjustment factor is 0.358. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.58 percent (10 percent × 0.358). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0111 + 0.0358 = 1.0469, for a total positive MIPS payment adjustment of 4.69 percent.

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

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

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible
clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians would receive a positive MIPS payment adjustment factor.

Table 56 illustrates the changes in payment adjustments based on the final policies from the 2019 MIPS payment year and the 2020 MIPS payment year, and on final policies for the 2021 MIPS payment year adopted in this final rule, as well as the statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.
### TABLE 56: Illustration of Point System and Associated Adjustments Comparison Between the 2019 MIPS payment year, the 2020 MIPS payment year and 2021 MIPS payment year

<table>
<thead>
<tr>
<th>Final Score Points</th>
<th>MIPS Adjustment</th>
<th>Final Score Points</th>
<th>MIPS Adjustment</th>
<th>Final Score Points</th>
<th>MIPS Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0-0.75</td>
<td>Negative 4%</td>
<td>0.0-3.75</td>
<td>Negative 5%</td>
<td>0.0-7.5</td>
<td>Negative 7%</td>
</tr>
<tr>
<td>0.76-2.99</td>
<td>Negative MIPS payment adjustment greater than negative 4% and less than 0% on a linear sliding scale</td>
<td>3.76-14.99</td>
<td>Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale</td>
<td>7.51-29.99</td>
<td>Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale</td>
</tr>
<tr>
<td>3.00</td>
<td>0% adjustment</td>
<td>15.0</td>
<td>0% adjustment</td>
<td>30.0</td>
<td>0% adjustment</td>
</tr>
<tr>
<td>3.01-69.99</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.</td>
<td>15.01-69.99</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.</td>
<td>30.01-74.99</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.</td>
</tr>
<tr>
<td>70.0-100</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.</td>
<td>70.0-100</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.</td>
<td>75.0-100</td>
<td>Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.</td>
</tr>
</tbody>
</table>

PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.
We note that in this final rule, with the exception of the increase in our small practice bonus in the quality performance category from 3 measure bonus points to 6 measure bonus points, our scoring algorithms have not changed from the CY 2019 PFS proposed rule and that the only policy change from the CY 2019 PFS proposed rule reflected in Figure 3 and Table 56 is that final scores greater than or equal to 75 points qualify for the additional payment adjustment for exceptional performance discussed at section III.1.3.j.(3) of this final rule. Please refer to the CY 2019 PFS proposed rule (83 FR 35979 through 35981) for examples of scenarios in which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 30 points for the 2021 MIPS payment year.

k. Third Party Intermediaries

We refer readers to §414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390) and the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819) for our previously established policies regarding third party intermediaries. In the CY 2019 PFS proposed rule (83 FR 35981 through 35986), we proposed to: (1) define third party intermediary and require third party intermediaries to be based in the U.S.; (2) update certification requirements for data submission; (3) update the definition of Qualified Clinical Data Registry (QCDR); revise the self-nomination period for QCDRs; update of information required for QCDRs at the time of self-nomination; update consideration criteria for approval of QCDR measures; define the topped out timeline for QCDR measures; (4) revise the self-nomination period for qualified registries; (5) define health IT vendor; (6) update the definition, criteria, and requirements for CMS-approved survey vendor; auditing criteria; and (7) revise probation and disqualification criteria. We finalize these proposals in the manner discussed herein.
(1) Third Party Intermediaries Definition

In the CY 2019 PFS proposed rule (83 FR 35981), at §414.1305, we proposed a new definition to define a third party intermediary as an entity that has been approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We also proposed to change the section heading at §414.1400 from “Third party data submissions” to “Third party intermediaries” to elucidate the definition and function of a third party intermediary (83 FR 35981).

As discussed in the CY 2019 PFS proposed rule (83 FR 35981), CMS IT systems are required to adhere to multiple agency and federal security standards and policy. CMS policy prohibits non-U.S. citizens from accessing CMS IT systems, and also requires all CMS program data to be retained in accordance with U.S. Federal policy, specifically National Institute of Standards and Technology (NIST) Special Publication (SP) 800-63, which outlines enrollment and identity proofing requirements (levels of assurance) for federal IT system access. Access to the Quality Payment Program would necessitate passing a remote or in-person Federated Identity Proofing process (that is, Equifax or equivalent). A non-U.S. based third party intermediary’s potential lack of a SSN, TIN, U.S. based address, and other elements required for identity proofing and identity verification would impact their ability to pass the necessary background checks. An inability to pass identity proofing may limit or fully deny access to the Quality Payment Program if the intent is to interact with the Quality Payment Program outside of the U.S. for the purposes of reporting and storing data.
These requirements are existing federal policies applicable to all HHS/CMS FISMA systems and assets, and the requirements are not specific to the Quality Payment Program. More information on these policies is available at the following websites: HHS Information Security and Privacy Policy (IS2P) (https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/index.html); CMS Information Systems Security and Privacy Policy (IS2P2) (https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/CMS-Information-Systems-Security-and-Privacy-Policy-IS2P2.html); OMB Memorandum 04-04, E-Authentication Guidance for Federal Agencies (https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy04/m04-04.pdf); and NIST SP 800-63 Digital Identity Guidelines (https://pages.nist.gov/800-63-3/). Therefore, in the CY 2019 PFS proposed rule (83 FR 35982) we proposed to amend §414.1400(a)(4) to indicate that a third party intermediary’s principle place of business and retention of associated CMS data must be within the U.S.

We would like to note, third party intermediaries that are authorized by us to submit data on behalf of MIPS eligible clinicians, groups, or virtual groups have not otherwise been evaluated for the capabilities, quality, or any other features or its products. The United States Government and CMS do not endorse or recommend any third party intermediary or its products. Prior to selecting or using any third party intermediary or its products, MIPS eligible clinicians, groups or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.

The following is a summary of the public comments received on the “Third Party Intermediaries Definition” proposals and our responses:
Comment: One commenter appeared to advocate that clinicians who must comply with MACRA should be prohibited from using online and/or software-based third party intermediaries that do not use attorneys to advise clinicians on the law. The commenter stated that, in order to protect clinicians from failure to comply with MACRA and to achieve higher MACRA compliance rates, CMS should restrict MIPS participants from using online or software-based third party intermediaries entirely unless the use is through an EMR/EHR dashboard. In addition, the commenter stated that CMS should only allow clinicians to achieve compliance themselves or to achieve compliance through the use of an attorney or an EMR/EHR dashboard.

Response: We do not believe it is appropriate to require third party intermediaries to furnish legal advice to clinicians. If a clinician wishes to receive legal advice regarding compliance with MACRA, or any other law or regulation, the clinician may hire his or her own legal counsel. To the extent the commenter is advocating to eliminate a clinician’s ability to report MIPS data through a third party intermediary, the comment is outside the scope of the rulemaking.

Comment: One commenter provided a comment related to the proposed opt-in policy. The commenter encouraged us to allow third-party intermediaries, such as qualified registries, to opt-in on behalf of clinicians and groups as a function of the services they provide and that the clinician opt-in should be at the TIN/NPI level.

Response: The opt-in policy is discussed in section III.I.3.c.(5) in this final rule, where we finalized that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report. We believe that an election to opt-in to MIPS
must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. We agree that after this decision is confirmed by the clinician or group it should be deliverable through a third party intermediary, if a clinician or group is utilizing a third party intermediary for their data submission. As a result, the third party intermediary should be able to transmit the clinician’s opt-in decision to CMS. Therefore, we are amending §414.1400(a)(4)(iv) that if the clinician chooses to opt-in in accordance with §414.1310, the third party intermediary must be able to transmit that decision to CMS. We refer readers to section III.I.3.c.(5) of this final rule for more information regarding low volume threshold exclusion.

After consideration of the public comments received, we are finalizing our proposal, as proposed, at §414.1305, to define a third party intermediary as an entity that has been approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We are also finalizing our proposal, as proposed, to change the section heading at §414.1400 from “Third party data submissions” to “Third party intermediaries” to elucidate the definition and function of a third party intermediary. In addition, we are finalizing our proposal, as proposed, to amend previously finalized policies at §414.1400(a)(4) to indicate that a third party intermediary’s principle place of business and retention of associated CMS data must be within the U.S. Lastly, we are amending §414.1400(a)(4)(iv) to state that if the clinician chooses to opt-in in accordance with §414.1310, the third party intermediary must be able to transmit that decision to CMS.

(2) Certification
We previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53807) at §414.1400(a)(5), that all data submitted to us by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete; and that this certification must occur at the time of the submission and accompany the submission. We have discovered it is not operationally feasible to require certification at the time of submission, or to require that the certification accompany the submission, for submission types by third party intermediaries, including data via direct, login and upload, login and attest, CMS Web Interface or Medicare Part B claims. We refer readers to section III.I.3.h.(1)(b) of this final rule for our proposed modifications to the previously established data submission terminology. In order to address these various submission types that are currently available, in the CY 2019 PFS proposed rule (83 FR 35982), we proposed to amend §414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary must be certified as true, accurate, and complete to the best of its knowledge and that such certification must be made in a form and manner and at such time as specified by CMS.

We did not receive any public comments on our proposed amendments to the certification requirement imposed on third party intermediaries.

We are finalizing our proposal, as proposed, at §414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge, and that such certification must be made in a form and manner and at such time as specified by CMS.

(3) Qualified Clinical Data Registries (QCDRs)
We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53807 through 53815) and §414.1400 for our previously finalized policies regarding QCDRs. In the CY 2019 PFS proposed rule (83 FR 35982 through 35984) we proposed to update the following: the definition of QCDR, the self-nomination period for QCDRs, information required for QCDRs at the time of self-nomination, and consideration of criteria for approval of QCDR measures.

(a) Proposed Update to the Definition of a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) at §414.1305, we finalized the definition of a QCDR to be a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35982), we want to ensure that QCDRs that participate in MIPS have access to clinical expertise in quality measurement and are able to provide and demonstrate an understanding of the clinical medicine, evidence-based gaps in care, and opportunities for improvement in the quality of care delivered to patients and priorities that are important to MIPS eligible clinicians. From our experiences with QCDRs to date, we have discovered that certain entities with predominantly technical backgrounds have limited understanding of medical quality metrics or the process for developing quality measures are seeking approval as a QCDR. A large number of entities that do not have the necessary clinical expertise to foster quality improvement have self-nominated or indicated their interest in becoming QCDRs. In reviewing previous QCDR measure submissions during the self-nomination and QCDR measure review and approval cycles in MIPS, we have observed that some entities were developing QCDR measures without a complete understanding of measure
constructs (such as what is required of a composite measure or what it means to risk-adjust), and in some instances, QCDRs were developing QCDR measures in clinical areas in which they did not have expertise. We are concerned that QCDR measures submitted by such entities for approval have not undergone the same consensus development, scientific rigor, and clinical assessment that is required for measure development, compared to those QCDR measures that are developed by specialty societies and other entities with clinical expertise.

We recognize the importance of these organizations’ expertise within the Quality Payment Program; however, do not believe that these types of entities with the absence of clinical expertise in quality measurement, meet the intent of QCDRs. We believe that with the increasing interest in QCDRs and QCDR measure development, it is important to ensure that QCDRs that participate in MIPS are first and foremost in the business of improving the quality of care clinicians provide to their patients through quality measurement and/or disease tracking and have the clinical expertise to do so.

In the CY 2019 PFS proposed rule (83 FR 35982 through 35983), we proposed beginning with the 2022 MIPS payment year, to amend §414.1305 to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. Specifically, a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35983), under §414.1400(b)(2)(ii), an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a
signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. Thus, we expect entities without clinical expertise in medicine and quality measure development that want to become QCDRs would collaborate or align with entities with such expertise in accordance with §414.1400(b)(2)(ii).

As a part of the self-nomination process, we will look for entities that have quality improvement, measure development, as well as clinical expertise. We will also follow up with the entity via, for example, email or teleconference, should we question whether or not the entity meets our standards. Alternatively, such entities may seek to qualify as another type of third party intermediary, such as a qualified registry. Becoming a qualified registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

The following is a summary of the public comments received on the proposal to update the definition of a QCDR and our responses:

Comment: Many commenters supported the proposal to modify the definition of a QCDR to limit approval to entities that have clinical expertise in medicine and quality measure development. Several commenters recommended CMS provide clarification on how such clinical and quality measure development expertise will be evaluated, with one commenter suggesting the definition of clinical expertise include having a majority-led physician Board of Directors or governing body and that expertise in clinical measure development include demonstrated QCDR measure development processes that take into account the CMS Blueprint for measure development and maintenance activities. A few commenters stated that CMS should establish processes for denying applications and/or measures that appear to not have had any
clinical influence rather than requiring the entire entity to have “expertise” and provide a
definition of what constitutes “clinical expertise in medicine and quality measure development.”

Response: We appreciate the commenters’ support to update the definition of a QCDR,
limiting approval to entities that have clinical expertise in medicine and quality measure
development. Specifically, we proposed that a QCDR would be defined as an entity with clinical
expertise in medicine and in quality measurement development that collects medical or clinical
data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to
foster improvement in the quality of care provided to patients. We appreciate the commenters’
suggestion that CMS provide more clarification on how such clinical and quality measure
development expertise will be evaluated. For example, while not exhaustive, some aspects that
may be considered during our evaluation are a QCDR’s: previous measure development
experience (serving on an NQF TEP, for example); experience with the measure development
Blueprint process, which can be found at https://www.cms.gov/Medicare/Quality-Initiatives-
Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf; ability to create and use
multi-strata and composite measures where appropriate; ability to risk adjust its own QCDR
outcomes measures; technical expertise to run a registry; and ability to reliably collect, retain,
aggregate, disseminate, and analyze data from their clinicians. We appreciate the commenter’s
suggestion to include having a majority-led physician Board of Directors or governing body, but
we do not mandate that the QCDR be led by a majority of physicians. We do consider clinical
expertise and experience in QCDR measure development and maintenance important, as shown
in our updated definition of a QCDR.

Comment: One commenter expressed concern regarding how CMS will allow technical
entities to partner with an external organization to gain clinical expertise, citing its opinion that
doing so would render the policy ineffective if this enables technical entities to bypass this requirement too easily. Another commenter stated that neither small nor large EHR vendors should be allowed to enter the QCDR space due to the former potentially collecting skewed data related to certain practice arrangements and patient populations and the latter potentially lacking the perspective of care improvement in medical specialties.

Response: We disagree that allowing technical entities to partner with an external organization to gain clinical expertise would render the policy ineffective. The policy is intended to include entities that are able to meet the definition, whether that be by a partnership with a clinical entity, or on their own. In addition, we disagree that neither small nor large EHR vendors should be allowed to collaborate to become a QCDR. As stated in the proposed rule, entities without clinical expertise in medicine and quality measure development, such as small or large EHR vendors, may collaborate or align with entities with such expertise in accordance with §414.1400(b)(2)(ii). In general, we do not believe that Health IT vendors, including EHR vendors, alone have the necessary clinical expertise. Having the option to collaborate could alleviate the likelihood of skewed data or the absence of perspective regarding care improvement in medical specialties, because a collaboration with a clinical organization would provide knowledge of patient populations, practice arrangements, and care improvement.

Comment: A few commenters disagreed with the proposed update to the definition of a QCDR, citing their beliefs that the updated definition is contrary to the promotion of the benefits of technology; will impose artificial barriers to entry into the market; dictate who can provide services to physicians instead of letting the free market decide; and discriminate against potential vendors because of a perceived advantage at quality measurement based on education, experience, etc. The commenters stated that CMS should only require QCDRs to collaborate
with specialty societies in the development of measures to ensure validity, clinical relevance, and proper risk adjustment.

**Response:** We disagree that the modified definition of QCDR opposes promoting the benefits of technology because there are many options through which MIPS eligible clinicians can utilize different third-party intermediaries to submit data, and this proposed change will not impact the ability for MIPS eligible clinicians to use these mechanisms. We also disagree that the modified definition of QCDR imposes barriers into the market or discriminates against potential vendors because we offer vendors with more of a technical background the opportunity to partner with an organization with greater clinical expertise in order to meet the new QCDR definition. The intent of the modified definition is to promote useful measure development and to emphasize that clinical expertise is critical in gaining useful measures. Furthermore, we believe that updating the definition of a QCDR will help organizations understand the criteria in which we evaluate them against. We want to ensure that the vendors we approve to participate as a QCDR are of a higher standard and understand the clinical science based off which they develop measures. It is important that QCDRs also understand how to construct measures, the analytics, and are able to ensure the measures are reliable and valid, not doing so may negatively impact the clinician’s reporting and final score. Health IT vendors and/or EHR vendors should collaborate with clinical organizations such as specialty societies for their experience not only in measure development but for their clinical expertise as well.

**Comment:** Some commenters stated that CMS should develop a process by which a clinician who believes they are unsupported by a QCDR can submit information to CMS for further investigation.
Response: If an eligible clinician would like to bring information to CMS’ attention regarding a QCDR being unsupportive as it pertains to reporting issues, we suggest the clinician contact the Quality Payment Program Service Center by emailing: QPP@cms.hhs.gov.

Comment: One commenter noted that the proposed change may preclude its continued approval by CMS as a QCDR because it does not dictate the timeline in which specialty societies perform measure development and without this approval, it would not be able to assist them in measure development when necessary.

Response: Our updated definition of a QCDR would be effective beginning with the 2022 MIPS payment year; and to clarify, we will not be “grandfathering” in existing QCDRs who do not meet the updated QCDR definition for the 2020 performance period. In coordination with the finalization of the new QCDR definition and the publication of the CY 2019 PFS final rule, we intend to notify existing QCDRs as to whether they would meet the new QCDR definition or not based on information submitted for a previous MIPS payment year.

Comment: A few commenters stated that CMS should finalize its proposal for the 2019 performance year instead of the 2020 performance year because removing non-clinician led vendors from the list of QCDRs will not pose a significant burden on eligible clinicians or group practices in 2019.

Response: While we appreciate commenters’ support, we would like to keep the effective timeframe of this policy (that is, the 2020 performance year) as proposed to provide existing QCDRs that would not meet the updated QCDR definition with an appropriate amount of time to comply or take other paths.

Comment: Many commenters who supported the proposal to update the definition of a QCDR also provided recommendations including: development of a separate definition for
QCDRs put forth by technology companies to differentiate them from QCDRs managed by specialty societies; requiring third-party entities that are not specialty societies that would like to become QCDRs to collaborate with specialty society QCDRs; and expansion of the definition of a QCDR to align with the 21st Century Cures Act (especially with regard to entities being clinician-led) or at minimum, revision of the definition to include clinical expertise in medicine, quality improvement, and quality measure/guideline development, as well as providing methods to ensure data quality, routine metric reporting, and quality improvement consultation.

Response: We do not agree that separate definitions are necessary to differentiate between QCDRs, as the definition includes criteria set for all QCDRs; or that the definition requires criteria as prescriptive as entities being clinician-led. There are flexibilities in place, such as collaboration with other entities such as large healthcare systems, regional collaboratives, or specialty societies, in order for vendors to meet the criteria in the definition. We believe we cover the areas of clinical expertise, measure development, and quality improvement work through this new definition. We believe that experience with data quality and routine metric reporting is related to their measure development experience and their registry experience, which is covered by the new QCDR definition and the criteria of requiring that the vendor must exist by January 1 of the performance period and have 25 participants submitting data to the QCDR (not necessarily for purposes of MIPS).

After consideration of the public comments received, we are finalizing our proposal to update the definition of a QCDR at §414.1305 beginning with the 2022 MIPS payment year, as proposed, to state that a QCDR is an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible
clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(b) Establishment of an Entity Seeking To Qualify as a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77364), we require at §414.1400(c)(2) that the QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement. We realize that a QCDR’s lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician’s ability to use a QCDR to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, we proposed to redesignate §414.1400(c)(2) as §414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period (83 FR 35983). These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement.

The following is a summary of the public comments received on the “Establishment of an Entity Seeking To Qualify as a QCDR” proposals and our responses:

Comment: Many commenters disagreed with the proposal to require QCDRs to have 25 participants by January 1 of the year prior to performance period. Commenters noted it would place an undue burden on QCDRs serving small specialties and inhibit the ability of new registries to qualify as QCDRs, thus discouraging the use of QCDRs to report MIPS data. One commenter suggested CMS work with stakeholders to develop a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program and the
requirements of the MACRA law. Another commenter stated that the existing requirement is sufficient to ensure QCDR preparedness, while another commenter stated that the threshold should be lowered or removed completely, at least for those QCDRs that have already been in operation and have lost participants when the low volume threshold increased significantly.

Response: We disagree with commenters that this proposed policy would cause undue burden or the ability of new entities to qualify as QCDRs. To clarify, this requirement would demonstrate that the entity has prior registry experience and the capability to accept, aggregate, calculate, provide feedback to their participants on, retain, and submit the data to CMS on the behalf of MIPS eligible clinicians. We have previously experienced during the past two performance periods that there have been instances of new QCDRs that are not ready to accept data from eligible clinicians from the start of the performance period due to operational issues within the QCDR, including instances of QCDRs withdrawing during the performance period because of reporting inexperience. We proposed this requirement to ensure that organizations have this experience prior to self-nomination. We continue to provide educational materials for QCDRs on what is necessary to meet program criteria and requirements. We clarify that the requirement to have at least 25 participants by January 1 of the year prior to performance period does not require that the entity’s prior registry experience be under MIPS or any other CMS program or that the participants be MIPS eligible clinicians. With increasing stakeholder interest in the use of third-party intermediaries to report for MIPS, we believe the threshold of 25 participants is a reasonable thresholds for QCDRs to attain.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to redesignate §414.1400(c)(2) as §414.1400(b)(2)(i) to state that beginning with the
2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(c) Self-Nomination Process

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813) for our previously established policies regarding the simplified self-nomination process for existing QCDRs in MIPS that are in good standing and web-based submission of self-nomination forms. We did not propose any changes to those policies in this final rule; however, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update: (1) the self-nomination period; and (2) information required at the time of self-nomination.

(i) Self-nomination Period

Under §414.1400(b), QCDRs must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. As indicated in the CY 2017 Quality Payment Program final rule (81 FR 77366), our goal has been to publish the list of approved QCDRs along with their approved QCDR measures prior to the beginning of the applicable performance period.

We have received feedback from entities that have self-nominated to be a QCDR about the need for additional time to respond to requests for information during the review process, particularly with respect to QCDR measures that the entity intends to submit to us for the applicable performance period. In addition, based on our observations of the previous two self-nomination cycles, we anticipate an increase in the number of QCDR measure submissions for our review and consideration. For the transition year of MIPS, we received over 1,000 QCDR measure submissions for review, and for the CY 2018 performance period, we received over
1,400 QCDR measure submissions. In order for us to process, review, and approve the QCDR measure submissions and provide QCDRs with sufficient time to respond to requests for information during the review process, while still meeting our goal to publish the list of approved QCDRs along with their approved QCDR measures prior to the start of the applicable performance period, we believe that an earlier self-nomination period is needed.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we also proposed to amend §414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore for the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019, and we will make QCDRs aware of this through our normal communication channels. We believe that updating the self-nomination period would allow for additional review time and measure discussions with QCDRs.

We refer readers to section III.I.3.k.(3)(c)(ii) of this final rule for a summary of the public comments received on these proposals and our responses.

(ii) Information Required at the Time of Self-Nomination
We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53814), where we finalized that as a part of the self-nomination review and approval process for the CY 2018 performance period and future years, we will assign QCDR measure IDs to approved QCDR measures, and the same measure ID must be used by any other QCDRs that have received permission to also report the measure. We have received some questions from stakeholders as to whether the QCDR measure ID must be utilized or whether it is optional. As stated in the CY 2018 Quality Payment Program final rule, QCDRs, including any other QCDRs that have received permission to also report the measure, must use the CMS-assigned QCDR measure ID. It is important that the CMS-assigned QCDR measure ID is posted and used accordingly, because without this ID we are not able to accurately identify and calculate the QCDR measures according to their specifications. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update §414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

The following is a summary of the public comments received on the “Self-Nomination Process” proposals and our responses:

Comment: Several commenters noted they would support the proposed change to the self-nomination timeline if CMS would adopt multi-year approval of QCDRs as they noted doing so would reduce burden, alleviate a shortened nomination timeline, potentially strengthen the measure development process in future years, encourage uptake of new measures, allow for uninterrupted data collection, and allow for more consistent and robust data collection and benchmarking.
Response: In the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval and sought comment from stakeholders as to how to mitigate our concerns. Moreover, a multi-year approval process would not take into consideration potential changes in criteria or requirements of participation for QCDRs that may occur as the MIPS program develops through future program years. We did not receive any suggestions or responses from stakeholders that would alleviate our concerns with adopting this policy. Therefore, we continue to believe multi-year approval of QCDRs is inappropriate at this time.

Comment: One commenter stated that in order to encourage QCDRs to continue seeking QCDR status, CMS should work with specialty-led QCDR stewards to further improve the self-nomination process and ensure a viable and private sector-run reporting option to alleviate burden and increase evidence-based decisions.

Response: We value stakeholder input and conduct process improvement on an ongoing basis. We will continue to seek opportunities to receive input throughout the year.

Comment: Many commenters disagreed with the proposal to change the QCDR self-nomination period, citing their beliefs that maintaining the September 1 through November 1 self-nomination period without change is necessary to minimize additional burden and constraints on QCDRs; provide QCDRs the time to prepare data to support measures in the application process; provide QCDRs an opportunity to gain insight into recent policy changes; and negate potentially adverse impacts to the life cycle of QCDRs, the maintenance process for existing QCDR measures, and/or development of new measures. One commenter stated that due to additional data being required as part of the self-nomination process, the revised self-nomination period would be more difficult. Another commenter suggested the change should
not be implemented until the CY 2021 performance period and noted QCDR approval will need to expand beyond 12 months to avoid a scenario where a QCDR is only approved for a few months before they must go through the self-nomination process again. Finally, another commenter suggested the self-nomination period be extended to 90 days due to its belief that the 60-day period is excessively challenging and burdensome in terms of the information required and additional requests to which QCDRs must be respond.

Response: As described in the CY 2019 PFS proposed rule (83 FR 35983), we have heard from QCDRs that they need additional time to respond to our requests for additional information during the QCDR measure review process, as well as requests for feedback or measure harmonization across QCDRs in a more extensive manner that would not be feasible with the current timeline. We believe with sufficient notice, providing stakeholders with educational material, and the implementation of the simplified self-nomination process we are minimalizing additional burden on QCDRs. Through the publication of self-nomination reference material prior to the self-nomination period, as we have done for the 2019 self-nomination period, we intend on giving QCDRs the utmost resources and support as they prepare to self-nominate prior to the closing of the self-nomination period. We plan to post self-nomination material prior to the start of the self-nomination period in July, thereby giving stakeholders’ time to prepare the necessary materials needed, inclusive of the additional information requested as a part of the self-nomination process. As we develop QCDR and qualified registry related policies for future rulemaking, we will factor in how the proposals impact an entity’s ability to self-nominate and participate in the program prior to deciding what year to implement the policies for. We do not believe that delaying the finalization of this proposal until the 2021 performance period of MIPS would benefit the QCDRs, as we have previously explained, QCDR self-nomination must occur
on an annual basis to take into consideration policy, participation requirement, and considerations to a QCDR or registry’s standing (if they are on probation or have been precluded).

We believe the benefits of moving up the self-nomination period to allow for additional time and discussion of QCDR measures is beneficial for both QCDRs and CMS. We disagree that the self-nomination period needs to be extended to a 90-day period, we believe with the resource materials provided, as well as us offering to meet with QCDRs prior to self-nomination to discuss their QCDR measures and receive preliminary feedback, QCDRs have the ability to better prepare for the self-nomination period.

**Comment:** A few commenters supported the proposal to update the QCDR self-nomination timeline. One commenter stated that CMS should use the updated nomination period to facilitate additional discussion with QCDRs regarding measure development. Another commenter stated that CMS should change its expectations for providing data for measures accordingly and allow a transition year to lessen the impact on the measure development life cycle and maintenance of existing measures.

**Response:** We agree that this change in the self-nomination period will allow for additional conversations on measure development and QCDR measure feedback. We disagree with the implementation of a transition year, considering that on annual basis we must review performance data to evaluate whether the measure demonstrates a gap in performance or whether the measure demonstrates topped out performance where no meaningful measurement can be obtained. As previously mentioned, QCDR measures do not have to go through the NQF’s Measures Application Partnership (MAP) committee prior to implementing them in MIPS. If a QCDR is unable to provide performance data reflecting a gap, the QCDR may provide for our
consideration citations to recent studies or clinical journals that demonstrate a need for measurement.

Comment: One commenter suggested CMS provide a definition of "minimal changes" regarding the QCDR self-nomination process as well as specifications around data requests to support QCDR measures.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53811), we stated that minimal changes include, but are not limited to: Limited changes to performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. Additional educational resources are available in the QPP resource library at https://qpp.cms.gov/.

Comment: One commenter recommended changes to the QCDR self-nomination process, including updating QCDR self-nomination application and materials to outline all of the information needed to determine QCDR status to avoid delays and misunderstandings and providing at least a 60-day notice of any changes to the QCDR vetting process, including review of measures and a minimum of 30 days to appeal changes. The commenter further stated that changes to the 2019 QCDR application requirements should not be made until after the final rule is released due to the current QCDR application timeline closing on November 1 coinciding with publication of the final rule and that since the majority of specialty QCDRs stewards are currently submitting QCDR applications, CMS should allow these QCDRs to fully comment on these new proposed standards to which they are being held and which they may not support. Alternatively, the commenter suggested CMS allow for a nimble 2019 QCDR application process, including changes to the licensing standards given the significant changes CMS proposes for 2019.
Response: To clarify, we proposed that the self-nomination period be moved for the 2020 performance period, not the 2019 performance period as indicated by the commenter, to allow for sufficient time and notice of the changes. We will continue to provide educational materials that will outline all of the information needed to evaluate a QCDR’s ability to meet participation standards and QCDR measure evaluation criteria prior to the start of the self-nomination period. With the publication of this final rule, we intend on communicating any changes to the review process. For the 2019 performance period, it is not feasible to allow for a minimum of 30 days to appeal changes due to our goal of approving and publicizing the QCDRs by the start of the performance period. By moving up the self-nomination period, we will be able to allow QCDRs to have more time to consider our QCDR measure feedback. Additionally, moving the timeline to earlier in the year will allow CMS to review the measures fully and provide feedback to the QCDR who submitted the measures. The earlier self-nomination will also allow QCDRs who submit clinically similar measures to another QCDR and whose measure(s) are rejected to reach out to the QCDR whose measures are approved to attempt to enter into a licensing use agreement with the QCDR with the approved measures if desired. It is the goal of CMS to post the most comprehensive list of approved QCDRs and their measures before the start of the performance period so that eligible clinicians intending to use a QCDR can review these materials and select the QCDR that best meets their needs. In this way, the eligible clinician may begin submitting data to the QCDR at the start of the performance period. By doing so, the clinician will be more likely to receive timely feedback from the QCDR regarding his/her performance (earlier in the year) which will allow for quality improvement to occur during the performance period instead of receiving this data later in the year or after the conclusion of the performance period.
The CY 2019 performance period self-nomination form reflects the proposed MIPS quality measures, Promoting Interoperability measures, and Improvement Activities as proposed in the CY 2019 PFS proposed rule. We include disclaimer language that indicates that measures and activity availability are subject to change, pending upon what is finalized in the final rule. We continuously take into consideration stakeholder feedback as we look into process improvements and policy development for future program years. We appreciate the commenters’ suggestions, and ask that they provide more detail as to the changes to the licensing standards that they recommend we implement for future consideration.

After consideration of the public comments received, we are finalizing our proposal to amend §414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. In addition, we are finalizing our proposal to update §414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

(d) QCDR Measure Requirements

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) for where we previously finalized standards and criteria used for selecting and approving QCDR measures. We finalized that QCDR measures must: provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS; and provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than
November 1 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (improvement activities and Promoting Interoperability) data starting with the 2018 performance period and in future program years. In the CY 2019 PFS proposed rule (83 FR 35983), we proposed to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at §414.1400(e) and (f) at §414.1400(b)(3). We also proposed to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year (83 FR 35983).

In the CY 2018 Quality Payment Program final rule (82 FR 53814), we noted our interest in elevating the standards for which QCDR measures are selected and approved for use and sought comment on whether the standards and criteria used for selecting and approving QCDR measures should be more closely aligned with those used for the Call for Quality Measures process described in the CY 2017 Quality Payment Program final rule (81 FR 77151). Some commenters expressed concern with this alignment, stating that the Call for Measures process is cumbersome, and would increase burden. Other commenters expressed the belief that the Call for Measures process does not recognize the uniqueness of QCDRs, and is not agile. We would like to clarify that our intention with any future alignment is to work towards consistent standards and evaluation criteria that would be applicable to all MIPS quality measures, including QCDR measures. We understand that some of the criteria under the Call for Measures process may be difficult for QCDRs to meet prior to submitting a particular measure for approval; however, we believe that the criteria under the Call for Measures process helps ensure that any new measures are reliable and valid for use in the program. Having a greater alignment in measure standards helps ensure that MIPS eligible clinicians and groups are able to select
from an array of measures that are considered to be higher quality and provide meaningful
measurement. As such, we believe that as we gain additional experience with QCDRs in MIPS, it
would be appropriate to further align these criteria for QCDR measures with those of MIPS
quality measures in future program years.

Therefore, in addition to the QCDR measure criteria previously finalized at §414.1400(f),
we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply select criteria used under
the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule
(82 FR 53636). Specifically, in addition to the QCDR measure criteria at proposed
§414.1400(b)(3), we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply the
following criteria beginning with the 2021 MIPS payment year when considering QCDR
measures for possible inclusion in MIPS:

● Measures that are beyond the measure concept phase of development.

● Preference given to measures that are outcome-based rather than clinical process measures.

● Measures that address patient safety and adverse events.

● Measures that identify appropriate use of diagnosis and therapeutics.

● Measures that address the domain for care coordination.

● Measures that address the domain for patient and caregiver experience.

● Measures that address efficiency, cost and resource use.

● Measures that address significant variation in performance.

We believe that as we gain additional experience with QCDRs in MIPS, it would be
appropriate to further align these criteria for QCDR measures with those of MIPS quality
measures in future program years. Specifically, we are considering proposing to require
reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking.

In addition, we refer readers to the CMS Quality Measure Development Plan at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf for more information regarding the measure development process.

The following is a summary of the public comments received on the “QCDR Measure Requirements” proposals and our responses:

Comment: A few commenters stated that CMS should offer multi-year approval of QCDR measures to maximize stability and predictability while minimizing redundancy. The commenters further stated that QCDRs should be allowed to make minor modifications to measures under this multi-year approval process based on updated guidelines, evidence, or measure methodologies and if QCDR measures were approved for 2 to 3 years, the earlier self-nomination deadline would not be as problematic for registry vendors and would streamline CMS’ process.

Response: We disagree that offering multi-year approval of QCDR measures would minimize redundancy, as this may actually lead to duplicative measures which is counter intuitive to our meaningful measures initiative. Multi-year approvals of QCDR measures does not account for the possibility of there being more robust QCDR measures of similar concepts being submitted for CMS consideration. We may consider a similar process for future years, which is used with MIPS quality measures, where we’d continue to evaluate all the measures on an annual basis and compare them to those submitted during the measure consideration period (self-nomination period) to determine what QCDR measures would be best to include for the
upcoming performance period. QCDRs making changes to their measures would have to self-nominate those changes for CMS’ approval, and if we receive measures of similar concept that are more robust they may be considered to replace the existing approved QCDR measures.

Comment: One commenter supported the proposal to include the CMS-assigned QCDR measure ID number when posting the approved QCDR measure specifications, and also when submitting data on the QCDR measures to CMS.

Response: We appreciate the commenter’s support.

Comment: One commenter stated that CMS should not approve highly duplicative measure concepts submitted at a later time as doing so increases confusion among physicians and competition among QCDRs while disregarding the time, resources, and intellectual property rights of the measure owners. Some commenters noted that measures are misaligned, overlapping and duplicative across QCDR and MIPS measures.

Response: We agree that duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. It is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across CMS programs.

Comment: A few commenters supported the proposal to update QCDR measure criteria and encouraged CMS to have dialogue with QCDRs regarding the submission of measures. One commenter stated that CMS should expand the policy toward having a common national framework for endorsement of measures by a national consensus body (which currently is the National Quality Forum) and set expectations when accepting QCDR measures that measure stewards would be expected to get endorsement after a certain defined time period.
Response: We will continue dialogue with QCDRs during our scheduled calls. As far as expanding our policy toward having a common national framework for endorsement of measures by a national consensus body, we agree this would be valuable and encourage QCDRs to have their measures NQF endorsed. However, it is not a necessary requirement at this time because of its potential increase in burden and potential unintended impacts on the ability of QCDRs to adapt their measures.

Comment: A few commenters stated that CMS should work with both specialty societies and vendors in facilitating the time and effort needed to successfully encourage reporting of specialty-specific process and outcome measures while ensuring proper review and that appropriate data can be collected and shared. One commenter suggested CMS develop a review process where CMS and its contractor consult with appropriate physician experts and QCDR stewards to ensure sufficient clinical expert review on the importance and relevancy of a measure.

Response: We hold QCDR measure preview calls to provide a forum to work with both specialty societies and vendors wishing to self-nominate QCDR measures. New entities wishing to review QCDR measure concepts with CMS, may request a meeting with CMS by contacting the Quality Payment Program Service Center at QPP@cms.hhs.gov. Existing QCDRs may contact our contractor support team to set up a QCDR measure preview call. We have several measure experts as part of our review process, many of which have specialty specific expertise. Furthermore, we hold calls prior to self-nomination to allow experts to discuss their QCDR measure concepts, and will also continue to schedule calls with QCDRs after the self-nomination period closes to provide feedback, which provides time for QCDRs to invite their clinical experts
to provide additional information and explanation that would provide us with clarifications that may lead to a QCDR measure reexamination.

**Comment:** Many commenters did not support the proposal to align QCDR measure requirements with the criteria used under the Call for Quality Measures Process due to their beliefs that applying this criteria to QCDR measures fails to recognize the unique role of QCDRs who fill critical gaps in traditional quality measure sets as they support different specialties, and that doing so would limit the number of measures available for QCDR participants, would create more stringent standards for QCDR measures resulting in additional burden, and be counterproductive toward the goal of encouraging the use of QCDRs. Commenters stated that rather than require these criteria, the criteria should be made optional, but strongly preferred, as there are existing evidence-based process measures that are still valuable to improving patient care and should still be considered for inclusion in the QCDR program; and that since some outcome measures which evaluate degenerative or rare incidences, conditions that are terminal with limited treatment options, or conditions which result in increased co-morbidities require measurement over the course of multiple years to have sufficient statistical power, CMS should continue the use of certain process measures until they can be easily converted to meaningful outcome measures.

**Response:** We believe that our process seeks to ensure reliable measures and expect all measures in the program, including QCDRs, to be held to that standard. We believe that it is imperative to raise the bar with QCDR measures in order to ensure that we move away from standard of care, low-bar, process, and/or duplicative measures. Specifically, we are considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking. In the CY 2018 Quality Payment
Program final rule (82 FR 53814), we state that as the MIPS program progresses in its implementation, we are interested in elevating the standards for which QCDR measures are selected and approved for use. As a part of our QCDR measure review process, we do consider the complexity of what is being measured, while being mindful that measures with high performance do not provide value with regards to the quality performance category in MIPS. There are process measures in MIPS that are considered high priority, we believe it is important to retain those so long as they demonstrate room for improvement and lead to meaningful outcomes.

**Comment:** One commenter suggested CMS clarify the process by which a measure would be assigned within the domains provided under the proposed alignment with the Call for Quality Measures process and offer greater transparency in the rationale for this assignment or outcome status. In addition, the commenter recommended that CMS defer to the rationale and status identified by the QCDR, in particular for clinician-led registries.

**Response:** During the self-nomination process, we ask the QCDR to assign their QCDR measure a NQS domain, Meaningful Measure Area, whether or not their measure is high priority and/or an outcome measure. As a part of the vetting process, we review those selections and will reach out to the QCDR should we not agree with their assignment.

**Comment:** One commenter stated that due to the announcement of approved measures continuing to occur on a fixed schedule shortly before the start of each MIPS performance period despite the rolling submission process for new MIPS measures through the Call for Quality Measures Process, CMS should transition to a rolling review and approval process for QCDR measures to allow stakeholders more time to implement new measures prior to the MIPS performance period. This commenter also stated that if CMS is unwilling to move to a rolling
review and approval process, the quality category performance period should be reduced. The commenter noted that the rolling submission process has not benefited measure owners, QCDRs, registries, and EHR vendors, all of which have very little time to modify their systems to include new measures post-approval and prior to the start of the next MIPS performance period.

Response: We note that a rolling review basis would adversely impact our ability to limit the number of duplicative measures that are similar in concept, which is inconsistent with the meaningful measure initiative. We believe that the change in the self-nomination period would allow for increased time in the measure review process, as well as provide additional time for QCDRs to respond to feedback provided by CMS. We do not believe a rolling review and approval process is appropriate, as it is not a process that is used for MIPS quality measures. We do not agree that the quality performance period should be reduced dependent on whether or not a rolling review and approval process is implemented as there is no correlation between the two processes.

Comment: One commenter suggested CMS should require measure developers to include a section in each measure that specifies how eligible clinicians and TINs should be attributed for that measure to assist in preventing different interpretations for measure attribution which could lead to TIN/NPI mismatches and resulting determinations by CMS that submitted data is inaccurate.

Response: We agree that attribution should be clearly stated in the QCDR measure specifications and appreciate the commenter’s feedback. We will take this suggestion into consideration as we review QCDR measure concepts, and will share this feedback with the QCDRs for their consideration.
After consideration of the public comments received, we are finalizing our proposal to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at §414.1400(e) and (f) at §414.1400(b)(3) and to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year. We are also finalizing our proposal to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636) in addition to the QCDR measure criteria previously finalized at §414.1400(f). Specifically, in addition to the QCDR measure criteria that we are finalizing at §414.1400(b)(3), we are also finalizing our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

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

(e) QCDRs Seeking Permission From Another QCDR To Use An Existing, Approved QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813), we finalized that
beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Furthermore, having multiple QCDRs report on the same QCDR measure allows for a larger cohort of clinicians to report on the measure, which helps establish more reliable benchmarks and may give some eligible clinicians or group a better chance of obtaining a higher score on a particular measure. However, we have experienced that this policy has created unintended financial burden for QCDRs requesting permission from other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures. MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries, MIPS eligible clinicians, and groups to report on for purposes of MIPS without a fee for use. Similarly, we believe, that once a QCDR measure is approved for reporting in MIPS, it should be generally available for other QCDRs to report on for purposes of MIPS without a fee for use. In the CY 2019 PFS proposed rule (83 FR 35984), we proposed at §414.1400 (b)(3)(ii)(C) that beginning with the 2021 MIPS payment year , as a condition of a QCDR measure’s approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35984) we also proposed at §414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or
topic may be approved in its place.

The following is a summary of the public comments received on the “QCDRs Seeking Permission from another QCDR to Use an Existing, Approved QCDR Measure” proposals and our responses:

Comment: Many commenters disagreed with CMS’ proposal to require QCDRs to enter into a measure licensing agreement with CMS beginning with the 2021 MIPS payment year, stating that QCDRs would be required to attest to these measures before knowledge that this proposal would be finalized and that they, therefore, did not know that they would be required to enter into mandatory licensing agreements for these measures at the time of attestation. Commenters specifically stated that this timeline would violate the Administrative Procedure Act. Other commenters stated that should the proposal be finalized, it would be unreasonable for QCDR measure stewards to implement the policy by January 1 of the 2019 performance period given that the self-nomination period closes prior to publication of the CY 2019 PFS final rule. Commenters stated that the proposal, if it is finalized, should be delayed at least 1 year to give QCDRs an opportunity to decide whether to continue participating in the program. One commenter stated that some specialty societies may delay their QCDR application until this issue has been addressed by CMS.

Response: Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing this proposal. Rather, while we believe our proposal is consistent with the Administrative Procedure Act, we are persuaded by the other concerns raised by stakeholders on the implementation of this policy and are therefore retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813).
Comment: Many commenters disagreed with the proposal to require QCDR measure owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval. Reasons cited for disagreeing with the proposal include beliefs that it does not acknowledge the cost in developing complex measures; would unfairly reduce costs for QCDRs that do not develop their own measures while increasing costs for QCDRs that do; would compromise the intellectual property of measure stewards as CMS would have a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval; would undermine the smooth operation of the QCDR measure market; is an arbitrary and capricious reversal of existing policy; violates intellectual property law, judicial precedent, executive order, and copyrights; nullifies the rights of copyright owners to collect reasonable royalties, maintain measure integrity, and limit inappropriate use; might remove the right of QCDR developers to have input into how CMS uses their measures; may result in a developer having to seek CMS’s approval prior to working with another payer entity for reporting of its measures; and ignores the time and resources spent in developing and maintaining measures.

Response: As noted above we are not finalizing this proposal. We note that we do not believe this proposal would have violated intellectual property rights or law, as QCDRs would not have been required to submit QCDR measures for approval, and if a QCDR had refused to enter into such a license agreement, the QCDR measure would have been rejected and another QCDR measure of similar clinical concept or topic may have been approved in its place. We will take the many concerns raised by commenters into consideration as we work with stakeholders to address this issue in the future.

Comment: Many commenters disagreed with the proposal to require QCDR measure
owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval believing it contradicts the intent of the Meaningful Measure Initiative by eliminating the incentive to develop innovative quality measures that focus on meaningful outcomes; will disincentivize societies from investing in the development of new and improved measures; may increase the incidence of inappropriate use of measures by QCDRs lacking the necessary clinical breadth of exposure/experience resulting in lower quality data being collected, decreased reliability and validity of results, and potential misclassification of providers; would negatively impact the quality of available measures and physician community support for the Quality Payment Program in general; would disincentivize QCDRs from remaining in business, resulting in loss of significant private sector knowledge and experience, as well as increasing the financial burden on the government to hire more federal contractors to replace lost innovation and creativity; and disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease, condition, procedure, or therapy-specific patient populations.

Response: We do not believe this proposed policy contradicts the Meaningful Measure Initiative, which seeks to reduce the number of duplicative measures in quality performance programs, thereby reducing clinician burden and complexity. However, as noted above we are not finalizing this proposal. We also note that with the finalization of the updated QCDR definition, we believe we will be able to negate any concerns of inappropriate use of QCDR measures by QCDRs who do not have the clinical expertise needed to understand the measure at hand. We have observed increasing interest in stakeholders becoming QCDRs, and believe that they will continue to drive innovation and competition within the market.

Comment: A few commenters suggested alternatives to the proposal to require QCDRs to license their measures to CMS. These alternatives include encourage licensing agreements
between QCDRs and reinforcing the ability of QCDRs to develop their own measures should they elect not to license them from other QCDRs. One commenter suggested that CMS should create a “measure complexity score” with a corresponding, volume-based, licensing fee payable to the QCDR holding the original measure in conjunction with an annual consolidation of measures to support harmonization requiring stakeholders to collaborate on a “shared” measure creation (with licensing fees split evenly) or lose the opportunity for future licensing fee payments. Another commenter recommended CMS propose including a cost-based algorithm that would be used to determine a specific QCDR measure fee which would protect organizations that could not afford the development of a quality measure or that were not able to develop a measure because a similar measure exists, as well as preventing QCDR measure developers from assigning unreasonable fees to their measures. One commenter recommended CMS establish a pilot program that would encourage collaboration across QCDRs and require users of QCDR measures to agree to adhere to certain requirements of the measure steward, as well as share measure performance information to implement and test measure changes, progressing all concepts to patient-centered outcome measures through measure retirement. Another commenter recommended that CMS follow NQF’s example that anyone can report the measure scores and there has to be public/free access for the measures to be used in clinical care, but the measure steward should be permitted to require licensing and fees for anyone who wants to use the measures for more sophisticated purposes, such as programming into software that will result in sales/profit. Other commenters cited their opinions that should the proposal be finalized, it should be done with modification to require a standard data dictionary be used for all QCDR measures and include risk adjustment as well as the same standard methodology used by the measure developer.
Response: We note that the suggestion to encourage licensing agreements between QCDRs was implemented in the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814); however, we have decided not to finalize the measure licensure policy at this time. Our goal in enacting such a policy was to promote measure harmonization and decrease the number of duplicative QCDR measures in the program. We appreciate the suggestion of a “measure complexity score” but envision such an approach would be difficult to implement. We would need additional information from stakeholders prior to implementing such a policy, such as how would CMS know how to correlate the volume and complexity to a specific score? What would that entail if on an annual basis the number of QCDRs who submit a similar measure concept increases, and what would they have to do in order to be a part of the harmonization effort? We request clarification on how a cost-based algorithm can be developed, and would also like to clarify that CMS does not regulate the minimum or maximum amounts that a QCDR may charge as a licensing fee.

We thank the commenter for their suggestion of implementing a pilot program where QCDRs would need to share measure performance information, test and implement measure changes, and work towards patient-centered outcome measures. We agree that the sharing of performance data, testing results, and moving towards outcome based measures are all important, but will need to look into the feasibility and operations of implementing such requirements. With regards to the development of a standard data dictionary, as described in the CY 2018 Quality Payment Program final rule (82 FR 53813), we encourage QCDR measure developer to utilize the current Measure Development Plan available at

https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2018-MDP-annual-report.PDF. Furthermore, as explained through posted sub-regulatory documents for the

**Comment:** Many commenters requested CMS work with them to adopt a market-based solution to create safeguards to protect the proper implementation of QCDR measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

**Response:** We will look to provide listening sessions to better understand and explore the feasibility of this approach.

**Comment:** Many commenters expressed concern with CMS' requests for harmonization of similar MIPS measures due to their belief that some vendors may be misusing measures and diminishing the integrity of the data, the quality of feedback to physicians, and ability to compare performance. The commenters further cited their belief that such harmonization can lead to inconsistencies in implementation, yielding incomparable results and inaccurate benchmarking due to lack of accountability and standardization across registries which may be employing different methods for obtaining, risk adjusting, and aggregating data, thereby creating variations in how clinicians are measured and how their care is classified.

**Response:** To clarify, in the CY 2019 PFS proposed rule (83 FR 35984), we indicated that the QCDRs would be required to use the QCDR measure without any modification, and would have to report on the measure utilizing the CMS assigned measure ID. We encourage QCDRs to work together through measure harmonization, and to reach out to QCDR measure
owners when they believe a revision to the measure specification is appropriate, for the QCDR
measure owner to consider.

Comment: A few commenters suggested the proposal to require QCDRs to license
measures to CMS should include allowing qualified registries and other non-QCDR submitter
types to also report QCDR measures; only counting measures developed by a QCDR to count
toward the 30 measure threshold; and requiring QCDR measure owners to provide detailed
specifications including ICD-10-CM codes, CPT codes, required clinical data elements, et cetera,
so that all QCDR registries administer the specification uniformly, and developing a system to
properly record and track ownership rights, including making ownership information CMS
collects available to QCDRs to better facilitate sharing of QCDR measures between QCDR
stewards. Commenters also suggested that CMS reserve the right of the measure owner to
review interim performance results of other QCDRs utilizing their measures with full
cooperation of the other QCDRs to ensure performance results do not vary significantly between
QCDRs, thereby ensuring alignment on execution of the measure specification between QCDRs
before performance is scored and future benchmarks are impacted.

Response: To clarify, we are only allowing other QCDRs to report on the QCDR
measures. Other submitter types would not have the QCDR measures available for reporting. As
discussed in the CY 2018 Quality Payment Program final rule (82 FR 53811), QCDRs have the
capability to develop and submit for consideration up to 30 QCDR measures per performance
period. However, there is no limit as to the number of MIPS quality measures they intend on
supporting for a given performance period. We disagree that QCDR measures should be
available for reporting by non-QCDR submitter types. As we provide QCDRs with feedback on
harmonizing or using QCDR measures owned by other QCDRs, we encourage them to reach out
to the QCDRs specifically for the detailed specification inclusive of ICD-10 and CPT codes, as each measure owner is responsible for tracking ownership rights. The MIPS quality measures provide a detailed measure specification to allow consistency in implementation, but data abstraction may include multiple methods. We would require QCDRs to follow a similar approach, where QCDRs would need to provide a detailed specification to the QCDRs approved to submit the QCDR measure. This would include any applicable ICD-10-CM codes, CPT codes, required clinical data elements, et cetera, to allow implementation with minimal variance. We would like to hear from QCDRs on whether or not they would find this useful; and if this effort will increase burden on their end regarding measure specification development. We will take the suggestion that CMS reserve the right of the measure owner to review interim performance results of other QCDRs utilizing their measures into consideration for future rulemaking.

**Comment:** A few commenters stated that the proposal blurs the line between QCDR measures and Quality Payment Program measures and would eliminate the ability for a QCDR to “test” a measure in the sandbox of their own QCDR before submitting it to CMS to become a Quality Payment Program measure under the Measures Under Consideration (MUC) process. Finally, one commenter suggested that if a measure owner was ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process.

**Response:** The QCDR measure approval process is not intended to act as a test bed for measure concepts, we expect QCDRs to have measures that are analytically sound, are reliable, and feasible. Furthermore, we certainly encourage that if a measure owner is ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process as discussed in section III.I.3.h.(2)(b)(i) of the CY 2019 PFS
proposed rule (83 FR 35898 through 35899).

Comment: One commenter stated its belief that the proposal does not align with the intended purpose of the MACRA grant for measure development, which they further noted demonstrates the federal government’s recognition of measure development expense. A second commenter stated that the proposal lacks provisions on how to determine whether a specific measure is intended for another population and that the absence of such provisions can lead to inappropriate implementations in patient populations with the inability of the measure owner to review data collected on their measures and maintain the measures appropriately.

Response: We do not believe this policy would not align with the MACRA grant for measure development, since generally across all quality programs we are looking to reduce the number of duplicative measures available for reporting and to transition to more outcomes based measures. We believe that QCDRs exist to address measurement gaps as identified by the specialists and that QCDRs are intended to address gaps in measurement that would better reflect a clinician’s scope of practice. Based on the updates to the QCDR definition we have finalized in this final rule (in the above section) for the 2020 performance period of MIPS, we believe we will be able to further vet QCDR applications to ensure that approved QCDRs would have the clinical expertise and measure development experience. We are also streamlining the number of measures available to clinicians in order to align with our Meaningful Measures initiative. We note that our review and approval of the QCDR measures will follow our existing process utilizing the QCDR measure evaluation criteria as detailed through sub-regulatory guidance in the 2019 QCDR Measure Development Handbook, located in the 2019 Self-Nomination Toolkit on the Quality Payment Program Resource Library webpage at

https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-
Resources.html. Once the QCDR measures have been finalized for the performance period, and the specification has been finalized, we intend to post the list of QCDR measure specifications for QCDRs to review and consider prior to deciding whether or not they wish to support additional QCDR measures. As a part of this consideration, we encourage QCDRs to review the measure specifications to determine the populations addressed.

Comment: A few commenters supported the proposal to require QCDRs to enter into licensing agreements with CMS as a condition of approval. Reasons cited include their beliefs that the proposal allows different vendors to have the ability to address different specialty needs appropriately thereby providing greater choice to eligible clinicians, increases the effectiveness of quality measurement, and increases the relevance and usefulness of measures in evaluating the quality of care provided to patients nationally by increasing the number of providers reporting data.

Response: We thank the commenters for their support but as noted previously we are not finalizing this policy at this time.

Comment: A few commenters stated that CMS should adopt a model where one measure is supported by one entity that represents a single clinical domain or subspecialty as they noted doing so will enhance consistency and validity across measurements; allow for a single method for data aggregation, analytics, and reporting; reduce benchmarking issues; decrease the risk of clinicians being misclassified in the quality of care they provide; and remedy CMS' lack of ability to co-aggregate data from multiple data sources and properly risk-adjust measures. The commenters noted that the approved registry should be required to meet standards for data which include rigor in explicitly defining data elements used in the measurement, serve as a single source of data aggregation and data normalization to secure data integrity, apply approved and
consistent statistical standards for analytics, respond to clinical and methodological questions, and be responsible for reporting requirements as defined by CMS. One commenter further noted that CMS policy should require QCDRs to always refer eligible clinician questions on specific measures back to the measure steward, prohibit vendors and other QCDRs from specifying CQMs into eCQMs without permission, require QCDRs to use current measure specifications, and require CMS to publicly post complete measure specifications, where appropriate, to the CMS Quality Payment Program resources website to ensure all registries are implementing the most updated measure specifications.

Response: We are not looking to set limitations, such as, one clinical domain being assigned to one entity. We have multiple instances where there are a few QCDRs covering similar areas (that is, surgery, anesthesia, rheumatology). We would appreciate thoughts on how we can reduce benchmarking issues to thereby incentivize QCDR measure reporting. QCDRs are required to meet CMS data aggregation and reporting requirements and agree that it is important that QCDRs are able to meet data integrity standards in using data elements for purposes of measurement. We believe there are circumstances out of CMS’ control where the clinician will reach out to the QPP service center for assistance with a measure related question or to the QCDR they are specifically working with. It would not be feasible to set such a requirement when we could not monitor that it would be followed. We encourage clinicians who have questions on the QCDR measure specifications to reach out directly to the QCDR measure owner in order to gain clarity on their questions. We agree, however, that the QCDR must use the measure in its original state. QCDRs have to use the measure in its “as is” state; meaning, how it was approved for the given performance period. We post QCDR measure specifications, inclusive of: the measure’s specialty; QCDR name; measure title; measure description;
denominator; numerator; denominator exclusions; denominator exceptions; numerator exclusions; data source used; NQF number (if applicable); NQS domain; whether the measure is high priority, outcome; measure type; whether the measure is inverse, proportional, continuous variable, ratio; the range of scores if the measure is continuous variable or ratio measures; number of performance rates submitted; overall performance rate; whether the measure is risk-adjusted; if risk-adjusted, and which score is risk-adjusted within the QPP resource library. The systems are programmed on an annual basis to only accept those QCDR measures and correlated specifications as approved for the upcoming performance period.

Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing at §414.1400 (b)(3)(ii)(C) that as a condition of a QCDR measure’s approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS, permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. Rather we are retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). We remain very concerned about duplicative measures and their impact to our meaningful measures initiative. We are eager to work with the stakeholder community to determine solutions for this issue and will continue to look for policy resolutions to address this issue.

We are finalizing our proposal at §414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID.

(4) Qualified Registries

We refer readers to §414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) for our previously finalized policies regarding qualified registries. In
the CY 2019 PFS proposed rule (83 FR 35984), we proposed to update: information required for
qualified registries at the time of self-nomination and the self-nomination period for qualified
registries.

(a) Establishment of an Entity Seeking To Qualify as a Qualified Registry

In the CY 2017 Quality Payment Program final rule (81 FR 77383), we state at
§414.1400(h)(2) that the qualified registry must have at least 25 participants by January 1 of the
performance period. These participants do not need to use the qualified registry to report MIPS
data to us; rather, they need to submit data to the qualified registry for quality improvement. We
realize that a qualified registry’s lack of preparedness to accept data from MIPS eligible
clinicians and groups beginning on January 1 of the performance period may negatively impact a
clinician’s ability to use a Qualified Registry to report, monitor the quality of care they provide
to their patients (and act on these results) and may inadvertently increase clinician burden. For
these reasons, in the CY 2019 PFS proposed rule (83 FR 35984), we proposed to redesignate
§414.1400(h)(2) as §414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year,
the qualified registry must have at least 25 participants by January 1 of the year prior to the
applicable performance period. These participants do not need to use the qualified registry to
report MIPS data to us; rather, they need to submit data to the qualified registry for quality
improvement.

We did not receive any comments on the “Establishment of an Entity Seeking To Qualify
as a Qualified Registry.” We are finalizing our proposal to redesignate §414.1400(h)(2) as
§414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry
must have at least 25 participants by January 1 of the year prior to the applicable performance
period.
(b) Self-Nomination Process

We refer readers to §414.1400(g), the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77383 and 82 FR 53815, respectively) for our previously established policies regarding the self-nomination process for qualified registries. We did not propose any changes to this policy.

(c) Self-Nomination Period

Under the previously finalized policy at §414.1400(g), qualified registries must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. To maintain alignment with the timelines proposed for QCDR self-nomination, as discussed in section III.I.3.k.(3)(c) of this final rule, we also proposed in the CY 2019 PFS proposed rule (83 FR 35985) to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Specifically, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at §414.1400(c)(1) that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore, the self-nomination period for qualified registries would begin on July 1, 2019 and end on September 1, 2019.
We did not receive any comments on the “Self-nomination Period” for Qualified Registries. We are finalizing our proposal to amend §414.1400(c) (1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process.

(5) Health IT Vendors or Other Authorized Third Parties That Obtain Data from MIPS Eligible Clinicians’ Certified EHR Technology (CEHRT)

We refer readers to §414.1400 and the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382) for our previously finalized policies regarding health IT vendors or other authorized third parties that obtain data from MIPS eligible clinicians. We finalized that health IT vendors that obtain data from a MIPS eligible clinician, like other third party intermediaries, would have to meet all criteria designated by us as a condition of their qualification or approval to participate in MIPS as a third party intermediary. This includes submitting data in the form and manner specified by us. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed to codify these policies at §414.1400(d). Although we specified criteria for a health IT vendor in the CY 2017 Quality Payment Program final rule, we failed to codify the definition of a health IT vendor. Therefore, in the CY 2019 PFS proposed rule (83 FR 35985), we proposed to define at §414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician’s CEHRT).
As indicated in footnote 1 of the CY 2017 Quality Payment Program final rule (81 FR 77014 through 77015), the term “health IT vendor” encompasses many types of entities that support the health IT requirements on behalf of a MIPS eligible clinician. A “health IT vendor” may or may not also be a “health IT developer” for the purposes of the ONC Health IT Certification Program (Program), and, in some cases, the developer and the vendor of a single product may be different entities. Under the 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. Other health IT vendors may maintain a range of data transmission, aggregation, and calculation services or functions, such as organizations which facilitate health information exchange.

We did not receive any comments on the “Health IT Vendors or Other Authorized Third Parties That Obtain Data from MIPS Eligible Clinicians’ Certified EHR Technology (CEHRT).” Therefore, we are finalizing our proposal to codify our previously established policies at §414.1400(d). We are also finalizing our proposal to define at §414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician’s CEHRT).

(6) CMS-Approved Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the criteria, required forms, and vendor business requirements needed to participate in MIPS as a CMS-approved survey vendor. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed at §414.1400(e) to codify these previously finalized criteria and requirements. Accordingly, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at §414.1400(e) that an entity seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a
survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. We also proposed to require that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. In addition, we proposed that a CMS-approved survey vendor must meet several criteria. First, we proposed to require that an entity have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering surveys in English and one of the following languages: Cantonese; Korean; Mandarin; Russian; or Vietnamese;
- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

Furthermore, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) that to be a CMS-approved survey vendor, the entity must also meet the following criteria:
• It must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data;
• The entity must have successfully completed, and required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors;
• The entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts;
• The entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and
• The entity must have sent an interim survey data file to CMS that establishes the entity’s ability to accurately report CAHPS data.

We also refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53818 through 53819) for our previously established policies regarding the updated survey vendor application deadline.

The following is a summary of the public comments received on the “CMS-Approved Survey Vendors” proposals and our responses:

Comment: A few commenters commended CMS for making the CAHPS for Physician Quality Reporting System (PQRS) survey available in Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese and for making the Medicare Accountable Care Organization CAHPS survey available in Cantonese, Korean, Mandarin, Portuguese, Russian, Spanish, and Vietnamese. These commenters encouraged CMS to work with stakeholders to develop validated
translations of all CAHPS surveys used in MIPS and APMs in at least the top ten primary languages among Medicare beneficiaries.

Response: We appreciate the commenters’ feedback. We have made the CAHPS for MIPS survey available in Spanish and we will continue to work with stakeholders to develop additional translations of the surveys. In addition, because the CAHPS for MIPS survey is available in Spanish and may become available in other languages in the future, we believe it is appropriate to modify our proposed requirement at §414.1400(e)(1)(iv) to more broadly state that an entity must have experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese.

After consideration of the public comments received, we are finalizing our proposal at §414.1400(e) to state that entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data; and that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. We are also finalizing our proposal at §414.1400(e) that a CMS-approved survey vendor must meet several criteria that consists of the following:

An entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
• At least 3 years of experience administering CAHPS surveys within the past 5 years;

• Experience administering CAHPS surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish or Vietnamese;

• Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

• Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

In addition, we are finalizing without change our proposal that an entity must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data; the entity must have successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors; the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts; the entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and the entity must have sent an interim survey data file to CMS that establishes the entity’s ability to accurately report CAHPS data.

(7) Auditing of Third Party Intermediaries Submitting MIPS Data
In the CY 2018 Quality Payment Program final rule (82 FR 53819), we established at §414.1400(j) policies regarding auditing of third party intermediaries submitting MIPS data. In the CY 2019 PFS proposed rule (83 FR 35985), we did not propose any changes to these policies. In this final rule, the provision that currently appears at §414.1400(j) is redesignated as §414.1400(g) and contains no substantive changes.

(8) Remedial action and termination of third party intermediaries

In the CY 2017 Quality Payment Program final rule (81 FR 77548), we finalized the criteria for probation and disqualification for third party intermediaries at §414.1400(k). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed to revise the numbering of this section and the title to more accurately describe the policies in this section. Specifically, we proposed to renumber this section as §414.1400(f) and to rename it as “remedial action and termination of third party intermediaries.” Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) changes to §414.1400(f) to amend, clarify, and streamline our policies related to remedial action and termination.

Our intent with these policies is to identify and remedy noncompliance with the applicable third party intermediary criteria, as well as identify issues that may impact the accuracy of or our ability to use the data submitted by third party intermediaries. Accordingly, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to amend §414.1400(f)(1) to state that we may take remedial action for noncompliance with applicable third party intermediary criteria for approval (a deficiency) or for the submission of inaccurate, unusable, or otherwise compromised data. In the CY 2017 Quality Payment Program final rule, we finalized our policy regarding data inaccuracies at §414.1400(k)(4). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed at §414.1400(f)(3) to expand data inaccuracies to include a determination
by us that data is inaccurate, unusable, or otherwise compromised. However, we did not propose to change the factors we may consider to make such a determination. In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed to move the notification requirement at \$414.1400(k)(6) to \$414.1400(f)(1) and to apply the requirement to all deficiencies and data errors.

Based on our early experience with third party intermediaries under MIPS and the challenges for both third party intermediaries and us in regards to timing and trying to resolve deficiencies and data errors within the various reporting and performance periods, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to amend the timeframes by which a third party intermediary must submit a Corrective Action Plan (CAP) to us or come into compliance. Specifically, we proposed \$414.1400(f)(2), which requires third party intermediaries to submit a CAP or correct the deficiencies or data errors by the date specified by us (83 FR 35986).

Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to consolidate at \$414.1400(f)(1) the grounds for remedial action against a third party intermediary currently specified at \$414.1400(k)(1) and (4) and to consolidate at \$414.1400(f)(2) the grounds for terminating a third party intermediary currently found at \$414.1400(k)(3), (5) and (7).

Therefore, we proposed at \$414.1400(f)(1) that if at any time we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may take certain remedial actions (for example, request a CAP) (83 FR 35986). In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed at \$414.1400(f)(2) that we may terminate, immediately or with advance notice, the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: we
have grounds to impose remedial action, we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us.

Additionally, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to consolidate at §414.1400(f)(1) the actions we may take if we identify a deficiency or data error that are set forth at §414.1400(k)(3) and (7). Thus, we proposed at §414.1400(f)(1) in the CY 2019 PFS proposed rule (83 FR 35986) that if we determine a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may require the third party intermediary to submit a CAP to us to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. We proposed to require that the CAP be submitted to CMS by a date specified by CMS.

In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data: (1) includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and (2) affects more than 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In addition, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) that if the third party intermediary has a data error rate of 3 percent or more, we will publicly disclose the entity’s data error rate on the CMS website until the data error rate falls below 3 percent.

We clarify in this final rule that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party
intermediary. In the CY 2017 Quality Payment Program final rule (81 FR 77387 through 77388), we explained that if a third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, we would annotate on the CMS qualified posting that the third party intermediary furnished data of poor quality and would place the entity on probation for the subsequent MIPS performance period. If a third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS Web site continue to note the poor quality of the data they are submitting for MIPS for one additional performance year. After 2 years on probation, the third party intermediary would be disqualified for the subsequent performance year. We also explained that data errors affecting in excess of 5 percent of MIPS eligible clinicians or group submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation for the following performance period (that is, without first placing the third party intermediary on probation).

Accordingly, it was always our intent that data errors affecting in excess of 3 percent of the MIPS eligible clinicians or group submitted by a third party intermediary would result in remedial action or disqualification (termination) of the third party intermediary. In this final rule, we are correcting an obvious error in the regulation text we proposed at §414.1400(f)(3)(ii) to clarify that if submitted data is inaccurate, unusable, or otherwise compromised if errors in the submitted data affect more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.
Finally, we proposed to remove our probation policy. Therefore, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to remove the definition of probation at §414.1400(k) (2) and references to probation in §414.1400(k) (1), (3) and (5).

The following is a summary of the public comments received on the “Remedial Action and Termination of Third Party Intermediaries” proposals and our responses:

**Comment:** One commenter stated that CMS should put in place a safe harbor policy in order to minimize the impact on clinicians when a data issue outside of a clinician’s or group’s control occurs due to a third party intermediary. The commenter indicated that, under those circumstances, CMS should automatically consider the clinician or group to have satisfied the quality performance category. The commenter cited concerns with the transition and upgrade to 2015 CEHRT and references data issues under 2016 PQRS related to the 2014 CEHRT upgrade.

**Response:** We do not agree that we should create a safe harbor policy to address the circumstances described by the commenter. Instead, we believe it would be appropriate to address data issues on a case-by-case basis. As we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53807), we expect third party intermediaries to develop processes to ensure that the data and information they submit to CMS on behalf of MIPS eligible clinicians, groups, and virtual groups are true, accurate, and complete; we also rely on the third party intermediaries to address these issues in its arrangements and agreements with other entities, including MIPS eligible clinicians, groups, and virtual groups.

**Comment:** One commenter agreed with the proposal to remove the probation policy.

**Response:** We appreciate the commenter’s support.

**Comment:** A few commenters disagreed with our proposal at §414.1400(f)(2) because it would allow us to immediately or with advance notice terminate a third party intermediary’s
ability to submit MIPS data without first placing the third party intermediary on probation. The commenters believe that termination should occur only with advance notice through a clearly defined process that reflects the current procedure set forth at §414.1400(f). Commenters suggested that CMS’ termination procedure include formal consideration of a CAP.

Response: We appreciate the commenters’ concerns, and therefore, we expect that in most circumstances, we would take remedial action, including imposition of a CAP, prior to terminating the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group. Before deciding whether to terminate a third party intermediary’s ability to submit MIPS data, we would take into account a third party intermediary’s actions, the severity of the non-compliance or errors at issue, and the potential for undue hardship or negative impact on affected eligible clinicians. In addition, we would expect to provide advance notice of most terminations; we would likely impose immediate termination on a third party intermediary’s ability to submit MIPS data only in circumstances where egregious non-compliance or data errors have occurred. However, if we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us, we may terminate the third party intermediary, immediately or with advance notice.

Comment: A few commenters stated that the proposed termination policy could result in undue hardship on or negatively impact affected eligible clinicians should termination occur during a performance period.

Response: We recognize that termination of a third party intermediary’s ability to submit MIPS data during a performance period may result in undue hardship on eligible clinicians who are supported by the third party intermediary. Therefore, we would consider whether a third
party intermediary is supporting eligible clinicians in deciding when to terminate the ability of
the third party intermediary to submit MIPS data. In addition, we will consider for future
rulemaking whether a third party intermediary should be required to submit to CMS a transition
plan that addresses how submission of data would be handled in the event that termination
occurs during a performance period.

Comment: A few commenters representing QCDRs and qualified registries stated that
CMS should clearly define, and provide examples of, a “data error” for purposes of determining
a third party intermediary’s data error rate, which may be disclosed publicly by CMS if it
exceeds 3 percent. In addition, the commenters stated that CMS should set forth how the data
error rate is calculated and develop a report that describes and differentiates data errors and other
“issues” that should be brought to a third party intermediary’s attention.

Response: The “data error rate” measures the amount of data submitted by a third party
intermediary that was “inaccurate, unusable, or otherwise compromised.” Additional material
regarding data inaccuracies and error rates is available in the “2019 Qualified Clinical Data
Registry (QCDR) Fact Sheet” and the “2019 Qualified Registry Fact Sheet” in the 2019 Self-
Nomination Toolkit for QCDRs & Registries, located in the Quality Payment Program Resource
Library at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-
Resources.html. We appreciate the suggestion of creating a report that describes data errors and
“other issues,” however, we believe that our existing material addresses the commenters’
concern.

After consideration of the public comments received, we are finalizing our proposal to
revise the numbering of §414.1400(k) as §414.1400(f) and to rename it as “remedial action and
termination of third party intermediaries.” We are also finalizing our proposal to amend, clarify, and streamline our policies related to remedial action and termination as follows:

- We are finalizing §414.1400(f)(1) to state that CMS may take one or more of the following remedial actions if we determine that a third party intermediary has ceased to meet one or more of the applicable third party intermediary criteria for approval or has submitted data that is inaccurate, unusable, or otherwise compromised: we will require the third party intermediary to submit by a deadline specified by CMS a CAP that addressed the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring; or we will publicly disclose the entity’s data error rate on the CMS website until the data error rate falls below 3 percent.

- We are finalizing §414.1400(f)(2) to state that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action; CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or, the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

- We are finalizing §414.1400(f)(3) to state that, for purposes of paragraph (f), CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if it: includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

1. Public Reporting on Physician Compare
This section contains our approach for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years, including MIPS, APMs, and other information as required by the MACRA and building on our previously finalized public reporting policies (see 82 FR 53819 through 53832).

Physician Compare (http://www.medicare.gov/physiciancompare) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the Physician Compare Initiative website at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53820), Physician Compare has continued to pursue a phased approach to public reporting under the MACRA in accordance with section 1848(q)(9) of the Act. Generally, all data available for public reporting on Physician Compare must meet our established public reporting standards under §414.1395(b). In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare under §414.1395(d). All data available for public reporting – measure rates, scores, and attestations, objectives, etc. – are available for review and correction.
During the targeted review process. See the CY 2018 Quality Payment Program final rule for details on this process (82 FR 53820).

Lastly, section 104(e) of the MACRA requires the Secretary to make publicly available, on an annual basis, in an easily understandable format, information for physicians and, as appropriate, other eligible clinicians related to items and services furnished to Medicare beneficiaries under Title XVIII of the Act. In accordance with section 104(e) of the MACRA, we finalized a policy in the CY 2016 PFS final rule (80 FR 71131) to add utilization data to the Physician Compare downloadable database.

We believe section 10331 of the Affordable Care Act supports the overarching goals of the MACRA by providing the public with performance information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As such, the following sections discuss the information previously finalized for inclusion on Physician Compare for all program years, as well as our finalized policies for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years.

We received several miscellaneous comments, but since these were not applicable to specific proposals made, these comments are outside the scope of this section and the proposed rule.

(1) Final Score, Performance Categories, and Aggregate Information

In the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy
to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. We will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel convened by our contractor, to determine how and where these data are best reported on Physician Compare.

A summary of the previously finalized policies related to each performance category of MIPS data, as well as finalized policies for year 3 and future years, follows. It is important to note just because performance information is available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must meet the public reporting standards, first. And, second, we are careful to ensure that we do not include too much information on public-facing profile pages in an effort not to overwhelm website users. Although all information submitted under MIPS is technically available for public reporting, we will continue our phased approach to making this information public.

(2) Quality

In the CY 2018 Quality Payment Program final rule (82 FR 53824), we finalized a policy to make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible. This includes all available measures across all collection types for both MIPS eligible clinicians and groups, for all future years. We will use statistical testing and website user testing
to determine how and where measures are reported on Physician Compare. We will not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category, under §414.1395(c). We will also include the total number of patients reported on for each measure included in the downloadable database (82 FR 53824).

We proposed to modify §414.1395(b) to reference “collection types” instead of “submission mechanisms” to accurately update the terminology (83 FR 35987), consistent with the proposal to add this term and its definition under §414.1305. We also proposed to revise §414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category (83 FR 35987). We proposed this change to encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public. We requested comment on these proposals.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Most commenters supported not publicly reporting first year data on quality measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter noted concern with delaying the public reporting of first year quality measures for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. A few commenters suggested that 3 years is a more appropriate length of time for delaying publicly reporting first year measures, stating this timeframe would allow CMS to adequately evaluate meaningful trends over time and provide clinicians with an
adequate period to fix data collection issues and give clinicians more time to respond to performance feedback. A few commenters requested that public reporting on Physician Compare be delayed until the transition years to full Quality Payment Program implementation end and there is more predictability, continuity, consistency, and decreased complexity in the program. In addition, several commenters submitted suggestions regarding transparency of publicly reported performance data. One commenter requested that Physician Compare note for publicly reported measures if a change to clinical guidelines occurred during the performance year, so that the data provided is not misleading to the public.

Response: We agree that not publicly reporting first year data on quality measures for the first 2 years they are in use is sufficient time to gain experience with them before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures unnecessarily hinders the ability to provide the public with transparent performance information after clinicians have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation or evaluation of more clinicians reporting a consistent set of measures, since, at this time, eligible clinicians and groups have the flexibility to select from a broad list of measures and do not all need to report the exact same measures. Regarding the comment suggesting public reporting be delayed until the Quality Payment Program is fully implemented, we note that we are required under section 1848(q)(9)(A) and (D) of the Act to publicly report certain MIPS eligible clinician and group performance information on Physician Compare.
However, we do recognize that we are in early stages of MIPS, which is why we are continuing to publicly report this information under a phased approach. In response to the suggestion to indicate, on Physician Compare, when a measure specification has changed, we note that if there are significant changes to a clinical guideline during the performance year and the measure specifications do not reflect the current standard of care, the measure is suppressed from MIPS scoring. Refer to III.I.3.i.(1)(b)(vii) of this final rule for more information on the scoring policy.

Only data that meet our established public reporting standards under §414.1395(b) will be publicly reported on Physician Compare.

Regarding the comments supporting data transparency, we agree that for public reporting to be meaningful to all stakeholders, transparency is key. Each year we strive to actively share information, via the Physician Compare initiative page and other channels, on our public reporting efforts as testing is completed and measures to be publicly reported are finalized. Last year in response to similar comments, we produced additional educational materials about the 5-star rating methodology and cut-offs, for example. We will continue our educational efforts as public reporting on Physician Compare evolves. We also reiterate our belief in the importance of clinicians reviewing their data for accuracy prior to it being publicly reported. All performance data publicly reported on Physician Compare will reflect the scores eligible clinicians and groups receive in their MIPS performance feedback, which are available for review and correction during the targeted review process.

After consideration of the comments, we are finalizing our proposal to revise §414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category. We did not receive any comments on changing “submission mechanism” to “collection type” for the purposes of public reporting,
and as a result are finalizing our proposal to modify §414.1395(b) to reference “collection types” instead of “submission mechanisms”.

(3) Cost

In the CY 2018 Quality Payment Program final rule (82 FR 53825), we finalized a policy to include on Physician Compare a subset of cost measures that meet the public reporting standards at §414.1395(b), either on profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available cost measures, and applies to both MIPS eligible clinicians and groups. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We previously finalized that we will not publicly report first year cost measures, meaning any measure in its first year of use in the cost performance category, under §414.1395(c).

Consistent with our proposal for first year quality measures, we proposed to revise §414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use in the cost performance category (83 FR 35987). We proposed this change to help clinicians and groups get feedback on these measures and learn from the early years of these new measures being calculated before measure are made public (83 FR 35987). We requested comment on this proposal.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Most commenters supported not publicly reporting first year data on cost measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter expressed concern that delaying the public reporting of first year cost measures
for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. Another commenter recommended, separately from the other cost measures, that we consider extending the timeframe for which the new episode-based cost measures are publicly reported, so that there is time to gain experience with collecting and analyzing these measures.

Response: We agree that not publicly reporting first-year data on cost measures for the first 2 years they are in use is sufficient time to gain experience with them, including for the new episode-based cost measures, before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures hinders the ability to provide the public with transparent information after clinicians will have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures, as the cost performance category’s full implementation is already delayed. We also do not believe there is a need or benefit to set a different timeframe for episode-based measures than there is for other cost measures that will also have 2 years of usage prior to being considered for public reporting.

After consideration of the comments, we are finalizing our proposal to revise §414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use.
(4) Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53826), we finalized a policy to include a subset of improvement activities information on Physician Compare, either on the profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available activities reported via all available collection types, and applies to both MIPS eligible clinicians and groups. For those eligible clinicians and groups that successfully meet the improvement activities performance category requirements, this information will be posted on Physician Compare as an indicator. We also finalized for all future years to publicly report first year activities if all other public reporting criteria are satisfied.

(5) Promoting Interoperability (PI)

In the CY 2018 Quality Payment Program final rule (82 FR 53827), we finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the Promoting Interoperability performance category, as technically feasible, for all future years. “Successful” performance is defined as obtaining the base score of 50 percent (82 FR 53826). We also finalized a policy to include on Physician Compare, either on the profile pages or in the downloadable database, as technically feasible, additional information, including, but not limited to, objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule (82 FR 53827; see 82 FR 53663 through 53688). This includes all available objectives, activities, or measures reported via all available collection types, and applies to both MIPS eligible clinicians and groups (82 FR 53827). We will use statistical testing and website user testing to determine how and where objectives, activities, and measures are reported on Physician Compare. We also finalized for all future years to publicly report first
year Promoting Interoperability objectives, activities, and measures if all other public reporting criteria are satisfied.

In addition, we finalized that we will indicate “high” performance, as technically feasible and appropriate, in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). “High” performance is defined as obtaining a score of 100 percent (82 FR 53826 through 53827).

As the Quality Payment Program progresses into year 3, and consistent with our work to simplify the requirements under the Promoting Interoperability performance category of MIPS, we proposed not to include the indicator of “high” performance and to maintain only an indicator for “successful” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988). Not including the “high” performance indicator while maintaining the “successful” performance indicator continues to provide useful information to patients and caregivers without burdening website users with the additional complexity of accurately differentiating between “successful” and “high” performance, as this proved difficult for users in testing. User testing to date shows that website users value this information overall, however, as they appreciate knowing clinicians and groups are effectively using EHR technology to improve care quality (83 FR 35988).

We requested comment on our proposal not to include the indicator for “high” performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988).
The following is a summary of the comments we received on our proposal and our responses.

**Comment:** The majority of commenters supported the proposal to move to a designation of “successful” only and to remove the “high” designation in the Promoting Interoperability performance category, as it offers a clear indication that clinicians are effectively using EHRs and would make the user experience more straightforward than delineating between multiple indicators. One commenter opposed the proposal to only include a “successful” indicator, since in future years it would be difficult to be “successful,” as defined, when the base scores, performance scores, and bonus scores are changed or removed. Another commenter requested clarification on how “successful” would be defined when the Promoting Interoperability performance category no longer includes a base score.

**Response:** We agree that moving from having both a “successful” and “high” indicator of an eligible clinician or group’s Promoting Interoperability performance to having a single indicator of “successful” not only shows that clinicians are effectively using EHRs, but also is easier for patients to understand. Additionally, it is more technically feasible to designate a single “successful” indicator than both a “successful” and “high” indicator as the Promoting Interoperability performance category scoring methodology evolves and as we evaluate operational facets of the data. We wish to also clarify that having only a “successful” indicator will apply to individuals and groups who have a Promoting Interoperability performance category score above zero.

After consideration of the public comments received, we are finalizing our proposal to not include the indicator of “high” performance and to maintain only an indicator for “successful” performance in the Promoting Interoperability performance category beginning
with year 2 of the Quality Payment Program. We note that in the CY 2017 Quality Payment Program final rule (81 FR 77397), we finalized a policy to include, as technically feasible, additional indicators, including but not limited to indicators such as, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. We have since determined that it is not technically feasible to include an indicator of “high” performance that meets our public reporting standards as defined at §414.1395(b) for year 1 of the Quality Payment Program. The reason we are not reporting this indicator, is because based upon conducting analysis against our public reporting standards, the scoring variability in the Promoting Interoperability performance category of the Quality Payment Program (year 1 to year 3) creates challenges that we are still uncovering for making the data useful to Physician Compare’s primary patient and caregiver audience.

Additionally, in reviewing the year 1 data (which was not available at the time the CY 2019 proposed rule was released) we have learned through user testing that patients and caregivers find clinician and group usage of EHR technology to generally be a meaningful indicator of quality, regardless of whether “successful” or “high” was noted. That is, including the word “high” did not result in patients and caregivers believing the clinician or group to be of higher quality than those that had the word “successful” next to their Promoting Interoperability performance category indicator. Therefore, the high performing indicator will not be reported in year 1, 2, 3 or future years of the Quality Payment Program on Physician Compare.

As noted above, we previously defined “successful” performance as obtaining the base score of 50 percent (82 FR 53826). As discussed in section III.I.3.h.(5) of this final rule, the Promoting Interoperability performance category will no longer have a base score beginning with year 3. To account for this change, we are finalizing a modified definition of “successful”
performance to mean a Promoting Interoperability performance category score above zero beginning with year 3. We will include the modified indicator (above zero) for years 1, 2, and 3 to avoid confusion and preserve year-to-year comparability, and the previously finalized indicator (base score) for years 1 and 2 for transparency and consistency with our previously finalized policy, as technically feasible.

We also solicited comment on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information may be considered for possible future inclusion on the website. We did not receive any comments.

(6) Achievable Benchmark of Care (ABC™)

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows website users to more easily evaluate the information published by providing a point of comparison between groups and between clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53829), we finalized a policy to use the Achievable Benchmark of Care (ABC™) methodology to determine a benchmark for the quality, cost, improvement activities, and Promoting Interoperability data, as feasible and appropriate, by measure and collection type for each year of the Quality Payment Program based on the most recently available data each year. We also finalized a policy to use this benchmark as the basis of a 5-star rating for each available measure, as feasible and appropriate. For a detailed discussion of the ABC™ methodology, and more information about how this benchmark together with the equal ranges method is currently used to determine the 5-star rating system for Physician Compare, see the CY 2018 Quality Payment Program final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, is available on the Physician Compare Initiative website at...
We appreciate comments received for this section, but since no proposals were made, these comments are outside the scope of this section and the proposed rule.

(a) Historical Data-Based Benchmarks

Benchmarks, and the resulting star rating, are valuable tools for patients and caregivers to use to best understand the performance information included on Physician Compare. Benchmarks can also help the clinicians and groups reporting performance information understand their performance relative to their peers, and therefore, help foster continuous quality improvement. In the initial years of the Quality Payment Program, we anticipated year-to-year changes in the measures available. As noted, we previously finalized a policy to determine the benchmark using the most recently available data (82 FR 53829). This ensured that a benchmark could be calculated despite potential year-to-year measure changes, but it also meant that the benchmark was not known to clinicians and groups prior to the performance period.

By year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020), we expect enough year-to-year stability in the measures available for reporting across all MIPS performance categories to use historical data to produce a reliable and statistically sound benchmark for most measures, by measure and collection type (83 FR 35988). Therefore, we proposed to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) (83 FR 35988). Specifically, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from
the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. For example, for the CY 2019 performance period, the benchmark developed using the ABC™ methodology would be calculated using CY 2017 performance period data and would be published by the start of CY 2019, as feasible and appropriate. If historical data is not available for a particular measure, we would indicate that and calculate the benchmark using performance data from the performance period. In this example, we would use CY 2019 performance period data to calculate the benchmark for CY 2019 performance period measures, as needed. This approach of utilizing historical data would be consistent with how the MIPS benchmarks are calculated for purposes of scoring the quality performance category. But, most importantly, this approach would provide eligible clinicians and groups with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period (83 FR 35988). We requested comment on this proposal.

The following is a summary of the comments we received regarding our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and our responses.

**Comment:** Two commenters supported using benchmarks based on performance from a prior period so that clinicians are able to understand how their measure scores will translate into a 5-star rating. One commenter cautioned that historical benchmarks may penalize those
clinicians who successfully managed costs at the onset of the benchmark while inadvertently incentivizing high spenders. Another commenter questioned whether there was enough stability year-to-year in MIPS to create valid and reliable benchmarks. Another commenter noted concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the Physician Quality Reporting System (PQRS). Another commenter cautioned that CMS needs to consider certain clinicians’ ability to affect quality and cost when treating patients. One commenter recommended we postpone using benchmarks for measures with no historical data, for example, a new MIPS measure with no performance data from a prior performance year.

Response: Regarding the concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the PQRS, we wish to clarify that only historical MIPS data will be used to create benchmarks; for example, year 3, which is 2019 data available for public reporting in late 2020, would use year 1 (CY 2017) MIPS data. Additionally, since these benchmarks will be based on the MIPS performance information that eligible clinicians choose to report, we assume that these measures, upon which the benchmarks will be based, reflect the areas in which eligible clinicians and groups believe they can most affect quality of care furnished. Since we are finalizing that we will not publicly report first year measures for the first 2 years they are in the program, new measures, which have no prior MIPS performance data, would not be available for public reporting until the third year they are in use, at which point there should be historical data upon which to set a historical benchmark if eligible clinicians and groups reported them. If, however, a measure does not meet our public reporting standards, for example due to lack of performance data available or insufficient sample size, then the measure would not be available for public reporting, and would
not need a benchmark. Regarding the concern about stability of data, we do believe that if a measure is in use for multiple years of MIPS that the performance should stabilize. We do not expect that clinicians and groups who manage costs effectively in 2017 should suffer a penalty by comparing their 2019 data to 2017 benchmarks. We appreciate the comment about high spenders and will plan to analyze impact. That said, we appreciate the concerns raised and will continuously evaluate the data against our public reporting standards for year-to-year stability.

We will also monitor whether the historical benchmarking approach inadvertently creates negative incentives, though early testing has not shown this to be the case. Regarding the suggestion to postpone using benchmarks for measures without historical data, we disagree and believe it is important for website users to understand clinician performance in a meaningful way. Our testing and experience to date has shown that the next best way to create benchmarks for information reported on Physician Compare, in the absence of historical data, is by using information from the most recent performance period.

After consideration of the comments, we are finalizing our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). Specifically, benchmarks will be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period will be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks will be published prior to the start of the performance period, as technically feasible.

(b) QCDR Measure Benchmarks
Currently, only MIPS measures are star rated on Physician Compare. QCDR measures, as that term is used in §414.1400(e), are publicly reported as percent performance rates. As more QCDR measure data is available for public reporting, and appreciating the value of star rating the measures presented to website users, we believe star rating the QCDR measures will greatly benefit patients and caregivers as they work to make informed health care decisions. Particularly in the quality performance category, we believe that reporting all measure data in the same way will ease the burden of interpretation placed on site users and make the data more useful to them. Therefore, we proposed (83 FR 35988 through 35989) to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed §414.1400(b)(3), as feasible and appropriate, using current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). We requested comment on this proposal.

The following is a summary of the comments we received to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures and our responses.

**Comment**: One commenter supported using the ABC™ methodology to create a benchmark for MIPS and QCDR measures, as well as creating a 5-star rating for QCDR measures, beginning with year 3 of the Quality Payment Program. Several commenters expressed concern about QCDR benchmarks, noting that measure scores could be misinterpreted.
on Physician Compare, particularly if the ABC™ methodology is used, since it may differ from the QCDR’s own rating methodology and further confuse patients. One commenter also noted that use of the ABC™ methodology for QCDR measures would cause clinician confusion and potentially misrepresent clinicians in the public domain if it results in benchmarks that are also different from the ones used in the MIPS scoring methodology. Another commenter noted the sample size for some QCDR measures will be too small for public reporting and encouraged CMS to work with QCDR measure owners in establishing benchmarks for QCDR measures.

Response: We reiterate our belief that star rating the QCDR measures will greatly benefit patients and caregivers. Because the QCDRs do not uniformly measure performance and each uses their own methodology, as commenters pointed out, in our experience it makes it more difficult for patients to use this information to make informed healthcare decisions. Regarding the concern about differences in MIPS scoring benchmarks and public reporting benchmarks, we note that we will continue to evaluate approaches to alignment, but reiterate that it is not always necessary or ideal to use the same methodology for scoring and public reporting given the unique goals of each. QCDR measures will undergo the same statistical testing as other measures do to ensure they meet our public reporting standards before they are publicly reported, and this testing does account for sample size concerns.

After consideration of the comments, we are finalizing our proposal to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed §414.1400(b)(3), as feasible and appropriate. This benchmark will use current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as
proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020).

(7) Voluntary Reporting

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of collection type, by eligible clinicians and groups that are not subject to the MIPS payment adjustments, as technically feasible, for all future years. If an eligible clinician or group that is not subject to the MIPS payment adjustment chooses to submit data on quality, cost (if applicable), improvement activities, or Promoting Interoperability, these data are available for public reporting. We also finalized that during the 30-day preview period, these eligible clinicians and groups may opt out of having their data publicly reported on Physician Compare (82 FR 53830). If these eligible clinicians and groups do not opt out during the 30-day preview period, their data will be available for inclusion on Physician Compare if the data meet all public reporting standards at §414.1395(b).

(8) APM Data

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to publicly report the names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not considered Advanced APMs related to the Quality Payment Program, such as Track 1 Shared Savings Program Accountable Care Organizations (ACOs), as technically feasible, for all future years. We also finalized a policy to link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible.

4. Overview of the APM Incentive
a. Overview

Section 1833(z) of the Act requires that an incentive payment be made (or, in years after 2025, a different PFS update) to QPs for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.

- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year’s estimated aggregate payments for Part B covered professional services. Beginning in payment year 2026, QPs receive a higher update under the PFS for the year than non-QPs.

- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.

- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, Qualifying APM Participant (QP) and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs). In
the CY 2019 PFS proposed rule (83 FR 35989 through 36006), we proposed clarifications and modifications to policies that we previously finalized pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, and the Calculation of All-Payer Combination Option Threshold Scores and QP Determinations. In this CY 2019 PFS final rule, we respond to public comments on those proposals and announce our final policies.

The following is a summary of the general public comments received on Advanced APMs and our responses:

Comment: Many commenters encouraged us to accelerate our efforts to develop more Advanced APM opportunities for clinicians. These commenters noted that Advanced APMs have great potential to incentivize high-quality and coordinated care while driving down overall costs, and encouraged us to continue developing Advanced APMs to offer clinicians more opportunity to participate in value-based payment and care delivery. Some commenters noted concern that no progress has been made in creating more opportunities for specialists and non-physician professionals to participate in Advanced APMs. The commenters encouraged CMS to develop Advanced APMs that provide opportunities for specialists and non-physician professionals, and to create additional pathways for specialists and non-physician professionals to meaningfully participate in existing Advanced APMs.

Response: We agree that APMs represent an important step forward in our efforts to move our healthcare system from volume-based to value-based care. We note that in 2018 a number of additional Advanced APM opportunities were made available, including the introduction of the Medicare ACO Track 1+ Model, and the introduction of new participants into some existing Advanced APMs, such as the Next Generation ACO Model and Comprehensive
Primary Care Plus (CPC+) Model. In 2019, there will be even more available Advanced APM opportunities including the Bundled Payments for Care Improvement Advanced Model, which began in October 2018, and the Maryland Total Cost of Care (which includes the Care Redesign Program and the Maryland Primary Care Program). Additionally, we are in the process of developing several new APMs and Advanced APMs, and continue to work with stakeholders on new model concepts.

Comment: Some commenters suggested CMS establish a clear pathway for clinicians to transition from MIPS to MIPS APMs and then to Advanced APMs. The commenters noted that MIPS APMs represent a stepping stone between MIPS and Advanced APMs providing clinicians a necessary glide path into risk-based contracts.

Response: The Quality Payment Program represents a significant opportunity to collaborate with the clinical community to advance policy that pays for what works – both for clinicians and patients – to create a simpler, sustainable Medicare program. We believe 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 believe 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, including MIPS APMs and Advanced APMs, we believe that by setting ambitious yet achievable goals, eligible clinicians will move with greater certainty toward these new approaches that incentivize the delivery of high-value care.

We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to
help clinicians understand Quality Payment Program requirements, how to use available tools to enhance their practices, improve quality, reduce cost, and progress to participation in APMs and Advanced APMs if that is the best choice for their practice.

Comment: Many commenters requested that we implement and test new models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The commenters noted that the stakeholder community is also well aware the Department has not selected any PTAC recommended models for testing. Specifically, the commenters noted that the PTAC had received 27 proposals for new physician-focused payment models, 15 of which have been reviewed by the PTAC with comments and recommendations sent to the Secretary. Of those, the commenters stated that 10 proposals were recommended favorably with six recommended for limited scale testing and four recommended for implementation, but the agency has taken no action to test or implement any of the recommended models.

Some commenters suggested we provide more direct, regular feedback to the PTAC and stakeholders to ensure they can address concerns and shortcomings earlier in the development process, so that the PTAC comment and recommendation process can yield physician-led APMs that will be tested and implemented. The commenters also requested that we provide technical assistance to stakeholders working to develop proposals for the PTAC, and specifically that we make claims data available to allow for more detailed financial modeling to be part of the development process.

Many commenters requested that we establish a clear process and timeline for responding to PTAC proposals in the future. The commenters suggested that a 60-day window from the date that the Secretary receives a recommendation from the PTAC would be appropriate.
Response: We believe that PTAC can help us make the shift from a healthcare system that pays for volume to one that pays for value. The commitment to health care payment innovation by the PTAC and the broader stakeholder community is evident in the number and types of specialties represented in the proposals being submitted to PTAC. CMS’ Center for Medicare and Medicaid Innovation (CMS Innovation Center) staff have met with stakeholders about proposed models, including some stakeholders that have submitted proposed physician-focused payment models to the PTAC.

We note that while it seems unlikely that all of the features of any PTAC-reviewed proposed model will be tested exactly as presented in the proposal, certain features of proposed models may be incorporated into new or existing models. As the CMS Innovation Center launches new value-based payment and service delivery models, the PTAC’s critical review of proposals will be a valuable resource. Additionally, the CMS Innovation Center will further engage with stakeholders that have submitted proposals related to new or existing models to leverage their experiences in the field.

While we will not provide technical assistance to individual stakeholders before they submit proposals, we encourage potential submitters to review the detailed responses from the Secretary to past comments and recommendations from the PTAC to guide development of their proposals. We also encourage stakeholders designing proposals to review the data resources available on the Office of the Assistance Secretary for Planning and Evaluation (ASPE) website at https://aspe.hhs.gov/resources-public-comment-physician-focused-payment-model-technical-advisory-committee. Lastly, available from the CMS Innovation Center website is a toolkit for Alternative Payment Model Design (APM Toolkit) to serve as a resource for any entities or individuals interested in developing ideas for APMs (https://www.cms.gov/Medicare/Quality-
Payment-Program/Resource-Library/Alternative-Payment-Model-APM-Design-Toolkit.pdf provides a detailed and comprehensive set of resources to help design an APM).

We note that PTAC meets on a periodic basis to review proposals for physician-focused payment models submitted by individuals and stakeholder entities. The PTAC prepares comments and recommendations on proposals that are received, determining whether such models meet the criteria established by the Secretary for physician-focused payment models in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008, 77496-77499) and codified at §414.1465. The PTAC’s comments and recommendations generally must be discussed during their public meetings and must be submitted to the Secretary. Subsequently, the Secretary reviews the comments and recommendations submitted by PTAC and posts a detailed response to these recommendations on the CMS Innovation Center website at https://innovation.cms.gov/initiatives/pfpms/. Given this standard timeline, we do not believe it would be realistic to set a strict 60-day timeframe for responding to physician-focused payment models recommended by the PTAC. As discussed in the CY 2018 Quality Payment Program final rule, the variation in the number and nature of proposals makes it difficult to establish such a deadline. However, HHS will continue to make every effort to respond expeditiously to the PTAC’s comments and recommendations.

b. Terms and Definitions

In the CY 2019 PFS proposed rule, we explained that as we continue to develop the Quality Payment Program, we have identified the need to propose changes to some of the previously finalized definitions. A complete list of the original definitions is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540).
In the CY 2018 Quality Payment Program final rule, to consolidate our regulations and avoid unnecessarily defining a term, we finalized removal of the defined term for “Advanced APM Entity” in §414.1305 and replaced instances of that term throughout the regulation with “APM Entity.” Similarly, we finalized replacing “Advanced APM Entity group” with “APM Entity group” where it appears throughout our regulations (82 FR 53833). We noted that these changes were technical and had no substantive effect on our policies.

In the CY 2019 PFS proposed rule, to further consolidate our regulations and to clarify any potential ambiguity, we proposed to revise the definition of Qualifying APM Participant (QP) at §414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM. The current definition of QP is based on an eligible clinician’s participation in an Advanced APM Entity, which no longer is a defined term. Simply replacing the term “Advanced APM Entity” with the term “APM Entity,” as we had in the CY 2018 Quality Payment Program final rule, does not fully convey the definition of QP because, as noted at the time, an APM Entity can participate in an APM that is, or is not, an Advanced APM; and QP status is attainable only through participation in an Advanced APM (82 FR 53833). Again we note that this proposed change is technical and will not have a substantive effect on our policies.

We solicited comments on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise the definition of Qualifying APM Participant (QP) at §414.1305 to provide that a QP is an eligible clinician determined by CMS to have met
or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM.

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 35989-35992), we included the following proposals, each of which is discussed in further detail below:

**Use of CEHRT:**

- We proposed to revise §414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at §414.1305 to document and communicate clinical care with patients and other health care professionals.
MIPS-Comparable Quality Measures:

- We proposed to revise §414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment must either be finalized on the MIPS final list of measures, as described in §414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

- We also proposed to revise §414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in §414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses:

- We proposed to revise §414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(3) Use of CEHRT

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that an Advanced APM must require at least 50 percent of eligible clinicians in each APM Entity to use CEHRT as defined at §414.1305 to document and communicate clinical care with patients and other health care professionals. Further, we proposed but did not finalize an increase to the requirement wherein Advanced APMs must require 75 percent CEHRT use in the subsequent year. Instead we maintained the 50 percent CEHRT use requirement for the second performance year and
beyond and indicated that we would consider making any potential changes through future rulemaking (81 FR 77412).

(b) Increasing the CEHRT use criterion for Advanced APMs.

In the CY 2019 PFS proposed rule, we proposed that, beginning for CY 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at §414.1305 to document and communicate clinical care with patients and other health care professionals.

According to data collected by the Office of the National Coordinator for Health Information Technology (ONC), over 3 in 4 office-based physicians adopted a certified EHR in CY 2015\(^\text{32}\), and approximately 9 in 10 clinicians have 2015 Edition certified technology available from their EHR developer\(^\text{33}\). Additionally, in response to the CY 2017 Quality Payment Program proposed rule, commenters encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. We further believe that most existing Advanced APMs already include provisions that would require participants to adhere to the level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

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Comment: Many commenters supported our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent in 2019. Some commenters noted that the use of CEHRT is a fundamental component of any Advanced APM and that such APMs are more likely to be successful if physicians are able to receive information on their patients in a seamless manner, as well as document and communicate clinical care with patients and other health care professionals.

Response: We appreciate the commenters’ support of our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019.

Comment: Many commenters requested that CMS not finalize the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019. Some commenters stated that such an increase could be too burdensome for some APM participants, especially in light of the regulatory requirement to upgrade from 2014 Edition CEHRT to 2015 Edition CEHRT in CY 2019. Other commenters noted the proposed increase could create a barrier to entry into Advanced APMs or create additional obstacles in designing APMs targeted for small or rural practices.

Response: We do not believe that the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 to 75 percent will be burdensome for APM participants. As noted above, approximately 9 in 10 clinicians have 2015 Edition certified technology available from their most recently reported EHR developer, and we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Also, in the CY 2017 Quality Payment Program final rule, we acknowledged that eligible clinicians would be expected to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in
2018, and that some eligible clinicians who had not yet adopted CEHRT may wish to delay acquiring CEHRT products until a 2015 Edition certified product is available. We also note that the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671-53672), to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Further, we note that most current Advanced APMs already include provisions that would require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs. Moving forward, though, we will consider the applicability of the CEHRT requirement for any potential models designed specifically for small or rural practices.

Comment: Many commenters requested that we consider delaying our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent until CY 2020. Commenters stated there already is a regulatory requirement to upgrade to 2015 edition CEHRT in CY 2019 and that clinicians participating in Advanced APMs should not be subject to additional health information technology requirements in a single year. Commenters also noted that maintaining the current Advanced APM minimum CEHRT use threshold for an additional year will allow time for organizations and clinicians to implement the upgrade to 2015 edition CEHRT and not discourage smaller practices that are in the process of upgrading their systems from participating in Advanced APMs.

Response: We appreciate commenters’ concerns, but as noted previously in this final rule, the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671 through 53672), to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015
Edition for use in 2019. We believe organizations and clinicians had sufficient time to implement upgrades and that it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Thus, we believe a delay in implementation of the increase in the Advanced APM minimum CEHRT use threshold increase is unnecessary.

Comment: Many commenters requested that CMS phase in the increase in the Advanced APM minimum CEHRT use threshold over time, or develop a glide path more reflective of the multi-year contracting cycles of APMs given that current contracts with Advanced APMs, were signed with the current Advanced APM minimum CEHRT use threshold in place. Some commenters also suggested that CMS could retain the current 50 percent Advanced APM minimum CEHRT use threshold, but allow APM Entities to attest that an additional percentage of eligible clinicians are either using CEHRT or other health information technology that augments or is an extension of CEHRT to achieve the specific goals of the APM.

Response: We reiterate that in the CY 2017 Quality Payment Program final rule, we stated that setting the threshold at 50 percent of eligible clinicians would allow APMs sufficient room to meet this requirement even if the APM includes some participants who do not have internet access, lack face-to-face interactions with patients, or are hospital-based. At that time, we recognized commenters’ concerns that raising the threshold to 75 percent in 2018 risked creating an overly rigorous standard for Advanced APMs and that it would be prudent to wait until we have more information on how the threshold would impact specific APMs, such as specialty APMs, before increasing the threshold. As noted previously in this final rule, we now understand that certified EHR adoption has been more widespread, and therefore do not believe that it is necessary to phase in the increase in the Advanced APM minimum CEHRT use threshold over time any more so than we already have by maintaining the threshold at 50 percent
for the 2017 and 2018 QP performance periods. We also note that most current Advanced APMs already include provisions that require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

**Comment:** One commenter suggested that CMS provide flexibility for APM Entities participating in Advanced APMs by allowing them to include eligible clinicians in the 75 percent threshold calculation who are actively working with their EMR vendors to transition to the 2015 Edition CEHRT. The commenter noted that there may be instances where EMR vendors are finalizing their certification process during the 2019 performance year, and that may prevent an APM Entity from fully complying with the 75 percent threshold.

**Response:** We reiterate that the Advanced APM CEHRT use criterion applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. This means that once an APM has been determined to be an Advanced APM (by requiring the specified percentage of eligible clinicians in each of its participating APM Entities to use CEHRT), the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM and may not involve a threshold calculation. We acknowledge there may be instances where EMR vendors are finalizing their certification process, but as noted previously, the requirement to use 2015 Edition CEHRT was delayed to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Therefore, we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019.

**Comment:** Many commenters noted that the proposed increase in the Advanced APM
minimum CEHRT use threshold could limit the ability of non-physician professionals, such as physical therapists, occupational therapists, audiologists, and speech-language pathologists, to meaningfully participate in APMs. The commenters noted that current CEHRT requirements are designed for prescribing professionals and do not capture tasks performed by non-physician professionals using different types of EHRs. Specifically, the commenters stated that the EHRs non-physician professionals often use have not been taken into account by ONC in developing the CEHRT standards and certification criteria, and therefore, they would not be able to meet the definition of CEHRT required for purposes of the Advanced APM minimum CEHRT use threshold. The commenters suggested that CMS establish a dedicated CEHRT program for non-physician and non-prescribing professionals and that CMS offer assistance in the form of funding and technical support to help these types of clinicians participate in Advanced APMs.

Response: We reiterate that the Advanced APM minimum CEHRT use threshold applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. We also note that the Advanced APM minimum CEHRT use threshold does not mean that all eligible clinicians in each participating APM Entity are required to use CEHRT, and that the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM. This means there can be a percentage of eligible clinicians participating in an APM Entity who are not using CEHRT and the APM Entity will still be in compliance with the APM’s terms and conditions. Understanding this may have a greater effect on non-physician or non-prescribing eligible clinicians, moving forward, we will monitor this issue for new APMs and will consider possible solutions to facilitate participation in Advanced APMs by non-physician or non-prescribing eligible clinicians that may not use CEHRT due to lack of certified systems for that specific
specialty.

After considering public comments, we are finalizing our proposal that, for QP Performance Periods beginning in 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity (or, for APMs in which hospitals are the APM Entities, each hospital, as specified in our current regulation) to use CEHRT as defined at §414.1305 to document and communicate clinical care with patients and other health care professionals. We are amending §414.1414(a)(1) to reflect this change.

(4) MIPS-Comparable Quality Measures

(a) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for an APM to be an Advanced APM is that it must provide for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(A) of the Act, which is the MIPS quality performance category. We generally refer to these measures in the remainder of this discussion as “MIPS-comparable quality measures.” We also explained that we interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM (81 FR 77414).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Advanced APM, an APM must base payment on quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure unless there is not an applicable outcome measure on the MIPS quality list at the time the APM is developed. The required outcome measure does not have to be one of those on the MIPS quality measure list. We did not specify that the outcome measure is required to be evidence-based, reliable, and valid.
We finalized these policies in the CY 2017 Quality Payment Program final rule and codified at §414.1415(b).

(b) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at §414.1415(b)(2) that at least one of the quality measures upon which an Advanced APM bases the payment must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria: used in the MIPS quality performance category as described in §414.1330; endorsed by a consensus-based entity; developed under section 1848(s) of the Act; submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that some have interpreted §414.1415(b)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS-comparable quality measures, even if they are not evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding will automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. Although we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of §414.1415(b)(2) without independent verification by a consensus-based entity, or based on our own assessment and determination, that they are evidence-based, reliable, and valid. We further believe the same principle applies to Qualified Clinical Data Registry (QCDR) measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable.
quality measures for purposes of §414.1415(b)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable quality measures (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution to avoid any adverse impact on APM entities, eligible clinicians, or other commenters, we have used the more permissive interpretation of the regulation text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period until our new proposal described, in this final rule, is effective on January 1, 2020. Recognizing that APMs and other payer payment arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we proposed to amend §414.1415(b)(2) to be effective as of January 1, 2020. Specifically, we proposed that at least one of the quality measures upon which an Advanced APM bases payment must be finalized on the MIPS final list of measures, as described in §414.1330; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.
The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported the proposal. Some commenters suggested that Advanced APMs should be required to include more than one MIPS-comparable quality measure.

Response: We appreciate the commenters’ support of our proposal. We reiterate that the quality measures criterion stipulates that to be an Advanced APM an APM must require at least one of the quality measures upon which an Advanced APM bases payment to be MIPS-comparable. This does not preclude an Advanced APM from including more than one MIPS-comparable quality measure. However, we also note that under the statute, not all quality measures under which an APM is assessed are required to be MIPS-comparable and not all payments under the APM must be based on MIPS-comparable quality measures. As such, we believe that by requiring only one quality measures upon which an Advanced APM bases payment to be MIPS-comparable, APMs have the latitude to base payment on quality measures that meet the goals of the APM and assess the quality of care provided to the population of patients that the APM participants are serving.

Comment: One commenter suggested that CMS consider Core Quality Measure Collaborative (CQMC) endorsement as meeting the criterion for a measure being endorsed by a consensus-based entity. The commenter noted that as more health care providers move toward the adoption of the CQMC Core Measure Sets, using the CQMC multi-stakeholder, consensus-based process in determining MIPS-comparable measures would further CMS’s goal of alignment between its programs and the CQMC Core Measure Sets.

Response: We note that, under MIPS, we currently try to align with the CQMC measures
as much as possible. However, for a measure to meet the criterion of MIPS-comparable, only measures on the list of consensus-endorsed measures maintained by the NQF will currently meet the criterion as being endorsed by a consensus-based entity because NQF is the consensus-based entity that endorses standardized healthcare performance measures for CMS as defined under 1890(b)(2) and (3) of the Act. Therefore, CQMC endorsement does not currently meet the criterion for a measure being endorsed by a consensus-based entity.

We also note, that we believe the revised criteria for the MIPS-comparable measures used in Advanced APMs do not prevent an APM from using a core measure set or using measures developed and included in other CMS programs, but instead provides the criteria for what constitutes a MIPS-comparable measure to meet the Advanced APM requirement (81 FR 77417). Not all quality measures upon which an APM bases payment are required to be MIPS-comparable, and not all payments under the APM must be based on MIPS-comparable measures. However, at least some payments must be tied to MIPS-comparable measures.

**Comment:** Some commenters expressed concern that designating measures determined to be evidenced-based, reliable, and valid by CMS as MIPS-comparable amounts to bypassing the standard vetting process of consensus-based entities; publishing in applicable specialty-appropriate, peer-reviewed journals; notice-and-comment rulemaking or separate publication in the Federal Register. The commenters suggested that all MIPS-comparable quality measures for the Advanced APM pathway should go through a fair and standard vetting process open to the medical profession rather than being independently determined and approved by CMS.

**Response:** As finalized in the CY 2017 Quality Payment Program final rule, we established an Innovation Center quality measure review process for those measures that are not NQF-endorsed or included on the final MIPS measure list. The sole purpose of this process is to
assess for purposes of the Advanced APM MIPS-comparable measure criterion whether these measures have an evidence-based focus, and are reliable and valid (81 FR 77418). In most instances, the Innovation Center internal committee responsible for this review process will make this determination for measures that were tested for use in Innovation Center models using internal analyses and other experts to demonstrate that the measure meets these criteria, and thus can be used as a MIPS-comparable measure before it is considered for inclusion in MIPS or submitted to the consensus based entity for endorsement consideration. The Innovation Center committee is not a substitute for those existing processes but allows the Innovation Center to innovate by using new measures that meet the same standards as MIPS measures. Therefore, we appreciate the commenters’ concerns but do not believe that the Innovation Center quality measure review process bypasses the currently established vetting process for quality measures.

After considering public comments, we are finalizing our proposal to revise §414.1415(b)(2) to clarify, effective January 1, 2020, to clarify that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in §414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(c) Outcome Measures: Evidence-Based, Reliable, and Valid

In §414.1415(b)(3), we generally require that the measures upon which an Advanced APM bases payment must include at least one outcome measure, but specify that this requirement does not apply if CMS determines that there are no available or applicable outcome measures in the MIPS quality measure lists for the Advanced APM’s first QP Performance Period. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid. Although it was our general expectation when developing the
CY 2017 Quality Payment Program final rule that outcome measures will meet this standard, we did not explicitly include this requirement.

In the CY 2019 PFS proposed rule, we proposed to modify §414.1415(b)(3) to explicitly require that an outcome measure must be evidence-based, reliable, and valid (unless, as specified in the current regulation, there is no available or applicable outcome measure), so that at least one outcome measure used for purposes of §414.1415(b)(1) must also be:

- Finalized on the MIPS final list of measures, as described in §414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

We proposed that this change would have an effective date of January 1, 2020, and would specifically require that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-comparable quality measure. This is intended to align with our parallel proposal for the Other Payer Advanced APM criteria that we discuss in section III.1.4.e.(3)(d)(iii) of this final rule.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Commenters supported the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. One commenter noted that this proposal is reasonable given the general growth in the use of outcome measures.
Response: We appreciate the commenters’ support, but note that our proposal does not eliminate the exception for models where there are no available or applicable outcome measures at the performance start date of the model.

Comment: One commenter expressed concerns with the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. The commenter noted that there is little variation in outcomes for many surgical procedures as judged by existing outcome measures, and that outcome measures alone are not sufficient to verify that the highest quality care is made available to patients. The commenter suggested CMS implement a framework that could provide a much clearer picture of the quality of care provided to the patient and includes elements such as: standards-based facility-level verification programs; patient reported experience and outcomes measures; and traditional quality measures including registry and claims-based measures.

Response: We acknowledge the commenter’s concerns regarding this use of outcomes measures and appreciate the commenter’s suggestions. The Advanced APM requirement for inclusion of one MIPS-comparable measure that is also an outcome measure does not represent a quality measure strategy for Advanced APMs. Rather, the statute identifies outcome measures as a priority measure type, and we wanted to encourage the use of outcome measures for quality performance assessment in APMs. The quality strategy for most Advanced APMs typically includes quality and/or utilization measures that correspond with the key payment and practice transformation activities being tested in the APM. This is why the majority of APMs include more than just one quality measure and many different types of quality performance measures (for example, process, clinical outcome, patient experience of care or patient reported outcome
measures) to assess the clinical care provided by eligible clinicians under the APM. Our goal in developing APMs is to ensure that all patients realize better care, improved clinical outcomes and more efficient cost-effective care. We believe our requirement that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-comparable quality measure further reinforces these goals.

Comment: One commenter expressed concern that CMS is placing too much emphasis on outcome measures. Specifically, the commenter suggested that CMS continue to support the use of process measures until meaningful outcome measures are available in more specialty areas.

Response: We note that we require only one of the quality measures to be an outcome measure, and have established an exception for models where there is no available or applicable outcome measure at the performance start date of the model. As such, we do not agree that we are emphasizing outcome measures over process measures.

After considering public comments, we are finalizing our proposal to revise §414.1415(b)(3), effective January 1, 2020, to require that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM, must either be finalized on the MIPS final list of measures as described in §414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid. As specified in the current regulation, this requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the Advanced APM's first QP Performance Period.

(5) Bearing Financial Risk for Monetary Losses
(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on: (1) setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods at §414.1415(c)(3)(i)(A). We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we will address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

(b) Generally Applicable Nominal Amount Standard

We proposed to amend §414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:
Comment: Many commenters supported our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021-2024. Commenters noted that maintaining the 8 percent revenue-based standard through the 2024 QP performance period will promote consistency for participants across performance periods and further support CMS’ efforts to transition clinicians into Advanced APMs.

Response: We appreciate the commenters’ support of our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021-2024.

Comment: Two commenters suggested that we limit the generally applicable revenue-based nominal amount standard to only include the average estimated total Part B revenue of participating providers and suppliers in APM Entities, rather than the average estimated total Part A and Part B revenues of providers and suppliers in APM Entities. The commenters stated that by including Part A revenue, CMS significantly disadvantages APM Entities, such as ACOs, that have hospital participants. The commenters noted that the APM Incentive Payment is based on payments for Part B covered professional services under the Medicare PFS, and as such, recommends that we revise the generally applicable revenue-based nominal amount standard to only consider Part B revenue under the Medicare PFS.

Response: We note that we did not propose to make changes to the types of revenue that are included in the generally applicable revenue-based nominal amount standard. However, we note that we disagree that the generally applicable revenue-based nominal amount standard should only include Part B revenues, as many APM Entities participating in Advanced APMs often include hospitals and other types of institutional providers or suppliers that may receive both Part A and B revenues. Additionally, the generally applicable revenue-based nominal amount standard is inclusive only of the Medicare Part A and B revenues of providers and
suppliers in participating APM Entities; therefore, if the providers and suppliers in a given APM Entity have only Medicare Part B revenues, only such revenues will be considered.

**Comment:** Some commenters suggested we reconsider establishing a separate, lower nominal amount standard for small and rural practices. The commenters stated that a lower revenue-based nominal amount standard is necessary to ensure that the challenging operational risks and expenses, which put such practices at greater financial risk when compared to larger practices, do not prevent participation in Advanced APMs. The commenters suggested establishing a nominal amount standard for small and rural practices that would be aligned with the Medical Home Model nominal amount standard or set equal to the percentage of the APM incentive payment that an eligible clinician might attain based on their participation in an Advanced APM. The commenters noted that a lower revenue-base nominal amount standard may encourage greater participation in APMs by small and rural practices.

**Response:** We will continue to monitor the impact of the generally applicable revenue-based nominal amount standard and Medical Home Model nominal amount standard on small practices and those in rural areas. We did not include any proposals in the CY 2019 PFS proposed rule regarding a separate standard for small or rural practices, but may consider revisiting establishing a lower revenue-based nominal amount standard for small practices and those in rural areas in future rulemaking.

**Comment:** Some commenters requested CMS consider the financial and administrative risk that non-physician practitioners face when joining Advanced APMs. Specifically, the commenters suggested that CMS should adopt a more inclusive interpretation of financial risk for monetary losses by including any losses incurred in the operation of the APM Entity rather than limiting financial risk only to losses or increased spending in the Medicare program. The
commenters stated that the magnitude of risk CMS currently requires for participation in an Advanced APM may prevent many eligible clinicians from considering participation in the limited Advanced APMs available.

Response: As we stated in the CY 2018 Quality Payment Program final rule, we recognize the substantial investments that many APM Entities make to become successful APM participants, and also the financial and administrative burden that eligible clinicians of all types face when deciding to join an APM Entity. Nonetheless, as we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity’s business risk exceeds a nominal amount. We also reiterate that business risk is generally a cost that is unrelated to performance-based payment under an APM. No matter how well or poorly an APM Entity performs when assessed for purposes of the APM, costs associated with business risk are not reduced or increased correspondingly. Therefore, we maintain our view that business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and are therefore not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420).

After considering public comments, we are finalizing our proposal to revise §414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024. We continue to believe that 8 percent of Medicare Parts A and B revenues of all providers and suppliers in participating APM Entities generally represents an appropriate standard for more
than a nominal amount of financial risk at this time. We also believe that maintaining a consistent standard for several more years will help APM Entities to plan for multi-year Advanced APM participation. We further believe that maintaining a consistent standard will allow us to evaluate how APM Entities succeed within these parameters over the applicable timeframe.

We also sought comment on whether, as APM entities and participating eligible clinicians grow more comfortable with assuming risk, we should consider increasing the nominal amount standard. Specifically, we requested comments on whether we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later.

Several comments stated we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later. We thank commenters for their feedback and will take this input into consideration for future years.

(6) Summary of Final Policies

Use of CEHRT:

- We are finalizing revisions to §414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT as defined at §414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures:

- We are finalizing revisions to clarify at §414.1415(b)(2), effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment in
paragraph (b)(1) of this section must either be finalized on the MIPS final list of measures, as described in §414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

- We are finalizing revisions at §414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in §414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

**Bearing Financial Risk for Monetary Losses:**

- We are finalizing revisions at §414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450).

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 3599 through 35994), we included the following proposals, each of which is discussed in further detail below:

QP Performance Period:

- We proposed that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that
the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election to Report to MIPS:

- We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician’s affirmative election to participate in MIPS will result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(3) QP Performance Period

In the CY 2017 Quality Payment Program final rule, we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446-77447). During that QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

We also finalized that for each of the three QP determinations, we will allow for claims run-out for 3 months, or 90 days, before calculating the Threshold Scores so that QP
determinations will be completed approximately 4 months after each snapshot date. As a result, the last of these three QP determinations is complete on or around January 1 of the subsequent calendar year, which is the year immediately prior to the MIPS payment year. For most MIPS data submission types, January 1 of the subsequent calendar year is also the beginning of the MIPS data submission period. This way, eligible clinicians know of their QP status prior to or near the beginning of the MIPS data submission period and know whether they should report any performance period data to MIPS for the applicable MIPS payment year.

Upon further consideration and based on our experience implementing the program to date, we believe providing eligible clinicians notification of their QP status more quickly after each of the three QP determination snapshot dates, and prior to the beginning of the MIPS data submission period after the last determination, will potentially reduce burden for eligible clinicians and APM Entities while improving their overall experience participating in the program.

We proposed that beginning in 2019 for each of the three QP determination dates, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period. We note that this proposal does not affect the QP Performance Period per se, but rather the date by which claims for services furnished during the QP Performance Period will need to be processed for those services to be included in calculating the Threshold Scores. To the extent that claims are used for calculating the Threshold Scores, such claims will have to be processed by no later than 60 days after each of the three QP determination dates, for information on the claims to be included in our calculations.

We solicited comment on this proposal.
The following is a summary of the public comments received on this proposal and our responses:

**Comment:** Many commenters supported the proposal to allow for claims run-out of 60 days (approximately 2 months), before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period. Commenters noted the importance for APM Entities to have information about their QP status as soon as possible after each snapshot to determine if they will need to take any additional action to report to MIPS or seek a QP determination under the All-Payer Combination Option should they fall short of the QP thresholds under the Medicare Option.

**Response:** We appreciate the commenters’ support of our proposal to allow for a claims run-out of 60 days before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

After considering public comments, we are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

(4) Partial QP Election to Report to MIPS

(a) Overview

Section 1848(q)(1)(C)(ii)(II) of the Act excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year and who does not report on applicable measures and activities as required under MIPS for the year. However, under section 1848(q)(1)(C)(vii) of the Act, an eligible clinician who is a Partial QP for a year and reports on
applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year.

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustment (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year.

We note that QP determinations are made at the individual eligible clinician level when the clinician is identified as participating in an Advanced APM on an Affiliated Practitioner List rather than a Participation List, or when an eligible clinician is in more than one APM Entity group in one or more Advanced APMs, and does not achieve QP status as part of any single APM Entity group (see §414.1425(b)(2) and (c)(4) our regulations).
We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity’s election for the group to participate in MIPS will result in MIPS participation (81 FR 77449).

For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician’s actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP’s behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

(b) Alignment of Partial QP Election Policies

We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, they will not be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.
We note that this proposed policy change would affect only situations where the Partial QP makes no election to either report to MIPS or to be excluded from the MIPS reporting requirements and payment adjustment. Under our proposed policy, all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment; whereas, if the Partial QP does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

**Comment:** Some commenters supported our proposal. Specifically, the commenters supported our proposal to exclude eligible clinicians determined to be a Partial QP for a year at the individual eligible clinician level from the MIPS reporting requirements and payment adjustment, in the absence of an explicit election to report to MIPS. Commenters noted this proposal will help to avoid confusion and prevent inadvertently subjecting eligible clinicians to MIPS reporting requirements and payment adjustments when information has been reported on their behalf.

**Response:** We appreciate the commenters’ support of our proposal to align the Partial QP election policy for eligible clinicians who are determined to be Partial QPs individually and for eligible clinicians who are determined to be Partial QPs at the APM Entity level.

**Comment:** One commenter expressed concern that our proposal may create additional confusion for eligible clinicians. Specifically, the commenter noted that many eligible clinicians may not be aware that they attained Partial QP status, and that an affirmative election is required
to participate in MIPS. The commenter also noted that such clinicians may assume that their
MIPS data is being reported on their behalf by their practice or TIN, and as a result may
inadvertently forego a potential positive MIPS payment adjustment.

The commenter suggested an alternative approach where CMS would apply the policy
which yields the most advantageous MIPS final score and subsequently the most advantageous
MIPS payment adjustment. The commenter noted that this alternative approach would work in
such a manner that in cases where data is submitted by a Partial QP, or on their behalf, that
would earn the Partial QP a MIPS final score resulting in a positive MIPS payment adjustment,
CMS would use that data to provide them a MIPS final score, regardless of whether they made
an election to participate in MIPS. In cases where data is submitted by a Partial QP, or on their
behalf, that would earn the Partial QP a MIPS final score resulting in a negative MIPS payment
adjustment, CMS would not use that data to provide them a MIPS final score, and they would be
exempt from MIPS based on the Partial QP status.

The commenter noted this alternative approach would eliminate all potential unintended
consequences and would be consistent with other CMS policies to use data that yields the most
advantageous result. The commenter also noted the alternative approach may further incentivize
participation in APMs and reduce burden on both eligible clinicians and CMS because eligible
clinicians would no longer have to make an election to affirmatively opt-in or opt-out of MIPS.

Response: We acknowledge that our proposal could, in certain limited instances, create
additional confusion for eligible clinicians, particularly eligible clinicians who may not be aware
that they attained Partial QP status and an affirmative election is required for them to participate
in MIPS. However, we note that clinicians’ QP status, including Partial QP status, is accessible
via the QPP Participation Status Tool via the Quality Payment Program website at
We also continue to believe our proposed approach will allow for greater operational simplicity while minimizing the possibility of unexpected participation in MIPS. We reiterate that all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment.

After considering public comments, we are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician’s affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(5) Summary of Final Policies

In this section, we are finalizing the following policies:

QP Performance Period:

- We are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election to Report to MIPS:
• We are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician’s affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77459). The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through
Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

**TABLE 57: QP Payment Amount Thresholds – All-Payer Combination Option**

<table>
<thead>
<tr>
<th>Payment Year</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023 and later</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QP Payment Amount Threshold</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Minimum</td>
<td>N/A</td>
<td>N/A</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>50%</td>
<td>50%</td>
<td>75%</td>
</tr>
<tr>
<td><strong>Partial QP Payment Amount Threshold</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Minimum</td>
<td>N/A</td>
<td>N/A</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>40%</td>
<td>40%</td>
<td>50%</td>
</tr>
</tbody>
</table>

**TABLE 58: QP Patient Count Thresholds – All-Payer Combination Option**

<table>
<thead>
<tr>
<th>Payment Year</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023 and later</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QP Patient Count Threshold</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Minimum</td>
<td>N/A</td>
<td>N/A</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>35%</td>
<td>35%</td>
<td>50%</td>
</tr>
<tr>
<td><strong>Partial QP Patient Count Threshold</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Minimum</td>
<td>N/A</td>
<td>N/A</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>25%</td>
<td>25%</td>
<td>35%</td>
</tr>
</tbody>
</table>
Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether an other payer arrangement meets the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangement from an external source. Similarly, we do not have the necessary payment amount and patient count information to
determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule, we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies (82 FR 53844 through 53890). A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891. In relevant part, we finalized the following:

**Payer Initiated Process**

- We finalized at §414.1445(a) and (b)(1) that certain other payers, including payers with payment arrangements authorized under Title XIX (the Medicaid statute), Medicare Health Plan payment arrangements, and payers with payment arrangements aligned with a CMS Multi-Payer Model, can request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter. We finalized that Remaining Other Payers, including commercial and other private payers, could request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 QP Performance Period, and annually each year thereafter. We generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process), and we finalized that the Payer Initiated Process would generally involve the same steps for each payer type for each QP Performance Period. If a payer uses the same other payer arrangement in other commercial lines of business, we finalized our proposal to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well. This policy is relevant
only to the initial year of Payer Initiated Other Payer Advanced APM determinations for which these submissions can be made only by payers with arrangements under Title XIX, Medicare Health Plans, or arrangements aligned with CMS multi-payer models.

**Eligible Clinician Initiated Process**

- We finalized at §414.1445(a) and (b)(2) that, through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process can be used to submit requests for determinations before the beginning of a QP Performance Period for other payer arrangements authorized under Title XIX. The Eligible Clinician Initiated Process is available for the 2019 QP Performance Period and each year thereafter.

**Submission of Information for Other Payer Advanced APM Determinations**

- We finalized that, for each other payer arrangement for which a payer requests us to make an Other Payer Advanced APM determination, the payer must complete and submit the Payer Initiated Submission Form by the relevant Submission Deadline.

- We finalized that, for each other payer arrangement for which an APM Entity or eligible clinician requests us to make an Other Payer Advanced APM determination, the APM Entity or eligible clinician must complete and submit the Eligible Clinician Initiated Submission Form by the relevant Submission Deadline.

- We removed the requirement, previously established at §414.1445(b)(3), that payers must attest to the accuracy of information submitted by eligible clinicians, and we also removed the related attestation requirement at §414.1460(c). Instead, we finalized an additional requirement at §414.1445(d) that an APM Entity or eligible clinician that submits information
under §414.1445(c) must certify that, to the best of its knowledge, the information it submits to us is true, accurate, and complete.

**QP Determinations under the All-Payer Combination Option**

- We finalized at §414.1440(e) that eligible clinicians may request that we make QP determinations at the individual eligible clinician level and that APM Entities may request that we make QP determinations at the APM Entity level.

- We finalized at §414.1440(d)(1) that we will make QP determinations under the All-Payer Combination Option based on eligible clinicians’ participation in Advanced APMs and Other Payer Advanced APMs for three time periods of the QP Performance Period: January 1 through March 31; January 1 through June 30; and January 1 through August 31. We finalized that we will use patient or payment data for the same time periods to calculate both the Medicare and the other payer portion of the Threshold Score calculation under the All-Payer Combination Option.

- We finalized at §414.1440(e)(4) that, to request a QP determination under the All-Payer Combination Option, APM Entities or eligible clinicians must submit all of the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline.

In this section of the final rule, we address policies within the following topics: Other Payer Advanced APM Criteria; Other Payer Advanced APM determinations; and Calculation of the All-Payer Combination Option Threshold Scores and QP Determinations.

(2) Summary of Proposals
In the CY 2019 PFS proposed rule (83 FR 35999-36006), we included the following proposals, each of which is discussed below:

**Other Payer Advanced APM Criteria:**

- We proposed to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity use CEHRT.

- We proposed to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.

- We proposed the following clarification to §414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:
  
  ++ Finalized on the MIPS final list of measures, as described in §414.1330;
  
  ++ Endorsed by a consensus-based entity; or
  
  ++ Determined by CMS to be evidenced-based, reliable, and valid.

- We proposed to revise §414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that must be:
  
  ++ Finalized on the MIPS final list of measures, as described in §414.1330;
  
  ++ Endorsed by a consensus-based entity; or
  
  ++ Determined by CMS to be evidenced-based, reliable, and valid.
We also proposed to revise our regulation at §414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we would continue to apply the current regulation for purposes of those determinations. This proposed revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

**Determination of Other Payer Advanced APMs:**

- We proposed details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

- We proposed to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers proposed in section III.I.4.e.(4)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

**Calculation of All-Payer Combination Option Threshold Scores and QP Determinations:**

- We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We proposed to modify our regulation at §414.1440(d) by
adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

- We also clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We proposed to codify this clarification by adding §414.1440(d)(4).

- We proposed to extend the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

(3) Other Payer Advanced APM Criteria

(a) Overview

In general, our goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We believe this alignment helps simplify the Quality Payment Program and encourage participation in Other Payer Advanced APMs (82 FR 53847).

(b) Investment Payments

Some stakeholders have requested that we take into account “business risk” costs such as IT, personnel, and other administrative costs associated with APM Entities’ participation in Other Payer Advanced APMs when implementing the financial risk standard. We did not
propose to modify our financial risk standard in response to this suggestion, and note that
financial risk in the context of Other Payer Advanced APMs is defined both in the Act (at section
1833(z)(2)(B)(iii)(II)(cc) for payment years 2021 and 2022, and section 1833(z)(3)(B)(iii)(II)(cc)
for subsequent years) and our regulations at §414.1420(d) so as to require that APM Entities in
the payment arrangement must assume financial risk when actual expenditures exceed expected
expenditures. However, we note that a payment arrangement with an other payer, like some
APMs, can be structured so that the APM provides an investment payment to the participating
APM Entities to assist with the practice transformation that may be required for participation in
the payment arrangement. This investment payment could be structured in various ways; for
example, it could be structured similarly to the Medicare ACO Investment Model under, which
expected shared savings payment were pre-paid to encourage new ACOs to form in rural and
underserved areas and to assist existing ACOs in meeting certain criteria; or it could be
structured so that the payment is made specifically to encourage participating APM Entities to
continue to make staffing, infrastructure, and operations investments as a means of practice
transformation; or it could have a different structure entirely.

Although CMS did not solicit comments regarding our statement on investment
payments, the following is a summary of the public comments we received:

Comment: Many commenters expressed concern that CMS will continue the current
policy that does not include investment payments in the definition and calculation of risk. The
commenters stated that this approach fails to recognize the significant investment that APM
Entities and eligible clinicians make in start-up and overhead costs in the development and
operations of APMs. Some commenters suggested that CMS should develop a method to capture
and quantify such risk.
Response: We reiterate that our policy has not changed. As we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity’s investment risk or business risk exceeds a nominal amount (81 FR 77420). Therefore, we maintain our view that investment risk or business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and therefore, are not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420). Other Payer Advanced APMs, like Advanced APMs, can be designed so that they include investment payments for participants, but those investment payments will not be considered financial risk when assessing whether a payment arrangement meets the Other Payer Advanced APM financial risk criterion.

(c) Use of CEHRT

(i) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that to be an Other Payer Advanced APM, the other payer arrangement must require at least 50 percent of participating eligible clinicians in each APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care (81 FR 77465). This CEHRT use criterion directly paralleled the criterion established for Advanced APMs in §414.1415(a)(1)(i).

In the CY 2018 Quality Payment Program final rule, we finalized that we would presume that an other payer arrangement meets the 50 percent CEHRT use criterion if we receive information and documentation from the eligible clinician through the Eligible Clinician Initiated
Process showing that the other payer arrangement requires the requesting eligible clinician to use CEHRT to document and communicate clinical care (see §414.1445(c)(2)).

(ii) Increasing the CEHRT Use Criterion for Other Payer Advanced APMs

We proposed to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT; this aligns with our proposals for the CEHRT use criterion for Advanced APMs.

According to data collected by ONC, since the CY 2017 Quality Payment Program final rule was published, EHR adoption has been widespread, and we want to encourage continued adoption. Additionally, in response to the CY 2017 Quality Payment Program proposed rule stakeholders encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. (83 FR 35990).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported increasing the CEHRT use criterion as of January 1, 2020, to 75 percent of participating eligible clinicians in each APM Entity.

Response: We appreciate the support for our proposal to change the Other Payer Advanced APM CEHRT use criterion to 75 percent.
**Comment:** Many commenters expressed concern with the proposed change to the current CEHRT use criterion stating that raising it to 75 percent of participating eligible clinicians in each APM Entity may be too burdensome. A few commenters noted that the CEHRT use criterion should not be increased by any amount. One commenter stated that the CEHRT use criterion should remain at 50 percent and allow APM entities to attest that APM participants are using health IT. Some commenters stated the increase is premature as the All-Payer Combination Option is beginning in 2019. Some commenters suggested that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts.

**Response:** We do not believe that such an increase in the Other Payer Advanced APM minimum CEHRT use threshold will be burdensome for APM participants. According to data collected by ONC, certified EHR adoption has been widespread with over 3 in 4 office-based physicians adopted a certified EHR in CY 2015, and we want to continue to encourage such adoption and use of CEHRT. Further, regarding the comments that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts, we remind the commenters that, although we proposed the same increase in the Advanced APM minimum CEHRT use threshold beginning January 1, 2019, the proposed increase for Other Payer Advanced APMs would not apply until January 1, 2020. We believe this is a sufficient amount of lead time, especially given the widespread adoption of EHRs.

After considering public comments, we are finalizing our proposal to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT.
(iii) Evidence of CEHRT Use

In the CY 2017 Quality Payment Program final rule, we adopted a CEHRT use criterion for Other Payer Advanced APMs that directly paralleled the CEHRT use criterion for Advanced APMs wherein Other Payer Advanced APMs must require at least 50 percent of eligible clinicians in each participating APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care.

We have since heard from payers and other stakeholders that CEHRT is often used under other payer arrangements even if it is not expressly required under the payment arrangement. Because CEHRT use is increasingly common among eligible clinicians, payers may not believe it is necessary to specifically require the use of CEHRT under the terms of an Other Payer payment arrangement.

Given this, we believe our current policy may needlessly exclude certain existing payment arrangements that could meet the statutory requirements for Other Payer Advanced APMs – including some where the majority of eligible clinicians use CEHRT, even if they are not explicitly required to do so under the terms of their payment arrangements.

We proposed that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. We specifically proposed to modify the regulation at §414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians).
We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment:** Many commenters expressed support for CMS’ proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used by at least 50 percent of eligible clinicians in 2019, and 75 percent of eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement.

**Response:** We appreciate the support for our proposal to allow for documentation that CEHRT is used at required levels by eligible clinicians.

After considering public comments, we are finalizing our proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement.

Specifically, we are finalizing our proposal to modify the regulation at §414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians.

(d) MIPS Comparable Quality Measures

(i) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for a payment arrangement to be an Other Payer Advanced APM is that it must apply quality measures comparable to those under the MIPS quality performance category (81 FR 77465).
In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Other Payer Advanced APM, a payment arrangement must have quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We generally refer to these measures in the remainder of this discussion as “MIPS-comparable quality measures.” We did not specify in our regulation that the outcome measure is required to be evidence-based, reliable, and valid (81 FR 77466). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified them in the regulation at §414.1420(c).

(ii) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at §414.1420(c)(2) that at least one of the quality measures used in the payment arrangement with an APM Entity must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria:

- Used in the MIPS quality performance category as described in §414.1330;
- Endorsed by a consensus-based entity;
- Developed under section 1848(s) of the Act;
- Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or
- Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that, as with the comparable policy for Advanced APMs as discussed at 81 FR 28302, some have read the regulation at §414.1420(c)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures
necessarily are MIPS-comparable quality measures, even if they have not been determined to be
evidence-based, reliable, and valid. We did not intend to imply that any measure that was
merely submitted in response to the annual call for quality measures or developed using Quality
Payment Program funding would automatically qualify as MIPS-comparable regardless of
whether the measure was endorsed by a consensus-based entity, adopted under MIPS, or
otherwise determined to be evidence-based, reliable, and valid. While we believe such measures
may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of
§414.1420(c)(2) without independent verification by a consensus-based entity or based on our
own assessment and determination that they are evidence-based, reliable, and valid. We further
believe the same principle applies to QCDR measures. If QCDR measures are endorsed by a
consensus-based entity they are presumptively considered MIPS-comparable quality measures
for purposes of §414.1420(c)(2); otherwise we would have needed independent verification, or to
make our own assessment and determination, that the measures are evidence-based, reliable, and
valid before considering them to be MIPS-comparable (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of
cautions in order to avoid any adverse impact on APM entities, eligible clinicians or other
stakeholders, we have used the more permissive interpretation of the text, wherein measures
developed under section 1848(s) of the Act and submitted in response to the MIPS Call for
Quality Measures will meet the quality criterion in implementing the program thus far, and
intend to use this interpretation for the 2019 QP Performance Period. Recognizing that APMs
and other payer arrangements that we might consider for Advanced APM and Other Payer
Advanced APM determinations are well into development for 2019, we proposed to use this
interpretation until our new proposal described below is effective on January 1, 2020.
Therefore, at §414.1420(c)(2), we proposed, effective January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must meet at least one of the following criteria:

- Finalized on the MIPS final list of measures, as described in §414.1330;
- Endorsed by a consensus-based entity; or
- Otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment**: A few commenters supported the proposal that at least one of the quality measures used in the payment arrangement with an APM Entity must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

**Response**: We appreciate the support for our proposal.

**Comment**: One commenter urged CMS to include a fourth way to determine a quality measure is “MIPS-like” by clarifying that all Medicare Advantage Star Rating measures are determined to be evidence-based, reliable, and valid by CMS. The commenter stated that these metrics were determined by CMS to be valid and reliable enough to use as a basis of MA plan payment.
Response: We believe that all active Medicare Advantage Star Rating quality measures ([https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html)) are evidenced-based, reliable, and valid when used at the health plan level. However, if a payer has changed the unit of analysis from applying it at the health plan level to using it at the provider level, as would likely be necessary in this context, this may have affected the reliability and validity of the measure. As such, we believe it is important that all such measures be independently determined by CMS to be evidenced-based, reliable, and valid in the context of their use in the payment arrangement in order to satisfy the Other Payer Advanced APM criterion. We would note that this determination that a quality measure is MIPS-comparable would be made using the information collected by CMS as part of the data submission process for Other Payer Advanced APM determinations.

After considering public comments, we are finalizing our proposal to revise §414.1420(c)(2) to clarify, effective as of January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must either be finalized on the MIPS final list of measures, as described in §414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(iii) Outcome Measures: Evidence-Based, Reliable, and Valid

In §414.1420(c)(3), we generally require that, to be an Other Payer Advanced APM, the payment arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid.

We proposed to revise §414.1420(c)(3), to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that
is used in the payment arrangement must be evidence-based, reliable, and valid. This proposal would have an effective date of January 1, 2020, and would specifically require that an outcome measure must also be MIPS-comparable. This proposal aligns with the similar proposal for Advanced APMs discussed at section III.I.4.e.(3)(d)(ii) of this final rule, so that an outcome measure used in the payment arrangement must also be:

- Finalized on the MIPS final list of measures, as described in §414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

The proposal would have an effective date of January 1, 2020. This proposed effective date is intended to provide stakeholders sufficient notice of, and opportunity to respond to, this change in our regulation because the current regulation does not explicitly require that an outcomes measure must be evidence-based, reliable, and valid and, as a result some Other Payer Advanced APMs that were submitted for determination in CY 2018 for the CY 2019 performance year may not include outcomes measures that are evidence-based, reliable, and valid.

We also proposed that, for such payment arrangements that are determined to be Other Payer Advanced APMs for the 2019 performance year and did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we will continue to apply the current regulation for purposes of those determinations. Additionally, payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later, will be assessed under the rules
of the current regulation meaning they do not need to include an outcome measure that is evidence-based, reliable, and valid to be an Other Payer Advanced APM. For all other payment arrangements the proposed revised regulation would apply beginning in CY 2020.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment:** One commenter supported the proposal that at least one outcome measure must be among the quality measures used in the payment arrangement with an APM Entity, and that the outcome measure must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

**Response:** We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to revise §414.1420(c)(3), effective January 1, 2020, to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that applies in the payment arrangement must either be finalized on the MIPS final list of measures as described in §414.1330, endorsed by a consensus-based entity, or determined by CMS to be evidence-based, reliable, and valid.

(e) Financial Risk for Monetary Losses

(i) Overview

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to add a revenue-based nominal amount standard to the generally applicable nominal amount standard for Other Payer Advanced APMs that is parallel to the generally applicable revenue-based nominal amount standard for Advanced APMs. Specifically, we finalized that an other payer arrangement
would meet the total risk component of the proposed nominal risk standard if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities. This standard is in addition to the previously finalized expenditure-based standard. We explained that a payment arrangement would only need to meet one of the two standards. We would use this standard only for other payer arrangements where financial risk is expressly defined in terms of revenue in the payment arrangement.

(ii) Generally Applicable Nominal Amount Standard

We proposed to amend §414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024. This change is consistent with the proposed amendment to our regulation to maintain the generally applicable revenue-based nominal standard at 8 percent for Advanced APMs during the same timeframe.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters expressed support for the proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for QP Performance Periods 2021 through 2024.

Response: We appreciate the support for our proposal to maintain the generally applicable revenue-based nominal amount standard.
After considering public comments, we are finalizing our proposal to revise §414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(4) Determination of Other Payer Advanced APMs

(a) Overview

In the CY 2017 Quality Payment Program final rule, we specified that an APM Entity or eligible clinician must submit, by a date and in a manner determined by us, information necessary to identify whether a given payment arrangement satisfies the Other Payer Advanced APM criteria (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we codified at §414.1445 the Payer Initiated Other Payer Advanced APM Determination Process and the Eligible Clinician Initiated Other Payer Advanced APM Determination Process pertaining to the determination of Other Payer Advanced APMs, as well as specifying the information required for Other Payer Advanced APM determinations (82 FR 53814 through 53873).

(b) Multi-Year Other Payer Advanced APM Determinations

In the CY 2018 Quality Payment Program final rule, we finalized that Other Payer Advanced APM determinations made in response to requests submitted either through the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process) or the Eligible Clinician Initiated Other Payer Advanced APM Determination Process (Eligible Clinician Initiated Process) would be in effect for only one year at a time. We sought additional comment regarding the current duration of payment arrangements and whether creating a multi-year determination process would encourage the creation of more multi-year payment
arrangements as opposed to payment arrangements that are for one year only. We also sought comment on what kind of information should be submitted annually after the first year to update an Other Payer Advanced APM determination (82 FR 53869 through 53870).

After consideration of this feedback, we proposed to maintain the annual submission process with the modifications outlined below for both the Payer Initiated Process and the Eligible Clinician Initiated Process. We proposed that beginning with the 2019 and 2020 submission periods for Other Payer Advanced APM determinations for performance year 2020, after the first year that a payer, APM Entity, or eligible clinician (which we refer to as the “requester” in the remainder of this discussion) submits a multi-year payment arrangement that we determine to be an Other Payer Advanced APM for that year, the requester would need to submit information only on changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement. In the initial submission, the requester would certify as usual that the information provided about the payment arrangement using the Payer Initiated Process or Eligible Clinician Initiated Process, as applicable, is true, accurate, and complete; would authorize CMS to verify the information; and would certify that they would submit revised information in the event of a material change to the payment arrangement. For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement.
Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment:** Many commenters supported the proposal that the requester would need to submit information only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement.

**Response:** We appreciate the support for our proposal to allow for multi-year submissions of payment arrangements.

After considering public comments, we are finalizing our proposal to maintain the annual submission process with the modifications outlined above for both the Payer Initiated Process and the Eligible Clinician Initiated Process.

For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect
changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Commenters supported the proposal that this process remain in place through the earlier of the end of the multi-payment arrangement or 5 years.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we will continue to apply the original Other Payer
Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

(c) Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process)

– Remaining Other Payers

In the CY 2018 Quality Payment Program final rule, we finalized that we will allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements (Medicare Advantage plans, section 1876 cost plans PACE organization operated under section 1894 of the Act, and similar plans, other than an APM under section 1833(z)(3)(C) of the Act, that provide Medicare benefits under demonstration or waiver authority), and payers with payment arrangements aligned with a CMS Multi-Payer Model to use the Payer Initiated Process to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter (82 FR 53854). We codified this policy at §414.1445(b)(1).

We also finalized that the Remaining Other Payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP Performance Period and each year thereafter (82 FR 53867).

In the CY 2019 PFS proposed rule, we proposed details regarding the Payer Initiated Process for the Remaining Other Payers that were not among those other payers permitted to use the Payer Initiated Process to submit their arrangements for Other Payer Advanced APM Determinations in 2018 (Remaining Other Payers). To the extent possible, we are aligning the
Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

In the CY 2018 Quality Payment Program final rule, we finalized that the Payer Initiated Process will be voluntary for all payers (82 FR 53855). We note that the Payer Initiated Process will be similarly voluntary for payers that were permitted to submit payment arrangements in 2018 and for Remaining Other Payers starting in 2019.

**Guidance and Submission Form:** As we have for the other payers included in the PayerInitiated Process (82 FR 53874), we intend to make guidance available regarding the Payer Initiated Process for Remaining Other Payers prior to their first Submission Period, which will occur during 2019. We intend to modify the submission form (which we refer to as the Payer Initiated Submission Form) for use by Remaining Other Payers to request Other Payer Advanced APM determinations, and to make this Payer Initiated Submission Form available to Remaining Other Payers prior to the first Submission Period. We proposed that a Remaining Other Payer will be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all payment arrangements and some questions that are specific to a particular type of payment arrangement, and we intend for it to include a way for payers to attach supporting documentation.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:
Comment: Commenters supported the proposal to require Remaining Other Payers to use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that Remaining Other Payers will use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

We proposed that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Remaining Other Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement.

Submission Period: We proposed that the Submission Period for the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations will open on January 1 of the calendar year prior to the relevant QP Performance Period for which we would make Other Payer Advanced APM determinations.
We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment:** One commenter supported the CMS proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

**Response:** We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

The finalized timeline for the Payer Initiated Process for Remaining Other Payers as well as the previously finalized timeline for the Payer Initiated Process for Medicaid and Medicare Health Plans, is summarized in Table 59 alongside the final timeline for the Eligible Clinician Initiated Process.
TABLE 59: Finalized Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020

<table>
<thead>
<tr>
<th>Payer Initiated Process</th>
<th>Date</th>
<th>Eligible Clinician (EC) Initiated Process*</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Medicaid</td>
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<td></td>
</tr>
<tr>
<td>Guidance sent to states, then Submission Period Opens</td>
<td>January 2019</td>
<td>Guidance made available to ECs, then Submission Period Opens</td>
<td>September 2019</td>
</tr>
<tr>
<td>Submission Period Closes</td>
<td>April 2019</td>
<td>Submission Period Closes</td>
<td>November 2019</td>
</tr>
<tr>
<td>CMS contacts states and posts Other Payer Advanced APM List</td>
<td>September 2019</td>
<td>CMS contacts ECs and states and posts Other Payer Advanced APM List</td>
<td>December 2019</td>
</tr>
<tr>
<td>Medicare Health Plans</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guidance made available to Medicare Health Plans, then Submission Period Opens</td>
<td>April 2019</td>
<td>Guidance made available to ECs, then Submission Period Opens</td>
<td>September 2020</td>
</tr>
<tr>
<td>Submission Period Closes</td>
<td>June 2019</td>
<td>Submission Period Closes</td>
<td>November 2020</td>
</tr>
<tr>
<td>CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List</td>
<td>September 2019</td>
<td>CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List</td>
<td>December 2020</td>
</tr>
<tr>
<td>Remaining Other Payers</td>
<td></td>
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</tr>
<tr>
<td>Guidance made available to Remaining Other Payers, then Submission Period Opens</td>
<td>January 2019</td>
<td>Guidance made available to ECs, then Submission Period Opens</td>
<td>September 2020</td>
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<tr>
<td>Submission Period Closes</td>
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<tr>
<td>CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List</td>
<td>September 2019</td>
<td>CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List</td>
<td>December 2020</td>
</tr>
</tbody>
</table>

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

**CMS Determination:** Upon the timely receipt of a Payer Initiated Submission Form, we will use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We proposed that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we will inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information. For each other payer arrangement for which the Remaining Other Payer does not submit sufficient information in a timely fashion, we will not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement will not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

We solicited comment on this proposal.
We did not receive any comments in response to this proposal.

We are finalizing our proposal that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we would inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information.

**CMS Notification:** We intend to notify Remaining Other Payers of our determination for each request as soon as practicable after the relevant Submission Deadline. We note that Remaining Other Payers may submit information regarding an other payer arrangement for a subsequent QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

**CMS Posting of Other Payer Advanced APMs:** We intend to post on the CMS Website a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant QP Performance Period, we intend to post a list of the payment arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process, and Other Payer Advanced APMs under Title XIX through the Eligible Clinician Initiated Process. After the QP Performance Period, we will update this list to include payment arrangements that we determine to be Other Payer Advanced APMs based on other requests through the Eligible Clinician Initiated Process. We intend to post the list of other payer arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process prior to the start of the relevant QP Performance Period, and then to update the list to include payment arrangements that we determine to be Other Payer Advanced APMs based on requests received through the Eligible Clinician Initiated Process.
(d) Payer Initiated Process – CMS Multi-Payer Models

In the CY 2018 Quality Payment Program final rule, we finalized that beginning for the first QP Performance Period under the All-Payer Combination Option, payers with a payment arrangement aligned with a CMS Multi-Payer Model may request that we determine whether that aligned payment arrangement is an Other Payer Advanced APM.

In the CY 2019 PFS proposed rule, we proposed to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers we have proposed in section III.14.g.(3)(c) of this final rule, or through the existing Medicaid or Medicare Health Plan payment arrangement submission process, as applicable.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models.

(5) Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77463). Beginning in 2021, in addition to the Medicare Option, an eligible clinician may alternatively become a QP through the All-Payer Combination Option, and an eligible clinician need only meet the QP threshold under one of the two options to be a QP for the payment year (81 FR 77459). We finalized that we will conduct
the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77459).

In the CY 2017 Quality Payment Program final rule, we finalized that we will calculate Threshold Scores under the Medicare Option through both the payment amount and the patient count methods, compare each Threshold Score to the relevant QP and Partial QP Thresholds, and use the most advantageous scores to make QP determinations (81 FR 77457). We finalized the same approach for the All-Payer Combination Option wherein we will use the most advantageous method for QP determinations with the data that has been provided (81 FR 77475).

(b) QP Determinations under the All-Payer Combination Option

In the CY 2018 Quality Payment Program final rule, we finalized that an eligible clinician may request a QP determination at the eligible clinician level, and that an APM Entity may request a QP determination at the APM Entity Level (82 FR 53880 through 53881). In the event that we receive a request for QP determination from an individual eligible clinician and also separately from that individual eligible clinician's APM Entity, we would make a determination at both levels. The eligible clinician could become a QP on the basis of either of the two determinations (82 FR 53881).

We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single (meaning the same) APM Entity. Therefore, this option would be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for which all clinicians who have reassigned their billing rights to the TIN are participating in the same APM Entity.

We solicited comment on this proposal.
The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

We proposed that, similar to our existing policies for individual and APM Entity requests for QP determinations under the All-Payer Combination Option, we would assess QP status based on the most advantageous result for each individual eligible clinician. That is, if we receive any combination of QP determination requests (at the TIN-level, APM Entity level, or individual level) we will make QP assessments at all requested levels and determine QP status on the basis of the QP assessment that is most advantageous to the eligible clinician.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to assess QP status based on the most advantageous result for each individual eligible clinician.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to assess QP status based on the most advantageous result for each individual eligible clinician.
(c) Use of Individual or APM Entity Information for Medicare Payment Amount and Patient Count Calculation under the All-Payer Combination Option

(i) Flexibility in the Medicare Option and All-Payer Combination Option Threshold Methods

In the CY 2018 Quality Payment Program final rule, we finalized that when we make QP determinations at the individual eligible clinician level, we would use the individual eligible clinician payment amounts and patient counts for the Medicare calculations in the All-Payer Combination Option. When we make QP determinations at the APM Entity level, we will use APM Entity level payment amounts and patient counts for the Medicare calculations in QP determinations under the All-Payer Combination Option. Eligible clinicians assessed at the individual eligible clinician level under the Medicare Option at §414.1425(b)(2) will be assessed at the individual eligible clinician level only under the All-Payer Combination Option. We codified these policies at §414.1440(d)(2) (82 FR 53881).

We noted in the CY 2019 PFS proposed rule that some may have read our regulation at §414.1440(d)(2) to suggest that consistency is required across the two thresholds requiring eligible clinicians or APM Entities to meet the minimum Medicare threshold needed to qualify for the All-Payer Combination Option and the All-Payer threshold using the same method—either payment amounts or patient counts. Although we did not directly address this specific question in our current regulation or in prior rulemaking, we are clarifying that eligible clinicians or APM Entities can meet the minimum Medicare threshold for the All-Payer Combination option using one method (whichever is most favorable), and the All-Payer threshold for the All-Payer Combination Option using either the same, or the other method. All data submitted to us for Other Payer Advanced APM determinations and, when applicable, QP determinations using the All-Payer Combination Option will be considered and evaluated; and eligible clinicians (or
APM Entities or TINs, as appropriate) may submit all data relating to both the payment amount and patient count methods. To avoid any potential ambiguity for the future, we proposed a change to §414.1440(d) to codify this clarification. We proposed to add a new §414.1440(d)(4) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method. We note that, in the preamble in the CY 2019 PFS proposed rule, we indicated that we would codify this proposed policy by adding a new §414.1440(d)(4) to our regulations. However, the corresponding proposed regulation text included the proposed policy as an amendment to the regulation text at §414.1440(d)(1) We intended to propose the policy reflected in the proposed regulation text, and due to a clerical error, inadvertently neglected to revise the description of the proposal in the preamble. As such, rather than adding a new §414.1440(d)(4), we intended to propose to amend the regulation at §414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Some commenters supported the proposal to allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.
Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal with the correction noted above, that we are amending the text in our regulation at §414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

(ii) Extending the Medicare Threshold Score Weighting Methodology to TIN Level All-Payer Combination Option Threshold Score Calculations

In the CY 2018 Quality Payment Program final rule, we explained that we recognize that in many cases an individual eligible clinician’s Medicare Threshold Scores would likely differ from the corresponding Threshold Scores calculated at the APM Entity group level, which would benefit those eligible clinicians whose individual Threshold Scores would be higher than the group Threshold Scores and disadvantage those eligible clinicians whose individual Threshold Scores are equal to or lower than the group Threshold Scores (82 FR 53881-53882). In situations where eligible clinicians are assessed under the Medicare Option as an APM Entity group, and receive a Medicare Threshold Score at the APM Entity group level, we believe that the Medicare portion of their All-Payer calculation under the All-Payer Combination Option should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group.

To accomplish this outcome, we finalized a modified weighting methodology. We finalized that when the eligible clinician’s Medicare Threshold Score calculated at the individual level would be lower than the Medicare Threshold Score calculated at the APM Entity group level, we would apply a weighting methodology to calculate the Threshold Score for the eligible
clinician. This methodology allows us to apply the APM Entity group level Medicare Threshold Score (if higher than the individual eligible clinician level Medicare Threshold Score), to the eligible clinician, under either the payment amount or patient count method, but weighted to reflect the individual eligible clinician’s Medicare volume. We multiply the eligible clinician’s APM Entity group Medicare Threshold Score by the total Medicare payments or patients made to that eligible clinician as follows:

\[
\left[ \text{APM Entity Medicare Threshold Score} \times \text{Clinician Medicare Payments or Patients} \right] + \text{Individual Other Payer Advanced APM Payments or Patients} \\
\text{Individual Payments or Patients (All Payers except those excluded)}
\]

In the CY 2019 PFS proposed rule, we proposed to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN’s All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group (82 FR 53881-53882). We note this extension of the weighting methodology would only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We would multiply the TIN’s APM Entity group Medicare Threshold Score by the total Medicare payments or patients for that TIN as follows:

\[
\left[ \text{APM Entity Medicare Threshold Score} \times \text{TIN Medicare Payments or Patients} \right] + \text{TIN Other Payer Advanced APM Payments or Patients} \\
\text{TIN Payment or Patients (All Payers except those excluded)}
\]

We proposed to calculate the TIN’s Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP
determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the proposed application of this weighting approach in the case of a TIN level QP determination would be consistent with our established policy.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

**Comment:** Commenters supported the proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

**Response:** We appreciate support for our proposal.

After considering public comments, we are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

(6) Summary of Final Policies

In this section, we are finalizing the following policies:

**Other Payer Advanced APM Criteria:**

- We are finalizing our proposal to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the percentage of eligible
clinicians participating in the other payer arrangement who are using CEHRT must be 75 percent.

- We are finalizing our proposal to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement. We codifying this change at §414.1420(b).

- We are finalizing the following clarification to §414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

  ++ Finalized on the MIPS final list of measures, as described in §414.1330;

  ++ Endorsed by a consensus-based entity; or

  ++ Determined by CMS to be evidenced-based, reliable, and valid.

- We are finalizing our proposal to revise §414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that meets the proposed criteria in paragraph (c)(2) of this regulation.

- We are also finalizing our proposal at §414.1420(c)(3)(i) that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year which did not include an outcome measure that is evidence-based, reliable, and valid, that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.g.(3)(b)
of this final rule), we would continue to apply the current regulation for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

**Determination of Other Payer Advanced APMs:**

- We are finalizing details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we are aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

- We are finalizing our proposal to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers that we are finalizing as described in section III.I.4.g.(3)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

**Calculation of All-Payer Combination Option Threshold Scores and QP Determinations:**

- We are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We are finalizing this proposal to revise §414.1440(d), by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.
- We also are finalizing our clarification that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We are finalizing our proposal with a correction to codify this clarification by amending §414.1440(d)(1).

- We are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

5. Quality Payment Program Technical Correction: Regulation Text Changes

a. Overview

We proposed certain technical revisions to our regulations in order to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

b. Regulation Text Changes

We proposed a technical correction to §414.1415(b)(1) of our regulations to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM (83 FR 36005). The addition of the word “quality” better aligns with section 1833(z)(3)(D) of the Act and with the policy that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77406), and corrects a clerical error we made in the course of revising the text of §414.1415(b)(1) for inclusion in the CY 2017 QPP final rule. This proposed revision would not change our current policy for this Advanced APM criterion.
We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing the technical correction to §414.1415(b)(1) to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

We also proposed technical corrections to §414.1420(d)(3)(ii)(B) (83 FR 36005). These changes align with the generally applicable nominal amount standard for Other Payer Advanced APMs that was finalized in the CY 2017 Quality Payment Program final rule, and the change to the generally applicable nominal amount standard in the CY 2018 Quality Payment Program final rule where we established a revenue-based nominal amount standard as part of the Other Payer Advanced APM criteria (82 FR 53849-53850). We finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and that a payment arrangement’s level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures, and the maximum allowable minimum loss rate must be 4 percent (81 FR 77471). Due to a clerical oversight, we inadvertently published two conflicting provisions in regulation text. At §414.1420(d)(3)(i), we correctly finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and at §414.1420(d)(3)(ii)(B) we incorrectly finalized that the risk arrangement must have a total potential risk of at least 4 percent of expected expenditures. We are effectuating this change by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable...

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter thanked the agency for making the technical correction to clarify that an Other Payer payment arrangement must require APM Entities to bear financial risk for at least 3 percent, not 4 percent.

Response: We thank the commenter for their support of this technical correction. After considering public comments, we are finalizing this technical correction by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at §414.1420(d)(3)(ii)(B) and consolidating §414.1420(d)(3)(ii)(A) into §414.1420(d)(3)(ii).

In the CY 2017 Quality Payment Program final rule, we finalized a capitation standard for the financial risk criterion under the Advanced APM Criteria and the Other Payer Advanced APM Criteria, respectively. We finalized that full capitation arrangements would meet the Advanced APM financial risk criterion and Other Payer Advanced APM financial risk criterion, and would not separately need to meet the generally applicable financial risk standard and generally applicable nominal amount standard in order to satisfy the financial risk criterion for Advanced APMs and Other Payer Advanced APMs (81 FR 77431; 77472). We proposed to clarify the application of the capitation standard by revising §414.1415(c) and §414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively (83 FR 36006).

We solicited comment on this proposal.
We did not receive any comments in response to this proposal.

We are finalizing our proposal to clarify the application of the capitation standard by revising §414.1415(c) and §414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively.

In finalizing §§414.1415(c)(6) and 414.1420(d)(7), we specified that a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. This language does not completely reflect our definition of capitation risk arrangements as discussed in the preamble at 81 FR 77430 where we state that, “capitation risk arrangements, as defined here, involve full risk for the population of beneficiaries covered by the arrangement, recognizing that it might require no services whatsoever or could require exponentially more services than were expected in calculating the capitation rate. … [a] capitation risk arrangement adheres to the idea of a global budget for all items and services to a population of beneficiaries during a fixed period of time.”

Therefore, we proposed to revise these regulations to align the Advanced APM Criteria, Financial Risk, Capitation provision at §414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at §414.1420(d)(7) with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430-77431 (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.
We are finalizing our proposal to revise the Advanced APM Criteria, Financial Risk, Capitation provision at §414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at §414.1420(d)(7) to align with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430-77431.

We also proposed a technical correction to remove the “; or” and replace it with a “.” at §414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under §414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under §414.1420(d)(3)(i) (83 FR 36006). As indicated in the CY 2018 Quality Payment Program final rule at 82 FR 53849-53850, where we established a revenue-based nominal amount standard for Other Payer Advanced APMs, in order to meet the generally applicable nominal amount standard under the Other Payer Advanced APM criteria, the total amount that an APM Entity potentially owes the payer or foregoes under a payment arrangement must be equal to at least: for the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to remove the “; or” and replace it with a “.” at §414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under §414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under §414.1420(d)(3)(i).
We also proposed to revise §414.1440(d)(3) to correct a typographical error by replacing the “are” with “is” in the third clause of the second sentence (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise §414.1440(d)(3) to correct a typographical error by replacing the “are” with “is” in the third clause of the second sentence.

c. Summary of Final Policies

We are finalizing these technical corrections to our regulations at §§414.1415(b)(1), 414.1420(d)(3)(ii), 414.1415(c), 414.1420(d), 414.1415(c)(6), 414.1420(d)(7), 414.1420(d)(3)(i), and 414.1440(d)(3) as proposed.

IV. Requests for Information

This section addressed two requests for information (RFI).

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to promoting interoperability and electronic health care information exchange (83 FR 36006 through 36009). We received approximately 79 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to price transparency and improving beneficiary access to provider and supplier charge
information (83 FR 36009 through 36010). We received approximately 94 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

V. Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success

A. Statutory and Regulatory Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as “the Affordable Care Act”). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 et seq.) by adding section 1899 to the Act to establish the Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. See 42 U.S.C. 1395jjj.

The final rule establishing the Shared Savings Program appeared in the November 2, 2011 Federal Register (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the “November 2011 final rule”)). We viewed this final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules.

Through subsequent rulemaking, we have revisited and amended Shared Savings Program policies in light of the additional experience we gained during the initial years of program implementation as well as from testing through the Pioneer ACO Model, the Next
Generation ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. A major update to the program rules appeared in the June 9, 2015 Federal Register (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the “June 2015 final rule”). A final rule addressing changes related to the program’s financial benchmark methodology appeared in the June 10, 2016 Federal Register (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations – Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the “June 2016 final rule”). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address updates to the Shared Savings Program quality measures, scoring, and quality performance standard, the program’s beneficiary assignment methodology and certain other issues.34

Policies applicable to Shared Savings Program ACOs have continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), CMS established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared

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34 See for example: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule (78 FR 74230, Dec. 10, 2013). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67548, Nov. 13, 2014). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2016; Final Rule (80 FR 70886, Nov. 16, 2015). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2017; Final Rule (81 FR 80170, Nov. 15, 2016). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2018; Final Rule (82 FR 52976, Nov. 15, 2017).
Savings Program.

The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114-255). Accordingly, we revised the program’s regulations in the CY 2018 PFS final rule to reflect these new requirements.

On February 9, 2018, the Bipartisan Budget Act of 2018 was enacted (Pub. L. 115-123), amending section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to a prospectively assigned beneficiary, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period, permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

On August 17, 2018 a proposed rule, titled "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success" (hereinafter referred to as the “August 2018 proposed rule”), appeared in the Federal Register (83 FR 41786). This proposed rule would provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are also accountable for repaying any shared losses). As part of the proposed redesign of the program, we proposed to establish two tracks under the program – the BASIC track and the ENHANCED track. These new participation options were designed to increase savings for the Trust Funds and
mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The August 2018 proposed rule would also provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; and promote the use of interoperable electronic health record technology among ACO providers/suppliers. We received 470 timely pieces of correspondence in response to the August 2018 proposed rule. In the following sections of this final rule, we address a subset of the proposals described in the August 2018 proposed rule. We summarize and respond to the significant public comments on these proposals and discuss our final policies with respect to these issues after taking into consideration the public comments we received on this subset of proposals. We are not addressing the other topics included in the August 2018 proposed rule at this time. We will summarize and respond to public comments on these other proposed policies in a forthcoming final rule. We also received comments that are outside the scope of the August 2018 proposed rule. We may consider these comments when evaluating current Shared Savings Program policies and contemplating future refinements to the program.

B. Finalization of Certain Provisions of the Shared Savings Program August 2018 Proposed Rule

In this section of the final rule, we discuss the proposal, the comments received, and the final action that we are taking for the following proposals in the August 2018 proposed rule:

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019 through June 30, 2019. We believe it is necessary to finalize the extension before these ACOs’ participation agreements expire on December 31, 2018, so that they can continue their participation in the program.
without interruption. It is also necessary to finalize the methodology for determining ACO quality and financial performance for the extension period in advance of the 6-month performance year beginning on January 1, 2019.

- Implementation of the provisions of section 50331 of the Bipartisan Budget Act of 2018 on voluntary alignment. The Bipartisan Budget Act was enacted earlier this year, and we believe it is most consistent with the requirements of the statute to revise our voluntary alignment policies effective with assignment for performance years starting on January 1, 2019, to reflect the additional flexibility given to beneficiaries in selecting their primary care provider.

- A modification to the definition of primary care services used in assigning beneficiaries to ACOs to reflect recent code changes. Including these codes in the definition of primary care services will improve the accuracy of the assignment methodology and help to ensure that beneficiaries are assigned to the ACO that is responsible for coordinating their overall care.

- Relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years. We believe it is necessary to finalize the changes to the extreme and uncontrollable circumstances policies for the Shared Savings Program as quickly as possible to ensure that relief is available for ACOs affected by the recent hurricanes in North Carolina and Florida and other disasters during 2018.

- Revisions to program requirements to further promote interoperability among ACO providers and suppliers. We believe it is necessary to finalize changes to our CEHRT use requirements to align with the Quality Payment Program.

We are also making technical changes to update the authority citation for 42 CFR part 425 to conform with OFR requirements.
The changes will be effective on December 31, 2018. Applicability or implementation dates may vary, depending on the policy, and the timing specified in this final rule. By indicating that a provision is applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year or agreement period.

1. Participation Options for Agreement Periods Beginning in 2019

In this final rule, we are addressing a subset of the proposals in the August 2018 proposed rule for participation options for agreement periods beginning in 2019. In the August 2018 proposed rule, we stated that we would forgo an application cycle for a January 1, 2019 agreement start date and proposed to allow for a July 1, 2019 agreement start date. We proposed an approach for determining financial and quality performance for two 6-month performance years during 2019, with the first from January 1, 2019 through June 30, 2019, for ACOs with participation agreements expiring on December 31, 2018, that elect a voluntary 6-month extension, and the second from July 1, 2019 through December 31, 2019, for ACOs entering a new agreement period beginning July 1, 2019. We also proposed an approach for determining financial and quality performance for the performance period from January 1, 2019 through June 30, 2019 for an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, referred to as “early renewals.”

In this final rule, we are addressing our proposals to allow for a voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, and to establish a methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. These proposals were necessary to prevent
some ACOs from experiencing an involuntary gap in participation as a result of our decision to forgo an application cycle in 2018 for a January 1, 2019 agreement start date. Therefore, in this section of the final rule, we summarize and respond to comments and address final actions specific to our proposals regarding the 6-month extension and the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As we describe in this section, some modifications to our proposals are necessary because of the limited scope of this final rule.

In a forthcoming final rule, we anticipate summarizing and responding to public comments on the other proposed policies related to determining financial and quality performance in 2019 for the following: (1) the performance period from January 1, 2019 through June 30, 2019, for ACOs starting a 12-month performance year on January 1, 2019, that terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019; and (2) the 6-month performance year from July 1, 2019 through December 31, 2019, for ACOs entering an agreement period beginning on July 1, 2019.

a. Voluntary Extension for a 6-Month Performance Year from January 1, 2019 through June 30, 2019, for ACOs whose Current Agreement Period Expires on December 31, 2018

In section II.A.7. of the August 2018 proposed rule (83 FR 41847), we explained that we were forgoing the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements, initial use of the Skilled Nursing Facility (SNF) 3-day rule waiver, and entry into the Track 1+ Model, and we proposed to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the proposed BASIC track or ENHANCED track, which would be
offered under the proposed redesign of the program’s participation options. We proposed the
July 1, 2019 start date as a one-time opportunity, and thereafter we would resume our typical
process of offering an annual application cycle that allows for review and approval of
applications in advance of a January 1 agreement start date.

We proposed that ACOs that entered a first or second agreement period with a start date
of January 1, 2016 could elect to extend their agreement period for an optional fourth
performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019.
This election to extend the agreement period would be voluntary and an ACO could choose not
to extend its agreement period, in which case it would conclude its participation in the program
with the expiration of its current agreement period on December 31, 2018.

We proposed that the ACO’s voluntary election to extend its agreement period must be
made in the form and manner and according to the timeframe established by CMS, and that an
ACO executive who has the authority to legally bind the ACO must certify the election. We
explained our expectation that this election process, if finalized, would begin in 2018 following
the publication of the final rule, as part of the annual certification process in advance of 2019
(described in section II.A.7.c.(2) of the August 2018 proposed rule (83 FR 41855)). We noted
that this optional 6-month agreement period extension would be a one-time exception for ACOs
with agreements expiring on December 31, 2018, and would not be available to other ACOs that
are currently participating in a 3-year agreement in the program, or to future program entrants.

In the August 2018 proposed rule, we noted that under the existing provision at §425.210,
the ACO must provide a copy of its participation agreement with CMS to all ACO participants,
ACO providers/suppliers, and other individuals and entities involved in ACO governance.
Further, all contracts or arrangements between or among the ACO, ACO participants, ACO
providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program’s regulations, including, but not limited to, those specified in the participation agreement with CMS. We proposed that an ACO that elects to extend its participation agreement by 6 months must notify its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities of this continuation of participation and must require their continued compliance with the program’s requirements for the 6-month performance year from January 1, 2019 through June 30, 2019.

As discussed in section II.A.2. of the August 2018 proposed rule (83 FR 41799 through 41800), we proposed modifications to the definition of “agreement period” in §425.20 to broaden the definition to generally refer to the term of the participation agreement. We also proposed to add a provision at §425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO (83 FR 41849). For consistency, we also proposed minor formatting changes to the existing provision at §425.200(b)(2) and (b)(3) to italicize the header text.

We also proposed to revise the definition of “performance year” in §425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in §425.200(c) or noted in the participation agreement. We also proposed revisions to §425.200(c) to make necessary formatting changes and specify additional exceptions to the definition of performance year as a 12-month period. Specifically, we proposed to add a
provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019. Similarly, we proposed to add a provision specifying that for an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019 (83 FR 41849).

In light of the proposed modifications to §425.200(c) to establish two 6-month performance years during CY 2019, we proposed revisions to the regulation at §425.200(d), which reiterates an ACO’s obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in a 6-month performance year during CY 2019 (83 FR 41849).

We also considered forgoing an application cycle for a 2019 start date altogether and allowing ACOs to enter agreement periods under the proposed BASIC track and ENHANCED track for the first time beginning on January 1, 2020. This approach would allow ACOs additional time to consider the redesign of the program, make organizational and operational plans, and implement business and investment decisions, and would avoid the complexity of needing to determine performance based on 6-month performance years during CY 2019. However, we noted that our proposed approach of offering an application cycle during 2019 for an agreement period start date of July 1, 2019 would allow for a more rapid progression of ACOs to the redesigned participation options, starting in mid-2019. We further noted that, under this alternative, we would also want to offer ACOs that started a first or second agreement period on
January 1, 2016, a means to continue their participation between the conclusion of their current 3-year agreement period (December 31, 2018) and the start of their next agreement period (January 1, 2020), should the ACO wish to continue in the program. We indicated that under that alternative, which would postpone the start date for the new participation options to January 1, 2020, we would allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of CY 2019.

We sought comment on these proposals and the related considerations, as well as the alternatives considered.

**Comment:** Regarding the program’s application cycles, most commenters generally supported CMS’ decision to forgo an application cycle during CY 2018 for a January 1, 2019 agreement start date. Several commenters explained their support for this decision was due to the significant revisions to program policies contained in the proposed rule.

**Response:** We thank commenters for their support of our decision to forgo the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements.

**Comment:** Of the comments addressing the length of the extension for ACOs with agreement periods expiring December 31, 2018, a few commenters generally supported the proposed participation options for agreement periods beginning in 2019, including the proposed 6-month extension. Several commenters stated their support for CMS’ proposal to allow ACOs with agreement periods ending December 31, 2018, to extend their agreements through June 30, 2019. Several commenters suggested that CMS allow ACOs whose agreement periods expire on December 31, 2018, an option to extend their current participation agreement by either 6 months
or 12 months. In addition, many commenters supported allowing these ACOs the opportunity to elect a voluntary 12-month extension of their current agreement period, for a fourth performance year from January 1, 2019 through December 31, 2019. One commenter, whose comment was primarily focused on the applicability of policies to Track 1 ACOs, specifically recommended that this 12-month extension option should be offered for Track 1 ACOs. One commenter suggested that CMS permit Track 3 ACOs a 12-month extension for the performance year from January 1, 2019 through December 31, 2019, and that CMS apply certain aspects of the proposed program redesign, including the use of factors based on regional FFS expenditures in establishing, updating and adjusting the ACO’s historical benchmark and the availability of beneficiary incentive programs, during this optional fourth 12-month performance year, enabling these Track 3 ACOs to gain experience with these policies before deciding whether to continue their participation in the Shared Savings Program in the ENHANCED track.

Some commenters explained that providing a 12-month extension option would give ACOs additional time to analyze program changes and prepare for the application process. One commenter expressed concern that a 6-month extension would provide a limited and inadequate amount of time for ACOs to consider participation options under a redesigned program, if a final rule establishing a July 1, 2019 start date is not issued until later in 2018. This commenter expressed the belief that this limited time to consider participation options in advance of a July 1, 2019 start date (if finalized) and general uncertainty about program policies would result in program attrition, due to ACOs and ACO participants electing not to continue in the program at the end of their current agreement. One commenter explained a 12-month extension would give ACOs additional time to evaluate whether they have the appropriate structure in place, implement processes to comply with new regulations, and make necessary changes to their ACO
participant and ACO provider/supplier networks.

One commenter explained a 12-month extension would provide current ACOs with additional time and experience under their current agreement periods. Some commenters explained that providing a 12-month extension could avoid the complexity and increased burden on providers, practices, ACOs, and CMS that could potentially result from ACOs’ participation in two, 6-month performance years in CY 2019. Other commenters raised concerns about making ACO participant list changes, and modifying agreements with their ACO participants, to allow for participation in two, 6-month performance years during CY 2019, with each performance year under a separate participation agreement: the first 6-month performance year under their current participation agreement (in an extension of their current agreement period); and the second 6-month performance year under a new participation agreement under one of the proposed redesigned participation options. Some commenters requesting a 12-month extension, or the choice between a 6-month or a 12-month extension, also raised concerns about the methodology for determining financial and quality performance for two, 6-month performance years during CY 2019. We summarize and respond to comments related to the methodology for determining performance for the 6-month performance year from January 1, 2019 through December 31, 2019, and other program policies applicable to ACOs participating in this 6-month performance year, in sections V.B.1.b. and V.B.1.c. of this final rule.

Response: We are not addressing in this final rule, comments on the timing for implementing the proposed redesign of the Shared Savings Program’s participation options. However, we believe it is important to allow for continuity in participation for ACOs whose participation agreements expire December 31, 2018.

We appreciate commenters’ concerns about preparing to enter a new agreement period in
light of uncertainty around the participation options that may be available. However, we note that, based on the proposals in the August 2018 proposed rule, ACOs whose agreement periods expire on December 31, 2018, that were interested in continuing their participation in the program have had an opportunity to identify their likely ACO participants for the proposed 6-month performance year from January 1, 2019 through June 30, 2019, and have received preliminary feedback from CMS for ACO participant list additions for the performance year beginning on January 1, 2019. Moreover, we believe these ACOs generally have begun preparing the necessary revisions to their agreements with ACO participants and ACO providers/suppliers and, if under a two-sided model to extend their repayment mechanism in anticipation of the possibility that we would finalize the proposed 6-month extension period. We believe these ACOs have also been weighing their participation options in advance of applying to renew for a subsequent agreement period, and will have additional time to make these determinations during the 6-month extension (if elected). In particular, ACOs reaching the conclusion of their second agreement period under Track 1, would have been weighing their participation options under two-sided models, given the current requirement that ACOs transition to a two-sided model by the start of their third agreement period. In fact, the 6-month extension allows ACOs completing their second agreement period in Track 1 to continue participation under their current agreement period and thereby receive additional time under a one-sided model that otherwise would not have been available to these ACOs under the program’s current regulations.

We also believe it is important to ensure we retain the flexibility to allow ACOs to more rapidly transition, starting as early as July 1, 2019, to the proposed new participation options, should they be finalized, including the participation options that would be Advanced APMs that
would allow eligible clinicians participating in the ACO to qualify for incentive payments under the Quality Payment Program. We believe that rapid transition to the new participation options would drive more meaningful systematic change in ACOs, which have the potential to control their assigned beneficiaries’ Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending.

At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. To reduce the possibility for selective participation bias that could adversely affect the Trust Funds, we believe the same option for extending their current participation agreement should be made available to all eligible ACOs whose agreement periods expire December 31, 2018, as opposed to offering ACOs the option to choose between either a 6-month or a 12-month extension, or offering extensions of different lengths to ACOs based on their current participation track. For example, we believe that if we offered a choice regarding the length of the extension, only ACOs that would expect to benefit from being rebased under new program policies would elect a 6-month extension in order to allow the regional rebasing policies to apply sooner.

We also decline to adopt the commenter’s suggestions that we finalize certain aspects of the proposed program redesign, such as the proposed modifications to the methodology for establishing, adjusting and updating an ACO’s historical benchmark, and certain payment and program flexibilities for eligible ACOs participating under two-sided models, and apply these policies to a subset of the ACOs electing the voluntary extension. Continuing to apply the current benchmarking methodology during the optional fourth performance year maintains ACOs’ existing historical benchmarks, allowing them to continue to build on their experience within
their current agreement period and provides a more predictable and stable benchmark during the 6-month extension period. We also decline to allow only ACOs that are eligible for and elect the extension to have access to and make use of additional program and payment flexibilities (such as a SNF 3-day rule waiver, unless previously approved, or a beneficiary incentive program) as a way of allowing these organizations to gain experience with these policies in advance of their broader availability (if finalized) to eligible ACOs participating in the program. Our proposals to extend the availability of a SNF 3-day rule waiver and to give ACOs the opportunity to offer beneficiary incentive programs were developed in conjunction with our proposed changes to the participation options for ACOs participating in the Shared Savings Program. Therefore, we believe these proposals need to be considered together as part of a forthcoming final rule addressing our proposals for the overall redesign of the Shared Savings Program. Further, we believe it would be cumbersome to determine ACOs’ eligibility for these flexibilities prior to the start of the performance year beginning January 1, 2019, particularly given the absence of a formal application cycle during CY 2018 during which ACOs could elect to apply for such opportunities.

**Comment:** One commenter pointed to the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41926), and our estimate that a 12-month extension for ACOs whose participation agreements expire on December 31, 2018, would reduce overall Federal spending by approximately an additional $100 million, as further justification for allowing a 12-month rather than a 6-month extension.

**Response:** We believe it is important to allow for continuity in participation for ACOs whose agreement periods expire on December 31, 2018. We also believe it is important to ensure ACOs more rapidly transition to new participation options in the event we finalize a mid-year
start date for those participation options in 2019. At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. The estimated impact of a 12-month extension for ACOs whose current agreement periods expire on December 31, 2018, is not comparable to the impact estimated for a 6-month extension for this same group of ACOs. To explain further, the impact estimate for a 12-month extension was estimated under a different hypothetical baseline. Differences in participation resulting from a 6-month or a 12-month extension were not a major factor in the impact estimate because under the proposed approach, a 12-month extension would not have changed the ultimate date that renewing ACOs would be required to transition to performance-based risk under the proposed redesign. For example, for Track 1 ACOs, a 12-month extension for performance year 2019 under Track 1 would result in the Track 1 ACO being eligible to participate in proposed BASIC track Level B during performance year 2020, whereas with a 6-month extension for a performance year from January 1, 2019 through June 30, 2019, under Track 1, would permit the ACO up to 1.5 years under proposed BASIC track Level B, because the ACO would not automatically transition from Level B to Level C at the start of performance year 2020 under the policies included in the proposed rule. In either event, however, the ACO would be required to participate in performance-based risk under Level C, D, or E of the BASIC track by performance year 2021. There were also a number of other competing factors working in different directions, such as the benchmark the ACO participates under, and the availability of Advanced APM incentive payments, which ultimately led to our projection that the 12-month extension would result in somewhat greater savings over 10 years when compared to the modeling of the proposed 6-month extension.

Comment: One commenter expressed confusion over whether the voluntary election for
a 6-month performance year from January 1, 2019 through June 30, 2019, was an option for ACOs within an agreement period (such as an ACO that entered an agreement period on January 1, 2018) as part of the proposed early renewal process.

**Response:** The optional 6-month extension is only available for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement period in the program because their agreements are not expiring. Thus, these ACOs do not require the option of a 6-month extension because their current agreement periods will continue during 2019 and they will not experience a gap in participation as a result of our decision to forgo the application cycle in 2018 for an agreement start date of January 1, 2019.

**Comment:** One commenter suggested that all Track 3 ACOs should be offered an extension of their current agreement period, regardless of the ACO’s agreement period start date.

**Response:** We proposed that the one-time, 6-month extension would only be available to ACOs whose agreement periods expire on December 31, 2018, in order to ensure that these ACOs would be able to continue participation in the Shared Savings Program without any gap. At this time, we decline the commenter’s alternative suggestion that we offer a similar 6-month extension to ACOs whose agreement periods expire in subsequent years. These ACOs would not need a 6-month extension because we anticipate a typical, annual application cycle would be available in future years so that these ACOs could renew their participation agreements and continue their participation in the program without interruption.

**Comment:** Some commenters urged CMS to provide additional guidance and education to ACOs on how ACOs should modify their agreements with their ACO participants for the 2019 performance periods. Several ACOs, with agreement periods expiring on December 31, 2018,
submitted comments describing the burden of executing updated participation agreements with their ACO participants to account for the 6-month extension and the start of a new agreement period under one of the new participation options. These commenters explained that expecting the program would offer an application cycle in CY 2018 for a January 1, 2019 agreement start date, their newly executed ACO participant agreements were structured according to the program’s current policies (under the program’s regulations and, as applicable, the terms of the Track 1+ Model) and do not account for the 6-month extension or modified participation options under the proposed redesign of the program. One commenter expressed concern that the extension would cause some ACO participants to be operating under a different ACO participation agreement, depending on whether they started participating in the ACO prior to January 1, 2019, or after January 1, 2019, resulting in different sets of expectations, for example with respect to the distribution of shared savings. According to one commenter, the time and cost spent on revising agreements with their ACO participants would significantly burden the ACO and its participants, and delay the execution of many initiatives to reduce costs and improve the quality of care as the ACO would spend time executing revised agreements with its ACO participants rather than focusing on other aspects of its operations. One commenter requested that ACOs whose agreement periods expire on December 31, 2018, be given ample time to secure extensions to their agreements with ACO participants for 2019.

Response: To prepare for the extension period, ACOs electing to extend their participation agreement with CMS must update their ACO participant agreements and SNF affiliate agreements, as applicable, before the beginning of the next performance year to reflect the extension of their current agreement period. As part of the annual certification process in advance of 2019, ACOs electing the 6-month extension will be required to certify that they have
notified their ACO participants and SNF affiliates, if applicable, of their continued participation in the Shared Savings Program in 2019, and that their ACO participant agreements and SNF affiliate agreements, if applicable, have been updated. However, ACOs will not be required to submit ACO participant agreement or SNF affiliate agreement extensions to CMS.

ACOs electing the extension would need to extend all current ACO participant and/or SNF affiliate agreements on or before December 31, 2018, so that entities will continue to be ACO participants or SNF affiliates, as applicable, for the performance year beginning on January 1, 2019. Additionally, the ACO will need to execute ACO participant agreements with any new ACO participants to be added to its ACO participant list effective January 1, 2019. We also note that these ACOs would have been required to revise their ACO participant and SNF affiliate agreements, as applicable, if they had been renewing their participation agreements for a new agreement period beginning January 1, 2019. We also note that we now allow ACOs, ACO participants and SNF affiliates to digitally sign their agreements, which should help to reduce any burden associated with extending agreements. We believe that the timing of the issuance of this final rule will permit sufficient time for ACOs electing to extend their participation agreements to take the necessary steps to extend their ACO participant and SNF affiliate agreements, as applicable, before the start of the 6-month performance year beginning January 1, 2019.

In response to the commenter’s concern that the extension would cause some ACO participants to be operating under different sets of expectations (depending on whether they started participating in the ACO prior to January 1, 2019 or after January 1, 2019), we note that for ACOs that elect the 6-month extension, the payment methodology under the ACO’s current track would be applicable to determining the ACO’s shared savings or shared losses, if
applicable, for the 6-month performance year from January 1, 2019 through June 30, 2019. This is the same payment methodology that has applied to the ACO for the duration of its agreement period, beginning on January 1, 2016.

Further, we note that with the exception of the requirements specified at §425.116, the ACO and its ACO participants have significant flexibility to determine the contractual terms that would apply with respect to all ACO participant agreements, including with respect to the use/distribution of shared savings (and payment of shared losses).

Comment: One commenter explained that current and prospective ACOs and their leaders are evaluating their options with respect to not only the Shared Savings Program start date, but also to participation in other potential models such as the Direct Provider Contracting (DPC) models anticipated to be tested by CMS’ Innovation Center. The commenter urged CMS to take the whole payment model landscape into account and to take any measures necessary to maximize the level of certainty for healthcare providers and to incentivize participation in higher-risk models over lower-risk models. For example, the commenter recommended that participants in the Shared Savings Program or current Innovation Center models should not be excluded from switching to a DPC model if and when such a model becomes available, regardless of where they are in their current agreement period or the lifecycle of their current model.

Response: We work to align and otherwise create synergies between the Shared Savings Program and the payment and service delivery models tested by the Innovation Center. We have policies in place to take into account overlap between the Shared Savings Program and Innovation Center models, which are designed to test new payment and service delivery models for the purpose of innovating in the areas of healthcare delivery and shared accountability for
quality and financial performance, whenever possible. We continue to monitor these policies and make refinements as we gain experience and lessons learned from these interactions. When new models are announced, we encourage ACOs and their leaders to engage in dialogue with the Innovation Center and Shared Savings Program staff to inform their decision-making regarding the participation options.

After considering the comments received, we are finalizing our proposal to allow ACOs that entered a first or second agreement period beginning on January 1, 2016, to voluntarily elect a 6-month extension of their current agreement period for a fourth performance year from January 1, 2019 through June 30, 2019. For the reasons discussed, we believe this extension is necessary in order to avoid an involuntary gap in participation and to provide ACOs with an opportunity to prepare for a more rapid transition to the proposed new participation options, including new Advanced APMs that would allow eligible clinicians participating in these ACOs to qualify for incentive payments under the Quality Payment Program.

We received no comments on the proposed modifications to the definitions of “agreement period” and “performance year” in §425.20 or to the regulation at §425.200 to establish the 6-month extension and to make certain technical and conforming changes. We are finalizing as proposed the modifications to the definition of “agreement period” in §425.20 to broaden the definition to generally refer to the term of the participation agreement and the revisions to §425.200(a) to allow for agreement periods greater than 3 years. We are also finalizing our proposal to add a provision at §425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and
certified by an ACO executive who has the authority to legally bind the ACO. For consistency, we are also finalizing as proposed the minor formatting changes to the existing provisions at §425.200(b)(2) and (b)(3) to italicize the header text.

We are also finalizing as proposed the revision to the definition of “performance year” in §425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in §425.200(c) or noted in the participation agreement. Therefore, we are also finalizing the proposed revisions to §425.200(c) to make necessary formatting changes and specify an additional exception to the definition of performance year as a 12-month period. Specifically, we are finalizing our proposal to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

In light of the modifications we are finalizing to §425.200(c) to establish a 6-month performance year during CY 2019, we are also finalizing the proposed revisions to the regulation at §425.200(d), which reiterates an ACO’s obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. As described elsewhere in this final rule, ACOs electing the voluntary 6-month extension will be required to report quality measures for the 2019 reporting period, based on CY 2019, consistent with the existing quality reporting process and methodology.
b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year from January 1, 2019 through June 30, 2019

(1) Background and Description of Methodology

Under our proposed approach to determining performance for the 6-month performance year from January 1, 2019 through June 30, 2019, after the conclusion of CY 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the Shared Savings Program during 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO’s participation for only half of the calendar year. In the August 2018 proposed rule, we explained this approach would avoid a more burdensome interim payment process that could accompany an alternative proposal to instead implement, for example, an 18-month performance year. Consistent with the 18- and 21-month performance years offered for the first cohorts of Shared Savings Program ACOs, such a policy could require ACOs to establish a repayment mechanism that otherwise might not be required, create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year, and delay ACOs seeing a return on their investment in program participation if eligible for shared savings.

We explained our belief that the proposed approach would allow continuity in program operations, including operations that occur on a calendar year basis. Specifically, the proposed approach would allow payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional
adjustments. We explained that deviating from a 12-month reconciliation calculation by using fewer than 12 months of performance year expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12-month benchmark years. As a result, we believed the proposed approach of reconciling ACOs based on a 12-month period would protect the actuarial soundness of the financial reconciliation methodology. We also explained our belief that the alignment of the proposed approach with the standard methodology used to perform the same calculations for 12-month performance years that correspond to a calendar year would make it easier for ACOs and other program stakeholders to understand the proposed methodology.

As is the case with typical calendar year reconciliations in the Shared Savings Program, we anticipated results with respect to participation during CY 2019 would be made available to ACOs in summer 2020. We explained that this would allow those ACOs that are eligible to share in savings as a result of their participation in the program during CY 2019 to receive payment of shared savings following the conclusion of the calendar year consistent with the standard process and timing for annual payment reconciliation under the program.

In section II.A.7.b.2 of the August 2018 proposed rule (83 FR 41851 through 41853), we described in detail our proposed approach to determining an ACO’s performance for the 6-month performance year from January 1, 2019 through June 30, 2019. We also proposed that these policies would apply to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). Our proposed policies addressed the following: (1) the ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality
reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO’s historical benchmark; and (5) the methodology for determining shared savings and shared losses. We proposed to specify these policies for reconciling the 6-month period from January 1, 2019 through June 30, 2019, in paragraph (b) of a new section of the regulations at §425.609.

We proposed to use the ACO participant list for the performance year beginning January 1, 2019, to determine beneficiary assignment as specified in §§425.402 and 425.404, and according to the ACO’s track as specified in §425.400. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41855 through 41856), we proposed to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019. Related considerations are discussed in section V.B.1.c.(2) of this final rule.

To determine beneficiary assignment, we proposed to consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019.

- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year we
could use an assignment window from October 1, 2017 through September 30, 2018, to align
with the off-set assignment window typically used to determine prospective assignment prior to
the start of a calendar year performance year. Beneficiaries would remain prospectively assigned
to the ACO at the end of CY 2019 unless they meet any of the exclusion criteria under
§425.401(b) during the calendar year.

As discussed in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), to
determine ACO performance during a 6-month performance year, we proposed to use the ACO’s
quality performance for the 2019 reporting period, and to calculate the ACO’s quality
performance score as provided in §425.502. We also proposed to use a different quality measure
sampling methodology depending on whether an ACO participates in both a 6-month
performance year (or performance period) beginning on January 1, 2019, and a 6-month
performance year beginning on July 1, 2019, or only participates in a 6-month performance year
from January 1, 2019 through June 30, 2019. As described in section V.B.1.c.(4) of this final
rule, given the limited scope of this final rule, at this time, we are finalizing only our proposal to
use the ACO’s latest certified participant list (the ACO participant list effective on January 1,
2019) to determine the quality reporting samples for the 2019 reporting period for ACOs that
extend their prior participation agreement for the 6-month performance year from January 1,
2019 to June 30, 2019.

Consistent with current program policy, we proposed to determine assignment for the
benchmark years based on the most recent certified ACO participant list for the ACO effective
for the performance year beginning January 1, 2019. This would be the participant list the ACO
certified prior to the start of its agreement period unless the ACO has made changes to its ACO
participant list during its agreement period as provided in §425.118(b). If the ACO has made
subsequent changes to its ACO participant list, we would adjust its historical benchmark to reflect the most recent certified ACO participant list. See the Medicare Shared Savings Program, ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf.

For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the benchmark and calculate performance year expenditures for assigned beneficiaries as though the performance year were the entire calendar year. The ACO’s historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We would apply the methodology for establishing, updating and adjusting the ACO’s historical benchmark as specified in §425.602 (for ACOs in a first agreement period) or §425.603 (for ACOs in a second agreement period), except that data from CY 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

- The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

- The benchmark would be updated to CY 2019 according to the methodology for using growth in national Medicare FFS expenditures for assignable beneficiaries described under §§425.602(b) (for ACOs in a first agreement period) and 425.603(b) (for ACOs in a second agreement period beginning January 1, 2016).
For determining financial performance during the 6-month performance year from January 1, 2019 through June 30, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO’s track under the terms of the participation agreement that was in effect on January 1, 2019: §425.604 (Track 1), §425.606 (Track 2) or §425.610 (Track 3) and, if applicable, the terms of the ACO’s participation agreement for the Track 1+ Model authorized under section 1115A of the Act. (See discussion in section II.F. of the August 2018 proposed rule (83 FR 41912 through 41914) concerning applicability of proposed policies to Track 1+ Model ACOs.) However, some exceptions to the otherwise applicable methodology were needed because we proposed to calculate the expenditures for assigned beneficiaries over the full CY 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019. We proposed to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for CY 2019 would be calculated for the ACO’s performance year assigned beneficiary population.
- We would compare these expenditures to the ACO’s updated benchmark determined for the calendar year as previously described.
- We would apply the MSR and MLR (as applicable).

++ The ACO’s assigned beneficiary population for the performance year starting on January 1, 2019, would be used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO’s performance year assigned population is below 5,000
beneficiaries, we proposed that the MSR/MLR would be determined based on the number of
assigned beneficiaries as described in section II.A.6.b. of the August 2018 proposed rule (83 FR
41837 through 41839).

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures
for its performance year assigned beneficiaries during CY 2019 must be below its updated
benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average
per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019
must be above its updated benchmark for the year by at least the MLR established for the ACO.

- We would determine the shared savings amount if we determine the ACO met or
exceeded the MSR, and if the ACO met the minimum quality performance standards established
under §425.502 as described in the August 2018 proposed rule and section V.B.1.c.(4) of this
final rule, and otherwise maintained its eligibility to participate in the Shared Savings Program.
We would determine the shared losses amount if we determine the ACO met or exceeded the
MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or
losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply
the difference between the updated benchmark expenditures and performance year assigned
beneficiary expenditures by the applicable final sharing rate based on the ACO’s track and its
quality performance as calculated under §425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply
the difference between the updated benchmark expenditures and performance year assigned
beneficiary expenditures by the applicable shared loss rate based on the ACO’s track and its quality performance as calculated under §425.502 (for ACOs in tracks where the loss sharing rate is determined based on the ACO’s quality performance).

- We would adjust the shared savings amount, if any, for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO’s track.

- We would compare the shared losses amount, if any, to the applicable loss sharing limit based on the ACO’s track.

- We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year or the final amount of shared losses that would be owed by the ACO for the 6-month performance year.

We sought comment on these proposals.

Comment: In general, some commenters supported CMS’ proposed policies governing how shared savings and shared losses would be calculated for the 6-month performance year from January 1, 2019 through June 30, 2019. Some commenters noted there is significant complexity with this approach and urged CMS to clarify and provide additional guidance and education to ACOs concerning how certain operational details will be addressed. Commenters raised concerns about certain aspects of the methodology for determining quality and financial performance for a 6-month performance year under the proposed approach, and other aspects of program participation affected by a 6-month performance year, which we summarize elsewhere.
within section V.B.1.b. and V.B.1.c. of this final rule, including (but not limited to) the approach to determining beneficiary assignment, flexibilities for making ACO participant list changes, quality reporting considerations, and interactions with the Quality Payment Program policies.

Response: We appreciate commenters’ support for the proposed approach for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As discussed in the August 2018 proposed rule, we continue to believe in the importance of using this approach to maintain alignment with program calculations made on a 12-month basis. This approach maintains alignment with the program’s existing methodology by using 12 months of expenditure data (for CY 2019) in determining the ACO’s financial performance and a 12-month period for quality measure assessment. In sections V.B.1.b. and V.B.1.c. of this final rule we respond to comments on the specific aspects of the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, and other aspects of program participation affected by a 6-month performance year. We acknowledge that this approach will add complexity to program policies and certain operational processes. To assist ACOs in understanding the operational details of participation in a 6-month performance year from January 1, 2019 through June 30, 2019, we anticipate providing education and offering outreach to ACOs on these policies through the various methods available, including guidance documents, webinars, FAQs and a weekly newsletter.

Comment: A few commenters expressed support for the proposed approach to determining beneficiary assignment for the 6-month performance year from January 1, 2019 through June 30, 2019.

Response: In finalizing the 6-month agreement period extension for ACOs that started a
first or second agreement period on January 1, 2016, we believe it is appropriate to finalize our proposed approach to determining beneficiary assignment for the performance year from January 1, 2019 through June 30, 2019. To determine beneficiary assignment for the 6-month performance year, we proposed to consider the allowed charges for primary care services furnished to beneficiaries during a 12-month assignment window, allowing for a 3-month claims run out. For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019. For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on beneficiaries’ use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year, we could use an assignment window from October 1, 2017 through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO for the performance year unless they meet any of the exclusion criteria under §425.401(b) during the calendar year. This approach would maintain alignment with our methodology for assigning beneficiaries to ACOs participating in a 12-month performance year, and allow us to use the same methodology to determine beneficiary assignment for all ACOs participating in a performance year beginning January 1, 2019. This approach would also be consistent with the methodology used to assign beneficiaries for the historical benchmark period.

Comment: One commenter noted that the proposal to pro-rate shared savings and shared losses to reflect the 6-month period of participation from January 1, 2019 through June 30, 2019, fails to account for habitual behavior of Medicare beneficiaries. The commenter explained that
most annual wellness visits are performed in the 3rd and 4th quarters of the calendar year, and quarter 1 and quarter 2 of the calendar year typically show lower healthcare utilization. According to the commenter, Medicare beneficiaries tend to wait to visit the doctor until their deductible is met, which usually occurs towards the end of the calendar year. The commenter indicated that this delay occurs even for preventive services, like annual wellness visits, that are free at the point of delivery. The commenter also seems to have an incorrect understanding that we are using only quarter 1 and quarter 2 data to determine financial performance for the 6-month performance year from January 1, 2019 through June 30, 2019, suggesting that an approach that only accounts for 6 months of expenditures would result in quality and financial performance determinations that do not fairly reflect the ACO’s quality of care and expenditures for assigned beneficiaries. Another commenter explained that Medicare expenditures demonstrate strong and well-known seasonality which would skew performance results when comparing performance from the first 6 months of the calendar year against a pro-rated benchmark which represents an annual average.

Response: Under the proposed approach to determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, as restated in this section of this final rule, we would continue to determine beneficiary assignment and expenditures on a 12-month basis. To determine beneficiary assignment, we would consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3-month claims run out. We would maintain the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, and risk adjustment. To determine shared savings and shared losses, we would calculate average per capita Medicare expenditures for Parts A and B services for CY 2019 for the ACO’s
performance year assigned beneficiary population and compare this amount to the updated historical benchmark. We would then pro-rate any shared savings or shared losses by multiplying the amounts by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. We believe this approach addresses the commenters’ concerns, because we would capture assigned beneficiaries’ expenditures for the entire CY 2019, which we would compare to a benchmark also based on 12 months of expenditures to maintain consistency and avoid any seasonality or other variation in expenditures that could result from the use of different timeframes. We continue to believe that this approach to reconciling ACOs for the 6-month performance year from January 1, 2019 through June 30, 2019, based on expenditures for the 12-month period corresponding to CY 2019 would protect the actuarial soundness of the financial reconciliation methodology.

Comment: A few commenters urged CMS to apply the regional benchmarking methodology in determining the historical benchmark for ACOs that first entered the program in 2013 or 2016 that elect a 6-month extension. One commenter stated that under the program’s current policies, the regional rebasing methodology would apply to ACOs that renew for a second or third agreement period beginning January 1, 2019. This commenter also pointed to CMS’ proposal in the August 2018 proposed rule to incorporate regional expenditures in benchmark calculations beginning with an ACO’s first agreement period for agreement periods beginning on July 1, 2019, and in subsequent years to underscore the urgency for ACOs that may be entering their seventh performance year of program participation without any regional adjustment to be under a benchmarking approach that could help to sustain their accountable care programs and allow them to drive further cost reductions. Several other commenters suggested that CMS rebase the historical benchmark for ACOs electing the extension from January 1, 2019
through June 30, 2019, so that the ACO’s historical benchmark years would be 2016, 2017, and 2018 (as opposed to 2013, 2014, and 2015 under the ACO’s current agreement period), using a regional rebasing methodology. One commenter explained that rebasing these ACOs’ benchmarks using regional factors would remove the drawback related to a delay in agreement period renewal for the organizations on the leading edge of the Shared Savings Program. This commenter also explained that benchmark rebasing would account for non-claims based payments during 2016, 2017, 2018 in the ACO’s historical benchmark, and would eliminate the delay in aligning the benchmark with the full range of services included in calculating performance year expenditures.

Response: We appreciate the comments, but we decline to accept the commenters’ suggestions to reset the benchmark for ACOs electing the 6-month extension to their current agreement period. As proposed, the 6-month extension allows for continued participation under the ACO’s current agreement period, which would not meet the conditions for applying the program’s methodology for rebasing the ACO’s historical benchmark under §425.603(a). Accordingly, we would continue to update and adjust the benchmarks for ACOs electing this extension using the methodology specified under §§425.602 and 425.603(b), as applicable. We also note that for ACOs with second agreement periods beginning on January 1, 2016, that elect the voluntary 6-month extension, the benchmark rebasing methodology that was used to determine their benchmark for their second agreement period accounts for a portion of the savings they generated in their prior agreement period as an adjustment to their historical benchmark. This adjustment coupled with the additional time they will be allowed to participate under their existing historical benchmark should continue to provide a strong incentive during the extension period.
In the August 2018 proposed rule (83 FR 41851), we explained our belief that the proposal to determine shared savings and shared losses for the 6-month performance year starting on January 1, 2019, using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year, requires the use of our authority under section 1899(i)(3) of the Act to use other payment models. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. We explained our belief that the proposed approach to calculating the expenditures for assigned beneficiaries over the full calendar year, comparing this amount to the updated benchmark for 2019, and then pro-rating any shared savings (or shared losses, which already are implemented using our authority under section 1899(i)(3) of the Act) for the 6-month performance year involves an adjustment to the estimated average per capita Medicare Part A and Part B FFS expenditures determined under section 1899(d)(1)(B)(i) of the Act that is not based on beneficiary characteristics. Such an adjustment is not contemplated under the plain language of section 1899(d)(1)(B)(i) of the Act. As a result, we stated it would be necessary to use our authority under section 1899(i)(3) of the Act to calculate performance year expenditures and determine the final amount of any shared savings (or shared losses) for a 6-month performance year during 2019, in the proposed manner.

In order to use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to calculate shared savings and shared losses for the proposed 6-month
performance year from January 1, 2019 through June 30, 2019, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We explained our belief that the proposed approach of allowing ACOs that started a first or second agreement period on January 1, 2016, to extend their agreement period for a 6-month performance year and of allowing entry into the program’s redesigned participation options beginning on July 1, 2019, if finalized, would support continued participation by current ACOs that must renew their agreements to continue participating in the program, while also resulting in more rapid progression to two-sided risk by ACOs within current agreement periods and ACOs entering the program for an initial agreement period. As discussed in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41915 through 41928), we explained our belief that this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we did not believe that the proposed methodology for determining shared savings or shared losses for ACOs in a 6-month performance year during 2019 would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we noted that the proposed approach to measuring ACO quality performance for a 6-month performance year based on quality data reported for CY 2019 would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would also have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they may be required to pay in tracks where the loss sharing rate is determined based on the ACO’s quality performance. Therefore, we noted our expectation that this proposed approach to reconciling ACOs for a 6-month performance year
during 2019 would continue to lead to improvement in the quality of care furnished to Medicare
FFS beneficiaries.

As discussed in the Regulatory Impact Analysis section of this final rule (section VII.),
we believe the approach to determining shared savings and shared losses for the 6-month
performance year from January 1, 2019 through June 30, 2019, for ACOs that elect to voluntarily
extend their agreement period meets the requirements for use of our authority under section
1899(i)(3) of the Act. The considerations we described in the August 2018 proposed rule were
relevant in making this determination. Specifically, we do not believe that the methodology for
determining shared savings or shared losses for ACOs in a 6-month performance year from
January 1, 2019 through June 30, 2019, (as finalized in this section) will result in an increase in
spending beyond the expenditures that would otherwise occur under the statutory payment
methodology in section 1899(d) of the Act. Finalizing the voluntary 6-month extension for
ACOs whose agreement periods expire on December 31, 2018, will support continued
participation by these ACOs, and therefore, also allow for lower growth in Medicare FFS
expenditures based on projected participation trends. Further, we believe the approach we are
finalizing for reconciling ACOs for a 6-month performance year from January 1, 2019 through
June 30, 2019, will lead to continued improvement in the quality of care furnished to Medicare
FFS beneficiaries. As described in section V.B.1.c.(4) of this final rule, the approach to
measuring ACO quality performance for the 6-month performance year from January 1, 2019
through June 30, 2019, based on quality data reported for CY 2019, will maintain accountability
for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs will
have an incentive to perform well on the quality measures in order to maximize the shared
savings they may receive and minimize any shared losses they may be required to pay in two-
sided risk tracks where the loss sharing rate is determined based on the ACO’s quality performance.

(3) Final Policies

After consideration of the public comments received, we are finalizing, with modifications, the proposed approach to determine financial and quality performance for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, as specified in paragraphs (a) and (b) of a new section of the regulations at §425.609. These modifications are necessary because this final rule only addresses the 6-month extension period, and does not address our proposal to establish a July 1, 2019 agreement start date. In summary, we will do the following to determine an ACO’s financial and quality performance during the 6-month performance year from January 1, 2019 through June 30, 2019: we will compare the ACO’s historical benchmark updated to CY 2019 to the expenditures during CY 2019 for the ACO’s performance year assigned beneficiaries. If the difference is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO will be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO will be liable for shared losses. ACOs will share in first dollar savings and losses. The amount of any shared savings will be determined using the applicable final sharing rate, which is determined based on the ACO’s track for the applicable agreement period, and taking into account the ACO’s quality performance for 2019. We will adjust the amount of shared savings for sequestration, and then cap the amount of shared savings at the applicable performance payment limit for the ACO’s track. Similarly, the amount of any shared losses will be determined using the loss sharing rate for the ACO’s track and, as
applicable, for ACOs in tracks with a loss sharing rate that depends upon quality performance, the ACO’s quality performance for 2019. We will then cap the amount of shared losses at the applicable loss sharing limit for the ACO’s track. We will then pro-rate any shared savings or shared losses by multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount will be the final amount of shared savings earned or shared losses owed by the ACO for the 6-month performance year.

Because we are not addressing the proposed July 1, 2019 agreement period start date for the proposed new BASIC track and ENHANCED track at this time, we note the following differences between our proposed approach (which contemplated that ACOs may be participating in both a 6-month performance year from January 1, 2019 through June 30, 2019, and a 6-month performance year from July 1, 2019 through December 31, 2019) and our final policies (which are limited to the 6-month performance year from January 1, 2019 through June 30, 2019, for eligible ACOs that elect to extend their agreement period, which would otherwise expire on December 31, 2018):

- We are omitting references that we proposed to include in §425.609(b) in order to establish the applicability of these policies to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). We are also making clarifying revisions to the introductory text in §425.609(b).

- As described in section V.B.1.c.(4) of this final rule we are finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30,
2019. We are finalizing our proposal to use the ACO’s latest certified ACO participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period.

- We are not addressing at this time the proposals for modifying the MSR/MLR to address small population sizes (83 FR 41837 through 41839). Therefore, the policies for determining shared savings and shared losses in the event the ACO’s assigned population falls below 5,000, as specified under the program’s current regulations at §425.110, would apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Therefore, we will specify in §425.609(b)(3)(ii)(C)(1) that the ACO’s performance year assigned beneficiary population is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO’s agreement period, this fixed MSR/MLR is applied. In the event an ACO’s performance year assigned population identified in §425.609(b)(1) is below 5,000 beneficiaries, the MSR/MLR is determined according to §425.110(b).

- We are also reserving paragraph (c) of §425.609 in the event that we finalize policies for a second 6-month performance year during CY 2019 in the future.

In section V.B.1.c. of this final rule, we discuss our decision to finalize other provisions from the August 2018 proposed rule related to determining performance for the 6-month performance year, as specified in paragraphs (d) and (e) of §425.609.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year

In the August 2018 proposed rule (83 FR 41854), we proposed that program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO’s chosen participation
track and based on the ACO’s agreement start date would be applicable to an ACO participating in a 6-month performance year, unless otherwise stated. We received no comments on this general proposal and we are finalizing this general approach as proposed. As we explained in the August 2018 proposed rule, this approach will allow routine program operations to continue to apply for ACOs participating under a shorter performance year. Further, it will ensure consistency in the applicability and implementation of our requirements across all program participants, including ACOs participating in a 6-month performance year.

In section V.B.1.b. of this final rule, we describe limited exceptions to our general policies for determining financial and quality performance which are necessary to ensure calculations can continue to be performed on a calendar year basis and using the most relevant data.

In this section, we describe program participation options affected by our decision to forgo an application cycle in CY 2018 for a January 1, 2019 start date, and offer a voluntary extension to allow ACOs whose agreement periods expire on December 31, 2018, to continue their participation in the program for a 6-month performance year from January 1, 2019 through June 30, 2019. We discuss modifications to program policies to allow for the 6-month performance year and related revisions to the program’s regulations. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41854 through 41860), these proposals were developed, in part, based on our proposal to offer an application cycle in CY 2019 for a July 1, 2019 start date. Therefore, we considered that some ACOs would participate in the program for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019, while other ACOs would only participate in one of these performance years. In this final rule, we
do not address the considerations related to the proposed July 1, 2019 agreement period start date because we are not addressing the proposal to offer that start date at this time.

(1) Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

Eligible ACOs may apply for use of a SNF 3-day rule waiver at the time of application for an initial agreement or to renew their participation. Further, as described in sections II.B.2.a. and II.F. of the August 2018 proposed rule (83 FR 41860, 41912), ACOs within a current agreement period under Track 3, or the Track 1+ Model may apply for a SNF 3-day rule waiver, which, if approved, would begin at the start of their next performance year.

In light of our decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement period start date, we are also not offering an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. Absent further rulemaking to establish participation options for a start date in 2019 that includes an opportunity for ACOs within existing agreement periods in Track 3 or the Track 1+ Model to apply for a SNF 3-day rule waiver, these ACOs would not have the opportunity to apply to begin use of the waiver until January 1, 2020.

(2) Annual Certifications and ACO Participant List Modifications

At the end of each performance year, ACOs complete an annual certification process. At the same time as this annual certification process, CMS also requires ACOs to review, certify and electronically sign official program documents to support the ACO’s participation for the upcoming performance year. As we stated in the August 2018 proposed rule (83 FR 41855), requirements for this annual certification, and other certifications that occur on an annual basis,
continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019.

Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with §425.118(a). A request to add ACO participants must be submitted prior to the start of the performance year in which these additions would become effective. An ACO must notify CMS no later than 30 days after termination of an ACO participant agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO’s quality reporting samples and financial performance. See §425.118(b)(3) and see also Medicare Shared Savings Program ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco-participant-list-agreement.pdf. As we explained in the August 2018 proposed rule (83 FR 41855), these policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

As we explained in the August 2018 proposed rule (83 FR 41855), ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, would have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, to June 30, 2019. To prepare for the possible implementation of this 6-month performance year, we allowed ACOs that started a first or second agreement period on
January 1, 2016, to submit change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists, and if applicable, SNF affiliate lists.

The program’s current regulations prevent duplication of shared savings payments; thus, under §425.114, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative that involves shared savings. In addition, under §425.306(b)(2), each ACO participant that submits claims for services used to determine the ACO's assigned population must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims run out for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment, then CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year; and the ACO may be subject to the pre-termination actions set forth in §425.216, termination under §425.218, or both.

Comment: Some commenters urged CMS to provide ACOs with opportunities to add and delete ACO participants throughout the performance years (or performance periods) during 2019 and to clarify when such opportunities would be available. These commenters urged CMS to provide additional guidance and education to ACOs on when participant list changes would be permitted. One commenter suggested that CMS should provide an additional opportunity for ACOs with agreement periods expiring on December 31, 2018, to add ACO participants and/or SNF affiliate TINs and CCNs for performance year 2019 because of the short period of time between the issuance of the proposed rule (August 9, 2018) and the final deadline for adding ACO participants for performance year 2019 (September 28, 2018). The commenter explained
that the proposed rule caused confusion and uncertainty, and as a result, the commenter believes many ACO participants missed the deadline to be added to the ACO participant lists of other ACOs. The commenter suggested that we should offer an additional opportunity to add ACO participants, with the deadline set for 1 month after publication of a final rule.

Response: During 2018, we allowed ACOs that started a first or second agreement period on January 1, 2016, to submit ACO participant change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists and, if applicable, SNF affiliate lists. We noted that the final disposition of any change request submitted by an ACO that started a first or second agreement period on January 1, 2016, would be contingent upon issuance of a final rule establishing an opportunity for these ACOs to continue their participation during 2019 without a gap in participation. As discussed in section V.B.1. of this final rule, we are finalizing the proposed 6-month extension for ACOs whose current participation agreement expire on December 31, 2018.

As a result, all ACOs, including those ACOs that will be eligible to elect the voluntary 6-month extension that we are finalizing this final rule, had multiple opportunities to submit change requests to add ACO participants and/or SNF affiliates for performance years starting on January 1, 2019. We also launched a new ACO management system during 2018 that is more user friendly, provides faster feedback, and encourages ACOs to submit change requests to add ACO participants and SNF affiliates with fewer errors than the system that was available in previous years. We do not believe it is operationally feasible to extend the date for ACOs to submit change requests after September 28, 2018, the date we communicated to ACOs as being the deadline to add ACO participants to be effective for performance years beginning on January 1, 2019. Allowing change requests seeking to add new ACO participants to be submitted very
close to the end of the calendar year would not provide sufficient time to review and screen providers/suppliers for program integrity issues and create 2019 assignment list reports, and may have other operational impacts (such as on timely production of certain other program reports). We note, however, ACO participants can be terminated and deleted from the ACO participant list at any time during a performance year. The ACO participant is no longer an ACO participant as of the termination effective date of the ACO participant agreement. Absent unusual circumstances, however, the ACO participant data will continue to be utilized for certain operational purposes.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO’s participation in a two-sided model and for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate the amount of shared losses owed and to collect this amount from the ACO (§425.204(f)(4)). We noted in our “Repayment Mechanism Arrangements” guidance document that we would consider this standard to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. See Medicare Shared Savings Program & Medicare ACO Track 1+ Model, Repayment Mechanism Arrangements, Guidance Document (July 2017, version #6), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf (herein Repayment Mechanism Arrangements Guidance).

In the August 2018 proposed rule (83 FR 41856), we noted that ACOs that started a first or second agreement period on January 1, 2016, in a two-sided model would have in place under
current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018, plus a 24-month tail period until December 31, 2020. We would expect an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, to likewise extend the term of its repayment mechanism so that it will be in effect for the duration of the ACO’s participation in a two-sided model plus 24 months following the conclusion of the agreement period (that is, until June 30, 2021). This would allow us sufficient time to perform financial calculations for the 6-month performance year from January 1, 2019 through June 30, 2019, and to use the arrangement to collect shared losses for that performance year, if necessary.

In a forthcoming final rule, we expect to summarize and respond to comments on our proposed changes to §425.204(f) regarding repayment mechanism requirements for ACOs that are in a two-sided model.

Comment: One commenter expressed concern over the lack of current guidance on the required amount of a repayment mechanism arrangement (particularly for Track 1+ Model ACOs) and on how to execute changes to an existing repayment mechanism arrangement in order to support an ACO’s participation during the 6-month performance year from January 1, 2019 through June 30, 2019. The commenter also indicated that changing repayment mechanism amounts mid-year would likely result in extra costs to an ACO.

Response: We appreciate the commenter’s concern. We may require a Track 1+ Model ACO to adjust its repayment mechanism amount if, during the ACO’s agreement period, changes in the ACO’s participant composition occur that result in the application of a relatively higher or lower loss sharing limit. For example, if a Track 1+ Model ACO reports changes to its
composition during the annual certification process in advance of the next performance year, and we determine that the ACO no longer qualifies for a revenue-based loss sharing limit, we may require the ACO to demonstrate that its repayment mechanism is sufficient to support losses for a higher amount under a benchmark-based loss sharing limit (83 FR 41841). We will notify an ACO if there is a significant change in its repayment mechanism amount warranting modification of its repayment mechanism arrangement and will specify the process for submitting to us revised repayment mechanism arrangement documentation for review. With regard to ACOs participating under Track 2 or Track 3, we clarify that, for the 6-month performance year from January 1, 2019 through June 30, 2019, we will not require any such ACO that elects to extend its participation agreement for such performance year to modify the amount we previously approved for the ACO’s repayment mechanism arrangement.

In addition, we have notified ACOs participating under a two-sided model that if they elect the 6-month extension from January 1, 2019 through June 30, 2019 then we expect that they will extend their repayment mechanisms in accordance with §425.204(f)(4). As we noted in our Repayment Mechanism Arrangements Guidance, we would consider §425.204(f)(4) to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. Accordingly, an ACO participating under a two-sided model that elects the 6-month extension from January 1, 2019 through June 30, 2019, should extend the term of its repayment mechanism until June 30, 2021.

We acknowledge that amending certain repayment mechanism arrangements could come at additional costs to ACOs. However, we believe it necessary that the repayment mechanism arrangements comply with Shared Savings Program and Track 1+ Model policy to ensure the ACO can repay losses for which it may be liable.
(4) Quality Reporting and Quality Measure Sampling

As described in the August 2018 proposed rule (83 FR 41856 through 41858), to determine an ACO’s quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to use the ACO’s quality performance for the 2019 reporting period as determined under §425.502. Under this proposed approach, we would account for the ACO’s quality performance using quality measure data reported for the 12-month CY 2019.

As we explained in the August 2018 proposed rule, the following considerations support this proposed approach. For one, use of a 12-month period for quality measure assessment maintains alignment with the program’s existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO’s financial performance. Also, this approach would continue to align the program’s quality reporting period with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019. Second, the measure specifications for the quality measures used under the program require 12 months of data. See for example, the Shared Savings Program ACO 2018 Quality Measures Narrative Specification Document (January 20, 2018), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf.

Third, in light of our proposal to use 12 months of expenditures (based on CY 2019) in determining shared savings and shared losses for a 6-month performance year, it would also be appropriate to hold ACOs accountable for the quality of the care furnished to their assigned
beneficiaries during this same timeframe. Fourth, and lastly, using an annual quality reporting cycle for the 6-month performance year would avoid the need to introduce new reporting requirements, and therefore, potential additional burden on ACOs.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. Beneficiary assignment is performed using the applicable assignment methodology under §425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under §425.401(b), as applicable. The samples for claims-based measures are typically determined based on the assignment list for calendar year quarter 4. The sample for quality measures reported through the CMS Web Interface is typically determined based on the beneficiary assignment list for calendar year quarter 3. The CAHPS for ACOs survey sample is typically determined based on the beneficiary assignment list for calendar year quarter 2.

For purposes of determining the quality reporting samples for the 2019 reporting period, we proposed to use the ACO’s most recent certified ACO participant list available at the time the quality reporting samples are generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year. We explained our belief that the use of the ACO’s most recent certified ACO participant list to assign beneficiaries according to the assignment methodology applicable based on the ACO’s most recent participation in the program during 2019 would result in the most relevant beneficiary samples for 2019 quality reporting. Additionally, we believed this proposed approach to determining the ACO’s quality reporting samples was also appropriate for an ACO that participated in only one 6-month performance year during 2019 because the most recent certified ACO participant list applicable for the performance year would also be the certified ACO participant list that is used to
determine financial performance.

We proposed two approaches to determine the certified ACO participant list, assignment methodology, and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. One approach was applicable to ACOs that enter a new agreement period under the proposed July 1, 2019 agreement start date, including ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, to June 30, 2019. For ACOs that enter a new agreement period beginning on July 1, 2019, we proposed to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period. This most recent certified ACO participant list would therefore be used to determine the quality reporting samples for the 2019 reporting year. A second approach was proposed for an ACO that extends its participation for the first 6 months of 2019, but does not enter a new agreement period beginning on the proposed July 1, 2019 agreement start date. This second approach is relevant to the policies we are finalizing in this final rule, for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs whose current participation agreements expire on December 31, 2018, and that voluntarily elect to extend their agreement period for a fourth performance year. Under this approach, we proposed to use the ACO’s latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019 through June 30, 2019, under §425.400, either preliminary prospective assignment or prospective assignment, with excluded
beneficiaries removed under §425.401(b), as applicable. We anticipated that the assignment windows for the quality reporting samples would be as follows, based on our operational experience: (1) samples for claims-based measures would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS Web Interface measures would be determined based on the assignment list for calendar year quarter 3; and (3) the sample for the CAHPS for ACOs survey would be determined based on the assignment list for calendar year quarter 2. We noted that this approach would maintain alignment with the assignment windows currently used for establishing quality reporting samples for these measures.

We proposed to specify the certified ACO participant list that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, in a new section of the regulations at §425.609(b).

Comment: Some commenters requested clarification about how quality reporting will take place for 6-month performance periods based on 12 months of data. Specifically, these commenters stated their assumption that all ACOs would only be responsible for reporting quality one time, during the typical January to March timeframe following the end of 2019. One commenter expressed concern that the proposed approach for two 6-month performance years and two financial reconciliations for performance years in CY 2019 would also require two separate quality reporting samples for measures reported through the CMS Web Interface. The commenter was concerned about the burden that would be imposed on ACOs by such a requirement, given that annual quality reporting requires a significant amount of ACO resources.

Response: We proposed to determine quality performance for the 6-month performance years during 2019 based on an ACO’s quality performance during the 12-month CY 2019 in
order to align with the program’s existing quality reporting methodology, measure specifications which require 12-months of data, and the APM scoring standard under MIPS. In addition, because we proposed to use quality performance during all of CY 2019, we proposed that ACOs would only have to report quality once for CY 2019, regardless of whether they complete their participation in the program following the conclusion of the 6-month performance year from January 1, 2019 through June 30, 2019, or they renew for a new agreement period beginning on July 1, 2019 (if finalized as proposed). Therefore, ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019 (if finalized as proposed), would report quality for one beneficiary sample for CY 2019.

We also note that for the 2019 reporting period, ACOs would be required to report quality data through the CMS Web Interface, according to the method and timing of submission established by CMS. The period for reporting quality data through the CMS Web Interface typically occurs for a 12-week period between January and March, following the conclusion of the calendar year. Thus, ACOs that participate in a 6-month performance year from January 1, 2019 through June 30, 2019, along with all other Shared Savings Program ACOs would be required to report for the 2019 reporting period, and would report quality data through the CMS Web Interface during the designated reporting period in early 2020. Further, ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, would be required to contract with a CMS-approved vendor to administer the CAHPS for ACOs survey for the 2019 reporting period, consistent with program-wide policies applicable to all other ACOs. We would apply the program’s sampling methodology, as we have described in the August 2018 proposed rule and this section of this final rule, to determine the beneficiaries eligible for the
samples for claims-based measures (as calculated by CMS), CMS Web Interface reporting, and the CAHPS for ACOs survey.

After consideration of the comments, we are finalizing without modification our proposal to determine an ACO’s quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, using the ACO’s quality performance for the 12-month CY 2019 (2019 reporting period) as determined under §425.502. We are also finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Given the limited scope of this final rule we are finalizing our proposal to use an ACO’s latest certified ACO participant list for the performance year from January 1, 2019 through June 30, 2019, (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. We are not addressing at this time our proposals related to the proposed July 1, 2019 agreement start date, including the policies for determining the quality reporting samples for ACOs that extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, and continue their participation in the program in a new agreement period beginning on July 1, 2019. We anticipate summarizing and responding to comments received on these proposals in a forthcoming final rule.

(5) Applicability of Extreme and Uncontrollable Circumstances Policies

In section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), we proposed to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. As discussed in section V.B.2.d of this final rule,
we are finalizing this proposal. In section II.E.4. of the August 2018 proposed rule, we indicated that if finalized, these policies would apply to ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019.

There were no comments directed specifically at our proposals with respect to the applicability of these policies for addressing the impact of extreme and uncontrollable circumstances on ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. We direct readers to review section V.B.2.d. of this final rule, for a more comprehensive discussion of the modifications to the program’s extreme and uncontrollable circumstances policies that we are finalizing with this final rule.

We are finalizing as proposed the policies for determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs affected by extreme and uncontrollable circumstances during CY 2019. In addition, we are also finalizing our proposal to specify, in a new section of the regulations at §425.609(d), the following policies related to determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for an ACO affected by extreme and uncontrollable circumstances during CY 2019: (1) in calculating the amount of shared losses owed by the ACO, CMS makes adjustments to the amount determined under §425.609(b), as specified in §425.606(i) (Track 2) or §425.610(i) (Track 3), as applicable; and (2) in determining the ACO’s quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in §425.502(f).

(6) Payment and Recoupment for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41858), we proposed policies regarding CMS’ notification to ACOs of shared savings and shared losses and the timing for ACOs’ repayment of
shared losses for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019.

In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to payment and recoupment for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this final rule would include a discussion of our proposal to reduce the shared savings payment for one 6-month performance year (or performance period) by the amount of any shared losses owed for the other 6-month performance year (or performance period).

In the August 2018 proposed rule, we proposed that the following policies would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019. Because we proposed to perform financial reconciliation for this 6-month performance year after the end of CY 2019, we anticipated that financial performance reports for the 6-month performance year would be available in Summer 2020, similar to the expected timeframe for issuing financial performance reports for the 12-month 2019 performance year (and for 12-month performance years generally).

We proposed to apply the same policies regarding notification of shared savings and shared losses and the timing of repayment of shared losses to ACOs in a 6-month performance year that apply under our current regulations to ACOs in 12-month performance years. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to specify
in a new regulation at §425.609 that CMS would notify the ACO of shared savings or shared losses, consistent with the notification requirements specified in §425.604(f) (Track 1), §425.606(h) (Track 2), and §425.610(h) (Track 3). Specifically, we proposed that the following approach: (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; (3) if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

We proposed to specify policies on payment and recoupment for ACOs in a 6-month performance year during CY 2019 in a new section of the regulations at §425.609(e).

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in providing performance results to ACOs participating in a 6-month performance year in CY 2019.

Response: We anticipate determining financial and quality performance for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, according to the typical annual projected timeline for making these determinations, and for issuing performance reports to ACOs. The ACO’s annual financial reconciliation report, quality performance reports, and additional informational reports and files, are typically made available in the summer following the conclusion of a 12-month performance year. We also plan to provide ACOs that participate in the 6-month performance year from January 1, 2019 through June 30, 2019, quarterly reports for the third and fourth quarter of CY 2019 (see discussion in section V.B.1.c.(8) of this final rule). We anticipate that we will make available to ACOs an annual schedule for report delivery for 2019. For example, see the 2018 Shared Savings Program
We are finalizing without modification our proposal to specify in a new section of the regulations at §425.609(e) that CMS will notify the ACO of shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, consistent with the notification requirements specified in §§425.604(f), 425.606(h), and 425.610(h), as applicable. Specifically, we will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. CMS will provide written notification to an ACO of the amount of shared losses, if any, that the ACO must repay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(7) Interactions With the Quality Payment Program

In the August 2018 proposed rule (83 FR 41859), we took into consideration how the proposed July 1, 2019 start date could interact with other Medicare initiatives, particularly the Quality Payment Program timelines relating to participation in APMs. In the CY 2018 Quality Payment Program final rule with comment period, we finalized a policy for APMs that start or end during the QP Performance Period. Specifically, under §414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM using claims data for services furnished during those dates on which the Advanced APM is actively tested. CMS performs QP
determinations for eligible clinicians in an APM entity three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31 (§414.1425(b)(1)). We explained that this meant that an APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31 – the last date on which QP determinations are made during a QP Performance Period (as specified in §414.1425(b)(1)). Therefore, we believed that our proposed July 1, 2019 start date for the proposed new participation options under the Shared Savings Program would align with Quality Payment Program rules and requirements for participation in Advanced APMs. However, we did not address QP determinations for eligible clinicians participating in an ACO whose agreement period expires on December 31, 2018, that elects a voluntary extension for the 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue in the program past June 30, 2019.

Further, as described in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), our proposal to use a 12-month period for quality measure assessment for either 6-month performance year during 2019 would maintain alignment with the program’s existing quality measurement approach, and align with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO’s financial performance for a 6-month performance year. Also, this approach would continue to align the program’s quality reporting period with policies under the Quality Payment Program (83 FR 41856). We explained that ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019.
Comment: One commenter indicated that, as proposed, it appears ACOs in a two-sided model may lose Advanced APM Entity status and sought clarity on the Advanced APM status for all participating ACOs. This commenter was specifically concerned about the Advanced APM status of the Track 1+ Model.

Response: We believe the comment reflects the need for clarification about whether eligible clinicians in an ACO that is participating in a track that meets the Advanced APM criteria and that elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, but does not continue its participation in the Shared Savings Program past June 30, 2019, would be eligible to become QPs during the 2019 QP Performance Period. Eligible clinicians who become QPs will earn the Advanced APM incentive payment and will not be subject to the MIPS reporting requirements and payment adjustments for the applicable year. The commenter may have been concerned that an agreement period that ends prior to the end of the QP performance period (August 31, 2019) would be considered an early termination and that the ACO would therefore lose its status as participating in an Advanced APM, which is not the case under our previously-finalized policy for Advanced APMs that start or end during a performance period. For an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, the agreement period would end during the QP performance period. However, because the ACO would have been active for more than 60 days, it would continue to be an APM entity in an Advanced APM in 2019 (§414.1425(c)(7)). Therefore, clinicians who obtain QP status based on the March 31, 2019, or June 30, 2019 snapshot through participation in an ACO with a 6-month extension of its
agreement period will: maintain QP status, be exempt from MIPS, and receive the APM incentive payment, as long as their ACO completes its agreement period by remaining in the program through June 30, 2019.

We also believe there is a need to clarify what happens to an eligible clinician’s QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, and either voluntarily terminates or is involuntarily terminated prior to June 30, 2019. If their ACO terminates or is involuntarily terminated any time after March 31, 2019, and before August 31, 2019, then eligible clinicians previously determined to have had QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM Scoring Standard (§414.1425(c)(5) and (6)). If their ACO terminates before March 31, 2019, then the eligible clinicians would not be scored under the APM Scoring Standard and will be assessed under regular MIPS scoring rules (§§414.1370(e) and 414.1425(b)(1)).

Comment: Some commenters requested clarification on how quality reporting for a 6-month performance period based on 12-months of data for 2019 will satisfy the MIPS quality reporting requirements for MIPS eligible clinicians in ACOs that elect to extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019. One commenter indicated there was no discussion of how the proposed 6-month extension period would impact scoring under the APM scoring standard.

Response: We believe the comments reflect the need for clarification about whether 2019 quality performance for a 6-month performance year under the Shared Savings Program will count the same as a full year of performance for purposes of the APM scoring standard if the
ACO ends its current agreement period at the end of the 6-month extension and chooses to not renew its agreement with a July 1, 2019 start date (if finalized as proposed). That is, would the 2019 quality reporting for the 6-month performance year count toward the final MIPS score in the same way that it would for an ACO that is participating in a full 12-month performance year in the program.

As discussed in this section of this final rule, we are finalizing a policy of using a 12-month period for quality performance assessment for the 6-month performance year from January 1, 2019 through June 30, 2019, in order to maintain alignment with the program’s existing quality measurement approach, and with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) participating in an ACO that completes a 6-month performance year from January 1, 2019 through June 30, 2019, would continue to be scored under MIPS using the APM Scoring Standard, based on quality data submitted for all of 2019 during the regular submission period in early 2020. Thus, for a Track 1 ACO in a 6-month performance year from January 1, 2019 through June 30, 2019, whose agreement period expires and the ACO does not renew to continue program participation, the ACO would be scored under the MIPS APM scoring rules for quality reporting based on the entire CY 2019.

(8) Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Year From January 1, 2019 Through June 30, 2019

Under the program’s current regulations at §425.702, we share aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year, during each quarter, and in conjunction with the annual reconciliation. In the August 2018 proposed rule (83 FR 41859), for ACOs that started a first or second agreement period on
January 1, 2016, that extend their agreement for an additional 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to continue to deliver aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the 6-month performance year. This would give ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the 6-month performance year by allowing them to continue to receive data, including demographic characteristics and expenditure/utilization trends for their assigned population for the entire calendar year. We believed this proposed approach would allow us to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries assigned to the ACO for the 6-month performance year would be compared to the ACO’s benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though under our proposed methodology for assessing the financial performance of ACOs in a 6-month performance year, the financial reconciliation for the 6-month performance year would involve consideration of expenditures from outside this period during 2019. We proposed to specify this policy in revisions to §425.702.

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in sharing claims files with ACOs participating in a 6-month performance year in CY 2019.

Response: In the August 2018 proposed rule, we did not describe in detail the applicability of the program’s policies on sharing beneficiary-identifiable claims data with ACOs
under §425.704. We proposed, generally, that unless otherwise stated, program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO’s chosen participation track and based on the ACO’s agreement start date would be applicable to an ACO participating in a 6-month performance year. Therefore, we would continue to provide beneficiary-identifiable claims data (referred to as claim and claim line feed files) to ACOs only during their participation in the program, including during the 6-month performance year from January 1, 2019 through June 30, 2019. ACOs would receive monthly Part A, B and D claim and claim line feed files during the 6-month performance year based on the ACO participant list they certify before the start of the performance year. Consistent with the program’s current data sharing policies, we would discontinue delivery of beneficiary-identifiable data to ACOs when their participation agreement is no longer in effect.

After consideration of the comments received, we are finalizing our proposal to deliver to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the performance year. This policy is specified in revisions to §425.702.

(9) Technical or Conforming Changes to Allow for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41859 through 41860), we proposed to make certain technical, conforming changes to certain provisions of the regulations, including additional changes to provisions discussed elsewhere in the proposed rule, to reflect our proposal to add a new provision at §425.609 to govern the calculation of the financial and quality results for the proposed 6-month performance years within CY 2019.

In this final rule, we are addressing only the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we
anticipate discussing comments received on the proposed 6-month performance year from July 1, 2019 through December 31, 2019, and the proposed 6-month performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

The following proposals discussed in the August 2018 proposed rule would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019.

Our proposal that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§425.315) would apply with respect to applicable payment determinations for performance years within CY 2019. To clarify, we proposed to amend §425.315 to incorporate a reference to the proposed provision for notification of shared savings and shared losses for ACOs in a 6-month performance year within CY 2019, as specified in §425.609(e).

Our proposal to add a reference to §425.609 in §425.100 in order to include ACOs that participate in a 6-month performance year during 2019 in the general description of ACOs that are eligible to receive payments for shared savings under the program.

Our proposal to amend §425.400(a)(1)(ii), which describes the step-wise process for determining beneficiary assignment for each performance year, to specify that this process would apply to ACOs participating in a 6-month performance year within CY 2019, and that assignment would be determined based on the beneficiary's utilization of primary care services during the entirety of CY 2019, as specified in §425.609.

Our proposal to further revise §425.400(c)(1)(iv), on the use of certain Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System
(HCPCS) codes in determining beneficiary assignment, to specify that it would be used in
determining assignment for performance years starting on January 1, 2019, and subsequent
years. We note that we also proposed certain other revisions to this provision in section II.E.3.
of the August 2018 proposed rule (83 FR 41896), as discussed in section V.B.2.c. of this final
rule.

Our proposal to revise §425.401(b), describing the exclusion of beneficiaries from an
ACO’s prospective assignment list at the end of a performance year or benchmark year and
quarterly during each performance year, to specify that these exclusions would occur at the end
of CY 2019 for purposes of determining assignment to an ACO in a 6-month performance year
in accordance with §§425.400(a)(3)(ii) and 425.609.

Our proposal, as part of the proposed revisions to §425.402(e)(2), which, as described in
section II.E.2. of the August 2018 proposed rule (83 FR 41894), specifies that beneficiaries who
have designated a provider or supplier outside the ACO as responsible for coordinating their
overall care will not be added to the ACO’s list of assigned beneficiaries for a performance year
under the claims-based assignment methodology, to allow the same policy to apply to ACOs
participating in a 6-month performance year during CY 2019. We are finalizing our proposed
revisions to §425.402(e)(2), as described in section V.B.2.b. of this final rule.

Our proposal to revise §425.404(b), on the special assignment conditions for ACOs that
include FQHCs and RHCs that provide services used in determining beneficiary assignment, to
specify its applicability in determining assignment for performance years starting on January 1,
2019, and subsequent performance years.

We also proposed to incorporate references to §425.609 in the regulations that govern
establishing, adjusting, and updating the benchmark, including the existing provisions at
§§425.602 and 425.603, to specify that the annual risk adjustment and update to the ACO’s historical benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, would use factors based on the entirety of CY 2019. For clarity and simplicity, we proposed to add a paragraph to each of these sections to explain the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the adjustment will reflect the change in severity and case mix between benchmark year 3 and CY 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the update to the benchmark will be based on growth between benchmark year 3 and CY 2019.

We also proposed to incorporate references to §425.609 in the following provisions regarding the calculation of shared savings and shared losses: §§425.604, 425.606, and 425.610. For clarity and simplicity, we proposed to add a paragraph to each of these sections explaining that shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, are calculated as described in §425.609. That is, all calculations will be performed using CY 2019 data in place of performance year data.

There were no comments directed specifically at our proposed technical and conforming changes to allow for 6-month performance years. We are finalizing as proposed the technical and conforming changes to the Shared Savings Program regulations as previously described in this section of this final rule, to allow them to apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019.

(10) Payment Consequences of Early Termination

In the August 2018 proposed rule (83 FR 41845 through 41847), we proposed policies to
govern the payment consequences of early termination for performance years beginning in 2019 and subsequent years, including for ACOs participating in 6-month performance years from January 1, 2019 through June 30, 2019, and July 1, 2019 through December 31, 2019, as well as for ACOs participating in 12-month performance years. We proposed to impose payment consequences for early termination by holding ACOs in two-sided models liable for pro-rated shared losses. This approach would apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs would be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year; but, we would allow an exception for ACOs that are participating in a 12-month performance year under the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the proposed BASIC track or ENHANCED track beginning July 1, 2019. In these cases, we would perform separate reconciliations to determine shared savings and shared losses for the ACO’s first 6 month period of participation in 2019 and for the ACO’s 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

In a forthcoming final rule we anticipate addressing comments received on proposals for the payment consequences of early termination from 12-month performance years and from 6-month performance years beginning on July 1, 2019, should we finalize the proposal to offer a July 1, 2019 start date for the new participation options. Therefore, in this section of this final rule we focus specifically on the proposals regarding the payment consequences of early termination as they relate to the 6-month performance year from January 1, 2019 through June 30, 2019.
We proposed that an ACO would be eligible to receive shared savings for a 6-month performance year during 2019 if it completes the term of the performance year, regardless of whether the ACO chooses to continue its participation in the program. That is, we would reconcile ACOs that started a first or second agreement period January 1, 2016, that extend their agreement period for a fourth performance year, and complete this performance year (concluding on June 30, 2019).

For an ACO that participates for a portion of a 6-month performance year during 2019, we proposed the following: (1) if the ACO terminates its participation agreement effective before the end of the performance year, we would not reconcile the ACO for shared savings or shared losses (if a two-sided model ACO); (2) if CMS terminates a two-sided model ACO’s participation agreement effective before the end of the performance year, the ACO would not be eligible for shared savings and we would reconcile the ACO for shared losses and pro-rate the amount reflecting the number of months during the performance year that the ACO was in the program. We proposed to specify these policies in amendments to §425.221(b).

We also proposed to revise the regulation at §425.221 to streamline and reorganize the provisions in paragraph (b), which we believed necessary to incorporate the proposed new requirements. We sought comment on these proposals.

We are not addressing our proposed modifications to program policies to impose payment consequences for early termination in this final rule. Accordingly, for ACOs participating in a performance year starting on January 1, 2019, we will continue to apply the program’s current policies for payment consequences of early termination. We believe that continuing to use the current approach would be simpler, both from the standpoint of CMS as the regulatory entity and operator of the program, and for ACOs as regulated entities already
familiar with the current policies. Under this approach, ACOs that terminate from a performance year starting on January 1, 2019, with an effective date of termination prior to the end of their performance year will not be eligible for shared savings or accountable for shared losses.

At this time, we are finalizing a subset of our proposed policies for determining payment consequences of early termination, to account for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Specifically, we are finalizing without modification our proposal that an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, is eligible for shared savings if the following conditions are met: CMS has designated or approved an effective date of termination that is the last calendar day of the performance year (June 30, 2019); the ACO has completed all close-out procedures specified in §425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied the criteria for sharing in savings for the performance year. Consistent with our existing policies, if the participation agreement is terminated at any time by CMS under §425.218, the ACO will not be eligible to receive shared savings for the performance year during which the termination becomes effective, and will not be accountable for any shared losses. Further, for an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, that elects to terminate early, we will apply the payment consequences of early termination consistent with the current regulations, and the ACO will not be eligible to receive shared savings for the performance year and will not be accountable for any shared losses.

We are finalizing the proposed revisions to §425.221 to allow us to consistently apply current program policies on the payment consequences of early termination or agreement expiration to ACOs in a 6-month performance year from January 1, 2019 through June 30, 2019. We are amending §425.221(b) to remove references to December 31st of a performance year and
instead to refer to the last calendar day of the performance year, so that the regulatory provisions will apply to ACOs regardless of whether they are participating in a 12-month or 6-month performance year. We are not addressing at this time the other proposed revisions to the regulation at §425.221, including the proposals to streamline and reorganize the provisions in paragraph (b).

2. Updating Program Policies

a. Overview

This section addresses various proposed revisions described in the August 2018 proposed rule (83 FR 41894 through 41911) that are designed to update policies under the Shared Savings Program. We proposed to revise our regulations governing the assignment process in order to align our voluntary alignment policies with the requirements of section 50331 of the Bipartisan Budget Act of 2018 and to update the definition of primary care services. We also proposed to extend the policies that we recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years. We also solicited comment on considerations related to supporting ACOs’ activities to address the national opioid crisis and the agency’s meaningful measures initiative. We proposed to discontinue use of the quality performance measure that assesses the level of adoption of CEHRT by the eligible clinicians in an ACO and proposed instead that ACOs be required to certify upon application to participate in the Shared Savings Program and annually thereafter that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds.

b. Revisions to Policies on Voluntary Alignment

(1) Background
Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO, if a system is available for electronic designation. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary. Section 50331 also requires the Secretary to establish a process under which a Medicare FFS beneficiary is notified of his or her ability to designate a primary care provider or subsequently to change this designation. An ACO professional is defined under section 1899(h) of the Act as a physician as defined in section 1861(r)(1) of the Act and a practitioner described in section 1842(b)(18)(C)(i) of the Act.

As we stated in the August 2018 proposed rule (83 FR 41894), we believe that section 50331 requires certain revisions to our current beneficiary voluntary alignment policies in §425.402(e). Prior to enactment of the Bipartisan Budget Act of 2018, section 1899(c) of the Act required that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. In order to satisfy this statutory requirement, we currently require that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see §425.402(b)(1)). As currently provided in §425.404(b), for performance year 2019 and subsequent performance years, for purposes of the assignment methodology in §425.402, CMS
treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, we use a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see §425.402(b)(2) through (4)). In the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented this claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, may voluntarily align with an ACO by designating a “primary clinician” they believe is responsible for coordinating their overall care using MyMedicare.gov, a secure online patient portal. MyMedicare.gov contains a list of all of the Medicare-enrolled practitioners who appear on the Physician Compare website and beneficiaries may choose any practitioner present on Physician Compare as their primary clinician.

Notwithstanding the assignment methodology in §425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at §425.401(a) and is not excluded from assignment by the criteria in §425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician as defined under §425.20 or a physician with one of the primary specialty designations included in §425.402(c) (see §425.402(e)). Such beneficiaries will be added prospectively to the ACO’s list of assigned beneficiaries for the subsequent performance year, superseding any assignment that might have otherwise occurred under the claims-based methodology. Further, beneficiaries may change their designation at any time through
beneficiaries who designate a provider or supplier outside an ACO, who is a primary care physician, a physician with a specialty designation that is considered in the assignment methodology, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care will not be added to an ACO’s list of assigned beneficiaries, even if they would otherwise meet the criteria for claims-based assignment.

(2) Summary of Proposed Revisions

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Under our current methodology, a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician; however, we will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at §425.20), a physician with one of the primary specialty designations included in §425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. Therefore, we proposed to modify our current voluntary alignment policies at §425.402(e)(2)(iii) to provide that we will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation, for example, a specialty of allergy/immunology or surgery, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. Specifically, we proposed to revise §425.402(e)(2)(iii) to remove the requirement that the ACO professional designated by the beneficiary be a primary
care physician as defined at §425.20, a physician with a specialty designation included at §425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. In addition, the provision at §425.402(e)(2)(iv) addresses beneficiary designations of clinicians outside the ACO as their primary clinician. The current policy at §425.402(e)(2)(iv) provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at §425.20, a physician with a specialty designation included at §425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as their primary clinician responsible for coordinating their overall care. Consistent with the proposed revisions to §425.402(e)(2)(iii) to incorporate the requirements of section 50331 of the Bipartisan Budget Act, we proposed to revise §425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional (see section 1899(c)(2)(B)(i) of the Act). As we explained in the August 2018 proposed rule (83 FR 41895), we believe the requirement in section 1899(c)(2)(B)(iii) of the Act that a beneficiary’s voluntary identification shall supersede any claims-based alignment is also consistent with eliminating the requirement that the beneficiary have received a service from an ACO professional in order to be eligible to be assigned an ACO. Therefore, we proposed to remove the requirement at §425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician
or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO. We stated that we believe this approach would reduce burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care during a specified period of time in order for a beneficiary to remain eligible for assignment to the ACO. Consistent with this proposal, we proposed to remove §425.402(e)(2)(i) in its entirety.

We noted that, under this proposal, if a beneficiary does not change their primary clinician designation, the beneficiary will remain assigned to the ACO in which that practitioner participates during the ACO’s entire agreement period and any subsequent agreement periods under the Shared Savings Program, even if the beneficiary no longer seeks care from any ACO professionals. Because a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. As we explained in the August 2018 proposed rule (83 FR 41895), we believe our proposed policy is consistent with the requirement under section 1899(c)(2)(B)(iii) of the Act that a voluntary identification by a beneficiary shall supersede any claims-based assignment. However, we also believe it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the Comprehensive ESRD Care (CEC) Model. CMS implemented the CEC Model to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for
Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B. Under the model, CMS is working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive. We believe that an ESRD beneficiary, who is otherwise eligible for assignment to an entity participating in the CEC Model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC Model. Such a beneficiary could be disadvantaged if they were unable to receive the type of specialized care for their ESRD that will be available from an entity participating in the CEC Model. Furthermore, we believe it could be difficult for the Innovation Center to conduct a viable test of a specialty or disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. Currently, the CEC Model completes its annual PY prospective assignment lists prior to the Shared Savings Program in order to identify the beneficiaries who may benefit from receiving specialized care from an entity participating in the CEC Model. Additionally, on a quarterly basis, a beneficiary may be assigned to the CEC Model who was previously assigned to a Track 1 or Track 2 ACO.

As a result, we believe that in some instances it may be necessary for the Innovation Center to use its authority under section 1115A(d)(1) of the Act to waive the requirements of section 1899(c)(2)(B) of the Act solely as necessary for purposes of testing a particular model. Therefore, we proposed to create an exception to the general policy that a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, we proposed that we would not assign such a beneficiary to the ACO when the beneficiary is also eligible for
assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. Under this proposal, if a beneficiary selects a primary clinician who is a Shared Savings Program ACO professional and the beneficiary is also eligible for alignment to a specialty care or disease specific model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) is necessary solely for purposes of testing the Model, the Innovation Center or its designee would notify the beneficiary of their alignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is an ACO professional in a Shared Savings Program ACO.

In the August 2019 proposed rule (83 FR 41896), we indicated that we would include a list of any models that meet these criteria on the Shared Savings Program website, to supplement the information already included in the beneficiary assignment reports we currently provide to ACOs (as described under §425.702(c)), so that ACOs can know why certain beneficiaries, who may have designated an ACO professional as their primary clinician, are not assigned to them. Similar information would also be shared with 1-800-MEDICARE to ensure that Medicare customer service representatives are able to help beneficiaries who may be confused as to why they are not aligned to the ACO in which their primary clinician is participating.
Section 1899(c)(2)(B)(ii) of the Act, as amended by section 50331 of the Bipartisan Budget Act, requires the Secretary to establish a process under the Shared Savings Program through which each Medicare FFS beneficiary is notified of the ability to identify an ACO professional as his or her primary care provider and informed of the process that may be used to make and change such identification. In the August 2018 proposed rule (83 FR 41896), we stated our intent to implement section 1899(c)(2)(B)(ii) of the Act under the beneficiary notification process at §425.312. We are not addressing this topic at this time. We will summarize and respond to public comments on this proposed policy in a forthcoming final rule.

We proposed to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years. We proposed to incorporate these new requirements in the regulations by redesignating §425.402(e)(2)(i) through (iv) as §425.402(e)(2)(i)(A) through (D), adding a paragraph heading for newly redesignated §425.402(e)(2)(i), and including a new §425.402(e)(2)(ii).

We noted that as specified in §425.402(e)(2)(ii) a beneficiary who has designated an ACO professional as their primary clinician must still be eligible for assignment to an ACO by meeting the criteria specified in §425.401(a). These criteria establish the minimum requirements for a beneficiary to be eligible to be assigned to an ACO under our existing assignment methodology, and we believe it is appropriate to impose the same basic limitations on the assignment of beneficiaries on the basis of voluntary alignment. We do not believe it would be appropriate, for example, to assign a beneficiary to an ACO if the beneficiary does not reside in the United States, or if the other eligibility requirements are not met.

We requested comments on our proposals to implement the new requirements governing
voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. We also sought comment on our proposal to create a limited exception to our proposed policies on voluntary alignment to allow a beneficiary to be assigned to an entity participating in a model tested or expanded under section 1115A of the Act when certain criteria are met. In addition, we welcomed comments on how we might increase beneficiary awareness and further improve the electronic process through which a beneficiary may voluntarily identify an ACO professional as their primary care provider through My.Medicare.gov for purposes of assignment to an ACO.

Comment: Many commenters supported the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. In particular, many commenters supported the proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Commenters were in favor of removing this requirement because it would allow a beneficiary to select a NP, PA, or CNS, who is participating in an ACO, as their primary clinician to voluntarily align to the ACO even if they do not receive care from any physicians participating in the ACO. Commenters suggested this more inclusive policy supports CMS’ goals of improving patient access and quality of care, and is consistent with patient-centered health care delivery. Additionally, some commenters specifically supported the proposal to allow a beneficiary to voluntarily designate any ACO professional, regardless of specialty, as their primary care provider for purposes of assignment to an ACO. In particular, commenters representing neurologists and palliative care practitioners were supportive of this proposed change. In addition, one commenter agreed that the proposed policy would allow “the opportunity for
patients to choose and establish a medical home with their clinician.” The commenter also supported voluntary alignment because it results in prospective beneficiary attribution, which the commenter preferred over the preliminary prospective assignment methodology with retrospective reconciliation.

Response: We appreciate the commenters’ support for the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018.

Comment: A few commenters proposed a change to section 1899(h)(1)(A) of the Act. Section 1899(c) of the Act requires the Secretary to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A). Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term “ACO professional”. Specifically, this provision establishes that a physician (as defined in section 1861(r)(1)) is an ACO professional for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. One commenter proposed a change to allow for “private NP led practices and NP led clinics” to be included as ACO professionals described in section 1899(h)(1)(A) of the Act. The commenter recommended this change in particular for rural areas, stating that NPs account for 1 in 4 medical providers in rural areas.

Response: Because commenters are requesting a change to the statute, these suggestions are outside the scope of this final rule. However, as many commenters noted above, the proposed changes to the voluntary alignment methodology will allow a beneficiary to align with
a NP, PA, or CNS participating in an ACO and ultimately be assigned to the ACO regardless of whether they receive care from a physician in the ACO. Additionally, we agree these non-physician practitioners play an important role in coordinating patient care and providing primary care services, as such we have included primary care services furnished by NPs, PAs, and CNSs in step 1 of our two-step claims-based assignment methodology (see §425.402(b)).

Comment: Some commenters opposed the proposed changes to the voluntary alignment methodology. One commenter expressed concern about beneficiary confusion if their practitioners participate in different ACOs or the beneficiary selects a practitioner outside of an ACO as their primary care provider. Similarly, one commenter expressed concern about an ACO’s ability to maintain an assigned population of 5,000 beneficiaries if beneficiaries can select any ACO professional regardless of specialty as their primary care provider. A few commenters disagreed with including all practitioner specialties citing differences in training, education, knowledge, and experience. Another commenter expressed concern about whether specialists are willing to take on the role of a primary care physician and manage the overall care of beneficiaries assigned to the ACO through voluntary alignment. Some commenters disagreed with the proposal to remove the requirement that a beneficiary receive a primary care service from an ACO professional, with a physician specialty used in assignment, during the assignment window. One commenter stated that removing the requirement would exacerbate a “leakage” problem that they described as a scenario where assigned beneficiaries receive some or all of their care from providers and suppliers outside the ACO. One commenter suggested beneficiaries should be required to renew their selection of their primary care clinician one year following the beneficiary’s entry into a long-term care setting. Another commenter suggested that beneficiaries who voluntarily align with an ACO be required to receive a minimum number of
primary care services from ACO professionals within the same ACO in order to remain aligned to the ACO.

Response: We disagree with these comments. We believe that when a beneficiary selects a primary clinician, they are identifying their primary care provider, regardless of specialty or whether the beneficiary has received a recent primary care service. We believe they are informing CMS that they view the practitioner as their primary care provider and responsible for managing their overall care. We also believe all practitioners, regardless of specialty, play an important role in coordinating care for beneficiaries and if a beneficiary selects a practitioner as their primary clinician, the beneficiary should be treated as having made an informed election. Although we understand the concern that an ACO could lose assigned beneficiaries due to their voluntary alignment with another ACO, we note that our experience to date shows that the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO via our two-step claims-based assignment methodology under §425.402(b). We also believe requiring beneficiaries to renew their primary clinician selection would create additional unnecessary burden on beneficiaries. Beneficiaries who have designated a primary clinician must have established a MyMedicare.gov account, which likely indicates that they are actively engaged in reviewing and managing their health information. We believe these engaged beneficiaries will also manage and update their primary clinician selections as necessary. We also disagree with establishing a requirement that a beneficiary receive a minimum number of primary care services from ACO providers/suppliers in the ACO in order to honor a beneficiary’s voluntary alignment selection. We believe our proposed approach is in accordance with the requirement under section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, that primary care provider selections take precedence over any
Comment: A few commenters suggested CMS simplify the process by which a beneficiary selects their primary clinician. Commenters suggested that, in addition to the electronic means of voluntary alignment, CMS allow beneficiaries to voluntarily align with their primary clinician through the ACO, at the point of care, through 1-800 Medicare, a smart phone application, or Physician Compare. One commenter noted they had experienced difficulties with CMS’ operationalization of the voluntary alignment policy through MyMedicare.gov.

Response: Currently, if beneficiaries need help in designating a primary clinician, they can call 1-800 Medicare to have a representative walk them through the process or use the “Empowering Patients to Make Decisions About Their Healthcare: Register for MyMedicare.gov and Select Your Primary Clinician” fact sheet available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/vol-alignment-bene-fact-sheet.pdf. We plan to continue to make refinements to our implementation of voluntary alignment in order to improve the user experience for beneficiaries and will take the commenters’ suggestions into consideration in developing future policies regarding voluntary alignment.

Comment: One commenter disagreed with allowing beneficiaries to voluntarily align with an ACO professional. The commenter cited difficulty tracking the cost of beneficiaries who are not assigned to an ACO through our two-step claims-based assignment methodology. Another commenter suggested we not hold an ACO accountable for a voluntarily aligned beneficiary for a performance year if the beneficiary does not receive any services from their primary clinician in the ACO during that performance year. Another commenter opposed voluntary alignment because they believe the costs for voluntarily aligned beneficiaries are not
reflected in an ACO’s historical benchmark.

Response: Consistent with section 1899(c)(2)(B)(i) of the Act, we are required to allow beneficiaries to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO if a system is available for electronic designation. To aid ACOs in identifying and tracking costs and Medicare services for voluntarily aligned beneficiaries, we provide ACOs with quarterly aggregate reports (see §425.702) that identify beneficiaries who have voluntarily aligned with the ACO, as well as monthly claim and claim line feed files (see §425.704) to aid ACOs in their operations. Additionally, as previously stated, we have found the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO in the applicable performance year based on our two-step assignment methodology. As required under section 1899(b)(2)(A) of the Act and the regulation at §425.100(a), ACOs participating in the Shared Savings Program must agree to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. Beneficiaries who voluntarily align to an ACO are prospectively assigned to the ACO for the performance year. Under the prospective assignment methodology, ACOs are accountable for their assigned beneficiary population regardless of where the beneficiaries receive the plurality of their primary care services during the performance year. We believe this is an appropriate approach when a beneficiary selects a practitioner as their primary clinician. As we stated earlier, we believe that when a beneficiary selects a primary clinician, the beneficiary is making an informed decision and identifying for CMS the provider or supplier whom they consider to be responsible for managing their overall care. The historical benchmark reflects the beneficiary population who received the plurality of their primary care services from the ACO during the three benchmark years and, in our experience, there is a high correlation
between the beneficiaries who are assigned based on our two-step claims-based assignment methodology and voluntarily aligned beneficiaries. As a result, we believe our current benchmarking methodology provides for a population of assigned beneficiaries during the benchmark years that is comparable to the population assigned during the performance years. We also note, in the future, when an ACO renews for a new agreement period and its previous performance years become historical benchmark years, beneficiaries who were voluntarily aligned to the ACO for those years will then be included in the historical benchmark calculations for the ACO’s new agreement period.

Comment: One commenter stated the current voluntary alignment process can be confusing and causes unnecessary delays in assigning beneficiaries to the ACO in which their primary clinician participates. The commenter suggested a rolling voluntary alignment process allowing beneficiaries who voluntarily align with an ACO to be added to the assignment list for that ACO during a performance year.

Response: We understand that our policy of performing beneficiary assignment annually can cause a delay between when a beneficiary selects their primary clinician and when the beneficiary is assigned to the ACO. However, we believe this approach reduces complexity and burden. For example, ACOs are able to clearly identify a date by which to communicate to their beneficiaries regarding the opportunity to designate a primary clinician if they would like to align with an ACO professional.

Comment: One commenter expressed concern that physicians with a specialty designation not used in assignment would become subject to the exclusivity requirements, which would limit an ACO participant to participation in a single ACO. The commenter opposed any policy that would require an ACO participant to be exclusive to a single Shared Savings Program
ACO in the event that a beneficiary voluntarily aligns to a practitioner billing under the TIN of that ACO participant.

Response: We agree with the concerns raised by the commenter and believe it is important to clarify the operational process we will implement if a beneficiary designates a clinician billing under the TIN of an ACO participant that participates in more than one Shared Savings Program ACO (as permitted under certain circumstances under §425.306(b)) as their primary clinician. ACO participants that do not bill for services that are considered in assignment will not be required to be exclusive to a single Shared Savings Program ACO as a result of the changes to the voluntary alignment methodology. In the circumstance where a beneficiary aligns with a clinician billing under an ACO participant TIN that is participating in more than one Shared Savings Program ACO, we will determine where the beneficiary received the plurality of their primary care services under our claims-based assignment methodology under §425.402(b). If the beneficiary did not receive the plurality of their primary care services from ACO professionals in either ACO, we will not assign the beneficiary to either of the ACOs. However, consistent with §425.402(c)(2)(iv), we will honor the beneficiary’s selection of a primary clinician and will not align the beneficiary to another ACO in which their primary clinician is not participating.

We did not receive any public comments on the proposal not to voluntarily align a beneficiary to the ACO in which their primary clinician participates when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services (for example, CEC).

After considering the comments received in response to the proposals to revise the
voluntary alignment methodology, we are finalizing the policies as proposed. Specifically, we are finalizing the policy to assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. We are also finalizing our proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Lastly, we are finalizing a policy not to voluntarily align a beneficiary to an ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services. Accordingly, we are also finalizing the proposed revisions to §425.402(e)(2) without modification.

c. Revisions to the Definition of Primary Care Services used in Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. We established the initial list of services that we considered to be primary care services in the November 2011 final rule (76 FR 67853). In that final rule, we indicated that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete codes used to identify primary
care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82 FR 34109 and 34110). Subsequently, in the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional chronic care management service codes, 99487, 99489, and G0506, and four behavioral health integration service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). These additions are effective for purposes of performing beneficiary assignment under §425.402 for performance year 2019 and subsequent performance years.

Accounting for these recent changes, we define primary care services in §425.400(c) for purposes of assigning beneficiaries to ACOs under §425.402 as the set of services identified by the following HCPCS/CPT codes:

**CPT codes**

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a Nursing Facility, excluding services furnished in a SNF which are reported on claims with place of service code 31).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients’ home).

(5) 99487, 99489 and 99490 (codes for chronic care management).
(6) 99495 and 99496 (codes for transitional care management services).

**HCPCS codes**

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the Annual Wellness Visits).

(3) G0463 (code for services furnished in electing teaching amendment hospitals).

(4) G0506 (code for chronic care management).

(5) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

As discussed in the CY 2018 PFS final rule (82 FR 53213), a commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking. We indicated that we would consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. In addition, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494, 99484 (82 FR 53078).

CPT codes 99304 through 99318 are used for reporting evaluation and management (E&M) services furnished by physicians and other practitioners in a SNF (reported on claims with POS code 31) or a nursing facility (reported on claims with POS code 32). Based on stakeholder input, we finalized a policy in the CY 2016 PFS final rule (80 FR 71271 through 71272) effective for performance year 2017 and subsequent performance years, to exclude services identified by CPT codes 99304 through 99318 from the definition of primary care services for purposes of the beneficiary assignment methodology when the claim includes the POS code 31 modifier designating the services as having been furnished in a SNF. We
established this policy to recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their true primary care needs. We continue to believe that it is appropriate for SNF patients to be assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the true primary care needs of these beneficiaries. As we discussed in the August 2019 proposed rule (83 FR 41897), ACOs serving special needs populations, including beneficiaries receiving long term care services, and other stakeholders have recently suggested that we consider an alternative method for determining operationally whether services identified by CPT codes 99304 through 99318 were furnished in a SNF. Instead of indirectly determining whether a beneficiary was a SNF patient when the services were furnished based on physician claims data, these stakeholders suggest we more directly determine whether a beneficiary was a SNF patient based on SNF facility claims data. These commenters recommended that CMS use contemporaneous SNF Medicare facility claims to determine whether a professional service identified by CPT codes 99304 through 99318 was furnished in a SNF, and therefore, should not be used for purposes of the beneficiary assignment methodology under §425.402. Specifically, these commenters suggested that we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by determining whether the beneficiary also received SNF facility services on the same date of service.

In the August 2018 proposed rule (83 FR 41897 through 41899), we proposed to make changes to the definition of primary care services in §425.400(c) to add new codes and to revise
how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services to include certain additional codes. Specifically, we proposed to revise the definition of primary care services in §425.400(c) to include the following HCPCS and CPT codes: (1) advance care planning service codes; CPT codes 99497 and 99498; (2) administration of health risk assessment service codes; CPT codes 96160 and 96161; (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure, CPT codes 99354 and 99355; (4) annual depression screening service code, HCPCS code G0444; (5) alcohol misuse screening service code, HCPCS code G0442; and (6) alcohol misuse counseling service code, HCPCS code G0443. In addition, in the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), CMS proposed to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services, (2) GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care, and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure. As we explained in the August 2018 proposed rule (83 FR 41897), we believe it would be appropriate to include these
codes in the definition of primary care services under the Shared Savings Program because these
codes are used to bill for services that are similar to services that are already included in the list
of primary care codes at §425.400(c). We also expect that primary care physicians, nurse
practitioners, physician assistants, and clinical nurse specialists frequently furnish these services
as part of their overall management of a patient. As a result, we believe that including these
codes would increase the accuracy of the assignment process by helping to ensure that
beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary’s
care.

The following provides additional information about the HCPCS and CPT codes that we
proposed to add to the definition of primary care services:

- **Advance care planning (CPT codes 99497 and 99498):** Effective January 1, 2016,
CMS pays for voluntary advance care planning under the PFS (80 FR 70955 through 70959).
See CMS, Medicare Learning Network, “Advance Care Planning” (ICN 909289, August 2016),
Medicare beneficiaries to make important decisions that give them control over the type of care
they receive and when they receive it. Medicare pays for advance care planning either as a
separate Part B service when it is medically necessary or as an optional element of a
beneficiary’s Annual Wellness Visit. We believe it would be appropriate to include both
Advance Care Planning codes 99497 and 99498 in the definition of primary care services under
the Shared Savings Program because the services provided as part of advance care planning
include counseling and other evaluation and management services similar to the services
included in Annual Wellness Visits and other evaluation and management service codes that are
already included in the list of primary care codes.

- **Administration of health risk assessment (CPT codes 96160 and 96161):** In the CY 2017 PFS final rule (81 FR 80330 through 80331), we added two new CPT codes, 96160 and 96161, to the PFS, effective for CY 2017, to be used for payment for the administration of health risk assessment. These codes are “add-on codes” that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. For example, if a health risk assessment service were administered during a physician office visit, then the physician would bill for both the appropriate office visit code and the appropriate health risk assessment code. We believe it would be appropriate to include CPT codes 96160 and 96161 in the definition of primary care services because these add-on codes frequently represent additional practice expenses related to office visits for evaluation and management services that are already included in the definition of primary care services.

- **Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355):** These two codes are also “add-on codes” that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. Code 99354 is listed on a claim to report the first hour of additional face-to-face time with a patient and code 99355 is listed separately for each additional 30 minutes of face-to-face time with a patient beyond the time reported under code 99354. Codes 99354 and 99355 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. (See Medicare Claims Processing Manual Chapter 12, Sections 30.6.15.1 Prolonged Services With Direct Face-to-Face Patient Contact Service (Codes 99354 - 99357) available at [https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-).
Prolonged Services (Codes 99354 - 99359) (Article Number MM5972, Revised March 7, 2017), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf. Although we do not currently include prolonged services codes CPT codes 99354 and 99355 on our list of primary care services, based on further review we believe it would be appropriate to include them on our list of primary care services to more accurately assign beneficiaries to ACOs based on all the allowed charges for the primary care services furnished to beneficiaries. In the August 2018 proposed rule (83 FR 41898), we noted that the definitions of codes 99354 and 99355 also include prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services. Therefore, we proposed to include the allowed charges for CPT codes 99354 and 99355, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

- **Annual depression screening (HCPCS code G0444), alcohol misuse screening (HCPCS code G0442), and alcohol misuse counseling (HCPCS code G0443):** Effective October 14, 2011, all Medicare beneficiaries are eligible for annual depression screening and alcohol misuse screening. (See CMS Manual System, Screening for Depression in Adults (Transmittal 2359, November 23, 2011) available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2359CP.pdf; and see CMS, MLN Matters, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (Article Number MM7633, Revised June 4, 2012), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf). Although these three codes have been in
use since before the implementation of the Shared Savings Program in 2012, based on further review of these services, we believe that it would be appropriate to consider these services in beneficiary assignment. Annual depression screening may be covered if it is furnished in a primary care setting that has staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. Alcohol misuse screening and counseling are screening and behavioral counseling interventions in primary care to reduce alcohol misuse. All three of these codes include screening and counseling services similar to counseling and other evaluation and management services included in the codes already on the list of primary care codes.

In the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), we proposed to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for services represented by CPT codes 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). All three of these codes are “add-on codes” that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base codes.

HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base evaluation and management codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the base evaluation and management code for an established patient when the visit includes primary care services. In contrast, new HCPCS code GCG0X is an add-on code intended to reflect the complexity inherent to evaluation and management services associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology,
allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. As we stated in the August 2018 proposed rule (83 FR 41899), we believe it would be appropriate to include both proposed new HCPCS codes GCG0X and GPC1X in our definition of primary care services because they represent services that are currently included in CPT codes 99201 through 99215, which are already included in the list of primary care codes in §425.400(c).

Finally, proposed new HCPCS code GPRO1 (prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure, in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) is modeled on CPT code 99354, a prolonged services code discussed earlier in this section which we proposed to add to our list of primary care services. HCPCS code GPRO1 is intended to reflect prolonged evaluation and management or psychotherapy service(s) of 30 minutes duration beyond the typical service time of the primary or base service, whereas existing CPT code 99354 reflects prolonged services of 60 minutes duration. As is the case for code 99354, code GPRO1 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. We stated that we believe it would be appropriate to include proposed HCPCS code GPRO1 on our list of primary care services for the same reasons we proposed to add CPT code 99354 to our list of primary care services. Because the proposed definition of HCPCS code GPRO1 also includes prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services, we proposed to include the allowed charges for HCPCS code GPRO1, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

We proposed to include these codes in the definition of primary care services when
performing beneficiary assignment under §425.402, for performance years starting on January 1, 2019, and subsequent years. However, we noted that our proposal to include the three proposed new “add-on codes”, GPC1X, GCG0X, and GPRO1, was contingent on CMS finalizing its proposal to create these new codes for use starting in 2019.

As discussed in section V.B.2.c.(1) of this final rule, ACOs and other commenters have expressed concerns regarding our current policy of identifying services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. We continue to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, as we explained in the August 2018 proposed rule (83 FR 41899), we agree with commenters that it might increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries if we were to revise our method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. We believe it would be feasible for us to directly and more precisely determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by analyzing our facility claims data files rather than by using the POS modifier 31 in our professional claims data files. Operationally, we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service. Therefore, we proposed to revise the regulation at §425.400(c)(1)(iv)(A)(2), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place to indicate more generally that we will exclude services billed under CPT codes
99304 through 99318 when such services are furnished in a SNF.

Under our current process, if CMS’ HCPCS committee or the American Medical Association’s CPT Editorial Panel modifies or replaces any of the codes that we designate as primary care service codes in §425.400(c), we must revise the primary care service codes listed in §425.400(c) as appropriate through further rulemaking before the revised codes can be used for purposes of assignment. As noted previously, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, consistent with our current process, we proposed to revise the primary care service codes in §425.400(c)(1)(iv) to replace HCPCS codes G0502, G0503, G0504 and G0507 with CPT codes 99492, 99493, 99494 and 99484 for performance years starting on January 1, 2019, and subsequent performance years.

We also noted that the regulations text at §425.400(c)(1)(iv) includes brief descriptions for the HCPCS codes that we have designated as primary care service codes, but does not include such descriptions for the CPT codes that we have designated as primary care service codes. For consistency, we proposed a technical change to the regulations at §425.400(c)(1)(iv)(A) to also include descriptions for the CPT codes. We also noted that one of the Chronic Care Management (CCM) codes, CPT code 99490, is inadvertently listed in the regulations text at §425.400(c)(1)(iv)(A)(6) along with the codes for Transitional Care Management (TCM) services. We proposed a technical change to the regulations to move CPT code 99490 up to §425.400(c)(1)(iv)(A)(5) with the other CCM codes.

We welcomed comments on the new codes we proposed to add to the definition of primary care services used for purposes of assigning beneficiaries to Shared Savings Program ACOs. In addition, we sought comment on our proposal to revise our method for excluding
services identified by CPT codes 99304 through 99318 when furnished in a SNF. We also sought comment on the other proposed technical changes to §425.400(c)(1)(iv). We also welcomed comments on any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking.

Comment: Some commenters supported the proposed changes to the definition of primary care services. One commenter suggested we include the Initial Preventive Physician Examination, or Welcome to Medicare Visit, as well as the annual wellness visit CPT codes in the definition.

Response: We appreciate the commenters’ support for the proposed amendments to the definition of primary care services. We also note we currently include the Welcome to Medicare (G0402) and annual wellness visit (G0438 and G0439) CPT codes in the definition of primary care services under §425.400(c).

Comment: Many commenters supported the proposal to modify §425.400(c)(1)(iv)(A)(2) to remove the exclusion of claims including the POS code 31 and in its place indicate more generally that we will exclude services billed under CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF, as determined based on whether there is a SNF facility claim with dates of service that overlap with the date of service for the professional service. One commenter supported this proposal because they noted it would better identify beneficiaries who have received short-term care and appropriately exclude them from assignment.

Response: We appreciate the commenters’ support for the proposal to modify §425.400(c)(1)(iv)(A)(2) to remove the exclusion of claims including the POS code 31 modifier and in its place to exclude services billed under CPT codes 99304 through 99318 when such
services are furnished in a SNF. We are finalizing the policy as proposed.

Comment: Concerning the proposal to remove the exclusion of claims including the POS code 31, one commenter suggested we use a longer claims run-out period to account for the institutional billing practices for SNFs. This commenter also stated they would “welcome transparency related to POS 31 and 32 claims-based attribution” in the claim and claims line feed files we provide to participating ACOs under §425.704.

Response: As we noted in the 2011 Shared Savings Program final rule (76 FR 67837), a 3-month claims run-out results in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. Additionally, the claim and claim line feed files furnished to ACOs under §425.704 contain Parts A and B claims data regarding beneficiaries who are either prospectively assigned to the ACO or who may be assigned to the ACO at the end of the performance year, depending on the assignment methodology under which the ACO participates. As long as the beneficiary has not declined to share their claims data, and the claim does not include protected health information related to substance use disorder treatment, ACOs receive both the claims for physician services and the facility level claims that would be used to determine whether a service billed under CPT codes 99304 through 99318 was furnished in a SNF.

Comment: A few commenters suggested we only include the newly proposed CPT/HCPCS codes under step 1 of the two-step assignment methodology. The commenters stated these codes should be used for “assigning beneficiaries on the basis of care furnished specifically by primary care physicians and not all ACO professionals.”

Response: We disagree with these comments. We continue to believe our current assignment methodology generally provides an appropriate balance between maintaining a
strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services (80 FR 32748). We also note that the list of specialty types included in step 1 and step 2 of the assignment methodology was informed by CMS medical officers knowledgeable about the services typically performed by physicians and non-physician practitioners (80 FR 32750) as well as comments received in response to the 2014 Shared Savings Program proposed rule.

**Comment:** One commenter suggested an alternative assignment methodology that the commenter believed would be similar to a methodology discussed in the CY 2019 PFS proposed rule which would distinguish between primary and secondary specialties for practitioners billing under the same TIN as part of a multispecialty group. The commenter stated this approach would improve the accuracy of the assignment methodology by focusing on evaluation and management services furnished by primary care providers, rather than specialists. Alternatively, this commenter suggested an assignment methodology similar to methodologies used by state agencies. According to the commenter, this assignment methodology would allow for exclusions, attribution, and tie-breaking steps to support a valid beneficiary population.

**Response:** We encourage the commenter to review our assignment methodology under the Shared Savings Program regulations at 42 CFR part 425, subpart E. Our current assignment methodology emphasizes primary care services provided by primary care clinicians in step one, before considering primary care services furnished by certain specialists in step two. However, we will continue to monitor this issue to determine whether there have been any changes or refinements that would allow us to more precisely identify both primary and secondary practitioner specialties in Medicare claims data and whether those changes should be accounted for in the assignment methodology used in the Shared Savings Program. Any changes to our
assignment methodology would be proposed through future rulemaking for the Shared Savings Program.

As discussed earlier in this final rule, the proposal to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for the office or other outpatient evaluation and management services represented by CPT codes 99201 through 99215 is not being finalized. Therefore, the proposal to include HCPCS “add-on codes”, GPC1X, GCG0X, and GPRO1 in the definition of “primary care services” will not be finalized at this time. We will revisit this proposal in future rulemaking and continue to monitor the annual rulemaking for the PFS to determine if we should propose any changes to the definition of primary care services for the Shared Savings Program to reflect proposed HCPCS/CPT coding changes.

We received no comments on the proposed technical changes to §425.400(c)(1)(iv). After considering the comments received, we are finalizing our proposed revisions to the definition of primary care services, with the exception of the proposal to include the three add-on HCPCS codes GPC1X, GCG0X, and GPRO1. Specifically, we are revising the definition of primary care services in §425.400(c) to add CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443. Additionally, we are finalizing, as proposed, the revisions to our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF and the proposed technical changes to §425.400(c)(1)(iv).

Consistent with the approach we have taken in the past when implementing changes to the assignment methodology, we will adjust ACOs’ historical benchmarks for the performance year starting on January 1, 2019, to account for the changes to the assignment methodology that
we are finalizing in this final rule.

d. Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program

(1) Background

Following the 2017 California wildfires and Hurricanes Harvey, Irma, Maria, and Nate, stakeholders expressed concerns that the effects of these types of disasters on ACO participants, ACO providers/suppliers, and the assigned beneficiary population could undermine an ACO’s ability to successfully meet the quality performance standards, and adversely affect financial performance, including, in the case of ACOs under performance-based risk, increasing shared losses. To address these concerns, we published an interim final rule with comment period titled Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (hereinafter referred to as the Shared Savings Program IFC) that appeared in the December 26, 2017 Federal Register (82 FR 60912). In the Shared Savings Program IFC, we established policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks for ACOs that were affected by extreme or uncontrollable circumstances during performance year 2017. The policies adopted in the Shared Savings Program IFC were effective for performance year 2017, including the applicable quality data reporting period for the performance year. We have considered the comments received on the Shared Savings Program IFC in developing the policies for 2018 and subsequent years.

The extreme and uncontrollable circumstances policies established in the Shared Savings Program for performance year 2017 align with the policies established under the Quality Payment Program for the 2017 MIPS performance period and subsequent MIPS performance periods (see CY 2018 Quality Payment Program final rule with comment, 82 FR 53780 through
In particular, in the Shared Savings Program IFC (82 FR 60914), we indicated that we would determine whether an ACO had been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO’s assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017 as determined under the Quality Payment Program or the ACO’s legal entity was located in such an area. In the Quality Payment Program IFC (82 FR 53897), we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis.

Because ACOs may face extreme and uncontrollable circumstances in 2018 and subsequent years, we proposed to extend the policies adopted in the Shared Savings Program IFC for addressing ACO quality performance scoring and the determination of the shared losses owed for ACOs affected by extreme or uncontrollable circumstances to performance year 2018 and subsequent performance years. In addition, in the Shared Savings Program IFC, we indicated that we planned to observe the impact of the 2017 hurricanes and wildfires on ACOs’ expenditures for their assigned beneficiaries during performance year 2017, and might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking. We considered this issue further in the August 2018 proposed rule (see 83 FR 41904 through 41906).

(2) Proposed Revisions

The financial and quality performance of ACOs located in areas subject to extreme and
uncontrollable circumstances could be significantly and adversely affected. Disasters may have several possible effects on ACO quality and financial performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, as well as, reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible. We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. Catastrophic events outside the ACO’s control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO’s benchmark in the subsequent agreement period. These factors could jeopardize ACOs’ ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

As we stated in the August 2018 proposed rule (83 FR 41900), because widespread disruptions could occur during 2018 or subsequent performance years, we believe it is appropriate to have policies in place to change the way in which we assess the quality and financial performance of Shared Savings Program ACOs in any affected areas. Accordingly, we proposed to extend the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program that were established for performance year 2017 to performance year
2018 and subsequent performance years. Specifically, we proposed that the Shared Savings Program extreme and uncontrollable circumstances policies for performance year 2018 and subsequent performance years would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. As we discussed in the Shared Savings Program IFC (82 FR 60914), we believe it is also appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because if an ACO is unable to submit its quality data as a result of a disaster occurring during the quality data submission window, we would not have the quality data necessary to measure the ACO’s quality performance for the performance year. For example, if an extreme and uncontrollable event were to occur in February 2019, which we anticipate would be during the quality data reporting period for performance year 2018, then the extreme and uncontrollable circumstances policies would apply for quality data reporting and quality performance scoring for performance year 2018, if the reporting period is not extended. We explained that we do not believe it is appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in the applicable performance year. Accordingly, we also proposed that the policies regarding quality reporting would apply with respect to the determination of the ACO’s quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for a performance year and the reporting period is not extended. However, we noted that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO’s financial performance for that performance year, it would not be appropriate to make an adjustment to shared losses in the event an extreme or uncontrollable
event occurs during the quality data reporting period.

Comment: Commenters overwhelmingly supported adopting permanent policies to mitigate the impacts of extreme and uncontrollable circumstances. Several commenters supported finalizing the proposals without modification; however, the majority of commenters suggested modifications to the proposed policies or requested that CMS adopt additional means of providing relief to disaster affected ACOs. The comments and recommendations are discussed below in sections V.B.2.d.(1), (2), and (3) of this final rule.

Response: We appreciate commenters’ support for adopting permanent policies to provide relief to ACOs that are affected by extreme and uncontrollable circumstances.

Comment: A few commenters recommended that CMS take into consideration whether an ACO has experienced an extreme and uncontrollable event during its agreement period when applying certain policies proposed in other sections of the August 2018 proposed rule, if finalized. These included proposed policies related to monitoring for financial performance, repayment mechanism amounts, reconciliation after termination and the determination of participant Medicare FFS revenue and prior participation for purposes of determining participation options.

Response: We thank commenters for their suggestions on ways to further limit the potential negative impacts of extreme and uncontrollable circumstances on ACOs affected by such events. We believe that these suggestions fall outside the scope of the proposals described in section II.E.4 of the August 2018 proposed rule that we are addressing in this final rule. We anticipate discussing our proposals related to other sections of the August 2018 proposed rule in a forthcoming final rule and will address comments related to those sections at that time.
(a) Modification of Quality Performance Scores for all ACOs in Affected Areas

As we explained in the Shared Savings Program IFC (82 FR 60914 through 60916), ACOs and their ACO participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, for 2017, we established a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, would qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. Specifically, we adopted a policy for performance year 2017 of determining whether an ACO had been affected by extreme and uncontrollable circumstances by determining whether 20 percent or more of the ACO’s assigned beneficiaries resided in counties designated as an emergency declared area in the performance year, as determined under the Quality Payment Program as discussed in the Quality Payment Program IFC (82 FR 53898) or the ACO’s legal entity was located in such an area. For 2017, we adopted a policy under which the location of an ACO’s legal entity was determined based on the address on file for the ACO in CMS’ ACO application and management system. We used 20 percent of the ACO’s assigned beneficiary population as the minimum threshold to establish an ACO’s eligibility for the policies regarding quality reporting and quality performance scoring for 2017 because, as we stated in the Shared Savings Program IFC, we believe the 20 percent threshold provides a reasonable way to identify ACOs whose quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected.

The 20 percent threshold was selected to account for the effect of an extreme or
uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS Web Interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS Web Interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we indicated that we believe the 20 percent threshold ensures that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS Web Interface samples in order to fully report on these measures. However, we also noted that it is possible that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas may have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted because the ACO legal entity may be unable to collect the necessary information from their ACO participants or may experience infrastructure issues related to capturing, organizing, and reporting the data to CMS. We stated that if less than 20 percent of the ACO’s assigned beneficiaries reside in an affected area and the ACO’s legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO’s ability to report or on the representativeness of the quality performance score that is determined for the ACO. For performance year 2017, we determined what percentage of the ACO’s performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective
assignment with retrospective reconciliation after the end of the performance year, these ACOs were able to use their quarterly assignment lists, which include beneficiaries’ counties of residence, for early insight into whether they were likely to meet the 20 percent threshold.

In the Shared Savings Program IFC, we modified the quality performance standard specified under §425.502 by adding a new paragraph (f) to address potential adjustments to the quality performance scores for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. We also modified §425.502(e)(4) to specify that an ACO receiving the mean Shared Savings Program ACO quality score for performance year 2017 based on the extreme and uncontrollable circumstances policies would not be eligible for bonus points awarded based on quality improvement in that year because quality data would not be available to determine if there was improvement from year to year.

In the Shared Savings Program IFC, we established policies with respect to quality reporting and quality performance scoring for the 2017 performance year. In anticipation of any future extreme and uncontrollable events, in the August 2018 proposed rule (83 FR 41901) we proposed to extend these policies, with minor modifications, to subsequent performance years as well. In order to avoid confusion and reduce unnecessary burdens on affected ACOs, we proposed to align our policies for 2018 and subsequent years with policies established for the Quality Payment Program in the final rule with comment period, entitled CY 2018 Updates to the Quality Payment Program (82 FR 53568). Specifically, we proposed to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and the applicable time periods. Generally, in line with the approach taken for 2017 in the Quality Payment Program IFC (82 FR 53897), we anticipated that the types of events that would be
considered an automatic triggering event would be events designated as a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, but indicated that CMS would review each situation on a case-by-case basis. We also proposed that CMS would have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO’s assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity. Additionally, we proposed to determine an ACO’s legal entity location based on the address on file for the ACO in CMS’ ACO application and management system.

In the Shared Savings Program IFC, we established a policy for performance year 2017 under which we determined the percentage of the ACO’s assigned population that was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. We begin producing the final list of assigned beneficiaries after allowing for 3 months of claims run out following the end of a performance year. However, the quality reporting period ends before the 3-month claims run out period ends. Therefore, in the August 2018 proposed rule we expressed concern that if, for future performance years, we continue to calculate the percentage of affected beneficiaries based on the ACO’s final list of assigned beneficiaries, it would not be operationally feasible for us to notify an ACO as to whether it meets the 20 percent threshold prior to the end of the quality reporting period because the final list of assigned beneficiaries is not available until after the close of the quality reporting period. We explained that we now believe it would be appropriate to base this calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which would be available with the quarter three program reports, generally in November of the applicable performance year. We also indicated this report would be available to ACOs participating in the
proposed 6-month performance year from January 1, 2019 through June 30, 2019. By basing the calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, we would be able to notify ACOs earlier as to whether they exceed the 20 percent threshold, and ACOs could then use this information to decide whether to report quality data for the performance year. Therefore, for performance year 2018 and subsequent performance years, we proposed to determine the percentage of an ACO’s assigned beneficiaries that reside in an area affected by an extreme and uncontrollable circumstance using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. We indicated that we could use this assignment list report regardless of the date(s) the natural disaster occurred. The assignment list report provides us with a list of beneficiaries who have received the plurality of their primary care services from ACO professionals in the ACO at a specific point in time. As this is the list that is used to determine the quality reporting sample, we believe it is appropriate to use the same list to determine how many of the ACO’s beneficiaries reside in an area affected by a disaster, such that the ACO’s ability to report quality data could be compromised. We proposed to revise §425.502(f) to reflect this proposal for performance year 2018 and subsequent years.

In the Shared Savings Program IFC (82 FR 60916), we described the policies under the MIPS APM scoring standard that would apply for performance year 2017 for MIPS eligible clinicians in an ACO that did not completely report quality. The existing tracks of the Shared Savings Program (Track 1, Track 2 and Track 3), and the Track 1+ Model are all MIPS APMs under the APM scoring standard. If finalized, we expect the BASIC track and ENHANCED track (based on Track 3) proposed in the August 2018 proposed rule would similarly be

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considered MIPS APMs under the APM scoring standard. In the August 2018 proposed rule (83 FR 41902), we noted, for purposes of the APM scoring standard, MIPS eligible clinicians in an ACO that has been affected by an extreme and uncontrollable circumstance and does not report quality for a performance year, and therefore, receives the mean ACO quality score under the Shared Savings Program, would have the MIPS quality performance category reweighted to zero percent resulting in MIPS performance category weighting of 75 percent for the Promoting Interoperability performance category and 25 percent for the Improvement Activities performance category under the APM scoring standard per our policy at §414.137(h)(5)(i)(B). In the event an ACO that has been affected by an extreme and uncontrollable circumstance is able to completely and accurately report all quality measures for a performance year, and therefore receives the higher of the ACO’s quality performance score or the mean quality performance score under the Shared Savings Program, we would not reweight the MIPS quality performance category to zero percent under the APM scoring standard. Additionally, unless otherwise excepted, the ACO participants will receive a Promoting Interoperability (PI) (formerly called Advancing Care Information (ACI)) performance category score under the APM scoring standard based on their reporting, which could further increase their final score under MIPS.

We proposed to revise §425.502(f) to extend the policies established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we proposed that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO’s assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface
quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO’s legal entity is located in such an area, we would use the following approach to calculate the ACO’s quality performance score as specified in proposed revisions to paragraphs (e) and (f) of §425.502.

- The ACO’s minimum quality score would be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO’s quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO’s quality performance score is used, the ACO would also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO would not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we would measure quality improvement based on a comparison between the ACO’s performance in that year and in the most recently available prior performance year in which the ACO reported quality. Under this approach, the comparison would continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years.

Additionally, we proposed to address the possibility that ACOs that have a 6-month performance year (or performance period) during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-
month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for addressing extreme and uncontrollable circumstances.

As described in section II.A.7 of the August 2018 proposed rule, we proposed to use 12 months of data, based on the calendar year, to determine quality performance for the 6-month performance year from January 2019 through June 2019 (83 FR 41856 through 41858). We explained our belief that it is necessary to account for disasters occurring in any month(s) of CY 2019 for ACOs participating in a 6-month performance year during 2019 regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. Therefore, for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019, affected by a disaster in any month of 2019, we would use the alternative scoring methodology specified in §425.502(f) to determine the quality performance score for the 2019 quality reporting period, if the reporting period is not extended. For example, assume that an ACO participates in the Shared Savings Program for a 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue its participation in the program for a new agreement period beginning July 1, 2019 (as proposed). Further assume that we determine that 20 percent or more of the ACO’s assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality
Payment Program, in September 2019. The ACO’s quality performance score for the 2019 reporting period would be adjusted according to the policies in §425.502(f).

We proposed to specify the applicability of the alternative scoring methodology in §425.502(f) for the 6-month performance year from January 1, 2019 through June 30, 2019, in the proposed new section of the regulations at §425.609(d).

We solicited comments on the proposed policies for assessing the quality performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years, including the applicable quality data reporting period for the performance year, unless the reporting period is extended.

**Comment:** One commenter incorrectly stated that CMS proposed to continue to use a threshold of 25 percent to determine the applicability of the proposed alternative quality scoring policies (rather than the actual 20 percent proposed) and noted that they agreed that this threshold was reasonable. This commenter also suggested that CMS consider other percentage thresholds, such as 5 percent or 10 percent, as test cases. The same commenter also encouraged CMS to look at the percentage of an ACO’s physicians and other health clinicians located in an impacted area as another means of determining which ACOs should be automatically eligible for the alternative quality scoring policy. This commenter suggested, for example, using a threshold of 50 percent of NPIs located in an impacted area, based on the practice locations listed in the Provider Enrollment, Chain, and Ownership System (PECOS).

**Response:** We are finalizing our proposal to continue to use 20 percent of assigned beneficiaries residing in a disaster-affected as one of the criteria for determining whether an ACO is eligible for the alternative quality scoring methodology. We will continue to monitor this criterion as we gain more experience with these policies. However, at present we believe that the
20 percent threshold, which was influenced by considerations related to ensuring a sufficient population size to allow affected ACOs to fully report on quality, remains a reasonable level. While we considered the commenter’s suggestion to expand the criteria for identifying affected ACOs to include ACOs for which 50 percent or more of the NPIs billing under the ACO participant TINs are located in an impacted area, we believe that including this additional criterion would create additional operational complexity and less transparency as we do not currently include information on the location of ACO providers/suppliers in program reports.

Comment: Several commenters stated that the proposed policy of using the higher of an ACO’s own quality score in the affected year or the national mean score unfairly penalizes ACOs that have had historically high quality performance. One commenter also noted that this approach could unfairly reward ACOs with historically low quality performance to the detriment of the Medicare Trust Funds. These commenters recommended that CMS should adopt an approach that considers an ACO’s own quality score from one or more prior years, if available. Some of the commenters explained this approach would be similar to a policy used in Medicare Advantage.

Commenters offered various suggestions on how to implement a policy that considers an ACO’s historic quality performance. A few commenters recommended that CMS use the highest of the ACO’s quality score for the affected performance year, the ACO’s quality score for the prior performance year (if available), or the national mean quality score. One commenter recommended following this approach for each individual quality measure. Suggestions from other commenters included: Using the higher of the ACO’s average quality score for the prior two years and the national mean for ACOs in their third or subsequent year in the program and using the national average score for ACOs in their first or second year in the program; Using the
higher of the affected year quality score and the prior year quality score, if one is available, and
otherwise using the higher of the affected year score and the national mean score; Using the
ACO’s historical quality performance instead of the mean when an ACO is in its third or
subsequent performance year in the program.

Several commenters also recommended that the proposed policies in this section be
extended to include all ACOs affected by a natural disaster, not just those that cannot report
quality data. A few commenters provided suggestive evidence that quality outcome measures
such as readmission measures may be subject to immediate and significant impacts in the event
of a natural disaster, which could have an adverse impact on an ACO’s quality score, particularly
given the non-linear nature of the program’s quality scoring methodology under which an ACO
receives zero points on a measure if it falls below the 30th percentile. Several commenters
requested that that those ACOs whose scores on readmissions measures (ACO-8, all-cause
readmissions and ACO-35, SNF readmissions) fall below the 30th percentile should be eligible
to have their quality score adjusted to account for the natural disaster.

Response: We acknowledge that for some ACOs, the mean quality score could be lower,
or higher, than the score those ACOs would have received in the absence of a disaster. However,
we have concerns with the recommended alternatives which would potentially apply an ACO’s
score from the prior year or apply a score that is an average of prior year scores, particularly for
ACOs in their early years of participation in the Shared Savings Program and for which the prior
years may have included a higher number of pay-for-reporting measures, thus making the quality
scores incomparable. Likewise, in section III.F.1.b. of this final rule we are finalizing several
quality measures for use beginning in performance year 2019. These measures will be pay-for-
reporting for the first 2 years of use (2019 and 2020). All else being equal, the addition of these
new pay-for-reporting measures will increase ACOs’ quality scores. Also, we note that ACO quality performance can vary from year to year and the fact that an ACO had a high quality score in prior years does not necessarily guarantee that the ACO would have had an above average score in the affected year in the absence of the natural disaster. Lastly, we would remind commenters that the national mean quality score includes the quality scores of 100 percent earned by ACOs in their first performance year, thus increasing the mean.

For these reasons, we are declining at this time to adopt commenters’ recommendations that we consider prior year quality scores as part of determining the quality performance scores of ACOs affected by extreme and uncontrollable circumstances and are finalizing the proposed policy. We are also declining to adopt the commenter’s recommendation to give special consideration to ACOs based on their performance on the ACO-8 and ACO-35 readmissions measures. We would also like to clarify that both the policy that we finalized for performance year 2017 in the Shared Savings Program IFC and the policy we are finalizing in this rule for performance year 2018 and subsequent performance years would apply to all ACOs deemed to be affected by an extreme and uncontrollable circumstance (20 percent or more of assigned beneficiaries residing in an affected area or legal entity located in such an area), including those ACOs that were able to report quality and those for which scores on ACO-8 and ACO-35 fell below the 30th percentile. We will continue to monitor quality performance among ACOs affected by extreme and uncontrollable circumstances, and as we gain more experience will consider whether any changes to the finalized policy are warranted.

Comment: One commenter agreed with setting a disaster-affected ACO’s quality score to the national mean but opposed using the mean score to calculate “future benchmarks or subsequent year thresholds until complete and accurate reporting can be achieved.” They noted
that “setting quality benchmarks to an artificial mean is not a valid approach to determine legitimate savings and losses.”

Response: We clarify that ACOs’ quality performance scores are not used to calculate quality measure benchmarks. Rather, the quality measure benchmarks are calculating using actual ACO performance and all other available and applicable Medicare FFS data.

Comment: One commenter recommended that all affected ACOs should receive the higher of the 2018 or 2019 Star Rating for each CAHPS measure

Response: We note that the Shared Savings Program does not provide a Star Rating to ACOs based on their CAHPS performance. Star Ratings are used for Medicare Advantage and Medicare Prescription Drug plans to provide quality and performance information to Medicare beneficiaries to assist them in choosing their health and drug services and, solely for Medicare Advantage plans, to implement the quality bonus payment adopted by Congress in the Patient Protection and Affordable Care Act. We believe that incorporating Star Ratings into the Shared Savings Program would need to be part of a larger effort that was not contemplated in the August 2018 proposed rule. In contrast, we believe our proposal of using the higher of an ACO’s own calculated quality score or the mean quality score serves as a way to mitigate negative impacts for disaster-affected ACOs in manner that can be readily incorporated into the existing structure of the Shared Savings Program quality scoring methodology.

Comment: A few commenters recommended that CMS remove claims associated with disaster-impacted beneficiaries and time periods or claims with disaster payment modifier codes when calculating the numerator and denominator of the readmissions measures and other claims-based quality measures.

Response: As we describe in section V.B.2.b. of this final rule, we have examined the use
of existing disaster payment modifiers during 2017 and have found their utilization to be low overall and to vary across ACOs, including those with comparably high shares of beneficiaries residing in disaster affected areas. Therefore, we have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims. We also have concerns about removing claims for beneficiaries residing in affected areas during affected time periods. In addition to adding considerable complexity, this approach could lead to the elimination of a large number of claims for some ACOs. This could lead to bias if the claims removed are systematically different from other claims for reasons apart from the natural disaster, such as because they are concentrated in a specific geographic area or time period and may also make it more difficult for CMS to provide an oversample of beneficiaries to ACOs for the CMS Web Interface sample.

Comment: One commenter requested that CMS provide additional clarity before finalizing any of the policies for extreme and uncontrollable circumstances proposed in the August 2018 proposed rule. In particular, the commenter requested that CMS provide additional clarification on how the agency would determine and announce whether the extreme and uncontrollable circumstances policies would apply or if the reporting period would be extended.

Response: We intend to make an initial determination about whether an ACO meets the criteria for being considered a disaster-affected ACO after quarter 3 assignment has been determined and before the start of the quality reporting period. We will make the final determination with respect to affected ACOs after the end of the calendar year in order to capture any additional extreme and uncontrollable circumstances that may occur in the remainder of the year or during the quality reporting period, if not extended. We will continue to use the quarter 3 assignment list as the basis for this final determination. In the event that CMS decides to extend
the quality reporting period, we would provide notification to ACOs through existing communication channels such as the Shared Savings Program newsletter or an email blast. We also note that if an ACO is determined to be an affected ACO as a result of an extreme or uncontrollable circumstance during the performance year, the alternative quality scoring methodology would apply, regardless of whether the quality reporting period is extended.

Comment: One commenter recommended that CMS adopt the same period as any Declaration of Emergency by the Secretary when determining the applicable time period for an extreme and uncontrollable circumstance instead of an alternative period selected by CMS that may not be as well-aligned with the reality of health services instability for areas under a declaration of emergency. Another commenter encouraged CMS to be transparent regarding the criteria used to determine the applicable time period and to work closely with Medicare Administrative Contractors and the Federal Emergency Management Agency to communicate these policies to ACOs.

Response: We are finalizing our proposals for extreme and uncontrollable circumstances, including our proposal that CMS will have the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred. Although we are not adopting fixed criteria for determining the applicable time periods, we note that for performance year 2017 we used the time periods associated with public health emergencies declared by the Secretary and listed on the CMS Emergency Response and Recovery website (now renamed the Emergency Preparedness & Response Operations website at https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home.html). We anticipate continuing this practice, which we believe to be transparent, going forward. Furthermore, for events for which the public health emergency declaration spans calendar years, we intend to treat the portion of
the period falling within each year as if it were a separate event for purposes of identifying ACOs eligible for the alternative quality scoring methodology and for computing any adjustment to shared losses.

Comment: One commenter expressed concerns about what they described as CMS’ “one-size-fits-all” approach for determining the time period during which an ACO would be subject to the extreme and uncontrollable circumstances policies. They encouraged CMS to allow ACOs an opportunity to request relief from shared losses and negative quality adjustments over a longer period of time, up to a full performance year, to be evaluated by CMS on a case-by-case basis. The commenter noted that the impact of a disaster occurring early in the year may have a different impact than one occurring later in the year and there may be long-lasting effects, which should not have counted against affected ACOs. They stated that the hardship exemption, which would be approved by CMS on a case-by-case basis, would have limited effect on the Trust Funds, but would be important for the integrity of the program by establishing a formal process for ACOs to request an exemption based on extenuating circumstances.

Response: We have elected to adopt automatic policies to address extreme and uncontrollable circumstances in lieu of hardship requests that must be considered on a case-by-case basis in order to increase certainty and reduce administrative burden for both ACOs and CMS. We will continue to monitor the impact of the policies that we are finalizing in this rule, and as we gain more experience, if warranted, we will propose additional modifications through future notice and comment rulemaking.

After considering the comments received, we are finalizing our proposals to extend the policies for determining the quality scores for ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent
performance years. Specifically, we are revising §§425.502(e) and 425.502(f) to state that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year, if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO’s assigned beneficiaries, as determined using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO’s legal entity is located in such an area, we will use the following approach to calculate the ACO’s quality performance score:

- The ACO’s minimum quality score will be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we will use the higher of the ACO’s quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO’s quality performance score is used, the ACO will also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO will not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we will measure quality improvement based on a comparison between the ACO’s performance in that year and in the most recently available prior performance year in which the ACO reported quality.

We clarify that if an ACO reports quality data in a year in which it is affected by an
extreme and uncontrollable circumstance, but receives the national mean quality score, we will use the ACO’s own quality performance score to determine quality improvement bonus points in the following year. For example, if an ACO reported quality data in years 1, 2, and 3 of an agreement period, but received the national mean quality score in year 2 as the result of an extreme or uncontrollable circumstance, we would determine quality improvement bonus points for year 3 by comparing the ACO’s year 3 quality score with its year 2 score. If the ACO received the mean score in year 2 because it did not report quality, we would compare year 3 with year 1 to determine the bonus points for year 3.

We also want to clarify one point regarding the interaction between this alternative quality scoring methodology and MIPS. As we noted above, the MIPS quality performance category is reweighted to zero if a disaster-affected ACO receives the mean quality score under the Shared Savings Program’s extreme and uncontrollable circumstance policy, because it did not or could not report quality data at the ACO (APM Entity) level, regardless of whether or not any of the ACOs participant TINs reported quality outside the ACO. This reweighting under MIPS results in MIPS performance category weighting of 75 percent for the PI performance category and 25 percent for IA performance category. If, for any reason, the PI performance category also is reweighted to zero, which could be more likely when there is a disaster, there would be only one performance category triggering the policy under which the ACO in question would receive a neutral (threshold) MIPS score, as per §414.1380(c) (see discussion at 83 FR 53778). If any of the ACO’s participant TINs do report PI, then the TIN or TINs’ PI performance category scores will be used to score the ACO under the MIPS scoring standard, the PI performance category will not be reweighted, and the policy to assign a neutral (threshold) MIPS score will not be triggered.
(b) Mitigating Shared Losses for ACOs Participating in a Performance-based Risk Track

In the Shared Savings Program IFC (82 FR 60916) we modified the payment methodology for performance year 2017 for performance-based risk tracks established under the authority of section 1899(i) of the Act, to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during 2017. Under this approach, we reduced the ACO’s shared losses, if any, determined to be owed for performance year 2017 under the existing methodology for calculating shared losses in the Shared Savings Program regulations at 42 CFR part 425 subpart G by an amount determined by multiplying the shared losses by two factors: (1) the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO’s assigned beneficiaries who resided in an area affected by an extreme and uncontrollable circumstance. For performance year 2017, we determined the percentage of the ACO’s performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO was determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO’s assigned beneficiaries resided in the disaster area. In this scenario, we would have adjusted the ACO’s shared losses in the following manner: $100,000 - ($100,000 × 0.25 × 0.25) = $100,000 - $6,250 = $93,750. The policies for performance year 2017 are specified in paragraph (i) in §425.606 for ACOs under Track 2 and §425.610 for ACOs under Track 3.

In the August 2018 proposed rule (83 FR 41903), we stated our belief that it would be appropriate to continue to apply these policies in performance year 2018 and subsequent years to address stakeholders’ concerns that ACOs participating under a performance-based risk track
could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO’s control given the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believe that ACOs participating in performance-based risk tracks might reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we adopted for performance year 2017 in the Shared Savings Program IFC, and which we proposed to continue for performance year 2018 and subsequent years, balances the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the portion of their final assigned beneficiary population that was outside the area affected by the disaster. In the August 2018 proposed rule, we explained our belief that, consistent with the policy adopted for performance year 2017 in the Shared Savings Program IFC, it would be appropriate to continue to use the final assignment list report for the performance year for purposes of this calculation. This final assignment list report would be available at the time we conduct final reconciliation and provides the most complete information regarding the extent to which an ACO’s assigned beneficiary population was affected by a disaster.

Additionally, we proposed to also address the possibility that ACOs that have a 6-month performance year during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from
July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019 for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for determining shared losses for ACOs affected by extreme and uncontrollable circumstances.

As described in section II.A.7. of the August 2018 proposed rule (83 FR 41849 through 41853) and the proposed provision at §425.609, we proposed to use 12 months of expenditure data, based on the calendar year, to perform financial reconciliation for the 6-month performance year from January 1, 2019 through June 30, 2019. Accordingly, for ACOs participating in a 6-month performance year during the first half of 2019, we believed it would be necessary to account for disasters occurring in any month(s) of CY 2019, regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster.

For ACOs with a 6-month performance year that are affected by an extreme or uncontrollable circumstance during CY 2019, we proposed to first determine shared losses for the ACO over the full calendar year, adjust the shared losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year according to the methodology proposed under §425.609. For example, assume that: a disaster was declared for October 2019 through December 2019; an ACO is being reconciled for its participation during the performance year from January 1, 2019 through June 30, 2019; the ACO is determined to have shared losses of $100,000 for CY 2019; and 25 percent of the ACO’s assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO’s losses in the following manner: $100,000 - ($100,000 × 0.25 × 0.25) = $100,000 - $6,250 = $93,750, then we would multiply these losses by the portion of the year the ACO participated =
Therefore, we proposed to amend §§425.606(i) and 425.610(i) to extend the policies regarding extreme and uncontrollable circumstances that were established for performance year 2017 to performance year 2018 and subsequent years. In addition, we proposed to include a provision at §425.609(d) to provide that the policies on extreme and uncontrollable circumstances would apply to the determination of shared losses for ACOs participating in a 6-month performance year during 2019.

In the August 2018 proposed rule (83 FR 41904), we noted that to the extent that our proposal to extend the policies adopted in the Shared Savings Program IFC to 2018 and subsequent performance years constitutes a proposal to change the payment methodology for 2018 after the start of the performance year, we believe that consistent with section 1871(e)(1)(A)(ii) of the Act, and for the reasons discussed in section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), it would be contrary to the public interest not to propose to establish a policy under which we would have the authority to adjust the shared losses calculated for ACOs in Track 2 and Track 3 for performance year 2018 to reflect the impact of any extreme or uncontrollable circumstances that may occur during the year.

We also explained that these proposed policies would not change the status of those payment models that meet the criteria to be Advanced APMs under the Quality Payment Program (see §414.1415). Our proposed policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the
requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the Quality Payment Program.

We also emphasized that all ACOs would continue to be entitled to share in any savings they may achieve for a performance year. ACOs in all tracks of the program will continue to receive shared savings payments, if any, as determined under subpart G of the regulations. The calculation of savings and the determination of shared savings payment amounts for a performance year would not be affected by the proposed policies to address extreme and uncontrollable circumstances, except that the quality performance score for an affected ACO may be adjusted as described in section II.E.4 of the proposed rule.

We solicited comments on the proposed policies for assessing the financial performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years.

Comment: Several commenters noted that ACOs are likely to experience increased expenditures as the result of a natural disaster. One commenter noted that studies have shown that natural disasters materially increase Medicare costs per beneficiary. A few other commenters noted that costs can increase because of the impact of the disaster on beneficiaries’ health, safety and anxiety causing increased utilization of services but also because waivers effected during declared Public Health Emergencies relax Medicare payment rules allowing more services to be covered than usual. Another commenter stated that an ACO may experience expenditure increases because its assigned beneficiaries migrate to areas with higher FFS payment rates in search of health care services in the wake of a natural disaster. This commenter noted that ACOs based in Puerto Rico could be significantly affected given that after a natural
disaster many beneficiaries migrate to the U.S. mainland where the FFS payment rates are substantially higher than on the island.

Several commenters shared the opinion that the proposed policy of adjusting shared losses adequately addresses the situation of ACOs that would have had shared losses in the absence of a natural disaster, but had higher shared losses as the result of the disaster. However, they expressed concern that the policy does not provide relief to ACOs that receive a smaller shared savings payment as a result of the disaster or ACOs for which an expenditure increase resulting from a disaster causes the ACO to fall short of its MSR (and thus miss out on shared savings entirely) or to exceed its MLR (and thus owe shared losses when it otherwise would not have had shared losses).

A few commenters recommended addressing this issue by modifying the update that is applied to an ACO’s benchmark for a performance year that is affected by an extreme and uncontrollable circumstance. For example, these commenters recommended that CMS apply a growth rate that is the higher of the national growth rate for assignable beneficiaries or the regional growth rate for assignable beneficiaries (excluding an ACO’s own assigned beneficiaries). They suggested that their recommendation should be used instead of the “current policy” for accounting for the impact of disasters on performance year expenditures, which they believed relies on the use of natural disaster payment modifiers. A few other commenters recommended that CMS use a blend of national and regional expenditure growth rates to update the benchmark as proposed in the August 2018 rule in “normal times” but use a purely regional growth rate in the event of an extreme and uncontrollable circumstance. The same commenters also suggested that CMS remove claims associated with disaster-affected beneficiaries during the relevant time periods or claims with a natural disaster payment modifier code, pending changes
to improve these codes, when calculating performance or benchmark year expenditures. It was unclear, however, whether they meant for these claims adjustments to be made instead of or in addition to their recommended changes to the update factors applied to the historical benchmark.

Several commenters raised concerns about the existing natural disaster modifier codes and whether, in their current form, they could be used to try to capture the negative impact on an ACO’s performance. They noted that some health care providers may not be aware of the existence of such codes and that the codes may not be used properly due to lack of training and competing priorities during an emergency event. They also noted that the existing codes do not capture instances of “unsafe place of discharge”, which they believe is a common reason for lengths of stay to be increased during a disaster and recommended that CMS expand existing modifier codes or add a new code to cover this circumstance. A few commenters recommended providing proper education on the use of such codes, which would allow these codes to serve as a more accurate means for identifying the impacts of natural disasters. Another commenter recommended that CMS allow an additional 6 to 12 months for providers to submit such codes to be considered in expenditure calculations.

Response: We are finalizing our proposed approach to mitigate shared losses for ACOs affected by extreme and uncontrollable circumstances without modification in this final rule. We acknowledge commenters’ concerns regarding the potential impact of extreme and uncontrollable circumstances on the financial performance of ACOs that do not owe shared losses and we appreciate the commenters’ recommendations for how to mitigate these impacts. However, because we did not propose to make any adjustments under these circumstances, these recommendations are outside the scope of this rulemaking. We will continue to monitor the financial performance of ACOs affected by extreme and uncontrollable circumstances, and as we
gain more experience will consider whether any changes to our policies for mitigating the effects of extreme and uncontrollable circumstances are warranted.

Furthermore, we note that although we considered the use of natural disaster payment modifiers in developing the original extreme and uncontrollable circumstances policy for performance year 2017, we did not adopt a policy that used such codes in the Shared Savings Program IFC, nor did we propose in the August 2018 proposed rule to use such codes to adjust benchmark or performance year expenditure calculations for performance year 2018 or subsequent years. We have examined the existing natural disaster payment modifiers (specifically the “DR” condition code used on institutional claims and the “CR” modifier code used on Part B institutional and non-institutional claims) in 2017 claims for ACO assigned beneficiaries. We found that these codes were not widely or consistently used and that there appears to be variation in their use among ACOs. For example, among 69 ACOs with 90 percent or more of assigned beneficiaries residing in a disaster affected area, we found that only 0.01 percent of institutional claims and only 0.0006 percent of non-institutional claims included such a code. Among this same group of ACOs, the total number of claims (institutional or non-institutional) containing one of these codes ranged from 0 to 155 with a mean of 14 and a median of 8. In a separate analysis, we found that claims completion rates were comparable in disaster-affected and non-affected years which suggests that the low levels of modifier usage are not necessarily due to delayed claim submission. Based on these analyses, as well as the comments offered in response to the August 2018 proposed rule, we also have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims.

As we described in the August 2018 proposed rule, and have recounted in this final rule, we have some concerns about removing claims for affected beneficiaries and time periods from
benchmark year expenditure calculations. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to performance or benchmark year expenditure calculations for ACOs affected by extreme and uncontrollable circumstances through further notice and comment rulemaking.

We also note that, although the policies regarding extreme and uncontrollable circumstances we are finalizing in this final rule do not include an explicit adjustment to the shared savings payment of a disaster-affected ACO, our alternative methodology for quality scoring can indirectly increase an ACO’s shared savings payment. In performance year 2017, 62 of 117 disaster-affected ACOs received the national mean quality score, as it was higher than the score the ACO would have received in the absence of the policy.

After considering the comments received, we are finalizing our proposal to extend the policy for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years. We are revising §§425.606(i) and 425.610(i) to indicate that we will reduce the amount of shared losses calculated for the performance year by an amount determined by multiplying (1) the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO’s assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. We are also finalizing our proposal, through a new provision at §425.609(d), to adjust shared losses for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019. For ACOs in a 6-month performance year we will first determine shared losses for the ACO over the full calendar year, reduce the ACO’s shared losses for the calendar year for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month
performance year.

(c) Determination of Historical Benchmarks for ACOs in Affected Areas

In the Shared Savings Program IFC, we sought comment on how to address the impact of extreme and uncontrollable circumstances on the expenditures for an ACO’s assigned beneficiary population for purposes of determining the benchmark (82 FR 60917). As we explained in the Shared Savings Program IFC (82 FR 60913), the impact of disasters on an ACO’s financial performance could be unpredictable as a result of changes in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. On the other hand, patient populations remaining in impacted areas might receive fewer services and have lower overall costs to the extent that healthcare providers are unable to reopen their offices because they lack power and water or have limited access to fuel for operating alternate power generators. Significant changes in costs incurred, whether increased or decreased, as a result of an extreme or uncontrollable circumstance may impact the benchmark determined for the ACO’s subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. An increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO’s historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures. Likewise, a decrease in expenditures for a particular calendar year would result in a lower benchmark value when the same calendar year is used to determine the ACO’s historical benchmark.
While considering options for adjusting ACOs’ historical benchmarks to account for disasters occurring during a benchmark year, we considered the effect that the proposed regional factors, that are discussed in section II.D.3. of the August 2018 proposed rule (83 FR 41886 through 41891), might have on the historical benchmarks for ACOs located in a disaster area. After review, we explained that we believe that when regional factors are applied to an ACO’s historical benchmark, the regional factors would inherently adjust for variations in expenditures from year to year, and thus would also adjust for regional variations in expenditures related to extreme and uncontrollable circumstances. For example, assume that an ACO experienced a reduction in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, also assume expenditures returned to their previously higher level in 2018 and this ACO subsequently renewed its ACO participation agreement in 2020. In 2020, when the ACO’s historical benchmark would be reset (rebased), the expenditures for 2017 (now a historical benchmark year) would be subject to a higher regional trend factor because expenditures increased back to the expected level in 2018, which would increase the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark increased even further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO’s historical benchmark. In contrast, consider an ACO that experienced an increase in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, assume expenditures returned to their previously lower level in 2018 and this ACO renewed its ACO participation agreement in 2020. In 2020, when the ACO’s historical benchmark would be reset, the expenditures for 2017 would be subject to a lower regional trend factor because expenditures
decreased back to the expected level in 2018, which would decrease the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark decreased further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO’s historical benchmark.

Our expectation that the proposed regional factors that would be used to establish an ACO’s historical benchmark would also adjust for variations in expenditures related to extreme and uncontrollable circumstances was supported by a preliminary analysis of data for areas that were affected by the disasters that occurred in performance year 2017. Our analysis of the data showed that, as a result of the disasters in these areas, expenditure trends for the performance year appeared below projections. For these areas, the expenditures began to increase after the disaster incident period ended, but expenditures were still below expectations for the year. Based on the expenditure trends beginning to return to expected levels after the disaster period, it would be reasonable to expect that expenditures would continue to increase to expected levels in 2018. This difference between the lower than expected levels of expenditures in 2017 and a return to expected expenditures in 2018, would result in a higher regional trend factor being applied to 2017 expenditures when they are used to determine an ACO’s historical benchmark. Although our analysis for the proposed rule was performed using the proposed regional factors, we expect that our existing benchmarking methodology at §425.603, which also incorporates regional factors in the determination of an ACO’s historical benchmark for its second or subsequent agreement period beginning in 2017 or later years, would have a similar result.

In the August 2018 proposed rule (83 FR 41905), in considering whether it might be necessary to make an additional adjustment to ACOs’ historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, we considered an
approach where we would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period. Such an approach would be expected to proportionally increase the historical benchmark for ACOs that experienced a decrease in expenditures, and conversely proportionally decrease the historical benchmark for ACOs that experienced an increase in expenditures for their assigned beneficiaries who were impacted by a disaster. Under this approach, for each of the historical benchmark years, we would identify each ACO’s assigned beneficiaries who had resided in a disaster area during a disaster period. The portion of expenditures for these assigned beneficiaries that was impacted by the disaster would be removed from the applicable historical benchmark year(s). The removal of these expenditures from the historical benchmark year(s) would allow the historical benchmark calculations to include only expenditures that were not impacted by the disaster. We believe this methodology for calculating benchmark expenditures would adjust for expenditure increases or decreases that may occur as a result of impacts related to a disaster.

We noted that if we were to implement such an adjustment to the historical benchmark, we believed it would be appropriate to avoid making minor historical benchmark adjustments for an ACO that was not significantly affected by a disaster by establishing a minimum threshold for the percentage of an ACO’s beneficiaries located in a disaster area. Based on data from 2017, quarter 3, over 80 percent of ACOs had less than 50 percent of their assigned beneficiaries residing in disaster counties, with over 75 percent having less than 10 percent of their assigned beneficiaries residing in disaster counties. Based on this data, we noted our belief that a minimum threshold of 50 percent of assigned beneficiaries residing in disaster counties could be
an appropriate threshold for the adjustment to historical benchmarks because historical benchmarks are calculated based on the ACO’s entire assigned beneficiary population in each benchmark year, rather than a sample as is used for quality reporting.

However, we were concerned that this methodology for calculating an adjustment might not be as accurate as the inherent adjustment that would result from applying regional factors when resetting the benchmark and may impact other expected expenditure variations occurring in the impacted areas. For example, if an additional disaster adjustment were to be applied, it might have unintended impacts when expenditure truncation is applied, it might inappropriately weight and not account for expected variations in expenditures between areas that were and were not impacted by the disaster, and it might compound effects that have already been offset by the regional adjustment. In addition, the expenditures, as adjusted, may not be representative of the ACO’s actual performance and aggregate assigned beneficiary population during the benchmark period.

In summary, we noted our belief that the regional factors that we had proposed to apply as part of the methodology for determining an ACO’s historical benchmark would reduce the expenditures in a historical benchmark year when they are greater than expected (relative to other historical benchmark years) as a result of a disaster and conversely increase expenditures in a historical benchmark year when they are below the expected amount. For these reasons, we believed that the proposal in section II.D.3. of the August 2018 proposed rule (83 FR 41887 through 41888) to apply regional factors when determining ACOs’ historical benchmarks, starting with an ACO’s first agreement period for agreement periods starting on July 1, 2019, and in subsequent years, would be sufficient to address any changes in expenditures during an ACO’s historical benchmark years as a result of extreme and uncontrollable circumstances, and
an additional adjustment, such as the method discussed previously in this section would not appear to be necessary. However, we noted that we would continue to evaluate the impact of the 2017 disasters on ACOs’ assigned beneficiary expenditures, and that we intended to continue to consider whether it might be appropriate to make an additional adjustment to the historical benchmark to account for expenditures that may have increased or decreased in a historical benchmark year as a result of an extreme or uncontrollable circumstance.

We solicited comments on these issues, including whether it is necessary to adjust ACOs’ historical benchmarks to account for extreme and uncontrollable circumstances that might occur during a benchmark year, and appropriate methods for making such benchmark adjustments. We also noted that the proposal in section II.D.3. of the August 2018 proposed rule to apply regional factors to determine ACOs’ historical benchmarks would apply starting with an ACO’s first agreement period for agreement periods starting on July 1, 2019, and in subsequent years and would therefore have no effect on benchmarks for ACOs in a first agreement period starting before July 1, 2019 (see 83 FR 41887). Accordingly, we solicited comments on whether and how an adjustment should be made for ACOs whose benchmarks do not reflect regional factors. We also invited comments on any additional areas where relief may be helpful or other ways to mitigate unexpected issues that may arise in the event of an extreme and uncontrollable circumstance.

**Comment:** A few commenters noted that expenditure increases in a performance year due to a natural disaster could lead to unjustly high benchmark year expenditures in an ACO’s subsequent agreement period which could create vulnerabilities for the Trust Funds. As described in the prior section V.B.2.d.(2) of this final rule, we received a few comments recommending modifications to the update that is applied to an ACO’s benchmark for a
performance year that is affected by an extreme and uncontrollable circumstance. Another commenter suggested removing claims from benchmark and performance year expenditures that have a disaster modifier code or are associated with a beneficiary residing a disaster-affected area during an affected time period.

Response: As discussed in the prior section V.B.2.d.(2) of this final rule, we intend to further consider commenters’ recommendations that we address the financial impacts of extreme and uncontrollable circumstances through the update that is applied to the historical benchmark and how this approach could mitigate potential negative impacts to ACOs or to the Medicare Trust Funds for the performance year in which a disaster occurs, performance years for which there was a disaster in one or more of the benchmark years, or cases where an ACO was affected by disasters in both the benchmark period and the performance year.

As described in the prior section V.B.2.d.(2) of this final rule, we have concerns about commenters’ recommendation to exclude claims with a natural disaster modifier code, or claims associated with disaster affected beneficiaries and time periods from benchmark or performance year expenditures. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to our methodology for calculating performance year or benchmark year expenditures through further notice and comment rulemaking.

Comment: One commenter opposed using regional factors as currently calculated by CMS to address concerns about the effect of extreme and uncontrollable circumstances on ACOs’ historical benchmarks. This commenter disagreed with CMS’ current approach, which includes ACO assigned beneficiaries when calculating regional expenditures. They stated that “[A]bsent a reform that addresses the underlying issue with the regional adjustment factor, applying it to ACOs in a region recovering from an extreme or uncontrollable circumstance will
perpetuate the flaws.”

Response: We continue to believe that the use of regional factors in establishing and updating the benchmark will provide an inherent adjustment for regional variations in expenditures related to extreme and uncontrollable circumstances. As the commenter notes, and under the June 2016 final rule, regional expenditure calculations in the Shared Savings Program are based on all assignable beneficiaries in an ACO’s regional service area including ACO assigned beneficiaries. We have detailed in that earlier rule our reasons for not excluding assigned beneficiaries from these calculations (see 81 FR 37960). Furthermore, we do not believe that inclusion of an ACO’s assigned beneficiaries would reduce the effectiveness of regional factors to inherently adjust for regional variations in expenditures related to extreme and uncontrollable circumstances as we have no reason to believe that such an event would have a differential impact on expenditures for assigned beneficiaries relative to expenditures for assignable beneficiaries that are not assigned to an ACO.

After considering comments we received on the determination of historical benchmarks for ACOs in areas affected by extreme and uncontrollable circumstances, we are not making any changes to the benchmarking methodology to address such events at this time. We will continue to monitor the impact of extreme and uncontrollable circumstances on benchmark expenditures and, if applicable, the extent to which any impact is mitigated by the use of regional factors in establishing and updating the benchmark. If warranted, we will propose additional modifications to our benchmarking methodology to address the effects of extreme and uncontrollable circumstances through future notice and comment rulemaking.

e. Program Data and Quality Measures

In section II.E.5. of the August 2018 proposed rule (41906 through 41908), we solicited
comments on possible changes to the quality measure set and modifications to program data shared with ACOs to support CMS’ Meaningful Measures initiative and respond to the nation’s opioid misuse epidemic. As part of the Meaningful Measures initiative, the agency’s efforts are focused on updating quality measures, reducing regulatory burden, and promoting innovation (see CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html). Under the Meaningful Measures initiative, we are working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first.

When we developed the quality reporting requirements under the Shared Savings Program, we considered the quality reporting requirements under other initiatives, such as the Physician Quality Reporting System (PQRS) and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS Final Rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. Currently, more than half of
the 31 Shared Savings Program quality measures are outcome-based, including--

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience;
- Outcome measures supporting care coordination and effective communication, such as unplanned admission and readmission measures; and
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes and control of high blood pressure.

As we explained in the August 2018 proposed rule (83 FR 41906), it is important that the quality reporting requirements under the Shared Savings Program align with the reporting requirements under other Medicare initiatives and those used by other payers in order to minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting. We sought comment, including recommendations and input on meaningful measures, on how we may be able to further advance the quality measure set for ACO reporting, consistent with the requirement under section 1899(b)(3)(C) of the Act that the Secretary seek to improve the quality of care furnished by ACOs by specifying higher standards, new measures, or both.

One particular area of focus by the Department of Health and Human Services is the opioid misuse epidemic. The Centers for Disease Control and Prevention (CDC) reports that the number of people experiencing chronic pain lasting more than 3 months is estimated to include 11 percent of the adult population. According to a 2016 CDC publication, 2 million Americans had opioid use disorder (OUD) associated with prescription opioids in 2014 (https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Since the implementation of Medicare Part D in 2006 to cover prescription medications, the Medicare program has become
the largest payer for prescription opioids in the United States (Zhou et al, 2016; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955937/). Safe and effective opioid prescribing for older adults is of particular importance because misuse and abuse of opioids can lead to increased adverse events in this population (for example, increased falls, fractures, hospitalization, ER visits, mortality), especially given the high prevalence of polypharmacy in the elderly. Polypharmacy is the simultaneous use of multiple drugs by a single patient, for one or more conditions, which increases the risk of adverse events. For example, a study by MedPAC found that some beneficiaries who use opioids fill more than 50 prescriptions among 10 drug classes annually (http://www.medpac.gov/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf?sfvrsn=0, MedPAC, 2015).

As part of a multifaceted response to address the growing problem of overuse and abuse of opioids in the Part D program, CMS adopted a policy in 2013 requiring Medicare Part D plan sponsors to implement enhanced drug utilization review. Between 2011 through 2014, there was a 26 percent decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid over-utilizers which may be due, at least in part, to these new policies. On January 5, 2017, CMS released its Opioid Misuse Strategy. This document outlines CMS’ strategy and the array of actions underway to address the national opioid misuse epidemic and is available at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.

We aim to align our policies under the Shared Savings Program with the priorities identified in the Opioid Misuse Strategy and the Department of Health and Human Services
Strategy to Combat Opioid Abuse, Misuse, and Overdose\textsuperscript{36} and to help ACOs and their participating providers and suppliers in responding to and managing opioid use, and are therefore considering several actions to improve alignment. Specifically, as we described in the August 2018 proposed rule, we are considering what information regarding opioid use, including information developed using aggregate Medicare Part D data, could be shared with ACOs. We are also considering the addition of one or more measures specific to opioid use to the ACO quality measures set. The potential benefits of such policies would be to focus ACOs on the appropriate use of opioids for their assigned beneficiaries and support their opioid misuse prevention efforts.

First, we are considering what information, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. We recognize the importance of available and emerging resources regarding the opioid epidemic at the federal, state, and local level, and intend to work with our federal partners to make relevant resources available in a timely manner to support ACOs’ goals and activities. We will also continue to share information with ACOs highlighting Federal opioid initiatives, such as the CDC Guideline for Prescribing Opioids for Chronic Pain (https://www.cdc.gov/drugoverdose/prescribing/guideline.html), which reviews the CDC’s recommended approach to opioid prescribing, and the Surgeon General’s report on Substance Use and Addiction, Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health (https://addiction.surgeongeneral.gov/) which focuses on educating and mobilizing prescribers to take action to end the opioid epidemic by improving prescribing practices, informing patients about the risks of and resources for opioid addiction, and encouraging health care professionals to take a pledge to end the opioid crisis. We also intend to

continue to highlight information about the opioid crisis and innovations for opioid treatment and prevention strategies in ACO communications and webinars by including topics such as innovative uses of health IT for opioid use disorder treatment and specifically for electronic clinical decision support consistent with the CDC guidelines, as available.

Although we recognize that not all beneficiaries assigned to Shared Savings Program ACOs have Part D coverage, we believe a sufficient number do have Part D coverage to make aggregate Part D data regarding opioid use helpful for the ACOs. As an example, we have found the following information for performance year 2016:

- Approximately 70 percent of beneficiaries assigned to ACOs participating in the Shared Savings Program had continuous Part D coverage.
- For assigned beneficiaries with continuous Part D enrollment, almost 37 percent had at least one opioid prescription. This percentage ranged from 10.6 percent to 58.3 percent across ACOs.
- The mean number of opioid medications filled per assigned beneficiary (with continuous Part D coverage) varied across ACOs, ranging from 0.3 to 4.5 prescriptions filled, with an average of 2.1 prescriptions filled.
- The number of opioid prescriptions filled for each assigned beneficiary with at least one opioid prescription filled varied across ACOs and ranged from 2.6 to 8.4 prescriptions, with an average of 5.5 opioid prescriptions filled.

ACOs currently receive, as part of the monthly claims and claims line feed data, Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing. We encourage ACOs to use this beneficiary-level data in their care delivery practices.
In the August 2018 proposed rule (83 FR 41907), we sought suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. The type of aggregate data should be highly relevant for a population-based program at the national level and have demonstrated value in quality improvement initiatives. We noted that we are particularly interested in high impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost. We aim to provide aggregate data that have validity for longitudinal analysis to enable both ACOs and the Shared Savings Program to trend performance across time and monitor for changes. Aggregate data on both processes and outcomes are appropriate, provided that the data are readily available. Types of aggregate data that we have begun to consider, based on the information available from prescription drug event records for assigned beneficiaries enrolled in Medicare Part D, include filled prescriptions for opioids (percentage of the ACO’s assigned beneficiaries with any opioid prescription, number of opioid prescriptions per opioid user), number of beneficiaries with a concurrent prescription of opioids and benzodiazepines; and number of beneficiaries with opioid prescriptions above a certain daily Morphine Equivalent Dosage threshold. We also sought comments on measures that could be added to the quality measure set for the purpose of addressing the opioid epidemic and addiction, more generally. We sought comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on measures related to addiction. In particular, we noted that we were considering the following relevant NQF-endorsed measures, with emphasis on Medicare beneficiaries with Part D coverage.
who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.

- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

In addition, we sought input on potential measures for which data are readily available, such as measures that might be appropriately calculated using Part D data, and that capture performance on outcomes of appropriate opioid management. We requested that comments on measures that are not already NQF endorsed include descriptions of reliability, validity, benchmarking, the population in which the measure was tested, along with the data source that was used, and information on whether the measure is endorsed and by what organization. We recognized that measures of the various aspects of opioid use may involve concepts related to integrated, coordinated, and collaborative care, including as applicable for co-occurring and/or chronic conditions, as well as measures that reflect the impact of interventions on patient
outcomes, including direct and indirect patient outcome measures. We also sought comment on opioid-related measures that would support effective measurement alignment of substance use disorders across programs, settings, and varying interventions.

Comment: A majority of commenters supported CMS’ focus on burden reduction stating that they are encouraged by the administration’s efforts to reduce reporting burden for healthcare providers. However, one commenter cautioned that although decreasing burden is a laudable goal, removing process measures could unfairly impact the quality scores of healthcare providers who care for vulnerable patients exposed to the harshest social determinants of health. Several commenters suggested that CMS strive toward a core measure set that identifies and harmonizes measures across multiple CMS programs, so that incentives and goals are aligned across healthcare providers and care settings.

Several commenters supported the agency’s Meaningful Measures Initiative stating that CMS should not only consider whether a measure is a process measure, but also whether the measure is considered a low-value process measure, before removing it from the Shared Savings Program quality measure set. In addition, these commenters supported CMS’ move toward the use of outcome measures, as the emphasis on improved health outcomes is an appropriate focus and goal.

Several commenters suggested future potential refinements to the Shared Savings Program measure set. One commenter urged CMS to better align the Shared Savings Program with Medicare Advantage, suggesting that there should be fewer measures that are included in a roadmap for implementation in both programs, because the different measures and the differing standards for compliance that are currently used cause confusion and require the use of limited provider and staff resources. In addition, this commenter stated that with a roadmap of measures,
organizations would be able to focus their energies on achieving these metrics in a systematic and deliberate fashion.

Another commenter expressed concern with the timing and burden of quality measurement and payment, suggesting that we streamline quality efforts to include ten specific outcome measures that have a social and public health impact and offering a financial incentive in connection with each measure to encourage physicians to drive, fund, and sustain continued quality efforts.

A few commenters suggested that CMS should focus on the prevention, treatment, and management of behavioral health. They stated that in the absence of effective behavioral health assessment tools, the vast majority of people with mental health conditions go unidentified in primary care settings, which in most cases leads to non-adherent patients and higher total medical costs. In addition, they stated that behavioral health is central to the prevention, treatment, and management of the preventable manifestations of diseases and health conditions. They suggested that CMS consider including broader measures that would encourage behavioral health and medical providers to work collaboratively to provide coordinated care.

Several commenters suggested that CMS consider developing a quality measure set that would evaluate the breadth of chronic conditions common in the patient population assigned to Shared Savings Program ACOs and use appropriate outcome measures to ensure assigned beneficiaries are receiving the necessary care. They noted that the proposed Shared Savings Program quality measure set discussed in section III.F.1.c. of the CY 2019 PFS proposed rule (83 FR 35876 through 35878) does not include measures related to respiratory conditions, like chronic obstructive pulmonary disease or asthma, diabetes, or additional conditions like heart failure. They encouraged CMS to include measures that evaluate the quality of care for these
conditions, such as, measures focused on the delivery of comprehensive lower extremity exams for diabetic patients, and rates of complications such as amputation. They stated that greater emphasis on management of chronic conditions is necessary to promote quality and improve patient outcomes. Another commenter suggested CMS should increase the number of claims-based measures in the Shared Savings Program measure set and provide ACOs with user-friendly, actionable reports that detail the ACO-specific data used to calculate specific measure performance. One commenter suggested that CMS consider quality measures that reinforce shared decision making, as part of treatment plans that align with the individual’s goals as this is a foundational component of high-quality patient-centered care.

Response: We thank the commenters for their thoughtful input on the quality measures used to assess the performance of ACOs under the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback in the development of our proposals.

Comment: The majority of commenters that addressed the potential inclusion of measures related to opioid use in the Shared Savings Program quality measure set were supportive of this effort. A few commenters noted that continued support and recognition for integration of EHRs and electronic sharing of health information, would promote improved communication between healthcare providers, which may help curb opioid abuse and addiction.

Several commenters supported CMS’ efforts to consider the possible addition of opioid use measures to the Shared Savings Program quality measure set in future program years, but some commenters recommended that CMS work with the measure developer and NQF to reduce the dosage threshold of two of the measures discussed in the August 2018 proposed rule to 90 MME per day to align with the CDC guidelines for Prescribing Opioids for Chronic Pain.
Another commenter agreed that promoting the measurement of opioid use and overuse, monitoring, and education through quality reporting is an important step in understanding and addressing the opioid crisis. A few commenters recommended that CMS utilize the Prescription Drug Monitoring Program (PDMP) Query measure, as most states have implemented PDMPs, and the PDMP Query measure is a reasonable step to improve and measure quality in opioid prescribing.

Another commenter stated that in general they support CMS’ considering the addition of opioid use measures to the Shared Savings Program measure set; however, they expressed their belief that opioid dosage measures are of low-value to the program because, “…since the issuance of Centers for Disease Control (CDC) and Prevention guidelines, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time.” This commenter noted that implementing a quality measure that could force a health provider to abruptly reduce or discontinue this medication regimen could have extreme adverse outcomes such as depression, loss of function, or even suicide. The commenter suggested CMS consider quality measures other than dosage measures when determining the most appropriate metrics to help address and respond to the opioid crisis.

One commenter expressed concern with the specific opioid related measures on which CMS sought comment for potential inclusion in the Shared Savings Program quality measure set. The commenter stated that quality measurement needs to focus on utilization of preventive strategies, such as screening and treatment for substance abuse, as well as pain management. This commenter disagreed with the potential inclusion of NQF #2940: Use of Opioids at Higher Dosage in Persons Without Cancer because a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics, on its own is not a good indication
of quality patient care. In addition, they expressed concerns with the potential inclusion of *NQF #2950: Use of Opioids from Multiple Providers in Persons Without Cancer* and *NQF # 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer* in the Shared Savings Program measure set, as these measures were developed with the intention of determining the quality of care provided by prescription drug health plans and because of the lack of information on the feasibility of ACOs’ collecting and reporting pharmacy claims data.

Another commenter noted that the three opioid measures CMS suggested for inclusion in the Shared Savings Program measure set are appropriately focused on the right patient population and address the major risks associated with opioid misuse - high dosages and multiple prescriptions. However, the commenter urged CMS to conduct testing to ensure the measures provide accurate, reliable data at the ACO level, as they are currently endorsed at the health plan level not the ACO level. The commenter suggested that the measures should be reported on a voluntary or pay-for-reporting basis rather than as pay-for-performance measures for the first few years after they are added to the measure set.

Another commenter expressed concern that including measures that are so specific will distract ACOs from focusing on what works for them and their assigned beneficiary population. As an alternative, the commenter suggested CMS provide webinars, education, tools, and data for ACOs to incorporate into their current structure for care management and patient engagement. Several commenters recommended that CMS provide aggregated data to ACOs on opioid use, but they also urged CMS to go further and provide aggregated beneficiary data on the use of all prescribed medications and their related diagnoses. Similarly, another commenter encouraged CMS to continue to add more real-time data to the quarterly quality reports so providers can leverage this data to improve patient care, address social inequities in health,
correct inefficiencies to drive down costs, and help to address the nation’s opioid epidemic and other pressing health crises.

Response: We thank the commenters for their thoughtful input on the possible addition of measures related to opioid use to the quality measure set for the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback from commenters before making any proposals with respect to the addition of opioid use measures.

f. Promoting Interoperability

Consistent with the call in the 21st Century Cures Act for interoperable access, exchange, and use of health information, the final rule entitled, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (2015 Edition final rule) (80 FR 62601) under 45 CFR part 170\(^{37}\) focused on health IT certification criteria that support patient care, patient participation in care delivery, and electronic exchange of interoperable health information. The 2015 Edition final rule, which was issued on October 16, 2015, aimed to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information and to facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface capabilities. These policies are relevant to assessing the use of CEHRT under the Quality Payment Program, Shared Savings Program, and other value based payment initiatives.

Under the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such

\(^{37}\) For more information, see https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.
as through the use of telehealth, remote patient monitoring, and other such enabling technologies. Consistent with the statute, ACOs participating in the Shared Savings Program are required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information (§425.112(b)(4)). Additionally, since the inception of the program in 2012, CMS has assessed the level of CEHRT use by certain clinicians in the ACO using a double-weighted quality measure (Use of Certified EHR Technology, ACO-11) as part of the quality reporting requirements for each performance year. Based on previously-finalized policies, for the 2018 performance year, we will use data derived from the Quality Payment Program’s Promoting Interoperability performance category to calculate the percentage of eligible clinicians participating in an ACO who successfully meet the Advancing Care Information Performance Category Base Score for purposes of ACO-11. Because the measure is used in determining an ACO’s quality score and for determining shared savings or shared losses under the Shared Savings Program, all eligible clinicians participating in Shared Savings Program ACOs must submit data for the Quality Payment Program’s Advancing Care Information performance category for performance year 2018, including those eligible clinicians who are participating in Shared Savings Program tracks that have been designated as Advanced APMs and who have met the QP threshold or are otherwise not subject to the MIPS reporting requirements.

In the August 2018 proposed rule (83 FR 41908), we noted that some alternative payment models tested by the Innovation Center, require all participants to use CEHRT even though certain tracks within those Models do not meet the financial risk standard for designation as
Advanced APMs. The primary rationale for this requirement is to promote CEHRT use by eligible clinicians and organizations participating in APMs by requiring them to demonstrate a strong commitment to the exchange of health information, regardless of whether they are participating in an APM that meets the criteria to be designated as an Advanced APM. Under the Quality Payment Program, an incentive payment will be made to certain Qualifying APM Participants (QPs) participating in Advanced APMs. Beginning in 2017, an eligible clinician can become a QP for the year by participating sufficiently in an Advanced APM during the QP performance period. Eligible clinicians who are QPs for a year receive a lump sum APM incentive payment for payment years from 2019 through 2024, and are excluded from the MIPS reporting requirements for the performance year and the MIPS payment adjustment for the payment year. In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. In the CY 2017 Quality Payment Program final rule, we established that Advanced APMs meet this requirement if the APM either—(1) requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or (2) for the Shared Savings Program, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity (§414.1415(a)(1)(i) and (ii)). In the CY 2017 PFS final rule, we updated the title and specifications of the EHR quality measure (ACO-11) to align with the Quality Payment Program criterion on CEHRT use in order to ensure that certain tracks under the Shared Savings Program could meet the criteria to be Advanced APMs.
Specifically, we revised the ACO-11 measure to assess ACOs on the degree of CEHRT use by all eligible clinicians participating in the ACO. Performance on the measure is determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Performance Category Base Score.

In light of our additional experience with the Shared Savings Program, our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center, in the August 2018 proposed rule, we indicated that we believe it would be appropriate to amend our regulations related to CEHRT use and the eligibility requirements for ACOs to participate in the Shared Savings Program. Specifically, we proposed to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Additionally, we proposed that, as a condition of participation in a track, or a payment model within a track, that meets the financial risk standard to be an Advanced APM, ACOs must certify that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold required for Advanced APMs as defined under the Quality Payment Program (§414.1415(a)(1)(i)). In conjunction with this proposed new eligibility requirement, we proposed to retire the EHR quality measure (ACO-11) related to CEHRT use, thereby reducing reporting burden, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years. In addition, consistent with our proposal to align with the Advanced APM criterion on use of CEHRT, we proposed to apply the definition of CEHRT under the Quality Payment Program (§414.1305), including any
subsequent updates to this definition, for purposes of the Shared Savings Program by adding a definition of “CEHRT” to §425.20.

First, we proposed that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM would have to attest and certify upon application to participate in the Shared Savings Program, and subsequently, as part of the annual certification process, that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. ACOs would be required to submit this certification in the form and manner specified by CMS.

We stated that our proposed requirement aligned with the requirements regarding CEHRT use in many alternative payment models being tested by the Innovation Center. Additionally, we noted that at the time of application, ACOs must have a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§425.112(b)(4)(i)(C)). Over the years, successful ACOs have impressed upon us the importance of “hitting the ground running” on the first day of their participation in the Shared Savings Program, rather than spending the first year or two developing their care processes. We stated our belief that requiring ACOs that are entering a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM to certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT would align with existing requirements under the Shared Saving Program and many Innovation Center alternative payment models and encourage participation by organizations that are more likely to meet the program goals. In addition, we stated that such a requirement would also promote greater emphasis on the importance of CEHRT use for care coordination. Finally, we noted that in the CY 2019 PFS
proposed rule, we had proposed to increase the threshold of CEHRT use required for APMs to meet criteria for designation as Advanced APMs under the Quality Payment Program to 75 percent (see 83 FR 35990). Given our proposed updates and modifications to the Shared Savings Program tracks in the August 2018 proposed rule, as well as the proposed changes to the requirements regarding CEHRT use under the Quality Payment Program, we explained that we believe it is important that only those ACOs that are likely to be able to meet or exceed the threshold designated for Advanced APMs should be eligible to enter and continue their participation in the Shared Savings Program. Because of this, and also our desire to align requirements across the different payment models and tracks in Shared Savings Program, as explained in more detail later in this section, we also considered whether to propose to require all Shared Savings Program ACOs, including ACOs in tracks or payment models within tracks that would not meet the financial criteria to be designated as Advanced APMs, to meet the 75 percent threshold proposed under the Quality Payment Program.

We proposed changes to the regulations at §425.204(c) (to establish the new application requirement) and §425.302(a)(3)(iii) (to establish the new annual certification requirement). We also proposed to add a new provision at §425.506(f)(1) to indicate that for performance years starting on January 1, 2019, and subsequent performance years, all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers. We noted that this proposal, if finalized, would not affect the previously-finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. In other words, MIPS eligible clinicians who are participating in ACOs would continue to report as
usual on the Promoting Interoperability performance category. We welcomed comment on these proposed changes. We also sought comment on whether the percentage of CEHRT use should be set at a level higher than 50 percent for ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM given that average ACO performance on the Use of Certified EHR Technology measure (ACO-11) has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements, suggesting that a higher threshold may be warranted now or in the future. We noted that a higher threshold percentage (such as 75 percent) would align with the proposed changes to the CEHRT use requirement under the Quality Payment Program that were included in the CY 2019 PFS proposed rule.

Further, for ACOs in tracks or models that meet the financial risk standard to be Advanced APMs under the Quality Payment Program, we proposed to align the proposed CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the Quality Payment Program. We noted that, although it would be ideal for all ACOs to meet the same CEHRT thresholds to be eligible for participation in the Shared Savings Program, there may be reasons why it may be desirable for ACOs in tracks or payment models within a track that do not meet the financial risk standard for Advanced APMs to have a different threshold requirement for CEHRT use than more sophisticated ACOs that are participating in tracks or payment models that qualify as Advanced APMs under the Quality Payment Program. For example, we noted that in order for an APM to meet the criteria to be an Advanced APM under the Quality Payment Program, it must currently require at least 50 percent of eligible clinicians in each participating APM entity to use CEHRT to document and communicate

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38 This estimate is based on calculations of primary care physician CEHRT use prior to the changes made to ACO-11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.
clinical care to their patients or other health care providers (in addition to certain other criteria). However, as previously noted, in the CY 2019 PFS proposed rule, we proposed to increase this threshold level under the Quality Payment Program to 75 percent of eligible clinicians in each participating Advanced APM entity. Therefore, for performance years starting on January 1, 2019, and subsequent performance years for Shared Savings Program tracks (or payment models within tracks) that meet the financial risk standard to be an Advanced APM, we proposed to align the CEHRT requirement with the Quality Payment Program Advanced APM CEHRT use criterion at §414.1415(a)(1)(i). Specifically, we proposed that such ACOs would be required to certify that they meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at §414.1415(a)(1)(i). We stated that requiring these ACOs to meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs would ensure alignment of eligibility requirements across all Shared Savings Program ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs were higher than 50 percent, those Shared Savings Program tracks (or payment models within a track) that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the Quality Payment Program. We anticipated that for performance years starting on January 1, 2019, the tracks (or payment models within tracks) that would be required to meet the CEHRT threshold designated at §414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, would include the proposed BASIC track, Level E, and the proposed ENHANCED track. ACOs in these tracks (or
a payment model within such a track) would be required to attest and certify that the percentage of the eligible clinicians in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the level of CEHRT use specified under the Quality Payment Program regulation at §414.1415(a)(1)(i). We noted that although this proposal might cause Shared Savings Program ACOs in different tracks (or different payment models within the same track) to be held to different requirements regarding CEHRT use, we believed it would be appropriate to ensure not only that ACOs that are still new to participation in the Shared Savings Program would not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT, but also that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program.

We proposed to add a new provision to the regulations at §425.506(f)(2) to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or a payment model within a track that meets the financial risk standard to be an Advanced APM under the Quality Payment Program. These ACOs would be required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold for CEHRT use by Advanced APMs at §414.1415(a)(1)(i). We sought comment on this proposal. We also sought comment on whether we should apply the same standard regarding CEHRT use across all Shared Savings Program ACOs, including ACOs participating in tracks or payment models within tracks that do not meet the financial risk standard to be designated as Advanced APMs, specifically Track 1 and the proposed BASIC track, Levels A through D, or maintain the
proposed 50 percent requirement for these ACOs as they gain experience on the glide path to performance-based risk.

We stated that, as a part of these proposals to require ACOs to certify that a specified percentage of their eligible clinicians use CEHRT, CMS would reserve the right to monitor, assess, and/or audit an ACO’s compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds. Additionally, we proposed to adopt for purposes of the Shared Savings Program the same definition of “CEHRT” as is used under the Quality Payment Program. We proposed to amend §425.20 to incorporate a definition of CEHRT consistent with the definition at §414.1305, including any subsequent updates or revisions to that definition. Consistent with this proposal and to ensure alignment with the requirements regarding CEHRT use under the Quality Payment Program, we also proposed to amend §425.20 to incorporate the definition of “eligible clinician” at §414.1305 that applies under the Quality Payment Program.

Additionally, we stated that if the proposal to introduce a specified threshold of CEHRT use as an eligibility requirement for participation in the Shared Savings Program is finalized, we believed this new requirement should replace the current ACO quality measure that assesses the Use of Certified EHR Technology (ACO-11). We explained that the proposed new eligibility requirement, which would be assessed through the application process and annual certification, would help to meet the goals of the program and align with the approach used in other MIPS APMs. Moreover, the proposed new requirement would render reporting on the Use of Certified EHR Technology quality measure unnecessary in order for otherwise eligible tracks (and
payment models within tracks) to meet the Advanced APM criterion regarding required use of CEHRT under §414.1415(a)(1)(i). As a result, continuing to require ACOs to report on this measure would impose undue reporting burden on eligible clinicians that meet the QP threshold and would otherwise not be required to report the Promoting Interoperability performance category for purposes of the Quality Payment Program. Therefore, we proposed to remove the Use of Certified EHR Technology measure (ACO-11) from the Shared Savings Program quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We proposed corresponding changes to the regulation at §425.506. We also reiterated that the removal of the Use of Certified EHR Technology measure (ACO-11) from the quality measure set used under the Shared Savings Program, if finalized, would not affect policies under MIPS for reporting on the Promoting Interoperability performance category and scoring under the APM Scoring Standard for MIPS eligible clinicians in MIPS APMs. In other words, eligible clinicians subject to MIPS (such as eligible clinicians in the proposed BASIC track, Levels A through D, Track 1, and other MIPS eligible clinicians who are required to report on the Promoting Interoperability performance category for purposes of the Quality Payment Program) would continue to report as usual on the Promoting Interoperability performance category. However, data reported for purposes of the Promoting Interoperability performance category under MIPS would not be used to assess the ACO’s quality performance under the Shared Savings Program. We welcomed public comment on the proposal to remove the quality measure on Use of Certified EHR Technology (ACO-11) from the Medicare Shared Savings Program measure set, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years.

Finally, as discussed previously in this section, in the CY 2017 Quality Payment Program
final rule, CMS finalized a separate Advanced APM CEHRT use criterion that applies for the
Shared Savings Program at §414.1415(a)(1)(ii). To meet the Advanced APM CEHRT use
criterion under the Shared Savings Program, a penalty or reward must be applied to an APM
Entity based upon the degree of CEHRT use among its eligible clinicians. We believed that this
alternative criterion was appropriate to assess the Advanced APM CEHRT use requirement
under the Shared Savings Program because, at the time, a specific level of CEHRT use was not
required for participation in the program (81 FR 77412).

As we explained in the August 2018 proposed rule (83 FR 41911), our proposal to
impose specific CEHRT use requirements on ACOs participating in the Shared Savings Program
would eliminate the need for the separate CEHRT use criterion applicable to the Shared Savings
Program APMs found at §414.1415(a)(1)(ii). We noted that if the proposal to incorporate
specific requirements regarding the use of CEHRT by Shared Savings Program ACOs were
finalized, ACOs seeking to participate in a Shared Savings Program track (or payment model
within a track) that meets the financial risk standard to be an Advanced APM would be required
to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document
and communicate clinical care to their patients or other health care providers meets or exceeds
the higher of 50 percent or the percentage specified in the CEHRT use criterion for Advanced
APMs at §414.1415(a)(1)(i). As a result, a separate CEHRT use criterion for APMs under the
Shared Savings Program would no longer be necessary.

Therefore, we proposed to revise the separate Shared Savings Program CEHRT use
criterion at §414.1415(a)(1)(ii) so that it would apply only for QP Performance Periods under the
Quality Payment Program prior to 2019. We sought comment on this proposal.

Comment: Several commenters supported the continued recognition for integration of
Electronic Medical Records (EMRs) and the sharing of health information between providers and suppliers.

Response: We thank the commenters for their support.

Comment: A majority of commenters supported our proposal to replace ACO-11 – Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers. In addition, many commenters urged CMS to clarify that MIPS eligible clinician participating in Shared Savings Program ACOs would not be required to report Promoting Interoperability (PI) and would instead see PI performance category weights redistributed equally to the Quality and Improvement Activities performance categories.

Response: As noted in the August 2018 proposed rule (83 FR 41909), the proposal to replace ACO-11: Use of Certified EHR Technology with a requirement that ACOs certify regarding the level of CEHRT use by eligible clinicians in the ACO would not affect any previously finalized requirements for MIPS eligible clinicians reporting on the PI performance category under MIPS. MIPS eligible clinicians who are participating in ACO tracks that are not Advanced APMs and/or who are not QPs would continue to report as usual on the PI performance category.

Comment: Several commenters asked CMS to clarify the proposals for Promoting Interoperability in the August 2018 proposed rule, in the final rule. Specifically, the commenters requested clarification on when complete implementation of the 2015 CEHRT edition was required for ACOs participating in the Shared Savings Program, as the proposal discussed in the August 2018 proposed rule would require an ACO to attest to the percentage of eligible
clinicians utilizing CEHRT at the time of application and annually thereafter. The commenters stated that a requirement that they attest to meeting the CEHRT use threshold at the time of application would negatively impact ACOs whose participants make CEHRT decisions (such as upgrades) based on a minimum consecutive 90-day reporting period as set forth by the Quality Payment Program. The commenters stated that clarification of the deadline for implementation was needed so healthcare organizations could have a clear understanding of the expectations, allowing them to plan accordingly, especially for those organizations that participate in more than one regulatory program. In addition, several commenters requested that CMS clarify its operational expectations with respect to the proposed new certification requirement, so that ACOs can confirm that they are able to confidently certify with respect to the level of CEHRT use in their ACO.

Response: We understand that ACOs need to know the deadline by which they must meet the proposed new requirements regarding the use of CEHRT and have an understanding of how they would be required to demonstrate that they have met the requirement. As we explained in the August 2018 proposed rule, we believe it is appropriate to ensure that ACOs new to participation in the Shared Savings Program not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT. At the same time, however, we also sought to align with the CEHRT use requirements under the Quality Payment Program to ensure that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. While our proposal was intended to require that ACOs achieve the applicable CEHRT use threshold starting in the 2019 performance year, we understand from commenters that the requirement that ACOs certify that the percentage of eligible clinicians in
the ACO that use CEHRT meets the applicable threshold at time of application could pose an operational challenge. For example, a commenter stated that, ACOs not yet operating on 2015 edition CEHRT may have implementation and cost barriers related to the upgrade of CEHRT that may place them in a non-complaint situation, given the short timeframe between the publication of the final rule and the start of performance year 2019.

Based on the comments received in response to the proposals in the August 2018 proposed rule and our desire to align with the Quality Payment Program, under which eligible clinicians must certify regarding their CEHRT use by the last day of the reporting period, we are not finalizing our proposal to require ACOs to certify at the time of application that they meet the applicable CEHRT requirements. However, we are finalizing our proposal to require ACOs to certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year.

ACOs will be required to submit this certification in the form and manner specified by CMS for performance years starting on January 1, 2019, and all subsequent performance years. For performance years starting on January 1, 2019, the annual certification will occur in the spring of 2019 for ACOs extending their participation agreement for 6 months, and in the fall of 2019 for ACOs that have a 12-month performance year during 2019. We believe this final policy is not only responsive to commenters’ concerns regarding the timing of the certification but also enables timely implementation of the requirement starting in 2019. As noted above, a majority of commenters supported our proposal to replace ACO-11—Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other
health care providers starting January 1, 2019. We also note that this new requirement aligns more closely with the requirements regarding CEHRT use imposed under the Next Generation ACO Model, which requires that participating ACOs certify compliance with the CEHRT use requirement in the fall of each performance year. As stated in the August 2018 proposed rule, we currently require that ACOs must have in place at the time of application a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§425.112(b)(4)(i)(C)). Because this policy is already in place, we believe that our decision not to finalize the proposal to require ACOs to certify with respect to their use of CEHRT at time of application to the Shared Savings Program will not undermine the policies under the program designated to promote and encourage the use of CEHRT.

Although the comments requesting clarification of our CEHRT proposals were not specific regarding the Shared Savings Program track for which they were seeking clarification, in this final rule we are clarifying the CEHRT threshold requirement for ACOs participating in an Advanced APM. Our intent at the time we proposed this policy was to preserve a minimum threshold of 50 percent CEHRT use for all ACOs in the Shared Savings Program, even if the requirement at §414.1415(a)(1)(i) were revised through future rulemaking to be below 50 percent. However, we now recognize that this proposed “higher of” policy generated undue complexity. In the unlikely event that the requirement for CEHRT use at §414.1415(a)(1)(i) were to be reduced to below 50 percent in the future, we would have the opportunity to revisit the Shared Savings Program threshold through future rulemaking. Accordingly, we are revising the proposed regulation at §425.506(f)(2) to remove the reference to the 50 percent threshold and to indicate that ACOs participating in a Shared Savings Program track that meets the financial risk standard to be an Advanced APM, would be required to demonstrate that the percentage of
eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the percentage specified in the CEHRT use criterion for Advanced APMs under §414.1415(a)(1)(i).

Comment: Several commenters suggested modifications to CMS’ proposal to require ACOs to certify that the percentage of eligible clinicians in the ACO using CEHRT meets the applicable threshold. Several commenters suggested that CMS delay the implementation of the certification requirement attestation until performance year 2020 to avoid inadvertently penalizing Track 1 ACOs that may not have sufficient time to meet the new CEHRT requirement. Several other commenters expressed concern that meeting the 50 percent CEHRT threshold would be a hardship for ACOs in Track 1, especially ACOs composed of independent physician practices and rural practices. These commenters recommended that CMS not finalize this new requirement, but if CMS were to finalize the 50 percent threshold, these commenters believed that CMS should extend exemptions to low-revenue ACOs or those ACOs in which the plurality of eligible clinicians qualify for a hardship exemption from the Promoting Interoperability performance category under the MIPS. Another commenter suggested that CMS require ACOs in a track (or payment model within a track) that meets the financial risk standard to be an Advanced APM to meet the 50 percent CEHRT requirement in the first performance year and then increase to 75 percent in the second performance year.

Response: We disagree with the suggestions that we delay implementation of the proposed new CEHRT use requirement or impose differential requirements for ACOs, depending on their performance year or other attributes. Since the inception of the Shared Savings Program in 2012, we have assessed the level of CEHRT use by certain clinicians in ACOs (ACO-11: Use of Certified EHR Technology) as part of the quality reporting requirements for each performance
year. In the CY 2017 PFS final rule, we revised the ACO-11 measure to assess ACOs on the degree of CEHRT use by eligible clinicians participating in the ACO in order to align with the Quality Payment Program. Starting in 2017, performance on this measure has been determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Category Base Score. We believe that this experience offers a foundation on which ACOs can build and create processes that allow them to determine the percentage of eligible clinicians participating in the ACO that use CEHRT during an applicable performance year. As noted in the August 2018 proposed rule (83 FR 41909 through 41910), average ACO performance on ACO-11: Use of Certified EHR Technology has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements.39 As a result, we do not believe it is unreasonable to expect Track 1 ACOs to meet the requirement that 50 percent or more of the eligible clinicians participating in the ACO use CEHRT beginning in the performance year starting on January 1, 2019. Furthermore, as noted above, our proposal to require ACOs to certify that they meet the applicable CEHRT threshold has no impact on the previously-finalized policy that MIPS eligible clinicians participating in ACOs will continue to report on the PI performance category. Under this policy, MIPS-eligible clinicians are required to use the 2015 version of CEHRT for purposes of reporting the promoting interoperability performance category (§414.1305). Accordingly, we believe our proposal to require this version to be used by eligible clinicians participating in Shared Savings Program ACOs aligns with existing requirements under the MIPS and does not impose a new requirement on ACOs. Further, we believe our decision not to finalize the requirement that ACOs certify with respect their level of

39 This estimate is based on calculations of CEHRT use by primary care physicians prior to the changes made to ACO-11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.
CEHRT use as part of the application process, and to implement the requirement solely through the annual certification during the performance year, will allow additional time for ACOs to update any internal processes as needed in order to meet this requirement during the performance year starting on January 1, 2019. In addition, as noted above, over the years successful ACOs have provided feedback that it is important to “hit the ground running” on their first day of participation in the Shared Savings Program, rather than spending several years developing their care processes. Based on this feedback, as well as commenters who supported the CEHRT proposal, we believe it is important to implement the proposed CEHRT use thresholds starting January 1, 2019. We believe that the use of these thresholds to assess CEHRT use by ACOs participating in the Shared Savings Program aligns with existing requirements under the program and encourages participation by organizations that are more likely to meet the program goals.

We received no comments on our proposals to change the regulation at §425.204(c) to establish the new application requirement and the regulation at §425.302(a)(3)(iii) to establish the new annual certification requirement. We also received no comments on our proposal to amend §425.20 to incorporate a definition of “CEHRT” consistent with the definition at §414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of “eligible clinician” at §414.1305 that applies under the Quality Payment Program. In addition, we received no comments on our proposal to amend the separate Shared Savings Program CEHRT use criterion at §414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019. Furthermore, we received no comments on our proposal to add a new provision to the regulation at § 425.506 to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or payment model within a track that does not
meet the financial risk standard to be an Advanced APM and ACOs in a track or payment model within a track that meets the financial risk standard to be an Advanced APM.

After considering the comments received, we are finalizing with modification our proposal that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. Specifically, we are finalizing the requirement that ACOs make this certification annually in the form and manner specified by CMS, but, for the reasons discussed above, we are not finalizing the proposal to require ACOs to make this certification at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. We reiterate that this final policy does not affect the previously finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. Accordingly, MIPS eligible clinicians who are participating in ACOs under a payment track that is not an Advanced APM and/or who are not QPs would continue to report as usual on the Promoting Interoperability performance category.

Similarly, after considering the comments received, we are also finalizing with modification our proposal with respect to ACOs in Shared Savings Program tracks that meet the financial risk standard to be an Advanced APM. We proposed that these ACOs would be required to certify at the time of application and annually thereafter that they meet the higher of
the 50 percent threshold proposed for ACOs in a track that does not meet the financial risk to be an advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at §414.1415(a)(1)(i).

For the reasons discussed previously, we are not finalizing the requirement that ACOs certify that they meet the higher of the 50 percent threshold or the applicable threshold under the Quality Payment Program. Rather, ACOs will be required to certify only that they meet the applicable threshold established under the Quality Payment Program. In addition, as also discussed, we are not finalizing our proposal that ACOs certify that they meet the CEHRT requirement at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent years, ACOs in a track that meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at §414.1415(a)(1)(i).

We are finalizing the proposed new provision at §425.506(f) with conforming modifications to reflect the policies we are finalizing in this final rule. As part of these modifications, we are omitting the reference to “a payment model within a track” because we are not addressing the proposal to create the BASIC track, with separate payment models at Levels A through E, at this time. We anticipate summarizing and responding to comments received on this proposal and other proposals related to the participation options under the Shared Savings Program in a forthcoming final rule. For the reasons discussed previously in this section, we are not finalizing the proposed changes to the regulation at §425.204(c) to establish the new application requirement; but, we are finalizing the proposed changes to the regulation at
§425.302(a)(3)(iii) to establish the new annual certification requirement. In addition, we are finalizing our proposed amendments to §425.20 to incorporate a definition of “CEHRT” consistent with the definition at §414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of “eligible clinician” at §414.1305 that applies under the Quality Payment Program. We are also finalizing our proposal to amend the separate Shared Savings Program CEHRT use criterion at §414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019.

As noted in the August 2018 proposed rule (83 FR 41910), CMS reserves the right to monitor, assess, and/or audit an ACO’s compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds.

Finally, after considering the comments received in response to the proposal to remove ACO-11: Use of Certified EHR Technology measure from the Shared Savings Program quality measure set, we are finalizing our proposal effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We are also finalizing the corresponding revisions to the regulation at §425.506 to reflect this change.

3. Applicability of Final Policies to Track 1+ Model ACOs

a. Background

In the August 2018 proposed rule (83 FR 41912), we discussed the applicability of proposed policies to Track 1+ Model ACOs. We explained that the Track 1+ Model was established under the Innovation Center’s authority at section 1115A of the Act, to test
innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children’s Health Insurance Program beneficiaries. We noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning on January 1, 2018. This includes 35 ACOs that entered the model within their current agreement period (to complete the remainder of their agreement period under the model) and 20 ACOs that entered into a new 3-year agreement period under the model.

To enter the Track 1+ Model, ACOs must be approved to participate in the model and are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf. Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with its authority under section 1115A(d)(1) of the Act, CMS has waived certain provisions of law that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model.

We explained that, unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with §425.212, Track 1+ Model ACOs are subject to all applicable regulatory changes, including but not limited to changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement, that become effective during the term of the ACO’s
Shared Savings Program Participation Agreement and Track 1+ Model Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We noted that the terms of the Track 1+ Model Participation Agreement permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

b. Unavailability of Application Cycles for Entry into the Track 1+ Model in 2019

In the August 2018 proposed rule (83 FR 41912 through 41913), we discussed the unavailability of application cycles for entry into the Track 1+ Model in 2019 and 2020. We explained that an ACO’s opportunity to join the Track 1+ Model aligns with the Shared Savings Program’s application cycle. The original design of the Track 1+ Model included 3 application cycles for ACOs to apply to enter or, if eligible and if applicable, to renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. The 2018 application cycle is closed, and as discussed elsewhere in the August 2018 proposed rule, 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7 of the August 2018 proposed rule (83 FR 41847) and section V.B.1.a of this final rule, we are not offering an application cycle for a January 1, 2019 start date for new agreement periods under the Shared Savings Program. Therefore, we similarly are not offering a start date of January 1, 2019, for participation in the Track 1+ Model.

We explained that existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model. Additionally, as discussed in section II.A.7.c.(1) of the August 2018 proposed rule (83 FR 41854 through 41855) and section V.B.1.c.(1) of this final rule, ACOs currently participating in the Track 1+ Model will not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, under our
decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. We will address proposals related to future application cycles in subsequent rulemaking.

c. Applicability of Proposed Policies to Track 1+ Model ACOs through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

In section II.F of the August 2018 proposed rule (83 FR 41913 through 41914), we provided a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs to allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. We explained that there are two ways in which the proposed policies would become applicable to Track 1+ Model ACOs: (1) through revisions to existing regulations that currently apply to Track 1+ Model ACOs; and (2) through revisions to the ACO’s Track 1+ Model Participation Agreement.

We sought comment on these considerations, and any other issues that we may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. We note that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020 (for ACOs that entered the model at the start of a 3-year agreement period), or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current 3-year agreement period.

Generally, comments regarding the application of specific proposals to Track 1+ Model ACOs have been addressed as part of the discussion of comments in the relevant section of this final rule. Accordingly, in this section of this final rule, we are not repeating comments related to the applicability of the proposed policies to ACOs participating in the Track 1+ Model.
Therefore, unless specified otherwise, the changes to the program’s regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to the regulations as finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to voluntary alignment policies (section V.B.2.b. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

- Revisions to the definition of primary care services used in beneficiary assignment (section V.B.2.c. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

- Discontinuation of quality measure ACO-11; requirement to attest as part of the annual certification that a specified percentage of the ACO’s eligible clinicians use CEHRT (section V.B.2.f. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

We will also apply the following policies finalized in this final rule to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Annual certification that the percentage of eligible clinicians participating in the ACO
that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under §414.1415(a)(1)(i) (section V.B.2.f. of this final rule). This certification is required to ensure the Track 1+ Model continues to meet the CEHRT criterion to qualify as an Advanced APM for purposes of the Quality Payment Program.

- For ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (as described in section V.B.1 of this final rule):
  
  ++ As described in section V.B.1.c.(3) of this final rule, the ACO should extend its repayment mechanism so that it remains in effect for 24 months after the end of the agreement period (June 30, 2021).
  
  ++ As described in section V.B.1.c.(10) of this final rule, the ACO is eligible for shared savings if the following conditions are met: the ACO completed the 6-month performance year starting on January 1, 2019; the ACO has completed all close-out procedures specified in §425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied the criteria for sharing in savings for the performance year.
  
  ++ We will determine performance for the 6-month performance year from January 1, 2019 through June 30, 2019, according to the approach specified in a new section of the regulations at §425.609(b), applying the financial methodology for calculating shared losses specified in the ACO’s Track 1+ Model Participation Agreement.
  
  ++ We will continue to share aggregate report data with the ACO for the entire CY 2019,
consistent with the approach described in section V.B.1.c.(8) of this final rule, and the terms of the ACO’s Track 1+ Model Participation Agreement.

- Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in§425.610(i) (section V.B.2.d. of this final rule) and, for ACOs that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, in §425.609(d) (section V.B.1.c.(5) of this final rule).