

# A Summary of the CY 2020 Physician Fee Schedule Proposed Rule

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## Table of Contents

<b>OVERVIEW .....</b>	<b>3</b>
<b>PROVISIONS OF THE PROPOSED RULE FOR PFS .....</b>	<b>3</b>
<b>Determination of PE RVUs .....</b>	<b>3</b>
Indirect Practice Expense Per Hour (PE/HR) Data .....	3
Low Volume Codes .....	3
Equipment Costs .....	3
Direct PE Inputs for Specific Services .....	4
<b>Determination of Malpractice RVUs .....</b>	<b>7</b>
<b>Geographic Practice Cost Indices (GPCIs) .....</b>	<b>8</b>
<b>Potentially Misvalued Services under the PFS .....</b>	<b>8</b>
<b>Payment for Medicare Telehealth Services under Section 1834(m) of the Act .....</b>	<b>10</b>
<b>Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) .....</b>	<b>10</b>
<b>Bundled Payments Under the PFS for Substance Use Disorders .....</b>	<b>18</b>
<b>Physician Supervision for Physician Assistant (PA) Services .....</b>	<b>19</b>
<b>Review and Verification of Medical Record Documentation .....</b>	<b>20</b>
<b>Care Management Services .....</b>	<b>21</b>
Transitional Care Management (TCM) Services .....	21
Chronic Care Management (CCM) Services .....	23
Principal Care Management (PCM) Services .....	25
Chronic Care Remote Physiologic Monitoring (RPM) Services .....	28
Comment Solicitation on Consent for Communication Technology-Based Services .....	28
Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) .....	29
<b>Coinsurance for Colorectal Cancer Screening Tests .....</b>	<b>29</b>
Screening vs. Diagnostic .....	29
Patient Deductibles .....	30
Request for Comment .....	30
<b>Therapy Services .....</b>	<b>30</b>
Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy .....	30
Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants .....	31
<b>Valuation of Specific Codes .....</b>	<b>35</b>
<b>Comment Solicitation on Opportunities for Bundled Payments under the PFS .....</b>	<b>38</b>
<b>Payment for Evaluation and Management (E/M) Visits .....</b>	<b>38</b>
Background .....	38
Proposed Policies for CY 2021 .....	40
Global Surgical Packages .....	43

Revaluing Office/Outpatient Visits within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services ... 44

**OTHER PROVISIONS OF THE PROPOSED REGULATIONS ..... 45**

**Changes to the Ambulance Physician Certification Statement Requirement ..... 45**

Exceptions to Certification Statement Requirement ..... 45

Addition to Staff Authorized to Sign Non-Physician Certification Statements ..... 45

**Proposal to Establish a Medicare Ground Ambulance Services Data Collection System ..... 46**

Background ..... 46

Proposals for the Data Collection Instrument ..... 47

**Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR) ..... 47**

**Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) ..... 48**

eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2020 ..... 48

Objective 1: Protect Patient Health Information in 2021 ..... 49

**Medicare Shared Savings Program ..... 49**

Proposed changes to the CMS Web Interface and Claims-based Measures ..... 49

Seeking comment on aligning the MSSP quality score with the MIPS quality score ..... 51

**Open Payments ..... 55**

**Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home**

**Infusion Therapy ..... 56**

**Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning**

**Improper Prescribing and Patient Harm ..... 56**

Enrollment of Opioid Treatment Programs ..... 56

Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535 ..... 60

**Deferring to State Scope of Practice Requirements ..... 62**

Ambulatory Surgical Centers ..... 62

Hospice ..... 63

**Advisory Opinions on the Application of the Physician Self-Referral Law ..... 64**

Background ..... 64

Proposed Revisions ..... 65

**CY 2020 Updates to the Quality Payment Program ..... 66**

Executive Summary ..... 66

MIPS Program Details ..... 67

Overview of the APM Incentive ..... 128

Quality Payment Program Technical Revisions ..... 134

**COLLECTION OF INFORMATION REQUIREMENTS ..... 135**

**REGULATORY IMPACT ANALYSIS ..... 139**

## Overview

On July 29, 2019, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2020 Medicare Physician Fee Schedule (MPFS) proposed rule. This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, including the Quality Payment Program (QPP) and the Medicare Shared Savings Program.

Page numbers in the summary refer to the public display version of the proposed rule which can be viewed [here](#). A CMS fact sheet on the non-Quality Payment Program (QPP) provisions is available [here](#). A fact sheet on the QPP provisions is available [here](#). Comments will be accepted through **September 27, 2019**. The final rule will be released in early November 2019.

## Provisions of the Proposed Rule for PFS ([p. 10](#))

### Determination of PE RVUs ([p. 16](#))

CMS reviews the step-by-step PE RVU methodology beginning on [p. 20](#).

### Indirect Practice Expense Per Hour (PE/HR) Data ([p. 17](#))

CMS reviews its history with developing PE/HR by specialty. In calculating practice expense values for specialties, CMS uses AMA survey data, most recently from 2007 and 2008 as part of the Physician Practice Expense Information Survey (PPIS). CMS used this data to provide transitional updates to PE/HR beginning in CY 2010 for the specialties that participated in the survey.<sup>1</sup>

In the past, for those specialties without SMS or supplemental survey data, CMS crosswalks the specialty to “similar specialties” to estimate a proxy PE/HR value. The PE/HR values for all specialties and, where applicable, crosswalks for these and other specialties are posted on the CMS website in the [CY 2020 PFS Proposed Rule PE/HR](#) file.

For newly recognized specialties without available data, **CMS proposes the following crosswalks ([p. 19](#)):**

- **Medical Toxicology (crosswalked to Emergency Medicine)**
- **Hematopoietic Cell Transplantation and Cellular Therapy (crosswalked Hematology/Oncology).**

### Low Volume Codes ([p. 24](#))

CMS makes special changes for service codes that it determines have low Medicare volumes because the specialty mix assignment (which impacts the PE levels) can fluctuate so much from year to year on a low volume code. To avoid this for low volume codes, CMS assigns an “expected specialty” to prevent large year-to-year fluctuations. **For CY 2020, CMS proposes to clarify specialty assignment for a list of cardiothoracic services, in particular CMS believed there was a mistake in previously crosswalking the codes to cardiac surgery and now proposes to crosswalk them to thoracic surgery ([p. 25](#)).** The list can be found in [Table 1](#).

### Equipment Costs ([p. 34](#))

**Equipment Utilization Rate Assumption.** In order to incorporate costs associated with equipment, CMS sets an equipment utilization rate assumption for distributing the costs associated with the equipment. In past rulemaking, CMS set an equipment utilization rate assumption of 50 percent for most equipment and a 90 percent equipment utilization rate assumption for expensive diagnostic equipment (as required by statute). CMS revisited past stakeholder complaints that a 50 percent utilization rate assumption is inaccurate and should be reduced. CMS again stated that it declined to do so in the absence of “robust, objective, auditable data,” but

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<sup>1</sup> CMS reiterated that it does not use the PPIS data for endocrinology or spine surgery because “these specialties currently are not separately recognized by Medicare,” and CMS has no method to blend PPIS data with Medicare-recognized specialty data ([p. 19](#)).

**CMS requested stakeholder submission of data to illustrate an alternative equipment utilization rate assumption** (p. 34).

**Equipment Maintenance.** CMS previously set an annual maintenance factor for all equipment of 5 percent. CMS reiterated its past belief that the 5 percent rate understates the cost of maintaining some equipment while overstates the maintenance cost for other equipment. While CMS received some data, the agency again states that it does not believe “that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs” (p. 35). CMS has identified no publicly available datasets on which to reconfigure the equipment maintenance factor. **CMS again states that it will continue to “investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.”** (p. 35).

**Interest Rates.** CMS proposes no changes to equipment interest rates (p. 35). The interest rates can be found in [Table 4](#).

### **Direct PE Inputs for Specific Services** (p. 36)

**Standardization of Clinical Labor Tasks** (p. 36). CMS reviewed previously finalized standard times for clinical labor tasks associated with digital technology (p. 37):

- “Availability of prior images confirmed”: 2 minutes
- “Patient clinical Information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist”: 2 minutes
- “Review examination with interpreting MD”: 2 minutes
- “Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue”: 1 minute
- “Technologist QC images in PACS, checking for all images, reformats, and dose page”:
  - Simple case: 2 minutes
  - Intermediate case: 3 minutes
  - Complex case: 4 minutes
  - Highly complex case: 5 minutes

CMS also again reviewed previously finalized standard times for clinical labor tasks associated with pathology services (p. 38):

- “Accession specimen/prepare for examination”: 4 minutes
- “Assemble and deliver slides with paperwork to pathologists”: 0.5 minutes
- “Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation”: 0.5 minutes
- “Clean room/equipment following procedure”: 1 minute
- “Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste”: 1 minute
- “Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)”: 1 minute

CMS again stated its belief that it does not believe that clinical labor tasks associated with pathology services would be dependent on number of blocks or batch size, and **CMS continues to believe these values “accurately reflect the typical time it takes to perform these clinical labor tasks.”** (p. 38).

As it did last year, CMS notes that the RUC has mandated use of a new PE worksheet that assists in making recommendations for standardized clinical labor tasks. **CMS continues to believe the new worksheet will assist CMS in simplifying and standardizing the clinical labor tasks listed in its direct PE database** (p. 40).

CMS posts [labor task public use file on the CMS website](#).

**Equipment Recommendation for Scope Systems (p. 40).** In previous rulemaking, CMS implemented a methodology that separates scopes, the associated video system, and scope accessories typical as distinct equipment for each code (p. 40).

Scope Equipment. CMS divides the scopes into the following types:

- Non-video scopes
- Flexible scopes (typically paired with one of the scope video systems)
  - Diagnostic (or non-channeled)
  - Therapeutic (or channeled)
  - Multi-channeled
- Semi-rigid scopes (typically paired with one of the scope video systems)
- Rigid scopes (typically paired with one of the scope video systems)

While CMS had instituted this process previously, it did not complete development of all of the pricing inputs. In 2017, CMS stated that it did not make recent changes regarding existing scope equipment because it was awaiting input from the RUC PE Subcommittee, while the RUC PE subcommittee stated that “no further action was required” after CMS previously finalized the policy (p. 42). Therefore, CMS made additional proposals for CY 2018. However, CMS did not finalize its proposal to create and price a single scope equipment code for each of the categories identified, but rather, finalized creation of scope equipment codes on a per-specialty basis (p. 42).

In last year’s rule, CMS delayed proposals to make changes to scope equipment “until CY 2020 in order to incorporate the feedback from [the RUC Scope Equipment Reorganization Workgroup]” (p. 43). Based on the feedback from the RUC Scope Equipment Reorganization Workgroup, **CMS proposes to add 23 new scope equipment codes which can be found in Table 5; CMS proposes to price the scope equipment items for those codes for which it received pricing information as found in Table 5 (p. 52).** However, CMS was limited in its ability to price several of the new scope equipment items because it did not receive any invoices for them (p. 45).

- **CMS noted invoice inconsistencies between ES080 (non-channeled flexible digital scope, laryngoscopy) and ES092 (non-video flexible scope, laryngoscopy) and proposes to list them as separate equipment items (p. 45).**
- **CMS noted invoice inconsistencies (outlier invoices for a high dollar amount) for ES075 (rigid scope, laryngoscopy); CMS proposes to include the higher priced items in ES065 because they appear to be stroboscopy system equipment (p. 46).**
- **CMS is adopting the workgroup recommendations for which HCPCS codes make use of the new scope equipment items, which can be found in Table 6.** However, there were 3 instances in which CMS believe the workgroup recommendations did not warrant replacement with the new scope equipment codes (p. 51):
  - CPT 45350 (Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids))
  - CPT 43232 (Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s))
  - CPT 31595 (Larynx nerve surgery)\* (Deleted)
- **CMS did not receive pricing information from the workgroup for 15 other scope equipment items; in these instances, CMS is not proposing to replace existing scope equipment with the new equipment items but welcomes feedback on the pricing of these scope equipment items and will transition the remaining scopes in future rulemaking (p. 52).**

Scope Video System: CMS previously defined a scope video system as (p. 43):

- A monitor
- A processor
- A form of digital capture
- A cart
- A printer

CMS did not finalize its 2018 pricing update for scope video systems with the intent to address changes in CY 2019 with input from stakeholders (p. 44).

Scope Accessories: CMS recognizes that there can be other accessories for use with scopes and finalized a proposal to separately price scope accessories (other than the scope video system) and individually evaluate whether to include as direct PE inputs for particular codes (p. 44).

**Technical Corrections to Direct PE Input Database and Supporting Files** (p. 52). CMS received input that there were “clerical inconsistencies” in the direct PE database. **CMS proposes to correct these inconsistencies in the direct PE database.** This includes:

- Deletion of non-facility inputs for
  - CPT 43231 (*Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination*)
  - CPT 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)*) (p. 52).
- Application of “special rule for multiple endoscopic procedures” to the family of codes for nasal sinus endoscopy surgeries:
  - “this proposal would treat this group of CPT codes consistently with other similar endoscopic procedures when the codes within the CPT code family are billed together with another endoscopy service in the same family” (where CPT 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) would be the base procedure (p. 53).
  - The affected codes are listed in [Table 7](#).

**Updates to Prices for Existing Direct PE Inputs** (p. 55)

- **General.** CMS proposes updating the name of equipment item EP001 from “DNA/digital image analyzer (ACIS)” to “DNA/Digital Image Analyzer (p. 55).
- **Market-Based Supply and Equipment Pricing Update.** For CY 2020, CMS proposes to update the price of one supply and one equipment item in response new analysis, as detailed in [Table 22: Proposed Invoices Received for Existing Direct PE Inputs](#). CMS notes that because all of the changes are in a single code family that the new pricing will take place completely in CY 2020 instead of a four year phase-in (p. 55).

In addition to these specific changes, CMS again reviewed its market research process and contractor activity beginning on p. 56. CMS reviewed the new pricing phase in policy finalized in CY 2019 (p.59) and will continue to apply as finalized (p. 65):

- CY 2019: 25/75 blend
- CY 2020: 50/50 blend
- CY 2021: 75/25 blend
- CY 2022: 100/0 blend

Based on input received from stakeholders, CMS stated that “[i]n each instance in which a commenter raised questions about the accuracy of a supply or equipment code’s recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to

ensuring that the recommended price was based on the correct item in question and clarified the unit of measurement.” (p. 61). In continuing to update pricing, ***CMS welcomes feedback from stakeholders “including the submission of additional invoices for consideration”*** (p. 62). CMS noted that stakeholders were submitting invoices by February 10<sup>th</sup> (the deadline for code valuation recommendations), but ***CMS notes that it will “consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices after February 10<sup>th</sup> or outside of the public comment process . . .”*** (p. 66).

For CY 2020, CMS states that it received invoice submissions for 30 supply and equipment items (p. 62). Based on this input and contractor review, CMS proposes update pricing for codes as listed in [Table 9](#). The complete list of updated supply and equipment pricing over the course of the transition period can be found in a [public use file on the CMS website](#).

- ***Adjustment to Allocation of Indirect PE for Some Office-based Services*** (p. 66). CMS referred to CY 2018 MPFS rulemaking where it established criteria for identifying services affected by the indirect PE allocation anomaly “that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings” as well as the finalized methodology for allocating indirect PE RVUs to more accurately assign PE indirect resources for these services. ***CMS proposes to continue its third year transition to this process for allocating indirect PE*** (p. 66).

### **Determination of Malpractice Relative Value Units (RVUs) (p. 67)**

To calculate the malpractice (MP) RVUs for paying physician fee schedule services, CMS relies on a methodology based on three factors:

- (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners;
- (2) Service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and
- (3) An intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU

**Timeline.** Under statute, CMS is required to review, and if needed, adjust MP RVUs every five years with CY 2020 being the next deadline for update (p. 67). CMS had previously finalized that specialty-specific risk factors would be updated every 5 years with updated premium data and remain unchanged between the 5 year reviews (p. 68). CMS reviewed the CY 2018 proposal to update the specialty-specific prior to the next 5 year review. CMS did not finalize the proposal after pushback from stakeholders.

CMS is also required by statute to review the Geographic Practice Cost Indices at least every 3 years, and CMS notes that this revision coincides with the required revision to the Malpractice RVUs in CY 2020 (p. 69). Because the MP premium data used to update the MP GPCIs are the same as that used to determine the specialty level risk factors, ***CMS proposes to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCI by reviewing MP RVUs at least every 3 years*** (p. 69).

**CY 2020 MP RVU Update** (p. 69). CMS also states that the process is largely the same as that used for the CY 2015 update with a few methodological refinements. The process includes use of specialty specific malpractice premium data and is also weighted geographically. A detailed description of the step-by-step process for calculating MP RVUs begins on p. 73. Note that CMS states that it offers more details in a document posted on its [website](#), *Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule*.



- Data Sources (p. 70):
  - Malpractice Premium Data (presumed in effect as of December 31, 2017): taken from “insurers with the largest market share in each state” (p. 70).
  - CY 2018 Medicare payment and utilization data
  - Higher of CY 2020 proposed wRVUs or the clinical labor portion of the direct PE RVUs
  - CY 2019 GPCIs
- Methodology Changes (p. 72): **CMS proposes the following methodology changes to its calculation of MP RVUs:**
  - **Using a broader set of filings from the largest market share insurers in each state, beyond those listed as “physician” and “surgeon” for a “more comprehensive data set”**
  - **Combining minor surgery and major surgery premiums to create the surgery service risk group<sup>2</sup>**
  - **Utilizing “partial and total imputation” for a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings**
- Specialty and Service Risk Group Risk Factors: **CMS proposes the specialty risk factors as detailed in Table 11.**
- TC-Only Services (p. 76). In determining the risk factor for suppliers of Technical Component (TC) Only services, CMS declined to use the data it has used in the past because it thinks further study is warranted and will address changes in future rulemaking, but believes that data for a broader set of TC-Only services are needed. In the interim, **CMS proposes to assign a risk factor of 1.00 for TC-Only services in the absence of data for clinicians that furnish TC only services (p. 76).**
- List of Expected Specialties for Low Volume Services (p. 81). **CMS seeks comment on the list of expected specialties for low volume codes; the list of codes and expected specialties is available for review on the CMS website.**

### Geographic Practice Cost Indices (GPCIs) (p. 83)

Statute requires CMS to review and adjust as necessary the Geographic Practice Cost Indices (GPCIs) at least every 3 years. GPCIs are used to “measure relative cost differences among localities compared to the national average for . . . work, practice expense, and malpractice” (p. 83).<sup>3</sup>

Statute requires CMS to review and adjust as necessary the Geographic Practice Cost Indices (GPCIs) at least every 3 years. However, statute also provides that if more than 1 year has passed since the last GPCI adjustment “the adjustment to be applied in the first year of the next adjustment shall be ½ of that adjustment that would have otherwise been made” (p. 83). CMS has not updated the GPCIs since 2018, and therefore, **CMS proposes that the CY 2020 adjustments will be phased in at ½ of what would otherwise be made (p. 83).**

The proposed CY 2020 GPCIs can be found in [Addenda D and E](#) on the CMS website.

### Potentially Misvalued Services under the PFS (p. 96)

**Public Nomination.** CMS reviewed its public nomination process for potentially misvalued codes (p. 102). CMS reiterated its process used in the past:

*We evaluate the supporting documentation submitted with the nominated codes and assess whether the*

<sup>2</sup> CMS notes that In the previous update, “only premiums for major surgery were used in developing the surgical risk factor” (p. 72).

<sup>3</sup> CMS notes that while there are permanent statutory floors that do not allow for the GPCI work factor to go below 1.5 for services furnished in Alaska and 1.0 in frontier states (as defined by statute), the statutory provisions that prevent a GPCI work factor from going below 1.0 in all other localities is set to expire on December 31, 2019 (p. 83).

*nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and **indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code**.<sup>4</sup> The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes ([p. 104](#)). (Emphasis added).*

CMS received 3 codes for review via public nomination<sup>5</sup>; CMS is adding one additional code itself for review.

- Public Nomination #1 & #2:
  - CPT 10005 (*Fine needle aspiration biopsy; including ultrasound guidance*)
  - CPT 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*)

CMS noted that the codes had already been extensively reviewed during CY 2019 rulemaking, where the RUC had recommended a 32 percent reduction in physician time and 5 percent wRVU reduction. However, the commenter stated that this was inappropriate as there has been increased intensity related to this code attributable “more complicated equipment, more stringent specimen sampling that allow for extensive examination of smaller and deeper lesions within the body”; in addition, the commenter disagreed with the crosswalk to CPT 36440 (*Push blood transfusion, patient 2 years or younger*); the commenter suggested that more appropriate crosswalk could be CPT 40490 (*Biopsy of lip*) and CPT 95865 (*Needle measurement and recording of electrical activity of muscles of voice box*) ([p. 104](#)). **CMS proposes that the these codes as potentially misvalued and is seeking comment** ([p. 105](#)).

- Public Nomination #3:
  - G0166 (*External counterpulsation, per treatment session*)

CMS notes that this code was reviewed during CY 2019 rulemaking and CMS accepted the RUC recommendations on the code. However, the commenter stated that the PE inputs considered for this code failed to reflect all of the resources required. **CMS proposes to add the code as potentially misvalued** ([p. 105](#)).

- CMS Nomination:
  - CPT 76377 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation*)

CMS states that a similar code (CPT 76367 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*)) was reviewed at the April 2018 RUC meeting. While stakeholders stated that the codes are sufficiently separate because they are used on two separate patient populations. However, CMS believes they are similar enough that both should be reviewed. **CMS proposes to add the code as potentially misvalued** ([p. 105](#)).

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<sup>4</sup> Note that CMS has altered its language from what was stated in the CY 2019 MPFS proposed rule: When articulating its public nomination process in the CY 2019 proposed rule, it stated “and indicate **whether we proposed** each nominated code as a potentially misvalued code.” During the CY 2012 rulemaking process where the potentially misvalued code public nomination process was introduced, CMS finalized the policy it proposed without modification: “We proposed that, in the following PFS proposed rule, we would publish a list of the codes received under the public nomination process during the previous year **and indicate whether the codes would be included in the current review of potentially misvalued codes**” ([link](#)).

<sup>5</sup> CMS also received a request for office and outpatient E/M codes, and while CMS agreed there were valuation issues with the codes, they noted the other work being done on the codes and did not propose adding them to the list of potentially misvalued services ([p. 106](#)).

### **Payment for Medicare Telehealth Services under Section 1834(m) of the Act (p. 108)**

CMS previously had a deadline of no later than December 31 of each calendar year to add services to the list of Medicare telehealth services or the next rulemaking cycle. **Beginning in CY 2019 CMS began accepting requests through February 10<sup>th</sup> (which aligns with the deadline for receipt of code valuation recommendations from the RUC) (p. 110).** Thus, to be considered for CY 2020 rulemaking, requests must have been received by February 10, 2019; CY 2021 requests must be received by February 10, 2020.

**CMS did not receive any public requests to add services to the Medicare Telehealth list for FY 2020 (p. 110).**

**CMS proposes to add the face-to-face portions of three (3) new G-codes [proposed in this rule](#) to the list of Medicare Telehealth services for CY 2020 (p. 111):**

- GYYY1 (Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month)
- GYYY2 (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month)
- GYYY3: (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure)

### **Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (p. 113)**

An effective treatment for OUD is known as medication-assisted treatment (MAT), which is defined as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder. Medicare has previously only covered certain medications associated with MAT (i.e., buprenorphine, buprenorphine-naloxone combination products, and extended-release injectable naltrexone) under Part B or Part D, along with reasonable and necessary counseling and behavioral therapy services. Medicare has not covered methadone for MAT because of the unique manner in which this drug (a schedule II controlled substance that is highly regulated because of the high potential for abuse) is dispensed and administered. Importantly, methadone for MAT can only be dispensed and administered by an opioid treatment program (OTP), and OTP entities were not previously allowed to bill and receive payment from Medicare, creating a gap in coverage for Medicare beneficiaries. Private plans, including qualified health plans (QHPs) and TRICARE have established coverage and payment for OUD treatment furnished by OTPs.

In an ongoing effort to address the opioid epidemic, and as required by section 2005 of the SUPPORT Act, **CMS proposes to establish rules to govern Medicare coverage of and payment for opioid use disorder (OUD) treatment services furnished by an opioid treatment program (OTP).** To accomplish this, **CMS proposes to establish definitions of OUD treatment services and OTP for purposes of the Medicare Program, along with a methodology for determining Medicare payment for such services provided by OTPs. CMS proposes to codify these policies in a new section of the regulations at § 410.67.**

#### **[Proposed Definitions \(p. 117\)](#)**

**Opioid use disorder treatment services. CMS proposes that the OUD treatment services that may be furnished by OTPs include the medications approved by the FDA for use in the treatment of OUD (i.e., buprenorphine, methadone, and naltrexone); the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing.**

**CMS also proposes to use its discretion to include other items and services that the Secretary determines are appropriate, to include the use of telecommunications for certain services. CMS proposes to codify this definition of OUD treatment services furnished by OTPs at § 410.67(b). As part of this definition, CMS also proposes to specify that an OUD treatment service is an item or service that is furnished by an OTP that meets the applicable requirements to participate in the Medicare Program and receive payment.**

**CMS seeks comment on any other items and services (not including meals or transportation as they are statutorily prohibited) currently covered and paid for under Medicare Part B when furnished by Medicare-enrolled providers/suppliers that the Secretary should consider adding to this definition. Comments should include any evidence supporting the impact of the use of such items and services in the treatment of OUD and enumeration of their costs. CMS is particularly interested in public feedback on whether intake activities (e.g., initial physical examination, initial assessments and preparation of a treatment plan, and periodic assessments) should be included in the definition of OUD treatment services. CMS would also like public feedback on whether there are any drug development efforts in the pipeline that could result in medications intended for use in the treatment of OUD with a novel mechanism of action that does not involve opioid agonist and antagonist mechanisms (that is, outside of activating and/or blocking opioid receptors). CMS welcomes comment on how medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action should be considered in the context of OUD treatment services provided by OTPs, and whether CMS should use its discretion to include such medications in the definition of OUD treatment services given the possibility that such medications could be approved in the future.**

**Opioid treatment program. CMS proposes to define “opioid treatment program” at § 410.67(b) as an entity that is an opioid treatment program as defined in 42 CFR 8.2 (or any successor regulation) and meets the applicable requirements for an OTP. CMS proposes to codify this definition at § 410.67(b). In addition, CMS proposes that for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. CMS further proposes that an OTP must have a provider agreement. CMS proposes to codify these requirements at § 410.67(c). Public comments on the proposed definition of OTP and the proposed Medicare requirements for OTPs are welcomed.**

#### **Proposed bundled payments for OUD treatment services (p. 132)**

**As mandated by law, CMS proposes to establish bundled payments for OUD treatment services (see above). CMS proposes to apply separate payment methodologies for the drug component and the non-drug component of the bundled payments, and calculate the full bundled payment rate by combining the two. CMS proposes to codify the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d).**

**Medicaid and TRICARE.** While CMS is authorized to consider payment rates for OUD treatment services by Medicaid and TRICARE, **the agency welcomes comment on the scope of private payer OTP coverage and payment rates established for OTPs furnishing comparable OUD treatment services**, which may be considered as part of the development of the final bundled payment rates.

#### **Aspects of the Bundle.**

**Duration of bundle (p. 138): CMS proposes that the duration of an episode of care for OUD treatment services would be a week (that is, a contiguous 7-day period that may start on any day of the week), and welcomes comments on whether it should consider a daily or monthly bundled payment.**

***Requirements for an Episode: CMS proposes to consider the requirements to bill for the full weekly bundle to be met if the patient is receiving the majority (i.e., 51 percent or more) of the services***

**identified in their treatment plan at that time.** For valuation, CMS assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month.

*Partial episode of care:* To provide more accurate payment to OTPs in cases where a beneficiary is not able to or chooses not to receive all items and services described in their treatment plan or the OTP is unable to furnish services, **CMS proposes to establish separate payment rates for partial episodes that correspond with each of the full weekly bundles.** Specifically, **where the OTP has furnished at least one of the items or services, but less than 51 percent, CMS proposes that it could bill for a partial weekly bundle. In cases in which the beneficiary does not receive a drug during the partial episode, CMS proposes that the code describing a non-drug partial weekly bundle must be used.** In cases where, for example, the OTP is transitioning the beneficiary from one OUD medication to another and therefore the beneficiary is receiving less than a week of one type of medication, the OTP could bill for two partial episodes (one for each of the medications), or one partial episode and one full episode. CMS intends to monitor this issue and will consider making changes in future rulemaking to ensure that the billing for partial episodes is not being abused. **CMS seeks comment on (1) the proposed approach to full and partial episodes, including the threshold that should be applied to determine when an OTP may bill for the full weekly bundle versus a partial episode and (2) the minimum threshold that should be applied to determine when a partial episode could be billed. CMS also seeks feedback on whether any other payers of OTP services allow for billing partial bundles and what thresholds they use.**

*Non-drug episode:* **CMS proposes to establish a non-drug episode of care for OTPs to bill for non-drug services,** for example, in cases where a patient is being treated with injectable buprenorphine or naltrexone on a monthly basis or has a buprenorphine implant.

*Drug and non-drug components (p. 141).* **CMS proposes to develop separate payment methodologies for the drug component and the non-drug (which includes the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing) components of the bundled payment.**

*Drug component:* Largely due to the wide variation in the cost of medications used by OTPs to treat OUD, **CMS proposes to base the OTP bundled payment rates, in part, on the type of medication used for treatment.** Below are the categories of bundled payments CMS proposes for the current FDA-approved drugs for treatment of OUD.

- ◆ Methadone (oral).
- ◆ Buprenorphine (oral).
- ◆ Buprenorphine (injection).
- ◆ Buprenorphine (implant).
- ◆ Naltrexone (injection).

**CMS also proposes to create a category of bundled payment describing a drug not otherwise specified to be used for new drugs.**

**New drugs:** As new opioid agonist and antagonist treatment medications to treat OUD are in developed and FDA-approved, **CMS proposes that OTPs would bill for the episode of care using the medication not otherwise specified (NOS) code, HCPCS code GXXX9 (or GXXX19 for a partial episode) and CMS would use the typical or average maintenance dose to determine the drug cost for the new bundle.** Pricing would be determined based on the relevant pricing methodology (see below) or invoice pricing (until either ASP pricing data or other necessary information is available). **CMS seeks comment on this proposed approach to the treatment of new drugs used for MAT in OTPs. CMS also seeks comments on how new medications that may be approved for use in the treatment of OUD with a novel mechanism of action should be**

**considered in the context of OUD treatment services provided by OTPs, as well as how such new drugs should be priced, and whether pricing should be determined using the same pricing methodology proposed for new opioid agonist and antagonist treatment medications, described above or whether an alternative pricing methodology should be used.**

*Non-drug component:* This includes all items and services furnished during an episode of care except for the medication.

**Counseling, Therapy, Toxicology Testing, and Drug Administration:** CMS notes that professionals furnishing therapy or counseling services for OUD treatment must be operating within state law and scope of practice to be covered. In addition, toxicology tests, such as urinalysis and hair/fluid analysis, would be considered to be OUD treatment services and included in the bundled payment. The bundle also includes the cost of drug dispensing and/or Administration.

**Other services:** **CMS seeks comment on any other items and services it might consider including as OUD treatment services under the Secretary's discretion.** If CMS were to finalize a definition of OUD treatment services that includes any other items or services, such as intake activities or periodic assessments as discussed above, it would consider whether any changes to the payment rates for the bundled payments are necessary.

*Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services (p. 146).* **CMS proposes to adjust the bundled payment rates through the use of an add-on code in order to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan.** This add-on code (HCPCS code GXX19) would describe each additional 30 minutes of counseling or group or individual therapy furnished in a week of MAT, which could be billed in conjunction with the codes describing the full episode of care or the partial episodes. CMS intends to monitor this issue and will consider whether it needs to make changes to this policy through future rulemaking to ensure that this adjustment is not being abused. **CMS seeks comment on the proposed add-on code and the threshold for billing.**

*Site of service (telecommunications) (p. 148).* **CMS proposes to allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries.** CMS invite comment as to whether this proposal, including whether furnishing these services through communication technology is clinically appropriate. CMS also invites public comment on other components of the bundle that may be clinically appropriate to be furnished via communication technology, while also considering SAMHSA's guidance that OTPs should pay exceptional attention to data security and privacy.

*Coding and payment rates (p. 150).* **CMS proposes to adopt a coding structure for OUD treatment services that varies by the medication administered, and to assign flat dollar payment amounts to the proposed OTP bundled services (HCPCS codes GXXX1-GXX19).** Note that OUD treatment services are not considered physicians' services and are paid outside the PFS, thus they would not be priced using relative value units (RVUs).

**Drug component: CMS proposes to use the typical or average maintenance dose to determine the drug costs for each of the proposed bundles. Specifically, CMS proposes to calculate payment rates using a 100 mg daily dose for methadone, a 10 mg daily dose for oral buprenorphine, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone. CMS invites public comments on its proposal to use the typical maintenance dose in order to calculate the drug component of the bundled payment rate for each of the proposed codes, as well**

**as the specific typical maintenance dosage level identified for each drug, and a process for identifying the typical maintenance dose for new opioid agonist or antagonist treatment medications approved by the FDA when such medications are billed using the medication NOS code, such as using the FDA-approved prescribing information or a review of the published, preferably peerreviewed, literature.**

**Potential Drug Pricing Data Sources:** *CMS proposes to estimate an OTP's costs for the drug component of the bundles based on available data regarding drug costs rather than a provider-specific cost-to-charge ratio or another more direct assessment of facility or industry-specific drug costs. CMS proposes that the payment amounts for the drug component of the bundles be based on CMS pricing mechanisms currently in place, but requests comment on other potential data sources for pricing OUD treatment medications either generally or specifically with respect to acquisition by OTPs.* Also, for oral drugs that CMS proposes to include in the OTP bundled payments and the agency does not receive manufacturer-submitted ASP data, CMS is considering several potential approaches for determining the payment amounts for the drug component of the bundles (i.e., invoice pricing). Based on comments received, CMS intends to develop a final policy for determining the payment amount for the drug component of the relevant bundles. **CMS invites public comment on any other potential data sources for estimating the provider acquisition costs of OTP drugs currently paid under either Part B or Part D.**

**Part B Drugs:** Currently, covered Part B drugs fall into three general categories: drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment, and other drugs specified by statute. **CMS proposes to use the ASP methodology to set the payment rates for the "incident to" drugs (limited to 100 percent of the volume-weighted ASP for a HCPCS code vs. 106 percent).** **CMS also proposes to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs, but adjust consistent with the above proposal. CMS seeks comments on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP rates.**

**Oral Drugs:** **CMS proposes to use the ASP methodology to set the payment rates for oral drugs, despite not currently receiving such data. CMS requests comment on whether manufacturers would be willing to submit ASP pricing data for OTP drugs currently covered under Part D on a voluntary basis. Similar to the above, CMS proposes to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP for a HCPCS code, and use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs, with the aforementioned adjustment. CMS seeks comments on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP rates.** If CMS does not receive ASP data, it is considering various mechanisms to estimate the payment amounts for oral drugs and seeks comment on these potential approaches.

**Approach 1:** Use wholesale acquisition cost (WAC) or invoice pricing in place of ASP as part of the ASP methodology

**Approach 2:** Use data retrieved from the online Medicare Prescription Drug Plan Finder

**Approach 3:** Use WAC

**Approach 4:** Medicaid's National Average Drug Acquisition Cost (NADAC) survey

**Alternative Methodone Pricing:** Follow TRICARE's methodology for methodone

**CMS proposes to codify this proposal to apply an alternative approach for determining the payment rate for oral drugs only if ASP data are not available, and requests comment on the potential alternative approaches set forth above, including any other alternate sources of data**

**to estimate the cost of these oral MAT drugs.** See [Table 14](#) for the payment rates based on the 5 potential alternatives.

***Non-drug component: CMS proposes to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone.*** CMS plans to monitor utilization of non-drug services by Medicare beneficiaries and, if needed, would consider in future rulemaking ways to tailor the TRICARE payment rate for these non-drug services to the Medicare population, including dually eligible beneficiaries. CMS would adjust the TRICARE payment rate for non-drug services for most of the other bundled payments to more accurately reflect the cost of administering the other drugs used in MAT.

***For the oral buprenorphine bundled payment, CMS proposes to retain the same amount as the rate for the methadone bundled payment based on an assumption that this drug is also being dispensed daily.***

***For the injectable drugs (buprenorphine and naltrexone), CMS proposes to subtract from the non-drug component, an amount that is comparable to the dispensing fees paid by several state Medicaid programs (\$10.50) for a week of daily dispensing of methadone and update the amount of this adjustment annually using the same methodology CMS proposes to use to update the non-drug component of the bundled payments.*** The payment rates for the non-drug component of the codes for the weekly bundled payments for buprenorphine implants would be adjusted to add an amount for insertion and/or removal based on a direct crosswalk to the non-facility payment rates under the Medicare PFS for the insertion, removal, or insertion and removal of these implants (see G0516, G0517 and G0518), and to remove the costs of daily drug dispensing.

***CMS proposes that the payment rate for the add-on code, HCPCS code GXX19, would be based on 30 minutes of substance use counseling and valued based on a crosswalk to the rates set by state Medicaid programs for similar services.***

Medication not otherwise specified: CMS would expect the non-drug component for medication not otherwise specified bundled payments (HCPCS code GXXX9) to be consistent with the pricing methodology for the other bundled payments and therefore, be based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees.

***For oral medications, CMS would use the rate for the non-drug services included in the TRICARE methadone bundle, based on an assumption that the drug is also being dispensed daily.***

***For the injectable medications, CMS would adjust the TRICARE payment rate for non-drug services using the same methodology proposed for injectable medications above (to subtract an amount for daily dispensing and add the non-facility Medicare payment rate for administration of the injection).***

***For implantable medications, CMS would also use the same methodology above, with the same crosswalked non-facility Medicare payment rates (for insertion, removal, and insertion and removal).***

**CMS seeks comments on all of the proposed pricing methodologies described in this section.**

***Partial episode of care: For HCPCS codes GXX10 and GXX11, CMS proposes that the payment rates for***



*the non-drug component would be calculated by taking one half of the payment rate for the non-drug component for the corresponding weekly bundles, but welcomes comment on other methods that could be used to calculate these payment rates. CMS proposes that the payment rates for the drug component of these partial episode bundles would be calculated by taking one half of the payment rate for the drug component of the corresponding weekly bundles.*

*For HCPCS codes GXX12 and GXX16, CMS proposes that the payment rates for the drug component would be the same as the payment rate for the drug component of the full weekly bundle so that the OTP would be reimbursed for the cost of the drug that is given at the start of the episode. For the non-drug component, CMS proposes that the payment rate would be calculated as follows: the TRICARE non-drug component payment rate (\$110.96), adjusted to remove the cost of daily administration of an oral drug (\$10.50), then divided by two; that amount would be added to the fee that Medicare pays for the administration of an injection (which is currently \$16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372).*

*For HCPCS codes GXX13, GXX14, GXX15, CMS proposes that the payment rates for drug component would be the same as the payment rate for the corresponding weekly bundle. For the non-drug component, CMS proposes the payment rate would be calculated as follows: the TRICARE non-drug component payment rate (\$110.96), adjusted to remove the cost of daily administration of an oral drug (\$10.50), then divided by two; that amount would be added to the Medicare non-facility payment rate for the insertion, removal, or insertion and removal of the implants, respectively (based on the non-facility rates for HCPCS codes G0516, G0517, and G0518, which are currently \$111.00, \$126.86, and \$204.70, respectively).*

*For HCPCS code GXX17 (code describing a non-drug partial episode of care), CMS proposes that the payment rate would be calculated by taking one half of the payment rate for the corresponding weekly bundle. CMS proposes that the payment rate for the code describing partial episodes for a medication not otherwise specified (HCPCS code GXX18) would be calculated based on whether the medication is oral, injectable or implantable, following the methodology described above. For oral drugs, CMS would follow the methodology described for HCPCS codes GXX10 and GXX11. For injectable drugs, CMS would follow the methodology described for HCPCS codes GXX12 and GXX16. For implantable drugs, CMS would follow the methodology described for HCPCS codes GXX13, GXX14, and GXX15. CMS welcomes comments on how partial episodes of care using new drugs with a novel mechanism of action (that is, non-opioid agonist and/or antagonist treatment medications) should be priced.*

[Table 15](#) outlines CMS' proposed codes, long descriptors, and valuations for OTP bundled services. ***CMS proposes that only an entity enrolled with Medicare as an OTP could bill these codes, and may only bill these codes (that is, no other codes paid under the MPFS may be billed by OTPs).***

*Place of Service (POS) Code for Services Furnished at OTPs (p. 180).* CMS is creating a new POS code specific to OTPs. Claims for OTP services would include this place of service code. Further guidance will be issued regarding the POS code that should be used by OTPs.

*Duplicative payments under Parts B or D (p. 181).* ***CMS proposes to consider payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment to be a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D.*** CMS will generally recoup the duplicative payment made to the OTP, given the OTP would be in the best position to know whether or not the drug that is included as part of the beneficiary's treatment plan is furnished by the OTP or by another provider or supplier given that the OTP is

responsible for managing the beneficiary's overall OUD treatment.

**Cost Sharing (p. 183).** CMS believe that there is flexibility for CMS to set the copayment amount for OTP Services, therefore, it ***proposes to set the copayment at zero for a time-limited duration, to minimize barriers to patient access to OUD treatment services.*** Setting the copayment at zero also ensures OTP providers receive the full Medicare payment amount for Medicare beneficiaries. CMS will continue to monitor the opioid crisis in order to determine at what point in the future a copayment may be imposed, and which point it would institute cost sharing through future notice and comment rulemaking. ***CMS welcome feedback from the public on its proposal to set the copayment at zero for a time-limited duration, such as for the duration of the national opioid crisis, and any other metrics CMS might consider using to determine when to start requiring a copayment.***

**Adjustments to bundled payment rates for OUD treatment services (p. 184).**

**Locality adjustment (p. 185).** CMS proposes to apply a geographic locality adjustment to the bundled payment rate for OTP treatment services.

*Drug component:* CMS is not proposing to apply a geographic locality adjustment to the drug component of the bundled payment rate for OTP services.

*Non-drug component:* ***CMS proposes to adjust the non-drug component of the bundled payment rates for OUD treatment services using an approach similar to the established methodology used to geographically adjust payments under the PFS based upon the location where the service is furnished. CMS is proposing to use the Geographic Adjustment Factor (GAF) to adjust the payment for the non-drug component of the OTP bundled payment to reflect the costs of furnishing the non-drug component of OUD treatment services in each of the PFS fee schedule areas. CMS invites public comment on its proposal to adjust the non-drug component of the OTP bundled payments for geographic variations in the costs of furnishing OUD treatment services using the GAF, as well as on any factors, other than the GAF, that could be used to make this payment adjustment.***

***CMS is interested in receiving information on whether rural areas have appropriate access to treatment for OUD, including any potential limitations on access to care for OUD in rural areas and whether there are additional adjustments to the proposed bundled payments that should be made to account for the costs incurred by OTPs in furnishing OUD treatment services in rural areas. CMS invites public comment on this issue and potential solutions it could consider adopting to address this potential issue through future rulemaking.***

**Annual update (p. 188).** CMS proposes to apply a blended annual update, comprised of distinct updates for the drug and non-drug components of the bundled payment rates, to account for the differing rate of growth in the prices of drugs relative to other services.

*Drug component:* ***CMS proposes to update the payment for the drug component based upon the changes in drug costs reported under the pricing mechanism used to establish the pricing of the drug component of the applicable bundled payment rate. CMS invites public comment on its proposed approach to updating the drug component of the bundled payment rates and on possible alternate methodologies for updating the drug component of the payment rate for OUD treatment services, such as use of the PPI for chemicals and allied products, analgesics.***

*Non-drug component:* ***CMS proposes to update the non-drug component of the bundled payment for OUD treatment services based upon the Medicare Economic Index (MEI), and using the most recently available historical annual growth in the MEI available at the time of rulemaking. CMS invites public comment on this proposal.***

## Bundled Payments Under the PFS for Substance Use Disorders ([p. 193](#))

In CY 2019 rulemaking, CMS sought comments on the potential for creating a bundled episode of care for management and counseling treatment for substance use disorders or opioid use disorders (OUDs). CMS states that it received 50 comments in response. In response to comments, **CMS proposes to establish bundled payments for “overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities”** ([p. 193](#)).

- If the patient’s treatment includes medically assisted treatment, **the bundled payment does not include payment for the medication itself**
- If the patient’s treatment includes medically necessary toxicology treatment, **the medically necessary toxicology testing would not be included in the bundle and would be billed separately under the Clinical Lab Fee Schedule**
- To operationalize the bundle, **CMS proposes the creation of two new G-codes for monthly bundles for overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment as well as an add-on code** ([p. 194](#); [p. 196](#)):
  - GYYY1 (Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month); **CMS proposes a wRVU of 1.70** ([p. 198](#)); **Proposed direct PE inputs for review in [Table 22](#).**
  - GYYY2 (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month); **CMS proposes a wRVU of 1.53** ([p. 199](#)); **Proposed direct PE inputs for review in [Table 22](#).**
  - GYYY3: (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure));<sup>6,7</sup> **CMS proposes a wRVU of 0.82** ([p. 200](#)); **Proposed direct PE inputs for review in [Table 22](#).**
- **CMS seeks comments on whether it should consider creation of a separately billable code to describe additional resources and what resource inputs it could consider to value the code** ([p. 195](#)).
- **CMS states that the codes are not limited to use by any specialty**, although CMS expects that they would be used most often by addiction specialty practitioners ([p. 195](#)).
- **CMS states that there is no requirement for any consultation with a specialist as a condition of payment for these codes** ([p. 196](#)).
- In order to provide duplicative billing with other medically necessary psychotherapy for other conditions, **CMS proposes that CPT 90832, 90834, 90837, 90853 may not be billed by the same practitioner in the same month as the proposed G-codes** ([p. 200](#)).
- **CMS proposes that in order to report the OUD bundle, a practitioner must first furnish a separately reportable initiating visit** ([p. 200](#)), which can be the same initiating visits that serve as initiating visits for CCM and BHI services ([p. 201](#)).
- **CMS proposes that the “counseling, therapy, and care coordination” in the proposed codes can be provided by “professionals who are qualified to provide the services under state law and within the scope of practice ‘incident to’ the services of the billing physician or other practitioner”; CMS provides that the billing clinician manage the patient’s overall care and supervise other individuals participating in the treatment** ([p. 201](#)); **CMS proposes that these codes will be added to the list that allows for general supervision of the non-face-to-face portions of the service** ([p. 202](#)).

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<sup>6</sup> CMS states that the add-on code is for instances where patients require resources that “substantially exceed” the resources in the base codes: “[T]he add-on code would address extraordinary circumstances that are not contemplated by the bundled code”; CMS also notes that it created that add-on code to safeguard against limitation on the appropriate amount of OUD ([p. 195](#)).

<sup>7</sup> CMS proposes that the add-on code can only be billed when total time spent by billing professional and the clinical staff providing services described by the base code “exceeds double the minimum amount of service time required to bill the base code each month” ([p. 197](#)).

- **CMS proposes that the billing practitioner or clinical staff must document obtaining beneficiary consent to receive the services, including consent to cost-sharing (p. 202).**
- **See also, provisions for these codes related to [Medicare Telehealth Services](#).**
- **CMS proposes to set the copayment for OUD services delivered at an OTP at zero; but notes that it does not have the statutory authority to eliminate deductibles or co-insurance (p. 204).**
- CMS notes that it would be willing to consider any new available CPT codes similar to the G-codes proposed here (p. 204).
- **CMS seeks comment on the use of MAT in the emergency department setting (including initiation of MAT and referral or follow-up care) and whether it should consider separate payment for such services in future rulemaking** given that, while OUD can first become noticeable in the emergency department, but there is “no specific coding that describes diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department setting” (p. 204).
- Provisions related to the use of these codes in the Rural Health Clinic (RHC) and Federally-Qualified Health Center (FQHC) setting can be found beginning on [p. 205](#).

### **Physician Supervision for Physician Assistant (PA) Services (p. 207)**

Through CMS’ efforts to collect input on reducing burden, CMS was made aware that PAs have been practicing more autonomously. CMS was also made aware that, in some instances, some states have changed state scope-of-practice laws to reflect this (p. 208). Stakeholders expressed concern that “the current regulatory definition of physician supervision could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population” (p. 208).

Current law requires that services furnished by a physician assistant (PA) be performed under the supervision of a physician.<sup>8</sup> CMS has implemented this by requiring that PA services require “general supervision” (rather than “direct supervision” or “personal supervision”). CMS reviews that under current regulation “general supervision” means that services “must be furnished under a physician’s overall direction and control, but the physician’s presence is not required” (p. 207). Some commenters have requested that the regulation be altered to allow PAs to operate like NPs and CNSs who are required<sup>9</sup> only to provide their services “in collaboration” with a physician.

**CMS seeks input on specific examples of changes in state law and scope of practice rules “that enable PAs to practice more broadly such that those rules are in tension with the Medicare requirement for general supervision of PA services” (p. 208).**

In addition to requesting more information on changes at the state level, **CMS proposes to redefine the physician supervision requirement for services delivered by a PA to state that the supervision requirement is**

<sup>8</sup> [Social Security Act §1861\(s\)\(2\)\(K\)\(i\)](#): “services which would be physicians’ services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician’s professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.”

<sup>9</sup> [Social Security Act §1861\(s\)\(2\)\(K\)\(ii\)](#): “services which would be physicians’ services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician’s professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;”

met when ***“the PA furnishes their services in accordance with state law and state scope of practice rules for PAs in a state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed”*** (p. 209). CMS also stated that if there is no state law governing physician supervision of PA services, ***“the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA’s approach to working with physicians in furnishing their services”*** (p. 210).

## **Review and Verification of Medical Record Documentation (p. 211)**

CMS reviewed several recent actions it took aimed at burden reduction:

- CMS’ CY 2019 provision that, for E/M documentation, it would be now be allowed for either the physician, resident, or nurse to document in the medical record that the teaching physician’s presence and participation requirements were met (rather than the previous requirement that the teaching physician documented those items him or herself) (p. 211). CMS subsequent received input suggesting that it was overly restrictive in that the documentation was only allowed to be conducted by a “physician, resident, or nurse” (p. 213).
- In [CMS Transmittal 3971](#) (E/M Service Documentation Provided by Students), CMS reduced “duplicative documentation requirements by allowing a teaching physician to review and verify (sign/date) notes made by a student in a patient’s medical record for E/M services, rather than having to redocument the information, largely duplicating the student’s notes” (p. 212).
- In [CMS Transmittal 4068](#) (E/M Service Documentation Provided by Students), CMS issued a correction, which contains definitions pertinent to teaching physician services. In particular, the manual instruction states that
  - A “student” is “an individual who participates in an accredited educational program (for example, a medical school) that is not an approved graduate medical education (GME) program”;
  - A student is “never considered to be an intern or a resident”; and that
  - CMS does not pay for services furnished by a student.

CMS has received stakeholder concern about definitions for teaching physician, student, and documentation when these publications are all taken together. CMS notes that nonphysician practitioners (NPPs) (including NPs, CNSs, and CNMs<sup>10</sup> as well as PAs) that are allowed to bill Medicare Part B are seeking relief from E/M documentation requirements that would allow them to “review and verify” medical record notes by students (p. 212). CMS received in put that the language does not specify “medical student” and that PAs and APRNs also educate students who are “individuals who participate in an accredited educational program that is not an approved GME program” (p. 213). In particular there was concern that “PA and APRN preceptors may be required to re-document E/M services in full when their students include notes in the medical records, without having the same option that teaching physicians do to simply review and verify medical student documentation” (p. 214).

In response to this input, ***CMS proposes to “establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team”*** (p. 214).

- CMS notes that this would apply to all Medicare-covered services paid under the Medicare Physician Fee Schedule (p. 214).

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<sup>10</sup> CMS in the rule refers to nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs) collectively as advanced practice registered nurses (APRNs) (p. 213).

- CMS adds that this includes notes documenting the practitioner’s presence and participation in services ([p. 215](#)).
- CMS clarified that the proposal does not modify the scope of or standards for documentation that is needed in the medical record to demonstrate medical necessity of services ([p. 215](#)).
- CMS also proposes conforming amendments to the regulations specific to teaching physicians (i.e., [§415.172\(b\)](#) and [§415.174\(a\)\(6\)](#)) to allow “physicians, residents, nurses, students, or other members of the medical team” to enter information in medical record that can be “reviewed and verified” by the teaching physician.

### Care Management Services ([p. 216](#))

CMS discusses recent updates to PFS payment policies to improve payment for care management and care coordination, including the creation and adoption of new CPT codes describing such services. CMS summarizes the new codes in [Table 16](#), and refers readers to the CMS [care management website](#) for more information. CMS estimates that approximately 3 million unique beneficiaries receive these services annually, with higher use of chronic care management (CCM), transitional care management (TCM), and advance care planning (ACP) services.

### Transitional Care Management (TCM) Services ([p. 217](#))

TCM services are defined by the following two codes:

- **CPT 99495** (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*), and
- **CPT 99496** (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*)

CMS notes that while utilization of TCM services has increased each year, it is still low when compared to the number of Medicare beneficiaries with eligible discharges – despite positive health outcomes associated with use of TCM services. Based on these findings, CMS believes that increasing utilization of TCH services could positively affect patient outcomes.

CMS notes that, when it initially established TCM billing, it also established a list of 57 HCPCS codes that cannot be billed during the 30-day period covered by TCM services by the same practitioner reporting TCM, consistent with restrictions put in place by the CPT Editorial Panel, due to concerns about duplication and overlap. Upon recent analysis, CMS has identified 14 codes on the list that are paid separately under the PFS and that, upon reconsideration, CMS believes may not substantially overlap with TCM services and may complement TCM services when medically necessary. These codes are listed in [Table 17](#), as excerpted below.

**TABLE 17: 14 HCPCS Codes that Currently Cannot be Billed Concurrently with TCM by the Same Practitioner and are Active Codes Payable by Medicare PFS**

Code Family	HCPCS Code	Descriptor
Prolonged Services without Direct Patient Contact	99358	Prolonged E/M service before and/or after direct patient care; first hour, non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service
	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes beyond the first hour of prolonged services
Home and Outpatient International Normalized Ratio (INR) Monitoring Services	93792	Patient/caregiver training for initiation of home INR monitoring
	93793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s)
End Stage Renal Disease Services (patients who are 20+ years)	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older
	90961	ESRD related services monthly with 2-3 face-to-face visits per month; for patients 20 years and older
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days
Complex Chronic Care Management Services	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month
	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes

**CMS proposes to revise its billing requirements for TCM by allowing TCM codes to be billed concurrently with any of the codes in [Table 17](#), with an aim of increasing medically appropriate use of TCM services. Before CMS finalizes its proposal, however, **CMS seeks comment on the following:****

- **Whether overlap of services exists, and if so, which services should be restricted from being billed concurrently with TCM?**
- **Whether any overlap would depend on whether the same or different practitioner reports the services. CMS notes that CPT reporting rules generally apply at the practitioner level, and CMS is seeking input from stakeholders as to whether its policy should differ based on whether it is the same or a different practitioner reporting the services?**
- **Whether the newest CPT code in the chronic care management services family (CPT code 99491 for CCM by a physician or other qualified health professional) overlaps with TCM or should be reportable and separately payable in the same service period?**

CMS also notes that it examined TCM payment rates and how they might negatively affect appropriate utilization of TCM services. CMS notes that the two TCM codes were resurveyed during 2018 as part of a regular RUC review of new technologies or services, leading the RUC to recommend a slight increase in work RVUs for

both codes. CMS believes the results from the new survey will better reflect the work involved in furnishing TCM services, and thus ***CMS is proposing the following RUC-recommended work RVUs:***

- **99495: 2.36**
- **99495: 3.10**

CMS is not proposing any direct PE refinements to the RUC's recommendations for this code family.

### **Chronic Care Management (CCM) Services ([p. 222](#))**

CCM services are comprehensive care coordination services per calendar month, furnished by a physician or non-physician practitioner (NPP) managing overall care and their clinical staff, for patients with two or more serious chronic conditions. There are currently two subsets of codes: non-complex chronic care management, and complex chronic care management, and they include:

- Non-complex: **CPT 99490** (*Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.*)
- Complex: **CPT code 99487** (*Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately); and*
- Complex: **CPT code 99489** (*each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).*)

As with TCM, CMS believes that CCM services, especially complex CCM services, continue to be underutilized. CMS also discusses some refinements to the codes that have been raised recently on [p. 222](#). CMS believes that refinements may be necessary to improve payment accuracy, reduce unnecessary burden, and help ensure that beneficiaries who need CCM services have access to them, as discussed below.

- **Non-Complex CCM Services by Clinical Staff (CPT 99490, GCCC1, GCCC2; [p. 223](#))**. CMS discusses stakeholder input suggesting that CMS should create an add-on code for non-complex CCM, such that non-complex CCM would be defined and valued in 20-minute increments of time with additional payment for each additional 20 minutes. CMS agrees that such coding changes would improve payment accuracy for non-complex CCM. Accordingly, ***CMS proposes to adopt two new G codes with new increments of clinical staff time instead of the existing single CPT code 99490. CMS intends that these would be temporary codes, used for PFS payment instead of CPT 99490 until the CPT Editorial Panel can consider revisions to the current CPT code set.*** The new codes would be as follows:
  - **HCPCS code GCCC1**(*Chronic care management services, initial 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and comprehensive*



- care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)). ([p. 225](#))
  - Work RVU: 0.61 (crosswalk from CPT 99490)
  - Intraservice time: 15 minutes
- **HCPCS code GCCC2** (Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4, 99491)). ([p. 225](#))
  - Work RVU 0.54 (crosswalk from CPT 11107 – Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure))
  - Intraservice time: 15 minutes

**CMS seeks comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel. CMS is also soliciting public comment on whether to limit the number of times GCCC2 can be reported in a given service period for a given beneficiary** since it is not clear how often more than 40 minutes of clinical staff time is spent, and once 60 minutes of clinical staff time is spent, then many or most patients might also require complex medical decision-making, described under existing coding for complex CCM. **CMS is seeking comment on whether and how often beneficiaries who do not require complex CCM (for example, do not require the complex medical decision making that is part of complex CCM) would need 60 or more minutes of non-complex CCM clinical staff time and thereby warrant more than one use of GCCC2 within a service period.**

- **Complex CCM Services (CPT 99487, CPT 99489, GCCC3, GCCC4; [p. 227](#)).** **CMS proposes to adopt two new G codes that would be used for billing under the PFS instead of CPT codes 99487 and 99489, and that would not include the service component of substantial care plan revision currently required under the existing CPT codes, as follows:**
  - **HCPCS code GCCC3 (instead of CPT 99387)** (Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)). ([p. 227](#))
    - Work RVU: 1.00 (crosswalk to CPT 99487)
  - **HCPCS code GCCC4 (instead of CPT 99489)** (each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)). ([p. 227](#))
    - Work RVU: 0.50 (crosswalk to CPT 99489)

CMS believes it is not necessary to explicitly include substantial care plan revision because patients requiring moderate to high complexity medical decision making implicitly need and receive substantial care plan revision, and the substantial care plan service component is potentially duplicative with the

medical decision making service component; as such, CMS believes it is unnecessary as a means of distinguishing eligible patients. CMS intends these would be temporary G codes to remain in place until the CPT Editorial Panel can consider revising the current code descriptors for complex CCM services. ***CMS is seeking comment on whether the benefit of proceeding with the G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.***

- **Typical Care Plan (p. 228).** When CMS finalize the original CCM code in the CY 2014 PFS, CMS finalized a CCM scope of service element for a patient-centered plan of care with the following characteristics (consistent with recommendations from the AMA's Complex Chronic Care Coordination Workgroup):  
*it is a comprehensive plan of care for all health problems and typically includes, but is not limited to, the following elements: problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; community/social services ordered; how the services of agencies and specialists unconnected to the practice will be directed/coordinated; identify the individuals responsible for each intervention, requirements for periodic review; and when applicable, revisions of the care plan.*

CMS notes that there is still some confusion in the medical community regarding what a care plan typically includes. CMS notes that because these are "typical" care plan elements, these elements do not comprise a set of strict requirements that must be included in a care plan for purposes of billing for CCM services. Nevertheless, ***CMS is proposing to eliminate the phrase "community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention" and insert the phrase "interaction and coordination with outside resources and practitioners and providers."***

***CMS' proposed new language would read: The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:***

- ***Problem list.***
- ***Expected outcome and prognosis.***
- ***Measurable treatment goals.***
- ***Cognitive and functional assessment.***
- ***Symptom management***
- ***Planned interventions.***
- ***Medical management.***
- ***Environmental evaluation***
- ***Caregiver assessment***
- ***Interaction and coordination with outside resources and practitioners and providers.***
- ***Requirements for periodic review.***
- ***When applicable, revision of the care plan.***

***CMS welcomes feedback on this proposal, including language that would best guide practitioners as they decide what to include in their comprehensive care plan for CCM recipients.*** Additional information regarding the existing requirements for billing CCM, including links to prior rules, is available on the [CMS website](#).

### **Principal Care Management (PCM) Services (p. 231)**

CMS notes a gap in coding and payment for care management services for patients with only one condition, since the current CCM codes require patients to have two or more chronic conditions. CMS has heard from a number of stakeholders, especially those in specialties that use the office/outpatient E/M code set to report the majority of their services, that there can be significant resources involved in care management for a single high

risk disease or complex chronic condition that is not well accounted for in existing coding. Therefore, ***CMS is proposing separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. A qualifying condition would typically be expected to last between three months and a year, or until the death of the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline. CMS is proposing that PCM services include coordination of medical and/or psychosocial care related to the single complex chronic condition, provided by a physician or clinical staff under the direction of a physician or other qualified health care professional.***

While CMS is not proposing any restrictions on the specialties that could bill for PCM, CMS expects that most of these services would be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. CMS expects that, in most instances, initiation of PCM would be triggered by an exacerbation of the patient's complex chronic condition or recent hospitalization such that disease-specific care management is warranted. CMS anticipates that in the majority of instances, PCM services would be billed when a single condition is of such complexity that it could not be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that overall care management for the patient's condition can be returned to the patient's primary care practitioner. If the beneficiary only has one complex chronic condition that is overseen by the primary care practitioner, then the primary care practitioner would also be able to bill for PCM services.

CMS anticipates that many patients will have more than one complex chronic condition. If a clinician is providing PCM services for one complex chronic condition, management of the patient's other conditions would continue to be managed by the primary care practitioner while the patient is receiving PCM services for a single complex condition. It is also possible that the patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously.

***For CY 2020, CMS is proposing to make separate payment for PCM services via two new G codes:***

- ***HCPCS code GPPP1 (Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities) (p. 233)***
  - Reported when, during the calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a single high risk disease or complex chronic condition.
  - Work RVU: 1.28 (crosswalk with CPT 99217 - *Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate])*)
- ***HCPCS code GPPP2 (Comprehensive care management for a single high-risk disease services, e.g. Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent***

adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities). ([p. 233](#))

- Reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition.
- Work RVU: 0.61 (crosswalk to CPT 99490)

CMS raises several considerations starting on [p. 235](#). As a result, CMS is seeking comment on several issues, including:

- **Whether both codes are necessary to appropriately describe and bill for PCM services?**
- **Whether it would be appropriate to create an add-on code for additional time spent each month (similar to HCPCS code GCCC2 discussed above) when PCM services are furnished by clinical staff under the direction of the billing practitioner?**
- **Any potential for duplicative payment between the proposed PCM services and other services, such as interprofessional consultation services or remote patient monitoring codes (see [p. 238](#) for full descriptions)?**

Additionally, CMS is concerned that a possible unintended consequence of making separate payment for care management for a single chronic condition is that a patient with multiple chronic conditions could have their care managed by multiple practitioners, each only billing for PCM, which could potentially result in fragmented patient care, overlaps in services, and duplicative services. While CMS is not proposing additional requirements for the proposed PCM services, CMS did consider alternatives such as requiring that the practitioner billing PCM must document ongoing communication with the patient's primary care practitioner to demonstrate that there is continuity of care between the specialist and primary care settings, or requiring that the patient have had a face-to-face visit with the practitioner billing PCM within the prior 30 days to demonstrate that they have an ongoing relationship. **CMS is seeking comment on whether requirements such as these are necessary or appropriate, and whether there should be additional requirements to prevent potential care fragmentation or service duplication.**

CMS is also proposing several additional requirements, as follows:

- **CMS is proposing that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. CMS is seeking comment on whether there are required elements of CCM services that the public and stakeholders believe should not be applicable to PCM, and should be removed or altered.**
- **CMS is proposing to add GPPP2 to the list of designated care management services for which CMS allows general supervision.**
- **CMS is proposing that PCM could not be billed by the same practitioner for the same patient concurrent with certain other care management services, such as CCM, behavioral health integration services, and monthly capitated ESRD payments.**
- **CMS is proposing that PCM would not be billable by the same practitioner for the same patient during a surgical global period, as CMS believes those resource costs would already be included in the valuation of the global surgical code.**

With respect to scope of service requirements, CMS notes that a high level summary of these requirements is available in [Table 18](#) and available through this [Medicare Learning Network resource](#). Both the initiating visit and the patient's verbal consent are necessary as not all patients who meet the criteria to receive separately billable PCM services may want to receive these services. The beneficiary should be educated as to what PCM services are and any cost sharing that may apply. Additionally, as practitioners have informed CMS that beneficiary cost sharing is a significant barrier to provision of other care management services, **CMS is seeking comment on how best to educate practitioners and beneficiaries on the benefits of PCM services.**

### **Chronic Care Remote Physiologic Monitoring (RPM) Services (p. 238)**

CMS notes that there is a current CPT code 99567, which is a treatment management code, billable after 20 minutes or more of clinical staff/physician/other qualified professional time with a patient in a calendar month.

CMS notes that the CPT Editorial Panel revised the CPT code structure for CPT 99457, effective beginning in CY 2020. The new code structure retains CPT 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20 minute intervals of the service. The new code descriptors for CY 2020 are:

- **CPT code 99457** (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*)
- **CPT code 994X0** (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*).
  - **CMS proposes a work RVU of 0.50 for this add-on code.**

**Finally, CMS is proposing that RPM services reported with CPT codes 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision**, since CMS believes that these codes should be included as designated care management services. CMS' discussion of designated care management services and their supervision requirements can be found on [p. 240](#).

### **Comment Solicitation on Consent for Communication Technology-Based Services (p. 240)**

In the CY 2019 PFS final rule, CMS finalized separate payment for a number of services that could be furnished via communications technology, including:

- HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*)),
- HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*)),
- CPT codes 99446-99449 (*Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*),
- CPT code 99451 (*Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and
- CPT code 99452 (*Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*).

While CMS finalized that verbal consent must be documented in the medical record for each service furnished, CMS has continued to hear from stakeholders that requiring advance beneficiary consent for each of these services is burdensome, as detailed further starting on [p. 241](#).

**CMS is seeking comment on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. During the consent process, the practitioner would make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. CMS is seeking**

**comment on the appropriate interval of time or number of services for which consent could be obtained, for example, for all these services furnished within a 6 month or one year period, or for a set number of services, after which a new consent would need to be obtained. CMS is also seeking comment on the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns.**

### **Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) (p. 242)**

RHCs and FQHCs are paid for general care management services using HCPCS code G0511, which is an RHC and FQHC-specific G-code for 20 minutes or more of CCM services, complex CCM services, or general behavioral health services. Payment for this service is set at the average of the national, non-facility payment rates for CPT codes 99490, 99487, and 99484. **CMS is proposing to use the non-facility payment rates for HCPCS codes GCCC1 and GCCC3 instead of the non-facility payment rates for CPT codes 99490 and 99487, respectively, if these changes are finalized for practitioners billing under the PFS.** CMS notes that it is not proposing any changes in the valuation of these codes. **Upon finalization, the payment for HCPCS code G0511 would be set at the average of the national, non-facility payment rates for HCPCS codes GCCC1 and GCCC3 and CPT code 99484.**

### **Coinsurance for Colorectal Cancer Screening Tests (p. 244)**

#### **Screening vs. Diagnostic**

CMS reviews statutory definitions related to colorectal cancer screening tests. Under Social Security Act [§1861\(pp\)](#):

- (1) *The term “colorectal cancer screening test” means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:*
  - A. *Screening fecal-occult blood test.*
  - B. **Screening flexible sigmoidoscopy.**
  - C. **Screening colonoscopy.**
  - D. **Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.**
- (2) *An “individual at high risk for colorectal cancer” is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn’s Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.*

In addition, CMS outlines the statutory provisions governing beneficiary coinsurance responsibilities for preventive services and the inclusion of these colorectal cancer screening services as preventive services, thus stating “there is no beneficiary responsibility for coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act” (p. 244). CMS states that under this provision, it pays 100% of the Medicare payment amount and beneficiaries are not required to pay Part B coinsurance. However, when these services are “diagnostic” rather than “screening,” CMS states that patients are responsible for the Part B coinsurance for that service (p. 245). Based on CMS’ interpretation of statute, CMS specifically excludes from the definition of “colorectal cancer screening services” “colonoscopies and sigmoidoscopies that begin as a screening service, but where a polyp or other growth is found and removed as part of the procedure” because CMS states that statute<sup>11</sup> dictates that “if, during the course of a screening colonoscopy, a lesion or growth is

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<sup>11</sup> [Social Security Act §1834\(d\)\(3\)\(D\)](#): “Special rule for detected lesions.—If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.”

detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal” (p. 245). Therefore, CMS states that beneficiaries are responsible for the usual coinsurance that applies to the services (p. 246).

### Patient Deductibles

Per statute, beneficiaries are required to meet their applicable deductible for the year before CMS will make payment for Medicare Part B services (p. 246). CMS notes that the ACA enacted a provision to make this provision inapplicable for “expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF,” which includes colorectal cancer screening tests *regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test* (p. 246). CMS notes, however, that this provision does not apply to the coinsurance. CMS acknowledges stakeholder comments encouraging the elimination of coinsurance in these scenarios, but CMS states that it does not have the statutory authority to do so.

### Request for Comment

CMS stated that it has released a wide variety of patient and physician educational materials to explain the benefit and the potential cost-sharing implications. Because of concerns around “surprise bills” for coinsurance if the procedure is determined to be “diagnostic,” ***CMS seeks comment on whether it should require physicians planning to furnish a colorectal cancer screening notify patients in advance that a screening colonoscopy could result in a “diagnostic” procedure where the patient would be responsible for a coinsurance payment*** (p. 247). ***CMS also states that it is considering adopting such a requirement in the final rule in accordance with the public comments*** (p. 248). This includes request for input on:

- Whether to require verbal notice with a notation in the medical record
- Whether to consider a different approach to informing patients of copay implications (e.g. written notice with standard language)
- What mechanism CMS could consider to monitor compliance with a notification requirement

### Therapy Services (p. 249)

#### Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy (p. 249)

Beginning January 1, 2018, section 50202 of the BBA of 2018 repealed the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining the cap amounts as limitations and requiring medical review to ensure therapy services are furnished when appropriate. Section 50202 also requires that after expenses incurred for the beneficiary’s outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier such as the KX modifier on claims. CMS implemented this provision by continuing to use the KX modifier. By using the KX modifier on the claim, the therapy supplier or provider is attesting that the services are medically necessary and that supportive justification is documented in the medical record. As with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). After the beneficiary’s incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Section 50202 also retained the targeted medical review (MR) process for 2018 and subsequent years, but established a lower threshold amount of \$3,000 rather than the \$3,700 threshold amount that had applied for the original manual MR process established by section 3005(g) of the Middle Class Tax Relief and Jobs Creation

Act of 2012 (MCTRJCA). The manual MR process with a threshold amount of \$3,700 was replaced by the targeted MR process with the same threshold amount through amendments made by section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

For CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is \$3,000 for PT and SLP services and \$3,000 for OT services. For purposes of applying the targeted MR process, CMS uses a criteria-based process for selecting providers and suppliers that includes factors such as a high percentage of patients receiving therapy beyond the medical review threshold as compared to peers. For information on the targeted medical review process, CMS directs readers to the therapy cap [website](#).

In the CY 2019 PFS final rule, when discussing the tracking and accrual process for outpatient therapy services in the section on the KX Threshold Amounts, CMS noted that it tracks each beneficiary's incurred expenses for therapy services annually by applying the PFS-based payment amount for each service less any applicable multiple procedure reduction for CMS-designated "always therapy" services. CMS also stated that it uses the PFS rates to accrue expenses for therapy services provided in critical access hospitals (CAHs) as required by statute.<sup>12</sup>

CMS notes that while it explained and implemented the changes required by section 50202 of the BBA of 2018 in the CY 2019 PFS rulemaking, CMS did not codify those changes in regulation text. ***CMS is now proposing to revise the regulations at §§ 410.59 (outpatient occupational therapy) and 410.60 (physical therapy and speech-language pathology) to incorporate the changes made by section 50202 of the BBA of 2018. CMS proposes to clarify through regulation text changes that the specified amounts of annual per-beneficiary incurred expenses are no longer applied as limitations but as threshold amounts above which services require, as a condition of payment, inclusion of the KX modifier; and that use of the KX modifier confirms that the services are medically necessary as justified by appropriate documentation in the patient's medical record. CMS proposes to specify through regulation text changes the therapy services and amounts that are accrued for purposes of applying the KX modifier threshold, including the continued accrual of therapy services furnished by CAHs directly or under arrangements at the PFS-based payment rates. CMS is also proposing to amend regulation text for the purpose of applying the medical review threshold to clarify the threshold amounts and the applicable years for both the manual MR process originally established through the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) and the targeted MR process established by MACRA, and including the changes made through section 50202 of the BBA of 2018 as discussed previously.***

### **Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants ([p. 252](#))**

Statute requires that, for services furnished on or after January 1, 2022, payment for outpatient physical and occupational therapy services for which payment is made under sections 1848 or 1834(k) of the Act which are furnished in whole or in part by a therapy assistant must be paid at 85 percent of the amount that is otherwise applicable. Statute further requires that CMS establish a modifier to identify these services by January 1, 2019, and that claims for outpatient therapy services furnished in whole or in part by a therapy assistant must include the modifier effective for dates of service beginning on January 1, 2020. Statute further requires that CMS implement the subsection through notice and comment rulemaking. In the CY 2019 PFS proposed and final rules, CMS established two modifiers – one to identify services furnished in whole or in part by a physical therapist assistant (PTA) and the other to identify services furnished in whole or in part by an occupational therapy assistant (OTA). The modifiers are defined as follows:

- **CQ Modifier:** Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant

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<sup>12</sup> CMS mistakenly indicated that the statutory requirement was extended by subsequent legislation, including section 50202 of the BBA of 2018. However, CMS clarifies on [p. 252](#) CMS finalized the change through the CY 2014 PFS final rule.



- **CO Modifier:** Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

In the CY 2019 PFS final rule, CMS clarified that the CQ and CO modifiers are required to be used when applicable for services furnished on or after January 1, 2020, on the claim line of the service alongside the respective GP or GO therapy modifier to identify services furnished under a PT or OT plan of care. The GP and GO therapy modifiers, along with the GN modifier for speech-language pathology (SLP) services, have been used since 1998 to track and accrue the per-beneficiary incurred expenses amounts to different therapy caps, now KX modifier thresholds, one amount for PT and SLP services combined and a separate amount for OT services. CMS also clarified in the CY 2019 PFS final rule that the CQ and CO modifiers will trigger application of the reduced payment rate for outpatient therapy services furnished in whole or in part by a PTA or OTA, beginning for services furnished in CY 2022. Additionally, CMS finalized a de minimis standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

CMS also explained in the CY 2019 PFS proposed and final rules that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to the services of, physicians or nonphysician practitioners (NPPs) including nurse practitioners, physician assistants, and clinical nurse specialists. This is because CMS' regulations for outpatient physical and occupational therapy services require that an individual furnishing outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist. As such, only therapists and not therapy assistants can furnish outpatient therapy services incident to the services of a physician or NPP; and, the new PTA and OTA modifiers cannot be used on the line of service of the professional claim when the rendering NPI identified on the claim is a physician or an NPP. ***CMS intends to revise CMS' manual provisions at Pub. 100-02, Medicare Benefit Policy Manual (MBPM), Chapter 15, section 230, as appropriate, to reflect requirements for the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020. CMS anticipates amending these manual provisions for CY 2020 to reflect the policies CMS adopts through the CY 2020 PFS notice and comment rulemaking process.***

In PFS rulemaking for CY 2019, CMS identified certain situations when the therapy assistant modifiers do apply. The modifiers are applicable to:

- Therapeutic portions of outpatient therapy services furnished by PTAs/OTAs, as opposed to administrative or other non-therapeutic services that can be performed by others without the education and training of OTAs and PTAs.
- Services wholly furnished by PTAs or OTAs without physical or occupational therapists.
- Evaluative services that are furnished in part by PTAs/OTAs (keeping in mind that PTAs/OTAs are not recognized to wholly furnish PT and OT evaluation or re-evaluations).

CMS also identified some situations when the therapy assistant modifiers do not apply. They do not apply when:

- PTAs/OTAs furnish services that can be done by a technician or aide who does not have the training and education of a PTA/OTA.
- Therapists exclusively furnish services without the involvement of PTAs/OTAs.

Finally, CMS noted that it would be further addressing application of the modifiers for therapy assistant services and the 10 percent de minimis standard more specifically in PFS rulemaking for CY 2020, including how the modifiers are applied in different scenarios for different types of services.

### [Applying the CQ and CO Modifiers \(p. 255\)](#)

CMS interprets the references in section 1834(v)(1) and (2) of the Act to outpatient physical therapy “service” and outpatient occupational therapy “service” to mean a specific procedure code that describes a PT or OT service.

To apply the de minimis standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, **CMS proposes to make the 10 percent calculation based on the respective therapeutic minutes of time spent by the therapist and the PTA/OTA, rounded to the nearest whole minute.** The minutes of time spent by a PTA/OTA furnishing a therapeutic service can overlap partially or completely with the time spent by a physical or occupational therapist furnishing the service. **CMS proposes that the total time for a service would be the total time spent by the therapist (whether independent of, or concurrent with, a PTA/OTA) plus any additional time spent by the PTA/OTA independently furnishing the therapeutic service. When deciding whether the therapy assistant modifiers apply, CMS proposes that if the PTA/OTA participates in the service concurrently with the therapist for only a portion of the total time that the therapist delivers a service, the CQ/CO modifiers apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes spent by the therapist furnishing the service. If the PTA/OTA and the therapist each separately furnish portions of the same service, CMS proposes that the CQ/CO modifiers would apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes – the sum of the minutes spent by the therapist and therapy assistant – for that service. CMS proposes to apply the CQ/CO modifier policies to all services that would be billed with the respective GP or GO therapy modifier.** CMS believes this is appropriate because it is the same way that CMS currently identifies physical therapy or occupational therapy services for purposes of accruing incurred expenses for the thresholds and targeted review process.

**For purposes of deciding whether the 10 percent de minimis standard is exceeded, CMS offers two different ways to compute this. The first is to divide the PTA/OTA minutes by the total minutes for the service – which is (a) the therapist’s total time when PTA/OTA minutes are furnished concurrently with the therapist, or (b) the sum of the PTA/OTA and therapist minutes when the PTA/OTA’s services are furnished separately from the therapist; and then to multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA. CMS proposes to round to the nearest whole number so that when this percentage is 11 percent or greater, the 10 percent de minimis standard is exceeded and the CQ/CO modifier is applied. The other method is simply to divide the total time for the service (as described above) by 10 to identify the 10 percent de minimis standard, and then to add one minute to identify the number of minutes of service by the PTA/OTA that would be needed to exceed the 10 percent standard.** CMS provides examples of when the 10 percent standard is exceeded and how to round the minutes and percentages to the nearest whole number on [p. 257](#) and directs readers to [Table 19](#) for minutes needed to meet or exceed using the “simple” method with typical times for the total time of a therapy service.

CMS clarifies that the 10 percent de minimis standard, and therefore the CQ/CO modifiers, are not applicable to services in which the PTA/OTA did not participate. To the extent that the PTA/OTA and the physical therapist/occupational therapist (PT/OT) separately furnish different services that are described by procedure codes defined in 15-minute increments, billing examples and proposed policies are included below in Scenario Two.

CMS acknowledges that application of the 10 percent de minimis standard can work differently depending on the types of services and scenarios involving both the PTA/OTA and the PT/OT. Therapy services are typically furnished in multiple units of the same or different services on a given treatment day, which can include untimed services (not billable in multiple units) and timed services that are defined by codes described in 15-minute intervals. The majority of the untimed services that therapists bill for fall into three categories: (1)

evaluative procedures, (2) group therapy, and (3) supervised modalities. CMS discuss each of these in greater detail below. Only one (1) unit can be reported in the claim field labeled “units” for each procedure code representing an untimed service. The preponderance of therapy services, though, are billed using codes that are described in 15-minute increments. These services are typically furnished to a patient on a single day in multiple units of the same and/or different services. Under CMS’ current policy, the total number of units of one or more timed services that can be added to a claim depends on the total time for all the 15-minute timed codes that were delivered to a patient on a single date of service.

CMS addresses its proposals for applying the CQ/CO modifiers using the 10 percent de minimis standard, along with applicable billing scenarios, by category, as follows:

- Evaluations and re-evaluations: CPT codes 97161 through 97163 for physical therapy evaluations for low, moderate, and high complexity level, and CPT code 97164 for physical therapy re-evaluation; and CPT codes 97165 through 97167 for occupational therapy evaluations for low, moderate, and high complexity level, and CPT 97168 for occupational therapy re-evaluation. ([p. 259](#))
- Group Therapy: CPT code 97150 (requires constant attendance of therapist or assistant, or both). ([p. 260](#))
- Supervised Modalities: CPT codes 97010 through 97028, and HCPCS codes G0281, G0183, and G0329. ([p. 261](#))
- Services defined by 15-minute increments/units: These timed codes are included in the following current CPT code ranges: CPT codes 97032 through 97542 – including the subset of codes for modalities in the series CPT codes 97032 through 97036; and, codes for procedures in the series CPT codes 97110 – 97542; CPT codes 97750 – 97755 for tests and measurements; and CPT codes: 97760 – 97763 for orthotic management and training and prosthetic training. ([p. 262](#)) (Also see scenarios below for time-based services.)

In each of the above scenarios, CMS assumes that the PTA/OTA minutes are for therapeutic services.

CMS’ policy for reporting of service units with HCPCS codes for both untimed services and timed services (that is, only those therapy services defined in 15-minute increments) is explained in section 20.2 of Chapter 5 of the Medicare Claims Processing Manual (MCPM), and further detailed starting on [p. 262](#), including current documentation requirements. CMS notes that it is not proposing changes to existing documentation requirements in this proposed rule. However, ***beginning January 1, 2020, in order to provide support for application of the CQ/CO modifier(s) to the claim, CMS proposes to add a requirement that the treatment notes explain, via a short phrase or statement, the application or non-application of the CQ/CO modifier for each service furnished that day.*** CMS would include this documentation requirement in subsection in Chapter 15, MBPM, section 220.3.E on treatment notes. ***Because the CQ/CO modifiers also apply to untimed services, CMS’ proposal to revise CMS’ documentation requirement for the daily treatment note extends to those codes and services as well.*** For example, when PTAs/OTAs assist PTs/OTs to furnish services, the treatment note could state one of the following, as applicable: (a) “Code 97110: CQ/CO modifier applied – PTA/OTA wholly furnished”; or, (b) “Code 97150: CQ/CO modifier applied – PTA/OTA minutes = 15%”; or “Code 97530: CQ/CP modifier not applied – PTA/OTA minutes less than 10% standard.”

Given that the minutes of service furnished by or with the PTA/OTA and the total time in minutes for each service (timed and untimed) are used to decide whether the CQ/CO modifier is applied to a service, ***CMS seeks comment on whether it would be appropriate to require documentation of the minutes as part of the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor’s medical review process conducted for these services. CMS is also interested in hearing from therapists and therapy providers about current burden associated with the medical review process based on CMS’ current policy that does not require the times for individual services to be documented.*** Based on comments received, if CMS were to adopt a policy to include documentation of the PTA/OTA minutes and total time (TT) minutes, the CQ/CO

modifier explanation could read similar to the following: “Code 97162 (TT = 30 minutes): CQ/CO modifier not applied – PTA/OTA minutes did not exceed the 10 percent standard.”

CMS provides the following examples of clinical scenarios to illustrate how the 10 percent de minimis standard would be applied under its proposals for timed codes when therapists and their assistants work together concurrently or separately to treat the same patient on the same day. These examples reflect how the therapist or therapy provider would decide whether the CQ or CO therapy assistant modifier should be included when billing for one or more service units of the 15-minute timed codes. Each scenario includes multiple variations with separate billing examples.

- Scenario One: Where only one service, described by a single HCPCS code defined in 15-minute increments, is furnished in a treatment day ([p. 266](#))
- Scenario Two: When services that are represented by different procedure codes are furnished ([p. 267](#)).

### ***Proposed Regulatory Provisions ([p. 271](#))***

***CMS is proposing to amend regulation text for outpatient PT and OT services, as well as for PT and OT services furnished by comprehensive outpatient rehabilitation facilities (CORFs), to establish as a condition of payment that claims for services furnished in whole or in part by an OTA or PTA must include a prescribed modifier; and that services will not be considered furnished in part by an OTA or PTA unless they exceed 10 percent of the total minutes for that service , beginning for services furnished on and after January 1, 2020.***

***CMS is also proposing to amend regulation text for outpatient PT and OT services, as well as for PT and OT services furnished by a CORF, to specify that claims from physical and occupational therapists in private practice paid under section 1848 of the Act and from providers paid under section 1834(k) of the Act for physical therapy and occupational therapy services that contain a therapy assistant modifier, are paid at 85 percent of the otherwise applicable payment amount for the service for dates of service on and after January 1, 2022.***

As specified in the CY 2019 PFS final rule, CMS also notes that the CQ or CO modifier is to be applied alongside the corresponding GP or GO therapy modifier that is required on each claim line of service for physical therapy or occupational therapy services. Beginning for dates of service and after January 1, 2020, claims missing the corresponding GP or GO therapy modifier will be rejected/returned to the therapist or therapy provider so they can be corrected and resubmitted for processing. CMS also clarifies that it does not interpret the therapy assistant requirements detailed above to apply to outpatient physical therapy or occupational therapy services furnished by CAHs, or by other providers for which payment for outpatient therapy services is not made under section 1834(k) of the Act based on the PFS rates.

### ***Valuation of Specific Codes ([p. 274](#))***

#### ***Background: Process for Valuing New, Revised, and Potentially Misvalued Codes ([p. 274](#))***

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS, and CMS notes it remains a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. CMS will continue to engage with stakeholders, including the RUC, with regard to its approach for accurately valuing codes, and welcomes feedback from all interested parties.

#### ***Methodology for Establishing Work RVUs ([p. 276](#))***

CMS notes that many commenters and stakeholders have expressed concerns over the years with its ongoing adjustment of work RVUs based on changes in the best information it had regarding the time resources involved in furnishing individual services. CMS has been particularly concerned with the RUC’s and various specialty

societies' objections to its approach given the significance of the RUC recommendations to CMS' process for valuing services and since much of the information CMS uses to make the adjustments is derived from the RUC survey process. CMS recognizes that adjusting work RVUs for changes in time is not always a straightforward process, so it has applied various methodologies to identify several potential work values for individual codes.

CMS has observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. CMS explains that when recommended work RVUs do not appear to account for significant changes in time, the agency has started with the RUC-recommended value and then applied different approaches (eg, survey data, building block, crosswalks to key reference or similar codes, magnitude estimation, the relationship between old and new time values) to identify potential values that reconcile the recommended work RVUs with the recommended time values. According to CMS, the agency does not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs; rather it uses the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options. More importantly, CMS does not imply that the decrease in time reflected in surveys should equate to a one-to-one or linear decrease in newly valued work RVUs; rather, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increase, significant decreases in time should be reflected in decreases to work RVUs.

CMS notes that stakeholders, including the RUC, have objected to CMS' use of these methodologies, deeming the agency's actions as inappropriate. Stakeholders have also raised objections to the way in which CMS employs the aforementioned methodologies (eg, reference services and crosswalks), which is inconsistent with the RUC's use. While CMS does not feel that it must employ them in the identical fashion, in the interest of minimizing confusion, it will limit its use of the term "crosswalk" to those cases where it is making a comparison to a CPT code with the identical work RVU.

[Table 20](#) contains a list of codes and descriptors for which CMS proposes work RVUs; this includes all codes for which it received RUC recommendations by February 10, 2019.

#### ***Methodology for the Direct PE Inputs to Develop PE RVUs (p. 282)***

[Table 21](#) details CMS' proposed refinements of the RUC's direct PE recommendations at the code-specific level. CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is \$0.35 or less, the refinement has no impact on the PE RVUs. Approximately half of the refinements listed in [Table 21](#) result in changes under the \$0.35 threshold and are unlikely to result in a change to the RVUs.

Regarding new supply and equipment items, for CY 2020, CMS received invoices for several items, which are detailed in [Tables 22 and 23](#). Stakeholders are reminded that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services.

Codes where no PE refinements are proposed for CY 2020 can be found in [Table 24](#).

#### ***Proposed Valuation of Specific Codes for CY 2020 (p. 289)***

Below is a list of key codes where CMS proposes new and revised values for CY 2020.

- ◆ [Tissue Grafting Procedures \(CPT Codes 15X00, 15X01, 15X02, 15X03, and 15X04\)](#)
- ◆ [Drug Delivery Implant Procedures \(CPT Codes 11981, 11982, 11983, 206X0, 206X1, 206X2, 206X3, 206X4, and 206X5\)](#)
- ◆ [Bone Biopsy Trocar-Needle \(CPT Codes 20220 and 20225\)](#)
- ◆ [Trigger Point Dry Needling \(CPT Codes 205X1 and 205X2\)](#)

- ◆ [Closed Treatment Vertebral Fracture \(CPT Code 22310\)](#)
- ◆ [Tendon Sheath Procedures \(CPT Codes 26020, 26055, and 26160\)](#)
- ◆ [Closed Treatment Fracture – Hip \(CPT Code 27220\)](#)
- ◆ [Arthrodesis – Sacroiliac Joint \(CPT Code 27279\)](#)
- ◆ [Pericardiocentesis and Pericardial Drainage \(CPT Code 3X000, 3X001, 3X002, and 3X003\)](#)
- ◆ [Pericardiotomy \(CPT Codes 33020 and 33025\)](#)
- ◆ [Transcatheter Aortic Valve Replacement \(TAVR\) \(CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366\)](#)
- ◆ [Aortic Graft Procedures \(CPT Codes 338XX, 338X1, 33863, 33864, 338X2, and 33866\)](#)
- ◆ [Iliac Branched Endograft Placement \(CPT Codes 34X00 and 34X01\)](#)
- ◆ [Exploration of Artery \(CPT Codes 35701, 35X01, and 35X01\)](#)
- ◆ [Intravascular Ultrasound \(CPT Codes 37252 and 37253\)](#)
- ◆ [Stab Phlebectomy of Varicose Veins \(CPT Codes 37765 and 37766\)](#)
- ◆ [Biopsy of Mouth Lesion \(CPT Code 40808\)](#)
- ◆ [Transanal Hemorrhoidal Dearterialization \(CPT Codes 46945, 46946, and 46X48\)](#)
- ◆ [Preperitoneal Pelvic Packing \(CPT Codes 490X1 and 490X2\)](#)
- ◆ [Cystourethroscopy Insertion Transprostatic Implant \(CPT Codes 52441 and 52442\)](#)
- ◆ [Orchiopexy \(CPT Code 54640\)](#)
- ◆ [Radiofrequency Neurotomy Sacroiliac Joint \(CPT Codes 6XX00, 6XX01\)](#)
- ◆ [Lumbar Puncture \(CPT Codes 62270, 622X0, 62272, and 622X1\)](#)
- ◆ [Electronic Analysis of Implanted Pump \(CPT Codes 62367, 62368, 62369, and 62370\)](#)
- ◆ [Somatic Nerve Injection \(CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450\)](#)
- ◆ [Genicular Injection and RFA \(CPT Codes 64640, 64XX0, and 64XX1\)](#)
- ◆ [X-Ray Exam – Sinuses \(CPT Codes 70210 and 70220\)](#)
- ◆ [X-Ray Exam – Skull \(CPT Codes 70250 and 70260\)](#)
- ◆ [X-Ray Exam – Neck \(CPT Code 70360\)](#)
- ◆ [X-Ray Exam – Spine \(CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120\)](#)
- ◆ [CT-Orbit-Ear-Fossa \(CPT Codes 70480, 70481, and 70482\)](#)
- ◆ [CT Spine \(CPT Codes 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, and 72133\)](#)
- ◆ [X-Ray Exam – Pelvis \(CPT Codes 72170 and 72190\)](#)
- ◆ [X-Ray Exam – Sacrum \(CPT Codes 72200, 72202, and 72220\)](#)
- ◆ [X-Ray Exam – Clavicle-Shoulder \(CPT Codes 73000, 73010, 73020, 73030, and 73050\)](#)
- ◆ [CT Lower Extremity \(CPT Codes 73700, 73701, and 73702\)](#)
- ◆ [X-Ray Elbow-Forearm \(CPT Codes 73070, 73080, and 73090\)](#)
- ◆ [X-Ray Heel \(CPT Code 73650\)](#)
- ◆ [X-Ray Toe \(CPT Code 73660\)](#)
- ◆ [Upper Gastrointestinal Tract Imaging \(CPT Codes 74210, 74220, 74230, 74X00, 74240, 74246, and 74X01\)](#)
- ◆ [Lower Gastrointestinal Tract Imaging \(CPT Codes 74250, 74251, 74270, and 74280\)](#)
- ◆ [Urography \(CPT Code 74425\)](#)
- ◆ [Abdominal Aortography \(CPT Codes 75625 and 75630\)](#)
- ◆ [Angiography \(CPT Codes 75726 and 75774\)](#)
- ◆ [X-Ray Exam Specimen \(CPT Code 76098\)](#)
- ◆ [3D Rendering \(CPT Code 76376\)](#)
- ◆ [Ultrasound Exam – Chest \(CPT Code 76604\)](#)
- ◆ [X-Ray Exam – Bone \(CPT Codes 77073, 77074, 77075, 77076, and 77077\)](#)

- ◆ [SPECT-CT Procedures \(CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3\)](#)
- ◆ [Cytopathology, Cervical-Vaginal \(CPT Code 88141, HCPCS Codes G0124, G0141, and P3001\)](#)
- ◆ [Biofeedback Training \(CPT Codes 908XX and 909XX\)](#)
- ◆ [Septostomy \(CPT Codes 92992 and 92993\)](#)
- ◆ [Remote Interrogation Device Evaluation \(CPT Codes 93297, 93298, 93299, and HCPCS code GTTT1\)](#)
- ◆ [Duplex Scan Arterial Inflow-Venous Outflow \(CPT Codes 93X00 and 93X01\)](#)
- ◆ [Myocardial Strain Imaging \(CPT Code 933X0\)](#)
- ◆ [Lung Function Test \(CPT Code 94200\)](#)
- ◆ [Long-Term EEG Monitoring \(CPT Codes 95X01, 95X02, 95X03, 95X04, 95X05, 95X06, 95X07, 95X08, 95X09, 95X10, 95X11, 95X12, 95X13, 95X14, 95X15, 95X16, 95X17, 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23\)](#)
- ◆ [Open Wound Debridement \(CPT Codes 97597 and 97598\)](#)
- ◆ [Negative Pressure Wound Therapy \(CPT Codes 97607 and 97608\)](#)
- ◆ [Ultrasonic Wound Assessment \(CPT Code 97610\)](#)
- ◆ [Online Digital Evaluation Service \(e-Visit\) \(CPT Codes 98X00, 98X01, and 98X02\)](#)
- ◆ [Emergency Department Visits \(CPT Codes 99281, 99282, 99283, 99284, and 99285\)](#)
- ◆ [Online Digital Evaluation Service \(e-Visit\) \(CPT Codes 9X0X1, 9X0X2, and 9X0X3\)](#)
- ◆ [Radiation Therapy Codes \(HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017\)](#)

### Comment Solicitation on Opportunities for Bundled Payments under the PFS ([p. 489](#))

While CMS cites global surgery codes and payment policies such as the Multiple Procedure Payment Reduction (MPPR) policy, it states that most payments under the Medicare Physician Fee Schedule are made for individual services. CMS states that it is interested in “exploring new options for establishing PFS payment rates or adjustments for services that are furnished together” (i.e. “bundled payment”)([p. 489](#)). CMS cites several examples of bundled payment models that are being tested by the Center for Medicare and Medicaid Innovation (the Innovation Center) ([p. 490](#)). This includes models that establish a “per beneficiary payment” for multiple services as well as condition-specific episodes of care. ***CMS is seeking to implement these concepts within the statutory framework of the PFS ([p. 490](#)).*** Therefore, ***CMS seeks comment on “opportunities to expand the concept of bundling to recognize efficiencies among physicians’ services paid under the PFS and better align Medicare payment policies” to improve individual health care, improve the health care of communities, and lower costs ([p. 490](#)).***

### Payment for Evaluation and Management (E/M) Visits ([p. 491](#))

#### Background

CMS provides a review of the current evaluation and management (E/M) coding and payment structure, including the three components of history, exam, and medical decision making (MDM) beginning on [p. 491](#). CMS again noted that:

- All E/M visits make up approximately 40 percent of allowed charges for physician fee schedule services; while
- Office/outpatient E/M visits make up approximately 20 percent of allowed charges for physician fee schedule services.

CMS also repeated its past observations that E/M visits represent a greater share of total allowed services for those clinicians who do not routinely “furnish procedural interventions or diagnostic tests” including:

- Primary care practitioners; and
- Specialists such as neurologists, endocrinologists, and rheumatologists.

And again states that some specialties tend to furnish lower level E/M visits more often than higher level E/M visits, specifically citing podiatry (p. 492), as well as that CMS then states that some specialties bill more E/M visits on the same day as they bill minor procedures, citing Dermatology and Otolaryngology (p. 493).

**Citations.** CMS cites the currently used [1995 E/M Documentation Guidelines](#) and the [1997 E/M Documentation Guidelines](#).<sup>13</sup> While CMS references the AMA's CPT codebook for E/M visits and some similarities to the E/M documentation guidelines, CMS points out that the AMA's CPT codebook (p. 493):

- Does not include examples of clinical work that comprise different levels of medical decision-making
- Does contain references to preventive care.

**Time.** CMS states, as it did last year, that (according to both Medicare billing and CPT coding rules), “when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level)” and provide citations from the various controlling documents (p. 494).

**Changes to Coding, Payment, and Documentation for CY 2021 in CY 2019 Final Rule (p.496).** CMS reviewed its CY 2021 policies that it had finalized during CY 2019 rulemaking:

- Collapsed payment rate for office and outpatient E/M visit levels 2-4 (p. 496); corollary flexibility to only meet documentation requirements for a level 2 to bill levels 2-4 (p. 497). ***CMS proposes to rescind these policies.***
- Retention of a separate payment rate for office and outpatient E/M visit level 5 (p. 496)
- Flexibility to report office and outpatient E/M levels 2-5 using either MDM or Time (or the current framework under the 1995 or 1997 guidelines (p. 497)
- Parameters for billing using Time Only (i.e. document medical necessity and that the billing practitioner personally spent the required amount of face-to-face time with the beneficiary) (p. 497)
- Addition of G-Codes for “additional resources” inherent to primary care visits and visits for “non-procedural specialized medical care” (only reportable with office and outpatient E/M visit levels 2-4 (p. 497). ***CMS proposes changes to the add-on codes (see below) (p. 511).***
- Addition of new extended visit G code (GPR01) (only reportable with office and outpatient E/M visit levels 2-4 (p. 497). ***CMS proposes to rescind this policy (p. 505).***

**Subsequent Stakeholder Input (p. 498).** CMS reviewed the additional input it received and public outreach conducted, including:

- CMS Listening Sessions: Conducted in January and February 2019
- AMA Joint CPT/RUC Workgroup & AMA RUC: the completed work:
  - Adopted revisions to the office/outpatient E/M code descriptors
  - Substantially revised both the CPT prefatory language and the CPT interpretive guidelines
  - Accompanying set of interpretive guidelines directed at determining levels of MDM for office and outpatient E/M visits
  - Recommendations for reevaluation of office and outpatient E/M codes (p. 501).
- Additional Stakeholders:
  - Objections to single payment rate for Levels 2-4
  - Purpose and use of complexity add-on codes remain ambiguous
  - Complexity add-on codes are contrary to current law prohibiting specialty-specific payment
  - Compounding of negative impacts by commercial insurers adopting Medicare policies

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<sup>13</sup> CMS notes substantial similarities between the 1995 and 1997 E/M documentation guidelines, but includes a comparison of the differences in how the 1995 and 1997 guidelines distinguish between level 2 and level 3 visits in [Table 25](#).



- Some suggested level selection should only be based on time
- Critique that CPT MDM revisions will result in increase in selection of levels 4 and 5
- Suggestion to add a Level 6
- Concern that current codes “fail to capture the full range of services provided by certain specialties, particularly primary care and other specialties that rely heavily on office/outpatient E/M services”
- Concern that current structure creates “payment disparities that have contributed to workforce shortages and beneficiary access challenges across a range of specialties”

### Proposed Policies for CY 2021 (p. 501)

**Documentation and Code Selection.** Beginning in CY 2021 (see p. 516 for implementation timeline), **CMS proposes to adopt the new coding, prefatory language, and interpretive guidance framework provided by AMA CPT (p. 501).** CMS states that it believes that these policies will result in greater administrative burden reduction than the policies CMS had previously finalized for CY 2021. These new policies include:

- Deletion of CPT 99201 (*Level 1 office/outpatient visit, new patient*) (p. 502)
- History and exam are no longer determinant of code level selection (p. 502)
- Number of body systems/areas reviewed and examined under history and exam would no longer apply (p. 502)
- Levels 2-5 would be selected by **level of MDM** (as redefined under CPT guidance) or by **Time Only** (using the new time ranges assigned to the CPT codes) (p. 502)
- Adoption of the single add-on code for prolonged office/outpatient E/M visits (CPT 99XXX) to be used only when Time is used to select E/M level and time for Level 5 is exceeded by 15 minutes or more on the date of service (p. 502). (See also, [Table 26](#) for example of reporting prolonged E/M visit time).

*99XXX (Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services))*

- **CMS proposes that CPT 99358 and 99359 (Prolonged E/M without Direct Patient Contact) would be no longer reportable with office/outpatient E/M visits (p. 503).**<sup>14</sup>

**CPT 99201 – 99215 Code Values (p. 505)**<sup>15</sup>. CMS notes that while it has already received the RUC-recommended values, it is still not proposing to assign the new values to the codes until CY 2021 (p. 506). **CMS proposes to reestablish separate payment levels for levels 2-4 (p. 511).** In addition, **CMS proposes to accept the RUC-recommended work values for all new and established patient office/outpatient E/M codes (p. 506).**

Regarding the RUC recommended times, **CMS proposes to accept the RUC-recommended times for each code level.** However, **CMS seeks input on what it perceives as a discrepancy created by the structure of the RUC survey for these codes which results in sometimes “component times as surveyed” and sometimes “total time as surveyed” (p. 508).** The survey results regarding both component times and total times can be found in [Table 27A](#).

<sup>14</sup> CMS notes that it believes the new prefatory language is ambiguous about whether CPT 99358 and 99359 can be reported instead of or in addition to new CPT 99XXX and whether the prolonged time would have to be spent on the visit date, within 3 days prior or 7 days after the visit date, or outside of this new “10 day window” for the base code (p. 504).

<sup>15</sup> In the CMS Fact Sheet on the CY 2020 proposed rule released on July 29, 2019, CMS states “We are not proposing to make AMA RUC-recommended changes to global surgery codes as we are in the process of gathering information on global surgery. We have had three reports prepared by RAND, which we release with the proposed rule. We encourage stakeholders to comment on the reports.” ([Link](#))

New Patient Office/Outpatient E/M Codes					
CPT Code	Proposed Descriptor	Current wRVU	Proposed CY 2021 wRVU	Current Total Time	Proposed Total Time
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter	0.93	<b>0.93</b>	22	<b>22</b>
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter	1.42	<b>1.6</b>	29	<b>40</b>
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter	2.43	<b>2.6</b>	45	<b>60</b>
99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60- 74 minutes of total time is spent on the date of the encounter. (For services 75 minutes or longer, see Prolonged Services 99XXX)	3.17	<b>3.5</b>	67	<b>85</b>

Established Patient Office/Outpatient E/M Codes					
CPT Code	Proposed Descriptor	Current wRVU	Proposed CY 2021 wRVU	Current Total Time	Proposed Total Time
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal)	0.18	<b>0.18</b>	7	<b>7</b>
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter	0.48	<b>0.7</b>	16	<b>18</b>
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter)	0.97	<b>1.3</b>	23	<b>30</b>
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter	1.5	<b>1.92</b>	40	<b>49</b>
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter. (For services 55 minutes or longer, see Prolonged Services 99XXX)	2.11	<b>2.8</b>	55	<b>70</b>

[Table 27B](#) also compares the current and proposed values and times with the values and time for what had been finalized for CY 2021 previously.

**Practice Expense.** Regarding PE inputs, **CMS proposes to remove ED021 (computer, desktop, with monitor) form all of the office/outpatient E/M codes because it does “not believe that this item would be allocated to the use of an individual patient for an individual service” and should rather be thought of as an indirect cost (p. 508; p. 511).**

## Add-on Codes ([p. 511](#)).

- **Complexity Add-on Code.** Even though CMS agrees that the office/outpatient E/M visit codes are an improvement, CMS continues to be concerned that the codes set “still does not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits” ([p. 511](#)). In particular, CMS believes there are three types of visits that are not adequately reflected:
  - Separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure
  - Primary care office/outpatient E/M visits for continuous patient care
  - Certain types of specialist office/outpatient E/M visits

CMS reviewed the add-on codes it had finalized for CY 2021 (in CY 2019 rulemaking):

- **GCG0X** (*Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established)*)
- **GPC1X** (*Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/ outpatient evaluation and management visit, new or established)*)

While CMS believes additional codes are needed, it recognizes that the previously finalized codes created confusion that could lead to issues with medical record documentation and billing ([p. 513](#)). CMS stated specifically that “the add-on coding is not intended to reflect any difference in payment based on the billing practitioner’s specialty, but rather the recognition of different per-visit resource costs based on the kinds of care the practitioner provides regardless of their specialty” ([p. 513](#)).

**CMS proposes to simplify the complexity add-on coding by consolidating the two add-on codes into a single add on code with a revised descriptor ([p. 513](#)):**

*GPC1X (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition. (Add on code, list separately in addition to office/outpatient evaluation and management visit, new or established)).*

- **CMS seeks input on whether it should return to a structure as finalized last year where it implements more than one add on code ([p. 514](#)).**
  - **CMS proposes a wRVU of 0.33 and physician time of 11 minutes ([p. 514](#))** (based on CPT 90785 (*Interactive complexity (List separately in addition to the code for primary procedure)*))
  - **CMS proposes GPC1X could be billed with every level of office and outpatient E/M visit ([p. 514](#))**
  - CMS notes that if CPT creates a code to duplicate this add on code that it would consider adoption in future rulemaking ([p. 514](#)).
- **Prolonged Office/Outpatient E/M ([p. 515](#)).** **CMS proposes to delete the prolonged services add on code finalized during CY 2019 rulemaking and adopt the CPT code and values as submitted by the AMA CPT and RUC ([p. 515](#)).** The following code will have a wRVU of 0.61 and 15 minutes of physician time:

99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*)

**CMS Impact Estimates.** CMS provides estimates of potential impacts associated with finalizing these policies for office/outpatient E/Ms in [Table 111](#). Generally, CMS notes that:

- Those specialties that bill higher level established patient visits, such as endocrinology or family practice, see the greatest increases as those codes were revalued higher relative to the rest of the office/outpatient E/M code set
- Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits.
- Other specialty level impacts are primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set and the relative increases to the particular office/outpatient E/M codes predominantly billed by those specialties ([p. 1188](#)).

Note, however, that CMS also states, “we do not believe we can estimate with any degree of certainty what the impact of potential changes might be” ([p. 1188](#)).

### **Global Surgical Packages ([p. 516](#))**

CMS states that in the AMA RUC recommendations on the reconfigured office/outpatient E/M codes that the AMA RUC also recommended “adjusting the office/outpatient E/M visits for codes with a global period to reflect the changes made to the values for office/outpatient E/M visits” ([p. 516](#)). CMS acknowledges that 10- and 90-day globals have post-operative visits included in their valuation but states that “these visits are not directly included in the valuation. Rather, work RVUs for procedures with a global period are generally valued using magnitude estimation” ([p. 517](#)).

Beginning on [p. 517](#), CMS reviews the challenges it believes it has accurately accounting for the number of visits in 10- and 90-day globals as well as its previous proposals aimed at improving valuation. This review included revisiting CMS’ implementation of a process for collecting data on the number and level of post-op visits. In CY 2017, CMS finalized the use of CPT 99024 (*Postoperative follow-up visit, normally excluded in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure*) for reporting post-operative services for codes that are reported annually by more than 100 practitioners and are reported more than 10,000 times or have allowed charges in excess of \$10 million annually. While CMS encouraged broad utilization of the code, the use of 99024 was only required by practices in groups of 10 or more practitioners in the following states:

- Florida
- Kentucky
- Louisiana
- Nevada
- New Jersey
- North Dakota
- Ohio
- Oregon
- Rhode Island

CMS also reviewed the analysis conducted by RAND for CMS<sup>16</sup> ([p. 520](#)).

- 10-day global periods with any post-op visits reported: 4%
- 90-day global periods with at least one associated post-op visit: 71%
- Percentage of total post-op visits reported of “expected” visits for 90 day global periods: 39%

In addition, RAND conducted surveys for CMS on 3 “high volume procedures”: cataract surgery, hip arthroplasty, and complex wound repair. CMS states that “findings on physician time and work from the survey were broadly similar to what we expected based on the Time File for cataract surgery and hip replacement and somewhat different for complex wound repair” ([p. 519](#)). CMS also discussed a third report by RAND for recommendations on how to revalue procedures based on collected data.

***CMS encouraged stakeholders to review the reports and stated that it will “continue to study and consider alternative ways to address the values for these services” ([p. 521](#)).***

### **Revaluing Office/Outpatient Visits within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services ([p. 521](#))**

CMS cites the values of office/outpatient E/M visits are linked to additional services, including:

- CPT 99495, 99496: cognitive impairment assessment
- CPT 99482: care planning
- CPT 90951-90961: certain ESRD monthly services
- G0438: Initial Preventive Exam
- G0439: Annual Wellness Visit

***CMS seeks input on adjusting the RVUs for these services given the changes proposed for the office/outpatient E/M visits and the fact that these codes are crosswalked to the office/outpatient E/M visit codes ([p. 521](#)).*** In addition, ***CMS seeks input on whether it should make “systematic adjustments to other related PFS services to maintain relativity between these services and office/outpatient E/M visits” ([p. 522](#)).***

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<sup>16</sup> Links to referenced RAND reports: (1) [RAND Claims Based Report](#); (2) [RAND Survey Report](#); and (3) [RAND Report on Revaluation of Global Periods](#).

## Other Provisions of the Proposed Regulations ([p. 525](#))

### Changes to the Ambulance Physician Certification Statement Requirement ([p. 525](#))

CMS proposes changes to reduce administrative burden aimed at providing clarity to ambulance providers and suppliers regarding “the physician or non-physician certification statement and add staff who may sign certification statements when the ambulance provider or supplier is unable to obtain a signed statement from the attending physician” ([p. 525](#)).

### Exceptions to Certification Statement Requirement ([p. 525](#))

Current regulation (§410.40(d)) sets standards for the medical necessity required for:

- Non-emergency, scheduled, repetitive ambulance services; and
- Non-emergency ambulance services unscheduled or scheduled on a repetitive basis.

CMS previously finalized regulations that directed:

- “a physician certification statement (PCS) must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that the transport is medically necessary” ([p. 525](#)); and subsequently added
- “a certification statement . . . could be obtained from authorized staff should the attending physician be unavailable” ([p. 526](#))

CMS has received feedback that the requirements could be overly restrictive or unnecessary given other documentation requirements. In particular, stakeholders identified interfacility transports (or “hospital to hospital transports”) and specialty care transports ([p. 526](#)).

In light of these concerns and CMS’ effort to reduce regulatory burden, **CMS proposes to reorganize the regulatory provisions and alter the language requiring that an order certifying medical necessity be obtained** ([p. 527](#)). CMS agrees with stakeholders that there are “ample opportunities for ambulance providers and suppliers to convey the information required in the certification statement” and provides several examples ([p. 527](#)). However, because of the statutory requirement, CMS clarifies that **ambulance providers and suppliers must still focus on clearly documenting the threshold determination that “other means of transportation are contraindicated and that the transport is medically necessary”** ([p. 527](#)). These changes to the non-physician certification statement would incorporate the existing requirements that apply when an ambulance supplier is unable to obtain the physician certification statement from the physician and obtains the non-physician certification statement; the requirements are listed on [p. 528](#). **CMS also proposes a provision that ambulance providers or suppliers must indicate on the claims form, when applicable, that a physician certification statement or non-physician certification statement is on file** ([p. 528](#)).

### Addition to Staff Authorized to Sign Non-Physician Certification Statements ([p. 529](#))

As indicated above, “a certification statement . . . could be obtained from authorized staff should the attending physician be unavailable.” When CMS added that provision it identified “staff”<sup>17</sup> as:

- Physician Assistants (PAs);
- Nurse Practitioners (NPs);
- Clinical Nurse Specialists (CNSs); and
- Discharge planners ([p. 530](#)).

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<sup>17</sup> The staff must be employed by the beneficiary’s attending physician or by the hospital or the facility where the beneficiary is being treated or from which the beneficiary is being transported; and the staff must have “personal knowledge” of the beneficiary’s condition at the time the ambulance transport is ordered or the service is furnished ([p. 530](#)).

***CMS proposes to add licensed practical nurses (LPNs), social workers, and case managers to the list of staff who may sign a certification statement when the ambulance provider is unable to obtain a signed PCS from an attending physician (p. 530). In addition, CMS requests comment on whether other staff should be included and identify licensure and position and the reason it would be appropriate for such staff to sign a certification statement (p. 531).***

## **Proposal to Establish a Medicare Ground Ambulance Services Data Collection System (p. 532)**

### **Background**

According to statute ([Social Security Act §1861\(s\)\(7\)](#)), Medicare covers ambulance services under Medicare Part B “where the use of other methods of transportation is contraindicated by the individual’s condition, but only to the extent provided in regulations.” Payments are made under the Medicare Ambulance Fee Schedule.

Payments are calculated with ([p. 532](#)):

- A base rate for the level of service;
- a separate payment for mileage to the nearest appropriate facility;
- a geographic adjustment factor; and
- “other applicable adjustment factors.”
- 2 permanent add-on payments:
  - A 50% increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles
  - A 50% increase to both the base and mileage rate for rural air ambulance transports.
- 3 temporary add-on payments:
  - A 3% increase to the base and mileage rate for ground ambulance transports that originate in rural areas
  - A 2% increase to the base and mileage rate for ground ambulance transports that originate in urban areas
  - A 22.6% increase in the base rate for ground ambulance transports that originate in “super rural” areas

Recent legislation requires the Secretary “to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services,” specified by December 31, 2019 ([p. 533](#)). CMS outlines the statutory requirements for the data collection beginning on [p. 533](#), including that the Secretary apply a 10 percent payment reduction beginning January 1, 2022 for ground ambulance provider or suppliers that do sufficiently submit data.<sup>18</sup>

**Research on Development of Ground Ambulance Data Collection System (p. 537).** CMS hired a contractor to help create recommendations related to a data collection system for ground ambulance, including development of a sampling plan that meets the statutory requirements. The contractor conducted:

- An environmental scan of existing peer-reviewed literature
- Interviews with ambulance providers and suppliers, billing companies, and other stakeholders
- Medicare claims and enrollment data analyses
- Analysis of The Moran Company Statistical and Financial Data Survey commissioned by the American Ambulance Association in 2012
- Analysis of the Ground Emergency Medical Transportation Cost Report form and instructions from California’s Medicaid program

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<sup>18</sup> CMS requests comments on the [air](#) ambulance industry and how it can work within statutory authority to ensure appropriate payment for air ambulance organizations ([p. 536](#)).

- Analysis of the Emergency Medical Services Cost Analysis Project EMSCAP framework
- Analysis of a 2012 GAO ambulance survey
- Analysis of the Rural Ambulance Service Budget Model

The contractor’s cumulative findings can be found online in a report, [Medicare Ground Ambulance Data Collection System- Sampling and Data Collection Instrument Considerations and Recommendations](#) (p. 540).

### Proposals for the Data Collection Instrument (p. 540)

- CMS proposals for the format of the data collection instrument can be found beginning on [p. 540](#). **CMS proposes to collect ground ambulance organization with a web-based survey that CMS developed specifically for this purpose** (p. 542).
- CMS proposals related to the scope of the cost, revenue, and utilization data collected begin on [p. 543](#). Generally, **CMS proposes to require ground ambulance organizations to report on total costs, total revenues, and total utilization** (p. 546).
- CMS proposals related to the data collection elements begin on [p. 548](#). The main elements can be found in [Table 29](#).
- CMS proposals related to sampling begin on [p. 578](#). CMS notes that the statute prohibits sampling the same ambulance supplier or provider in 2 consecutive years (p. 580). **CMS proposes that percent of ground ambulances be sampled from the all strata identified as part of the data collection effort** (p. 582). The variables for stratification are discussed beginning on [p. 586](#).
- CMS proposals related to collecting and reporting information under the Data Collection System begin on [p. 592](#). **CMS proposes that the first data collection period will be January 1, 2020 – December 31, 2021** (p. 593).
- CMS proposals related to the payment reduction for failure to report can be found beginning on [p. 595](#).
- CMS proposals related to the proposed hardship exemption can be found beginning on [p. 597](#).
- CMS proposals related to the public posting of data collection can be found on [p. 601](#).

### Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR) (p. 602)

CMS provided an historical overview of cardiac rehab post-acute myocardial infarction (p. 602). Legislation enacted in 2008 (the Medicare Improvements for Patients and Providers Act of 2008) added Medicare Part B coverage for cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) (p. 603). Current regulations implementing those statutory provisions provide coverage for CR and ICR for beneficiaries with one or more of the following conditions (p. 603):

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- Heart or heart-lung transplant

Previous legislation stated for **CR** that other cardiac conditions can be added with a National Coverage Determination (NCD) (p. 603). Through this process, CMS established coverage of CR to beneficiaries with stable<sup>19</sup>, chronic heart failure (i.e. patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks).

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<sup>19</sup> CMS defined “stable” as “patients who have not had recent (less than 6 weeks) or planned (less than 6 months) major cardiovascular hospitalizations or procedures” (p. 603).



Congress, via Section 51004 of the Bipartisan Budget Act of 2018, directed CMS to add covered conditions for ICR, including stable, chronic heart failure (i.e. patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks).

Therefore, *CMS proposes to expand ICR coverage to include* (p. 605):

- ***Stable, chronic heart failure (i.e. patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks)***
- ***“other cardiac conditions as specified under an NCD.”***

CMS noted that the statute limits the conditions to which coverage can be extended must be limited to cardiac conditions (not conditions such as cancer, metabolic syndrome, diabetes, or peripheral artery disease) (p. 605).

## **Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (p. 606)**

### **eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2020**

To keep eCQM specifications current and minimize complexity, *CMS proposes to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period.* As such, the eCQMs available for Medicaid EPs in 2020 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2020 performance period. CMS anticipates that this proposal would reduce burden for Medicaid EPs, and that the system changes required for EPs to implement this change would not be significant. Importantly, CMS expects that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications.

***For 2020, CMS proposes to continue to require that Medicaid EPs report on any 6 eCQMs that are relevant to their scope of practice, including at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure).*** If no outcome or high priority measures are relevant to a Medicaid EP’s scope of practice, the clinician may report on any 6 eCQMs that are relevant. In this context, high priority measures would either be those identified as high-priority in the quality performance category of MIPS, those e-specified measures from the previous year’s core set of quality measures (Child and Adult Core Sets), and measures identified by the state that align with their state health goals and programs. ***CMS seeks comment on whether these three methods should be altered or removed, or if others should be considered for 2021.***

***CMS proposes that the 2020 eCQM reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year be a minimum of any continuous 274-day period within CY 2020.*** States would be required to allow sufficient time for EPs to attest for program year 2020 beyond January 1, 2021 so that EPs may, should they choose to do so, select EHR and eCQM reporting periods that take place at any time within the 2020 calendar year through December 31, 2020. ***CMS seeks comment on whether an alternative might be preferable to its proposal (eg, not providing flexibility in the 274-day reporting period or proposing a date earlier than December 31 to end the reporting period).***

For Medicaid EPs demonstrating meaningful use for the first time, the reporting period would remain any continuous 90-day period within the calendar year, as in previous years.

## Objective 1: Protect Patient Health Information in 2021

As a result of feedback and other factors, **CMS proposes to allow Medicaid EPs to conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state.** For example, a Medicaid EP who has not completed a security risk analysis for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required analysis by December 31, 2021. States could require Medicaid EPs to submit evidence that the security risk analysis has been completed as promised, even after the incentive payment has been issued, and could require EPs to attest that if a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. If finalized, CMS would work with states to develop post-payment verification and audit processes.

## Medicare Shared Savings Program ([p. 617](#))

This section provides background on the Medicare Shared Savings Program (MSSP) and its evolution over time, as well as information on how CMS has used the annual CY MPFS rules to address quality reporting and certain other issues for the MSSP.

In this section, **CMS discusses aligning the MSSP quality measure set with proposed changes to the Web Interface measure set under MIPS per previously-finalized policy; proposes a change to the claims-based measures; and solicits comment on aligning the MSSP quality score with the MIPS quality performance category score. CMS also proposes a technical change to correct a cross-reference within a provision of the MSSP's regulations on the skilled nursing facility (SNF) 3-day rule waiver, to conform with previous changes adopted in the December 2018 final rule, as detailed on [p. 641](#).**

## Proposed changes to the CMS Web Interface and Claims-based Measures ([p. 620](#))

In the 2017 PFS final rule, CMS stated that CMS does not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately. Therefore, to avoid confusion and duplicative rulemaking, CMS adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the MSSP. In accordance with the policy adopted in the CY 2017 PFS final rule, CMS is not making any specific proposals related to changes in CMS Web Interface measures reported under the MSSP. **Rather, CMS refers readers to Appendix 1, [Table C](#) (Existing Quality Measures Proposed for Removal Beginning with the 2022 MIPS Payment Year) and [Table Group A](#) (New Quality Measures Proposed for Addition Beginning with the 2022 MIPS Payment Year) of this proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures for performance year 2020 (2022 MIPS Payment Year).**

Based on the changes being proposed in Appendix 1, [Table C](#) of this proposed rule, ACOs would no longer be responsible for reporting the following measure for purposes of the MSSP starting with reporting for performance year 2020:

- **ACO – 14 Preventive Care and Screening Influenza Immunization: In the event CMS does not finalize the removal of this measure, CMS would maintain the measure with the “substantive” change described in Appendix 1, [Table C](#) (Previously Finalized Quality Measures Proposed for Removal in the 2022 Payment Year and Future Years) of this proposed rule. CMS has reviewed the proposed “substantive” change and CMS does not believe that this change to the measure would require that CMS revert the measure to pay-for-reporting for the 2020 performance year as CMS could create a historical benchmark.**

Additionally, CMS is proposing to add the following measure to the CMS Web Interface for purposes of the QPP:

- **ACO-47 Adult Immunization Status: Based on the policies being proposed for purposes of MIPS in Appendix 1, [Table Group A](#) of this proposed rule, MSSP ACOs would be responsible for reporting the**

Adult Immunization Status measure (ACO-47) starting with quality reporting for performance year 2020. **Consistent with CMS' existing policy regarding the scoring of newly introduced quality measures, this measure would be pay-for-reporting for all ACOs for 2 years (performance years 2020 and performance year 2021). The measure would then phase into pay-for-performance beginning in performance year 2022.**

CMS also discusses changes to the following measures, as detailed below:

- **ACO-17 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** As discussed in [Table DD](#) (Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year), CMS notes that it has determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for this measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule and is unduly burdensome on clinicians. Moreover, due to the current guidance, CMS is unable to rely on historical data to benchmark the measure. **Therefore, for the 2018 performance year CMS is designating the measure pay-for-reporting.** Additionally, CMS is proposing to update the CMS Web Interface measure numerator guidance for purposes of the Quality Payment Program. To the extent that this proposed change constitutes a change to the MSSP measure set after the start of the 2019 performance period, CMS believes that it would be contrary to the public interest not to modify the measure as proposed in [Table DD](#). **If this modification is finalized as proposed, consistent with CMS' discussion in the CY 2018 PFS final rule, CMS expects CMS would be able to use historical data reported on the measure to establish an appropriate 2019 benchmark that aligns with the updated specifications and the measure would be pay-for-performance for performance year 2019 and subsequent year.**
- **ACO-43 Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional risk adjustment):** CMS notes that AHRQ made an update to the measure that will require a change to the measure specifications for performance year 2020. Currently, ACO-43 assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, and urinary tract infection. The updated measure will only include two conditions, bacterial pneumonia and urinary tract infection. This measure is a composite measure and the rate of hospital discharges is approximately equal to the sum of the rates of hospital discharges for each of its components. Therefore, the removal of dehydration will likely decrease the composite rate by approximately the rate of dehydration discharges. **Based on this substantive change, CMS proposes to redesignate ACO-43 as pay-for-reporting for 2020 and 2021.** However, CMS also considered creating a benchmark using historical data for bacterial pneumonia and urinary tract infection and keeping the measure pay-for-performance. As this is a claims-based measure, CMS has access to historical data for both bacterial pneumonia and urinary tract infection so CMS would be able to create a historical benchmark for the revised measure. **CMS seeks comment on this proposal and the alternative approach considered.**

[Table 32](#) shows the MSSP quality measure set for performance year 2020 and subsequent performance years that would result if the QPP proposals are finalized, including the phase-in schedule for the proposed Adult Immunization Status measure (ACO-47). If proposals are finalized, the net result would be a set of 23 measures on which ACOs' quality performance would be assessed for performance year 2020 and subsequent performance years. The 4 domains would include the following numbers of quality measures ([See Table 33](#)):

- Patient/Caregiver Experience of Care – 10 measures.
- Care Coordination/Patient Safety – 4 measures.
- Preventive Health – 6 measures.
- At Risk Populations – 3 measures.

[Table 33](#) provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes.

### **Seeking comment on aligning the MSSP quality score with the MIPS quality score (p. 628)**

CMS begins by discussing the current approach to assessing ACOs for quality performance starting on [p. 628](#). CMS then discusses how MSSP ACOs are assessed under the MIPS APM Scoring Standard across the four MIPS performance categories, starting on [p. 630](#). CMS also discusses potential eligibility for the Advanced APM track of the QPP on [p. 631](#).

Currently, under the MSSP, ACOs in performance years other than the first performance year of their first agreement period are allocated up to two points for quality measures that are pay-for-performance, according to where their performance falls, relative to benchmark deciles. Incomplete reporting of any CMS Web Interface measure will result in zero points for all CMS Web Interface measures, and the ACO will fail to meet the quality performance standard for the performance year. Similarly, if a CAHPS for ACOs Survey is not administered and/or no data is transmitted to CMS, zero points will be earned for all Patient/Caregiver Experience measures, and the ACO will fail to meet the quality standard for the performance year. The quality measure set for the MSSP also includes certain claims-based measures that are not part of the MIPS quality performance category, and CMS currently calculate performance rates on these claims-based measures for purposes of determining an ACO's overall quality score under the MSSP.

In contrast, when a group submits measures for the MIPS quality performance category via the CMS Web Interface, each measure is assessed against its benchmark to determine how many points the measure earns. For the 2019 MIPS performance period, a group can receive between 3 and 10 points for each MIPS measure (not including bonus points) that meets the data completeness and case minimum requirements by comparing measure performance to established benchmarks. If a group fails to meet the data completeness requirement on one of the CMS Web Interface measures, it receives zero points for that measure; however, all other CMS Web Interface measures that meet the data completeness requirement are assessed against the measure benchmarks, and the points earned across all measures are included in the quality performance category score. Currently, the only administrative claims-based measure used in MIPS is the All-Cause Readmission measure, which is only calculated for groups with 16 or more eligible clinicians. These differences between the MSSP quality measure set and the MIPS quality measure set highlight the different quality measurement approaches for which MSSP ACOs must simultaneously evaluate, prioritize, and target resources that may be better directed toward patient care if the quality measurement approaches under the MSSP and MIPS were more closely aligned.

CMS believes that using a single methodology to measure quality performance under both the MSSP and the MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients, and reduce burden as ACOs would be able to track to a smaller measure set under a unified scoring methodology. **Accordingly, CMS is soliciting comment on how to potentially align the MSSP quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology.**

**First, CMS is requesting comments on replacing the MSSP quality score with the MIPS quality performance category score, for ACOs in MSSP tracks (or payment models within a track) that do not meet the definition of an Advanced APM (currently, Track 1 and BASIC Track Levels A, B, C and D).** Allowing for a single quality performance score for both programs would eliminate the need for ACOs to focus their resources for quality improvement on maximizing performance under two separate quality reporting requirements with distinct scoring methodologies. Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. For MSSP

quality scoring purposes, CMS could utilize the MIPS quality performance category score, converted to a percentage of points earned out of the total points available, as the ACO's quality score for purposes of financial reconciliation under the MSSP. CMS notes that for performance year 2017 (the only year from which CMS has complete data available), the weighted mean MIPS quality performance category score for ACOs in MSSP tracks (or payment models within a track) that do not meet the definition of an Advanced APM) was 45.01 and the weighted median MIPS quality performance score for these ACOs was 46.8, out of a possible 50 points assigned for the quality performance category.

ACOs in tracks (or payment models within a track) that meet the definition of an Advanced APM whose eligible clinicians are QPs for the year and thus are excluded from the MIPS reporting requirements, do not receive a quality performance category score under MIPS. Instead the quality data the ACO reports to the CMS Web Interface is used along with the ACO's CAHPS data and the administrative claims-based measures calculated by us, solely for the purpose of scoring the quality performance of the ACO under the MSSP quality scoring methodology. As an alternative, given that CMS currently collect the necessary data from these ACOs, CMS could also calculate a quality score for these ACOs under the MIPS scoring methodology, and use this score to assess the quality performance of the ACO for purposes of the MSSP. Using this score would also inform eligible clinicians participating in these ACOs of their MIPS quality score in the event that they lose QP status and are scored under the MIPS APM scoring standard.

Utilizing a MIPS quality performance category score to assess the quality performance for purposes of the MSSP ACOs in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the ACO participant TINs' eligibility to receive Advanced APM incentive payments. Rather, under this approach CMS would utilize the same scoring methodology to determine the quality performance, for MSSP ACOs that are participating in Advanced APMs as would be used to assess the quality performance of ACOs in MSSP tracks (or payment models within a track) that do not meet the definition of an Advanced APM, creating further alignment of performance results and further synergies between the MSSP and MIPS. **CMS welcomes comment on the approach of using the MIPS quality performance category score to assess quality performance for purposes of the MSSP quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs. CMS also welcomes comment on potential alternative approaches for scoring MSSP quality performance in a way that more closely aligns with MIPS.**

In addition, **CMS is also soliciting comment on simplifying MIPS by implementing a core measure set using administrative claims-based measures that can be broadly applied to communities or populations and developing measure set tracks around specialty areas or public health conditions to standardize and provide more cohesive reporting and participation.** CMS provides more information on these approaches [later in the rule](#).

Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. In the discussion of MIPS proposals, CMS is proposing to add the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category. If this measure were to be added to MIPS quality performance category, implementation of the measure would be delayed until the 2021 performance period for MIPS. If the MCC measure were to be included in the MIPS quality performance category, CMS would also consider including the MIPS claims-based measures (MCC and MIPS All-Cause Readmission measure) in the MIPS APM scoring standard for ACOs in tracks (or payment models within a track) that are not Advanced APMs and in the MIPS quality performance category equivalent score for ACOs in tracks that are Advanced APMs. CMS would then use this score for purposes of assessing quality performance under the MSSP for all ACOs. CMS discusses how these MIPS claims-based measures are similar to and different from those currently used to assess ACO

quality under the MSSP on [p. 636](#).

**CMS welcomes comment on potentially including all of the MIPS claims-based measures in the MIPS quality performance category score for ACOs (instead of the 3 claims-based measures that are currently included in the MSSP quality score), and using this score (converted to a percentage of points earned out of the total points available) in place of the current MSSP quality score to assess quality performance for all ACOs for purposes of the MSSP.** CMS would also continue to assess ACOs on the CAHPS for ACOs survey but quality performance would be calculated by MIPS based on the methodology used for scoring the CAHPS for MIPS survey and included in the MIPS quality performance category score. The scoring and benchmarking approach for the CAHPS for MIPS is to assign points based on each summary survey measure (SSM) and then average the points for all the scored SSMs to calculate the overall CAHPS score. In contrast, ACOs currently, receive up to 2 points for each of the 10 SSMs for a total of 20 points.

In addition, **CMS is soliciting comment on determining the threshold for minimum attainment in the MSSP using the MIPS APM quality performance category scoring,** including potentially increasing the minimum attainment level required for determining eligibility to share in savings. ACOs in the first performance year of their first agreement period are considered to have met the quality performance standard and therefore to be eligible to share in savings or minimize shared losses, if applicable, when they completely and accurately report all quality measures. ACOs in all other performance years are required to completely and accurately report and meet the minimum attainment level on at least one measure in each domain, to be determined to have met the quality performance standard and to be eligible to share in savings. For these ACOs, minimum attainment is defined as a score that is at or above 30 percent or the 30th percentile of the performance benchmark. The 30th percentile for the MSSP is the equivalent of the 4th decile performance benchmark under MIPS APM quality performance category scoring. As CMS look to more closely align with MIPS quality performance category scoring in future years, CMS is considering how to determine whether ACOs have met the minimum attainment level. For example, minimum attainment could continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS quality performance category score that is at or above the 4th decile across all MIPS quality performance category scores would be required for ACOs in all other performance years under the MSSP. ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would not meet the quality performance standard for the MSSP and thus would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would be subject to compliance actions and possible termination. CMS recognizes that a requirement that ACOs achieve an overall MIPS quality performance category score (or equivalent score) that meets or exceeds the 4th decile across all MIPS quality performance category scores is a higher standard than the current requirement that ACOs meet the 30th percentile on one measure per MSSP quality domain; however, statute not only gives CMS discretion to establish quality performance standards for the MSSP, but also indicates that CMS should seek to improve the quality of care furnished by ACOs over time by specifying higher standards. CMS believes that increasing the minimum attainment level would incentivize improvement in the quality of care provided to the beneficiaries assigned to an ACO. Furthermore, CMS believes it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. Additionally, given the maturity of the MSSP, CMS is also considering setting a higher threshold, such as the median or mean quality performance category score across all MIPS quality category scores, for determining eligibility to share in savings under the MSSP for all ACOs, other than those ACOs in their first performance year of their first agreement period. **CMS welcomes comment on these potential approaches or other approaches for determining MSSP quality minimum attainment using MIPS data.**

**CMS is also seeking comment on how to potentially utilize the MIPS quality performance category score to adjust shared savings and shared losses under the MSSP, as applicable.** Currently, for all MSSP ACOs and Track 1+ Model ACOs, the ACO's quality score is multiplied with the maximum sharing rate of the track to determine

the final sharing rate and therefore the amount of shared savings, if applicable. For some ACOs under two-sided models, specifically ACOs in Track 2 and the ENHANCED track, a higher quality score results in the ACO receiving a higher proportion of shared savings in all MSSP tracks and the Track 1+ Model, or greater mitigation of shared losses in Track 2 and the ENHANCED track. CMS could apply the MIPS quality performance category score to determine ACOs' shared savings and shared losses, if applicable, in the same manner. For instance, as an alternative to the current approach to determining shared savings payments for MSSP ACOs, CMS could establish a minimum attainment threshold, such as a score at or above the 4th decile of all MIPS quality performance category scores or the median or mean quality performance category score, that if met would allow ACOs to share in savings based on the full sharing rate of their track.

**CMS welcomes comment on these or other potential approaches for utilizing the MIPS quality performance category score or an alternative score in determining shared savings or shared losses under the MSSP.**

In addition, CMS is considering an option under which CMS would determine the MIPS quality performance category score for all MSSP ACOs as it is currently calculated for non-ACO group reporters using the CMS Web Interface. That is, ACOs would receive a score for each of the measures they report and zero points for those measures they do not report. This would be a change from the current methodology under which ACOs must report all Web Interface measures to complete quality reporting. If CMS were to adopt the MIPS quality performance category score as the MSSP quality score, CMS would consider no longer imposing a different quality standard for ACOs in the first year of their first participation agreement versus ACOs in later performance years. CMS believes that requiring all ACOs regardless of time in the program to be assessed on quality performance would be an appropriate policy since nearly 100 percent of ACOs consistently satisfactorily report all quality measures. **CMS welcomes comment on this alternative for determining the MIPS quality performance category score.**

Lastly, **CMS is seeking comment on using the MIPS quality improvement scoring methodology rather than the MSSP Quality Improvement Reward to reward ACOs for quality improvement.** Under the MSSP, CMS currently allows ACOs not in their first performance year in the program to earn a Quality Improvement Reward in each of the four quality domains. In contrast, under MIPS improvement points are generally awarded as part of the MIPS quality performance category score if a MIPS eligible clinician (1) has a quality performance category achievement percent score for the previous performance period and the current performance period; (2) fully participates in the quality performance category for the current performance period; and (3) submits data under the same identifier for the 2 consecutive performance periods. If CMS were to adopt the MIPS quality performance category score for the MSSP quality score, quality improvement points earned under MIPS would be included in that score, and CMS would not have a need to add additional points to it. **CMS welcomes public comment on this or other approaches to considering improvement as part of using the MIPS quality performance category or an equivalent score, to determine quality performance under the MSSP.**

**CMS is seeking stakeholder feedback on the approaches discussed in this section of the proposed rule and any other recommendations regarding the potential alignment of the MSSP quality performance standard with the MIPS quality performance category in the assessment of ACO quality performance in the future for purposes of the MSSP.**

## Open Payments (p. 643)

***CMS proposes to revise several Open Payments regulations, which would be effective for data collected beginning in CY 2021 and reported in CY 2022. Specifically, CMS proposes: (1) expanding the definition of a covered recipient to include the categories specified in the SUPPORT Act; (2) expanding the nature of payment categories; and (3) standardizing data on reported covered drugs, devices, biologicals, or medical supplies. CMS is also proposing a correction to the national drug codes (NDCs) reporting requirements for drugs and biologicals that, should the rule be finalized as proposed, would be effective 60 days following the publication of the final rule.***

***Expanding the definition of a covered recipient. CMS proposes to revise the definition of “covered recipient” to include PAs, NPs, CNSs, CRNAs, and CNMs, and reference the definitions where they are currently defined in statute.***

***Nature of Payment Categories.*** Given stakeholder feedback, ***CMS proposes to consolidate accredited/certified and unaccredited/non-certified continuing education programs into a single “medical education programs” category.***

In addition, ***CMS proposes three additional categories that would operate prospectively and would not require the updating of previously reported payments or other transfers of value that may fall within these new categories.*** Those are as follows:

- **Debt Forgiveness:** This would be used to categorize transfers of value related to forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician who holds an ownership or investment interest.
- **Long-Term Medical Supply or Device Loan:** Section 403.904 currently contains an exclusion from reporting for the loan of a covered device, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days, or a quantity of 90 days of average use, respectively. This new category would be used to characterize the loans of covered devices or medical supplies for longer than 90 days.
- **Acquisitions:** This addition would provide a category for characterizing buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest.

***CMS proposes to define “long-term medical supply or device loan as “the loan of supplies or a device for 91 days or longer.”***

***Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies. CMS proposes that the device identifier (DI) component, the mandatory fixed portion of the unique device identifier (UDI) assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable GPOs provide. CMS proposes to require applicable manufacturers and applicable GPOs to provide the DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly. CMS also proposes to reincorporate language that specifically requires reporting of national drug codes (NDCs).***



## Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy ([p. 654](#))

As a result of passage of the 21<sup>st</sup> Century Cures Act, a separate benefit was created to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of DME in the beneficiary's home, beginning January 1, 2021.

Prior to the furnishing of home infusion therapy to an individual, the law stipulates that the physician who establishes the therapy plan for the individual shall provide notification of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part. As such, **CMS solicits comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B. CMS also invites comments on any additional interpretations of this notification requirement.**

## Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm ([p. 656](#))

### Enrollment of Opioid Treatment Programs ([p. 656](#))

The SUPPORT Act classifies opioid treatment programs (OTPs) as Medicare providers (though only with respect to the furnishing of opioid use disorder treatment services). This will enable OTPs that meet all applicable statutory and regulatory requirements to bill and receive payment under Medicare for furnishing such services to Medicare beneficiaries.

CMS provides additional details regarding the statutory and regulatory definition (at 42 CFR part 8<sup>20</sup>) and requirements for OTPs starting on [p. 656](#). These requirements include:

- Accreditation ([p. 657](#)). An OTP must have a current, valid accreditation by an accrediting body or other entity approved by the SAMHSA, the federal agency that oversees OTPs.
- Certification ([p. 657](#)). Along with accreditation, an OTP must have a current, valid certification by SAMHSA for such a program, as detailed further in the rule.
- OTP Enrollment ([p. 658](#)). Statute requires that an OTP be enrolled in the Medicare program to qualify as an OTP and to bill and receive payment from Medicare for opioid use disorder treatment services.

***The provisions of this proposed rule would establish requirements that OTPs must meet in order to enroll in Medicare.***

CMS discusses the current Medicare enrollment process starting on [p. 659](#), including general requirements; provisions to enable further action against providers and suppliers that pose certain risks; screening and fee requirements; denial and revocation reasons; and other changes to address various program integrity issues. CMS also discusses the Medicare Enrollment Application (Form CMS-855) starting on [p. 661](#), including detailing information collected and provider enrollment transactions that require the use of the form.

CMS discusses its legal authority for establishing requirements and procedures with which OTPs must comply to enroll and remain enrolled in the Medicare program, starting on [p. 663](#). CMS notes that, in establishing and implementing an overall Medicare OTP process and implementing an overall program integrity strategy, its objectives will extend to matters such as: (1) monitoring OTP billing patterns; (2) ensuring the proper payment of OTP claims; (3) performing OTP audits as required by law; (4) making certain that OTP beneficiaries receive

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<sup>20</sup> 42 CFR Part 8 addresses Medication Assisted Treatment for Opioid Use Disorders, including requirements for OTPs.

quality care; and (5) taking action (enrollment-related or otherwise) against non-compliant or abusive OTP providers. In other words, CMS emphasizes that it should not be assumed for purposes of the OTP process that the term “program integrity” is limited to the provider enrollment concept, for it actually applies to many other types of payment safeguards as well.

CMS details its proposed OTP enrollment requirements starting on [p. 664](#). These include:

- Addition of 42 CFR 424.67 and general OTP requirement to enroll ([p. 664](#)). ***CMS proposes to establish a new 42 CFR 424.67 that would include most of CMS’ proposed OTP provisions. In paragraph (a), CMS is proposing that in order for a program to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP and enroll in the Medicare program under the provisions of subpart P of this part and this section.*** Subpart P outlines the requirements and procedures of the enrollment process.
- Procedures and compliance ([p. 664](#)). CMS proposes several specific enrollment requirements that OTPs must meet that either clarify or supplement those contained in subpart P, including:
  - Form CMS-855B ([p. 664](#)). ***CMS proposes that an OTP must complete in full and submit the Form CMS-855B application (“Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers”) and any applicable supplement or attachment thereto to its applicable Medicare contractor.*** While CMS recognizes that the Form CMS-855B is typically completed by suppliers rather than providers, CMS believes that certain unique characteristics of OTPs (for example, OTPs would only bill Medicare Part B) make the Form CMS-855B the most suitable enrollment application for OTPs. As part of this general requirement concerning CMS-855 form completion, CMS proposes two subsidiary requirements as part of the aforementioned supplement/attachment:
    - ***First, CMS proposes that the OTP must maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians and other eligible professionals who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician’s or other eligible professional’s first and last name and middle initial, Social Security Number, National Provider Identifier, and (4) license number (if applicable).***
    - ***Second, CMS that the OTP must certify via the Form CMS 855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in regulation.***

CMS does not believe that the requirements duplicate any other information collection effort involving OTPs. While SAMHSA’s approved accreditation bodies do verify that eligible professionals have appropriate licensure, they do not collect this information on a form, screen against federal databases, or have a database that keeps this information. CMS, however, intends to conduct these activities.

- Application fee ([p. 666](#)). Under current regulations, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee. (\$586 for CY 2019) Section 424.502 defines an institutional provider as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations, which are exempt from the fee requirement if they are enrolling as a physician or non-physician practitioner organization), Form CMS-855S, Form CMS-20134, or an associated Internet-based PECOS enrollment application. Since an OTP would be required to complete the Form CMS-855B to enroll in Medicare as an OTP, CMS believes that an OTP would meet the definition of an institutional provider under § 424.502. It would therefore be required to pay an application fee;

***CMS is proposing to clarify this requirement to pay the fee in regulation text.***

- Categorical risk designation (p. 667). Current regulations outline screening categories and requirements based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny CMS applies. There are three categories of screening: higher, moderate, and limited. ***CMS is proposing to assign newly enrolling OTPs to the high categorical risk level***, and details associated screening requirements starting on [p. 667](#). CMS discusses its rationale for its proposal, including identified risks, starting on [p. 668](#). Given the foregoing, CMS is proposing four regulatory provisions. ***First, CMS is proposing to state that newly enrolling OTP providers will be screened at the high categorical risk level. Second, CMS is proposing to add newly enrolling OTPs to the types of providers and suppliers screened at the high categorical risk level. Third, CMS is proposing to specify that OTPs that are revalidating their current Medicare enrollment would be screened at the moderate categorical risk level. Fourth, CMS proposes to require that, upon revalidation, the OTP successfully complete the moderate categorical risk level screening required in order to remain enrolled in Medicare.***
- Certification (p. 670). ***CMS is proposing that to enroll in Medicare, an OTP must have in effect a current, valid certification by SAMHSA for such a program.*** While CMS discusses the availability of provisional certification with SAMHSA, ***CMS proposes that it would not accept a provisional certification for OTP enrollment in Medicare in lieu of full certification.***
- Management employees (p. 671). Under current requirements, an enrolling provider or supplier must disclose all of its managing employees on the Form CMS-855 application. CMS' regulations define a managing employee as a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over (or who directly or indirectly conducts) the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier. ***CMS is proposing that all of the OTP's staff that meet the regulatory definition of managing employee must be reported on the Form CMS-855 application and/or any applicable supplement.*** Such individuals would include, but not be limited to, the OTP's medical director and program sponsor.
- Standards specific to OTPs (p. 671). CMS proposes the following additional requirements with which OTPs must comply in order to enroll in Medicare:
  - ***CMS proposes that an OTP must not employ or contract with a prescribing or ordering physician or other eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted of a federal or state felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries, based on the same categories of detrimental felonies, as well as case-by-case detrimental determinations.*** This provision would apply irrespective of whether the individual in question is: (1) currently dispensing narcotics at or on behalf of the OTP; or (2) a W-2 employee of the OTP.
  - ***CMS proposes that the OTP must not employ or contract with any personnel, regardless of whether the individual is a W-2 employee of the OTP, who is revoked from Medicare, or who is on the preclusion list under §§ 422.222 or 423.120(c)(6).***
  - ***CMS proposes that the OTP must not employ or contract with any personnel (regardless of whether the individual is a W-2 employee of the OTP) who has a current or prior adverse action imposed by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.*** CMS would consider the factors

enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this provision.

- Provider agreement (p. 673). Statute specifies that all Medicare providers must enter into a provider agreement and outlines required terms of the agreement. Consistent with these requirements, CMS is proposing to revise various regulations to include OTPs within the category of providers that must sign a provider agreement in order to participate in Medicare. ***CMS proposes that an OPT must sign (and adhere to the terms of) a provider agreement with CMS in order to participate and enroll in Medicare.*** Additionally, CMS discusses its authority to terminate a provider agreement and a provider's ability to appeal the termination, which CMS notes is similar to appeals for revocation of enrollment, starting on [p. 674](#). Given the linkage, CMS is concerned about the potential for duplicate appeals process involving a revoked OPT. Therefore, ***CMS proposes that an OPT's appeals under a Medicare revocation and a provider agreement termination must be filed jointly and, as applicable, considered jointly by CMS under part 498.*** CMS notes that there is precedence for such a consolidated approach as described on [p. 675](#). ***CMS would appreciate comment on its proposed consolidated appeals process, including suggestions of alternative processes and the potential operational components thereof.***
- Other applicable requirements (p. 675). To ensure that the OTP meets all other applicable requirements for enrollment, ***CMS is proposing that the OTP must comply with all other applicable requirements for enrollment specified in 424.67 and in part 424, subpart P.***
- Denial of enrollment and appeals thereof (p. 676). ***CMS is proposing that CMS may deny an OTP's enrollment application on either of the following grounds:***
  - ***The provider does not have in effect a current, valid certification by SAMHSA or fails to meet any other applicable requirement***
  - ***Any of the reasons for denial of a prospective provider's or supplier's enrollment application in 424.530 applies.***

***CMS is also proposing that an OTP may appeal the denial of its enrollment application.***

- Continued compliance, standards, and reasons for revocation (p. 676). ***CMS is proposing to state that, upon and after enrollment, an OTP must remain validly certified by SAMHSA and remains subject to, and must remain in full compliance with, the provisions of 424.67 and in part 424, subpart P. CMS also proposes that it may revoke an OTP's enrollment if the provider does not have a current, valid certification by SAMHSA or fails to meet any other applicable requirement or standard in 424.67, including, but not limited to, the OTP standards; or if any of the revocation reasons in 424.535 applies. Finally, CMS is proposing that an OTP may appeal the revocation of its enrollment.***
- Prescribing individuals (p. 677). ***CMS proposes that the prescribing or medication ordering physician's or other eligible professional's NPI must be listed on Field 17 (the ordering/referring/other field) of the Form CMS-1500 (Health Insurance Claim Form).*** CMS notes that its use of the term "medication ordering" is merely intended to reiterate that its proposed provision applies to any physician or other eligible professional who prescribes or orders drugs in the OTP arena. ***CMS also proposes to further clarify that all other applicable requirements in 424.67, part 242, and part 8 must also be met.***
- Relationship to 42 CFR part 8 (p. 678). ***CMS proposes to state in regulation text that 424.67 shall not be construed as (1) supplanting any of the provisions in part 8; or (2) eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8.***

- Effective and Retrospective Date of OTP Billing Privileges (p. 678). Section 424.520 of Title 42 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers. This effective date is the later of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location. Section also 424.521(a) states that these clinicians and suppliers may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to: (1) 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or (2) 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act precluded enrollment in advance of providing services to Medicare beneficiaries. ***CMS proposes to include newly enrolling OTPs within the scope of both § 424.520(d) and § 424.521(a)***. CMS believes that the effective and retrospective billing dates addressed therein achieves a proper balance between the need for the prompt provision of OTP services and the importance of ensuring that each prospective OTP enrollee is carefully and closely screened for compliance with all applicable requirements.

## **Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535 (p. 679)**

### ***Improper Prescribing (p. 679)***

Under regulations at § 424.535(a)(14), CMS may revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that: (1) is abusive, and/or represents a threat to the health and safety of Medicare beneficiaries ; or (2) fails to meet Medicare requirements. Since the provision's inception in 2014, CMS has revoked the enrollments of practitioners who have engaged in a variety of improper prescribing practices. CMS believes these administrative actions have helped to shield beneficiaries and the program at large from improper prescribing practices.

CMS is concerned about potential instances where OTP physicians and other eligible professionals prescribe drugs in an improper fashion. This is an especially important consideration given the nationwide opioid epidemic and the need to reduce opioid abuse. Given this, CMS believes that § 424.535(a)(14) should no longer be restricted to Part D drugs but must extend to all Medicare drugs, including Part B drugs. In the introductory text of § 424.535(a)(14), CMS currently state that CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part D drugs. ***CMS is proposing to revise this paragraph to include Part B drugs so CMS would specify the prescribing of "Part B or D drugs."*** CMS notes that this proposal would affect prescriptions of any Part B or D drugs, not merely those prescriptions given to beneficiaries using OTPs.

### ***Patient Harm (p. 681)***

***CMS is proposing to add a new revocation reason and a new denial reason to regulation text to permit CMS to revoke or deny, as applicable, a physician's or other eligible professional's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.***

***In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:***

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:
  - License restriction(s) pertaining to certain procedures or practices,
  - Required compliance appearances before state oversight board members,
  - Required participation in rehabilitation or mental/behavioral health programs,
  - Required abstinence from drugs or alcohol and random drug testing,
  - License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge)
  - Administrative/monetary penalties; or
  - Formal reprimand(s).
- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.
- Any other information that CMS deems relevant to its determination.

CMS currently lacks the legal basis to take administrative action against a physician or other eligible professional for a matter related to patient harm based solely on an IRO determination or an administrative action (excluding a state medical license suspension or revocation) imposed by a state oversight board, a federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. CMS believes, however, that its general rulemaking authority gives CMS the ability to establish such legal grounds. CMS has long been concerned about instances of physician or other eligible professional misconduct, and CMS believes its authority to take action to stem such behavior should be expanded to include the scenarios identified herein. CMS discusses its rationale on [p. 682](#).

CMS recognizes that situations could arise where a state oversight board has chosen to impose a relatively minor sanction on physician or other eligible professional for conduct that CMS deem more serious. CMS notes, however, that CMS, rather than state boards, is ultimately responsible for the administration of the Medicare program and the protection of its beneficiaries. CMS accordingly believes that it should have the discretion to review such cases to determine whether, in the agency's view, the physician's or other eligible professional's conduct warrants revocation or denial. CMS emphasizes that it would only take such a measure after careful consideration of all of the factors outlined above.

The addition of this revocation and denial reasons would apply to physicians and other eligible professionals in OTP and non-OTP settings. Revocation or denial action could be taken against physicians and other eligible professionals in solo practice or who are part of a group or any other provider or supplier type.

***To clarify the scope of the term "state oversight board" in the context of these proposed revocation and denial reasons, CMS proposes to define this term in regulation text. Specifically, CMS would state that "state oversight board" means "any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the state." This definition would apply for purposes of the new denial and revocation reasons only.***

***CMS welcomes comment not only on CMS' proposed definition of "state oversight board" but also on CMS'***

**proposed revocation and denial authorities. CMS is especially interested in securing public feedback on additional means of preventing fraud, waste, and abuse in OTP setting; for instance, CMS would appreciate suggestions—based on stakeholder experience in the OUD and OTP arenas—from which CMS could develop further regulatory authority to take action against problematic OTPs.**

## Deferring to State Scope of Practice Requirements ([p. 685](#))

### Ambulatory Surgical Centers ([p. 685](#))

CMS provides background on ambulatory surgical centers (ASCs) starting on [p. 685](#), including information on the type of care furnished in ASCs, the number of Medicare certified ASCs, and the health, safety, and other requirements they must meet to participate in Medicare. CMS specifically highlights the following three ASCs' Conditions for Coverage (CfCs):

- Section 416.42, “Condition for coverage -Surgical services”, states that surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC. The requirement at § 416.42(a)(1) requires a physician to examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed. Section 416.42(a)(2) allows anesthetists, in addition to physicians, to evaluate each patient for proper anesthesia recovery.
- Section 416.52, “Conditions for coverage – Patient admission, assessment and discharge”. This condition sets standards pertaining to patient pre-surgical assessment, post-surgical assessment, and discharge requirements that must be met before patients leave the ASC. Specifically, the discharge requirements at § 416.52(b)(1) require that a post-surgical assessment be completed by a physician, or other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice, and ASC policy.

CMS has received many requests to align the anesthetic risk and pre-surgery evaluation standard at § 416.42(a)(1) with the pre-discharge standard at § 416.42(a)(2) by allowing an anesthetist, in addition to a physician, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure. For those ASCs that utilize non-physician anesthetists, also known as certified registered nurse anesthetists (CRNAs)<sup>21</sup>, this revision would allow them to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure to be performed by the physician. CMS believes this alignment provides for continuity of care for the patient and allows the patient’s anesthesia professional to have familiarity with the patient’s health characteristics and medical history.

***CMS is proposing to revise § 416.42(a), Surgical services, to allow either a physician or an anesthetist, as defined at § 410.69(b)<sup>22</sup>, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed.*** By amending the CfCs to allow an anesthetist or a physician to examine and evaluate the patient before surgery for anesthesia risk and the planned procedure risk, CMS would be making ASC patient evaluations more consistent by allowing the option for the same clinician to complete both pre- and post- procedure anesthesia evaluations.

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<sup>21</sup> Per CMS: CRNAs are advanced practice registered nurses who administer more than 43 million anesthetics to patients each year in the United States. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the PFS amount for services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in most rural hospitals. A study published by Nursing Economic\$ in May/June 2010, found that CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model. ([p. 687](#))

<sup>22</sup> CMS defines anesthetist to include both an anesthesiologist's assistant and a certified registered nurse anesthetist.

This proposed change is a continuation of CMS' efforts to reduce regulatory burden. This change would increase supplier flexibility and reduce burden, while allowing qualified clinicians to focus on providing high-quality healthcare to their patients. **CMS is also requesting comments and suggestions for other ASC requirements that could be revised to allow greater flexibility in the use of NPPs, and reduce burden while maintaining high quality health care.**

### **Hospice (p. 688)**

CMS provides background on hospice care starting on [p. 688](#), including its emphasis on palliative and its use of an interdisciplinary approach to deliver multidisciplinary care. CMS notes that Section 51006 of the Bipartisan Budget Act of 2018 revised the statute to add PAs to the statutory definition of the hospice attending physician for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician in the hospice regulations in the FY 2019 hospice final rule.

CMS details its expectations about the role of the attending physician, the role of the hospice in delivering physician services, and the engagement of an attending physician (if any) with the hospice interdisciplinary group and patient care starting on [p. 689](#). CMS specifically notes that the attending physician is not meant to be a person offered by, selected by, or appointed by the hospice when the patient elects to receive hospice care and the hospices requirement to provide physician services to meet the patient's hospice-related needs and all other care needs to the extent that those needs are not met by the patient's attending physician.

The hospice patient's chosen attending physician may, at times, write orders for services and medications as they relate to treating conditions determined to be unrelated to the patient's terminal prognosis. Section 418.56(e) requires hospices to coordinate care with other providers who are also furnishing care to the hospice patient, including the patient's attending physician who is providing care for conditions determined by the hospice interdisciplinary group to be unrelated to the patient's terminal prognosis. As part of this coordination of care, it is possible that hospices may receive orders from the attending physician for drugs that are unrelated to the patient's terminal prognosis.

However, stakeholders have raised concerns regarding the requirements of § 418.106(b). As currently written, hospices may not accept orders for drugs from attending physicians who are PAs because § 418.106(b) specifies that hospices may accept drug orders from physicians and NPs only. ***CMS proposes to revise § 418.106(b)(1) to permit a hospice to accept drug orders from a physician, NP, or PA. CMS proposes that the PA must be an individual acting within his or her state scope of practice requirements and hospice policy. CMS also proposes that the PA must be the patient's attending physician, and that he or she may not have an employment or contractual arrangement with the hospice.*** The role of physicians and NPs as hospice employees and contractors is clearly defined in the hospice CoPs; however, the CoPs do not address the role of PAs. Therefore, CMS believes that it is necessary to limit the hospice CoPs to accepting only those orders from PAs that are generated outside of the hospice's operations.

CMS notes that the role of a PA is not defined in the hospice CoPs because the statute does not include PA services as being part of the Medicare hospice benefit. As such, there are no provisions in the hospice CoPs to address specific PA issues such as personnel requirements, descriptions of whether such services would be considered core or non-core, or provisions to address issues of co-signatures. To more fully understand the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs, **CMS request public comment on the following questions:**

- **What is the role of a NPP in delivering safe and effective hospice care to patients?**
- **What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?**
- **Nursing services are a required core service within the Hospice benefit, as provided in section**



1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?

- In light of diverse existing state supervision requirements, how should NPP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?
- What requirements and time frames currently exist at the state level for physician co-signatures of NPP orders? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?
- What are the essential personnel requirements for PAs and other NPPs?

## Advisory Opinions on the Application of the Physician Self-Referral Law ([p. 694](#))

### Background

CMS reviewed the statutory and regulatory history related to advisory opinions. Of note:

- The Balanced Budget Act of 1997 requires that the Secretary issue written advisory opinions whether a referral relating to Designated Health Services (DHS) is prohibited under the **physician self-referral law**; the Secretary issued regulations related to this in January 1998 ([p. 694](#)). Notable provisions include:
  - Each advisory opinion shall be binding on the parties requesting the opinion
  - *The Secretary shall take into account the regulations related to OIG opinions related to the Antikickback Statute and its safe harbors.*<sup>23</sup>
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary in consultation with the Attorney General (via the Office of the Inspector General (OIG)) to issue advisory opinions related to the **Antikickback Statute** and its safe harbors. The OIG issued a rule related to this in February 1997 with clarifications and revisions in 1998 and 2008 ([p. 695](#)). These opinions are also binding as to the Secretary and the parties requesting the opinion. Statute prohibits these opinions from addressing:
  - Whether Fair Market Value (FMV) shall be or was paid or received for any goods, services, or property; and
  - Whether an individual is a “bona fide” employee under the Internal Revenue Code

These provisions related to what the Secretary is prohibited from addressing were also incorporated into the physician self-referral regulations ([p. 695](#)).

CMS also states that the OIG provisions of the statute also provide that “the failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B of the Act.” These provisions were also incorporated into the physician self-referral regulations ([p. 695](#)).

Regulation also laid out the process for requesting and issuing OIG advisory opinions; CMS states that CMS “largely adopted” the OIG’s approach for purposes of issuing physician self-referral law advisory opinions ([p. 696](#)).

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<sup>23</sup> “We interpret Congress’ directive to take into account OIG regulations to mean that we should use the OIG regulations as our model, but that we are not bound to follow them (63 FR 1647)” ([p. 696](#)).

## Proposed Revisions

CMS states that it has received input requested that CMS “reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician’s referrals to an entity with which he or she has a financial relationship would be prohibited” under the physician self-referral law ([p. 696](#)). (CMS lists a summary of the comments on [p. 697](#)). CMS makes special note that the physician self-referral law is strict liability, and therefore, “parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law’s exceptions” ([p. 699](#)).

To address concerns from stakeholders and differences between the Physician Self Referral Law and the Antikickback Statute, CMS makes the following proposals<sup>24</sup>:

- **CMS proposes that an advisory opinion request must “relate to” (change from “involve”) (a) an existing arrangement; or (b) one into which the requestor “in good faith, specifically plans to enter” ([p. 701](#)).**
- **CMS proposes to reject advisory opinion requests (or not issue an advisory opinion) that “do not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion” (and requestor does not reply to requests for additional information) ([p. 702](#)).**
- **CMS proposes that it may elect to not accept a request for an advisory opinion “if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or is the subject of a proceeding involving HHS or other law enforcement agencies, and issuing an advisory opinion could interfere with the investigation or proceeding” ([p. 702](#)).** Note that this change would be less restrictive than current regulatory language that allows CMS to not issue the advisory opinion “if it is aware that the same, or substantially same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities” ([p. 701](#)).
- **CMS proposes to modify the time period in which it must issue an advisory opinion after receiving a request from 90 days to 60 days ([p. 704](#)).** CMS also seeks comment on whether it should implement an option to request an expedited review.
- **CMS proposes changes to the certifications that must be made as part of the process to stated that it need only be “signed by an officer that is authorized to act on behalf of the requestor,”** which more flexible than current requirement that it be the CEO or comparable officer (or a managing partner if it requested by a corporation) ([p. 705](#)). CMS also seeks comment on whether to eliminate the certification requirement given that there are other statutory provisions that prohibit material false statements to a federal agency.
- **CMS proposes to change the fee structure for requesting an advisory opinion to an hourly fee of \$220 ([p. 706](#)).** CMS notes that if it were to implement the expedited review option that it would pair that with an hourly rate of \$440. CMS is also considering put a cap on the amount of fees that could be charged and seeks comments on what that amount should be. (Current regulation requires an initial fee of \$250; CMS seeks comment on whether this should be eliminated).
- **CMS proposes that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would “preclude the imposition of sanctions . . . with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued” ([p. 708](#)).**
- **CMS proposes that “the Secretary will not pursue sanctions . . . against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion” that received a favorable opinion ([p. 708](#)).** CMS goes on to state that “[i]f parties to an arrangement are uncertain as to whether CMS would view it

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<sup>24</sup> CMS directly addresses request that CMS accept advisory opinion requests for hypothetical arrangements. CMS notes that it is not proposing to do so because this could overwhelm the agency and regardless could be inappropriate, but *CMS seeks input on whether it should do so in the future* ([p. 700](#)).

as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request to query whether a referral is prohibited under section 1877 of the Act because the arrangement is materially indistinguishable from an arrangement that received a favorable advisory opinion” (p. 709).

- **CMS proposes language “to recognize that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates that application of the self-referral law and regulations to specific facts and circumstances” (p. 709).**
- **CMS seeks comment on whether CMS should change regulation to retain a more limited right to rescind an advisory opinion (e.g. only when there is a “material regulatory change that impacts the conclusions” or when a party asks for reconsideration after a negative advisory opinion) (p. 709).**
- CMS makes other minor and technical modifications on [p. 710](#).

## **CY 2020 Updates to the Quality Payment Program (p. 711)**

### **Executive Summary (p. 711)**

This section of the proposed rule sets forth changes to the Quality Payment Program (QPP) for the fourth year of the program, which starts on January 1, 2020, except as otherwise noted for specific provisions.

CMS notes that participation in both tracks of the QPP – Advanced Alternative Payment Models (APMs) and the Merit-based Incentive Payment System (MIPS) – have increased from 2017 to 2018. The number of QPs – Qualifying APM Participations – nearly doubled from 2017 to 2018, from 99,076 to 183,306 clinicians. In MIPS, 98 percent of eligible clinicians participated in 2018, up from 95 percent in 2017.

For the 2022 payment year and based on estimated Advanced APM participation during the 2020 QP Performance Period, CMS estimates that between 175,000 and 225,000 clinicians will become Qualifying APM Participants (QPs). As a QP for the 2022 payment year, an eligible clinician is excluded from 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. CMS estimates that the total lump sum APM Incentive Payments will be approximately \$500-600 million for the 2022 QPP payment year.

CMS estimates that approximately 818,000 clinicians would be MIPS eligible clinicians for the 2020 MIPS performance period.<sup>25</sup> In the 2022 MIPS payment year, CMS estimates that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments (\$584 million) and positive MIPS payment adjustments (\$584 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional \$500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance for MIPS eligible clinicians whose final score meets or exceeds the additional proposed performance threshold of 80 points. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2022 MIPS payment year and the distribution of final scores under the program.

### **Definitions (p. 717)**

**At § 414.1305, CMS proposes to define the following terms:**

- **Aligned Other Payer Medical Home Model**
- **Hospital-based MIPS eligible clinician**
- **MIPS Value Pathway**

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<sup>25</sup> 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 into MIPS.

**CMS also proposes to revise at § 414.1305 the following term:**

- **Rural area**

These terms are discussed in the sections below.

## **MIPS Program Details ([p. 719](#))**

### ***Transforming MIPS: MIPS Value Pathways Request for Information ([p. 719](#))***

#### **MVP Framework ([p. 719](#))**

##### **Overview ([p. 720](#))**

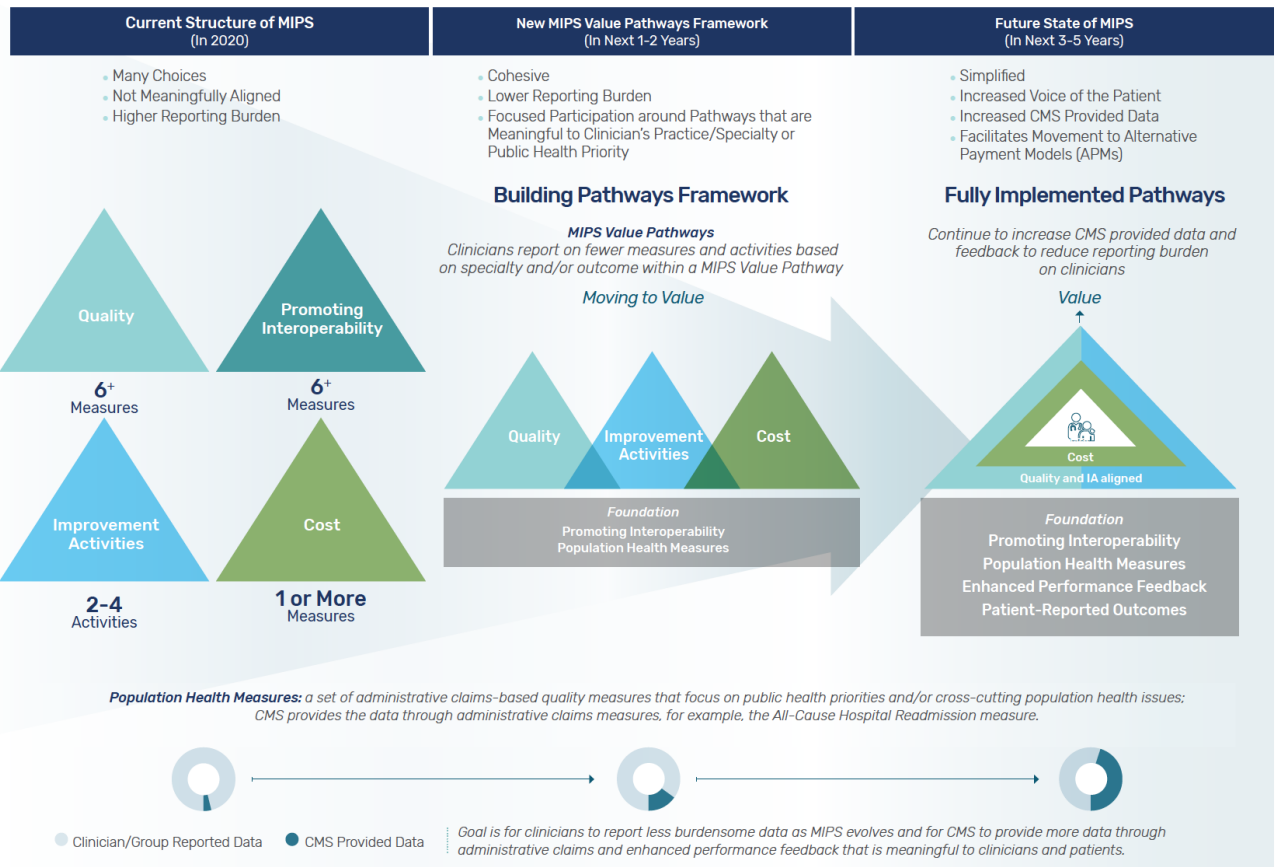
CMS believes it is important to transform the current MIPS program and enter a future state, which includes a more cohesive and simplified participation experience for clinicians, increased voice of the patient, increased data and feedback to clinicians to reduce reporting burden, and facilitated movement to APMs. According to CMS, any solution to improving MIPS performance measurement data must account for the large variation in specialty, size, and composition of clinician practices. At the same time, CMS believes it must balance flexibility with a degree of standardization to hold clinicians accountable for the quality of care, identify and reward high value care, and limit burden.

With these goals in mind, ***CMS proposes to apply a new MIPS Value Pathways (MVP) framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians.*** The MVP framework would create a more cohesive participation experience by connecting measures and activities from across the four MIPS performance categories that are relevant to a specialty or medical condition, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. Although CMS would aim to implement the MVP framework as early as feasible, CMS proposes to apply the framework beginning with the 2021 performance period so that it can seek feedback on the details of this framework and address additional details of the methodology in next year's rulemaking cycle. CMS intends to continue to integrate new MVPs so that eventually, all MIPS eligible clinicians would have to participate through an MVP or a MIPS APM. CMS also plans to engage with clinician professional organizations and front-line clinicians to develop the MVPs.

This effort aims to remove APM participation barriers as clinicians and practices prepare to successfully manage risk and build out their quality infrastructures. According to CMS, critical practice infrastructure components that support higher value care and readiness to join APMs include performance measurement tracking, performance improvement processes, interoperability, and data information systems that assist clinicians and practices in monitoring performance and adopting new workflows and care delivery methods. CMS understands that clinicians want timely performance feedback data on quality and cost to track their performance and prepare to take on risk, as required in Advanced APMs, and CMS intends to provide enhanced feedback and data analysis information to clinicians in the future.

CMS' vision for the future of MIPS is illustrated below. Additional graphics, including a Surgical MVP, is available for download [here](#).

# MIPS Value Pathways



**We Need Your Feedback on:**

<p><b>Pathways:</b> What should be the structure and focus of the Pathways? What criteria should we use to select measures and activities?</p>	<p><b>Participation:</b> What policies are needed for small practices and multi-specialty practices? Should there be a choice of measures and activities within Pathways?</p>	<p><b>Public Reporting:</b> How should information be reported to patients? Should we move toward reporting at the individual clinician level?</p>
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CMS built the MIPS program recognizing the large variation in specialty, size, and composition of clinician practices, providing broad flexibility for clinician choice of measures and activities, data submission types, and individual or group level participation. While this flexibility has resulted in high participation rates, CMS believes it also has inadvertently resulted in a complex MIPS program that is not producing the level of robust clinician performance information it envisioned to meet patient needs and spur clinician care improvements. CMS has heard from stakeholders that MIPS presents clinicians with too much complexity and choice (e.g., several hundred MIPS and QCDR quality measures), causing unnecessary burden; that performance requirements are confusing; that it is difficult for clinicians to choose measures that are meaningful to their practices and have a direct benefit to beneficiaries; and that the program does not allow for sufficient differentiation of performance across practices due to clinician quality measures selection bias.

CMS cites the MedPAC’s June 2017 Report to Congress, which documented the need for changes to the MIPS program to increase clarity, reduce complexity, and make the burden of data submission worthwhile through higher impact. CMS also cites MedPAC’s March 2018 Report to Congress, which recommended using a uniform set of population-based measures for clinicians who are not participating in an advanced APM. CMS believes a hybrid approach is warranted – where clinicians are measured on a unified set of measures and activities around a clinician condition or specialty, layered on top of a base of population health measures, which would be included in virtually all of the MVPs.

### **Clinician Data Feedback** ([p. 724](#))

CMS has heard stakeholder requests and recognizes the critical need for data feedback to assist clinicians in understanding their performance and preparing to take on risk as required in Advanced APMs. CMS intends to provide enhanced clinician driven data feedback and analysis information under the future MVP approach. It is interested in whether clinicians would like to see outlier analysis or other types of actionable data feedback and seeks comments on clinician data feedback content and timing later in this section.

### **Enhancing Information for Patients** ([p. 724](#))

CMS believes that its performance measurement, including MVPs, should focus more on patient reported measures, including patient experience and satisfaction measures and clinical outcomes measures, when feasible since clinicians can use feedback from the patient perspective to inform care improvement efforts. CMS also believes that whenever feasible, the MIPS program should provide meaningful information at the individual clinician level, and that there is a need for specific specialty information from multispecialty groups. CMS is considering approaches to use the MVPs to require reporting relevant to multiple specialty types within a group to provide more comprehensive information for patients. CMS seeks comment later in this section on best ways to identify which MVPs should be reported by multispecialty groups and how it should balance the need for information at the individual clinician level with the burden of reporting.

CMS is also looking at ways that it can gather and display information that is useful to patients. [Later in this rule](#), it considers developing and reporting on Physician Compare a “value indicator” representing each clinician’s performance on cost, quality, and the patient’s experience of care.

### **Implementing MVPs** ([p. 725](#))

#### **MVP Definition, Development, Specification, Assignment, and Examples** ([p. 725](#))

##### Definition

The four guiding principles CMS would use to define MVPs are:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

***To begin implementing MVPs, CMS proposes to define a MIPS Value Pathway at § 414.1305 as a subset of measures and activities specified by CMS. MVPs may include, but would not be limited to, administrative claims-based population health, care coordination, patient-reported (which may include patient reported outcomes, or patient experience and satisfaction measures), and/or specialty/condition specific measures. MVPs would include a population health quality measure set, and measures and activities such that all four MIPS performance categories are addressed, and each performance category would be scored according to its current methodology. Under MVPs, the current MIPS performance measure collection types would continue to be used to the extent possible, but these details need to be worked out and would be addressed in next year’s rulemaking cycle.***

MVPs would be organized around clinician specialty or health condition and encompass a set of related measures and activities. CMS intends to ensure equity in MVPs so that clinicians are not advantaged by reporting one MVP over another (e.g., in terms of reporting burden and scoring), but also wants to include measures that have opportunities for improvement. As an initial step, CMS proposes [later in this rule](#) to require

that beginning with the 2020 Call for measures process, MIPS quality measure stewards must link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible.

The most significant change with MVPs is that eventually all MIPS eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be connected around a clinician specialty or condition. CMS also intends that a population health measure/administrative claims-based measures would be layered into measuring the quality performance category, applied whenever there is a sufficient case minimum.

Cost measures would be specific to the MVP and applied only when a clinician or group meets the case minimum. MVPs could potentially also allow for the use of multi-category measures, should they be developed, as clinician feedback has indicated there is an interest in the development of these performance measures that simultaneously address two or three of the MIPS performance categories.

CMS envisions Promoting Interoperability performance category measures, which focus on the meaningful use of certified EHR technology to support care coordination and electronic health information exchange, to be a key structural part of any MVP. Initially, there would be a uniform set of Promoting Interoperability measures in each MVP, though in future years CMS may consider customizing the Promoting Interoperability measures in each MVP. At this time, CMS is not considering making modifications to the Promoting Interoperability performance category as it becomes incorporated into the MVP framework. CMS believes that interoperability is a foundational element and thus would apply to all clinicians, regardless of MVP, for whom that category is required.

Later in this section, CMS seeks feedback on how many improvement activities should be included in an MVP, how much flexibility there should be in selecting improvement activities, and the extent to which improvement activities in MVPs should be specialty specific or condition-focused versus focused on other areas relevant to the practice, such as patient experience and engagement, team-based care, and care coordination.

CMS' goal in using MVPs is to standardize which measures and activities are reported, both to reduce clinician burden and better measure performance among comparable clinicians while appropriately recognizing the variability of clinician practices and potentially reducing barriers to moving into APMs, which generally measure quality for their respective participants using the same quality measures. CMS also looks to APMs for methods of linking quality and value measurement, as APMs are designed around value, and address quality, cost, and care redesign for a specific population.

#### Examples

CMS provides four illustrative examples of MVPs in [Table 34](#). In these examples, CMS presents no more than four quality or cost measures or improvement activities for each performance category. However, the exact number of measures and activities could vary across MVPs. CMS envisions that it would no longer require the same number of measures or activities for all clinicians, but focus on what is needed to best assess the quality and value of care within a particular specialty or condition. To assign quality measures in these examples, CMS prioritized outcome and patient reported measures, non-topped out measures, and eCQMs.

The examples in [Table 34](#) are illustrative only, but CMS envisions that it would start building MVPs by reviewing the existing specialty measure sets for the quality performance category. However, some specialty measure sets contain multiple conditions or concepts, so CMS does not envision a one-to-one correlation between the specialty measure sets and MVPs. CMS also anticipates that all measures in the Promoting Interoperability performance category would initially be applicable to each MVP unless an exclusion applies; thus, it assigns all Promoting Interoperability measures to all MVPs.

### MVP Selection/Assignment

CMS anticipates that eventually many clinicians would have at least one relevant MVP, while other clinicians may have several. In particular, multispecialty groups will likely have more than one relevant MVP. If technically feasible, CMS would like to establish a methodology that allows it to identify and assign in advance the relevant MVP(s) for MIPS eligible clinicians or groups and require the clinician or groups to report on those MVPs. In addition, CMS would consider folding MIPS APM measures and activities into MVPs and developing an assignment process as described in the CY 2018 QPP final rule (82 FR 53785 through 53787), applying a hierarchy which applies APM entity final scores over any other final score.

CMS has received feedback that some clinicians would prefer a clear list of what specific measures and activities they have to perform versus various options of measures and activities to report. CMS believes a methodology in which clinicians are informed of the potential MVP(s) that are available to them would be simpler to communicate and allow for both clinicians and CMS to better understand what measures and activities should be submitted. CMS is considering assigning MVPs to clinicians and groups, if technically feasible, starting with the 2021 MIPS performance period as MVPs become available and would propose the MVP assignment process in next year's rulemaking cycle. As an alternate option, CMS could consider self-assignment of MVPs for the 2021 MIPS performance year period with the intention of assigning MVPs to clinicians starting in the 2022 MIPS performance period, when there are potentially a greater number of MVPs available.

CMS is also considering approaches to assigning MVPs to multispecialty groups to be inclusive of the different specialties providing care to patients. Alternatively, it is considering approaches that would allow for self-assignment of MVPs where multispecialty groups would select one or more MVPs that are most relevant to the specialty mix within the group.

CMS believes the approach to MVPs must find the right balance between having a sufficient number of MVPs to allow clinicians to report on measures and activities relevant to their practices, without developing so many MVPs that reporting is diluted and developing benchmarks is hampered. For example, CMS would not want to have several MVPs for the same specialty or condition because then only a portion of the MIPS eligible clinicians are reporting on the quality measures, which limits the ability to develop benchmarks and to make meaningful comparisons of clinicians.

CMS also discusses in this section its interest in electronic Clinical Quality Measures (eCQMs) and encourages stakeholders to submit electronically specified measures for CMS consideration. CMS recognizes that there are challenges related to development of new eCQMs, but is interested in their potential use in MVPs to reduce reporting burden.

Clinicians and groups who would not have an applicable MVP for the 2021 MIPS performance period would continue the current process of reporting MIPS measures and activities for the four performance categories.

### Implementation Timeline

CMS anticipates that it will have a number of MVPs proposed for the 2021 MIPS performance period. However, CMS recognizes there are many operational considerations that should be taken into account. Over the next year, it may convene public forum listening sessions, webinars, and office hours, or use additional opportunities such as the pre-rulemaking measures process to understand what is important to stakeholders in regards to MVPs.

### Requests for Feedback on MVPs

In light of the discussion above, CMS requests feedback on the following topics:

*MVP Approach, Definition, Development, Specification, Assignment, and Examples*



- CMS requests public comments on the MVP guiding principles, as well as on how to best develop MVPs to allow for the development of better comparative data, reduce burden, and provide valuable information to patients and clinicians.
- Should CMS consider other guiding principles as it defines and develops MVPs?
- In addition to gathering feedback from this proposed rule, how does CMS best engage stakeholders in the development of MVPs?
  - How would stakeholders like to be engaged in MVP development? What type of outreach would be the most effective in gathering the voice of the patient in the MVP concept and the selection of measures?
  - For quality measures, should CMS initiate a “Call for MVPs” that aligns with policies developed for the Call for Measures and Measure Selection Process, described in [later in this rule](#), or should CMS use an approach similar to the process used to solicit recommendations for new specialty measure sets and revisions to existing specialty measure sets as described [later in this rule](#)?
- How should MVPs be organized, for example, around specialties and areas of practice? Alternatively, should MVPs be organized to address a small number of public health priorities, for example, HIV care or healthcare-associated infections? Please refer to [Table 34](#) for examples of specialty MVPs.
- How can CMS ensure the right number of MVPs that result in comparable and comprehensive information that is meaningful for the clinicians, patients, and the Medicare program? How should CMS limit the number of MVPs? Should each specialty have a single MVP?
- How should CMS build on Promoting Interoperability, a foundational component of MVPs, as it links the four categories within MVPs? How could it best promote the use of HIT and interoperability in practices not yet using EHRs? (see additional questions below)
- How can MVPs effectively reduce barriers to clinician movement into APMs, such as practice inexperience with cost measurement and lack of readiness to take on financial risk?

#### Selection of Measures and Activities for MVPs

- CMS seeks feedback on the level of choice that should be provided to clinicians for MVP selection or selection of measures and activities within an MVP. Should clinicians and groups be able to self-select an MVP or should an MVP be assigned?
  - If assigned, CMS requests comments on the best way to assign an MVP – should it be based on place of service codes, specialty designation on Part B claims, or in the case of groups, should the assigned MVP(s) be based on the specialty designation of the majority of clinicians in the group, specific services, or other factors?
  - CMS also seeks comment on circumstances when it should allow clinicians and groups to select an alternative MVP, rather than the one or more MVP(s) assigned.
- Please provide feedback on the example MVPs in [Table 34](#) that might help CMS in its development of additional MVPs. Should MVPs include only required measures and activities, or a small list of quality measures and activities from which clinicians could choose what to report?
- What criteria should be used for determining which measures and activities should be included in an MVP, such as prioritizing outcome, high priority and patient-reported measures; limiting the number of quality measures to four; including only cost measures that align with quality measures; etc.? How should performance categories and associated measures and activities be linked (e.g., quality measures aligned with cost measures)?
- For the quality measures, should clinicians and groups be required to use a certain collection type (eCQMs, MIPS Clinical Quality Measures [MIPS CQMs], CMS Web Interface, or QCDR measures) in order to have a comparable data set in the MVPs? What will clinicians’ administrative burden be for changing to a new, specific collection type for a measure, for example, changing from MIPS CQM to an eCQM?

- Currently there are similar measures addressing the same clinical topic, with different collection types (for example, eCQMs, MIPS CQMs, QCDR measures, etc.) that have different specifications and separate benchmarks. What methodology could be used to develop a single benchmark when multiple collection types are used? Another solution CMS may consider to ensure comparable measure data and request feedback on is to require a single collection type.
- How many improvement activities should be included in an MVP, how much flexibility should there be in selecting improvement activities, and to what extent should improvement activities in MVPs be specialty specific or condition-focused versus focused on other areas relevant to the practice, such as patient experience and engagement, team-based care, and care coordination? For example, should improvement activities in MVPs be restricted to activities directly related to the clinical outcomes of the quality and cost measures in the MVP, for example, IA PM 4 “Glycemic Management Services” for a Diabetes MVP, or should the selection of improvement activities include cross-cutting activities, for example, IA EPA 1 Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record?
  - Should attestation to participation in a specialty accreditation program satisfy the improvement activities performance category requirements for an MVP? CMS is interested in exploring approaches to leverage participation in specialty accreditation programs, such as the American College of Surgeons’ Commission on Cancer accreditation program, since these programs may promote the evaluation and improvement of clinical processes and care. Should this option be available for all MVPs or limited to specific MVPs, such as particular specialties for which accreditation programs are available? What criteria should we use to identify such programs?
- As noted earlier, initially, there would be a uniform set of Promoting Interoperability measures in each MVP. However, CMS believes that eligible clinicians could benefit from more targeted approaches to assessing the meaningful use of health IT and seeks comment on how the Promoting Interoperability performance category could evolve in the future to meet the goal of greater cohesion between the MIPS performance categories. One approach is to explore which Promoting Interoperability measures would be directly aligned with measures in other MIPS performance categories. For instance, many improvement activities are enabled by, or could be enabled by, the use of certified health IT including care coordination and patient engagement through health information exchange. CMS could develop Promoting Interoperability measures which measure the use of health IT in conducting these improvement activities, while relevant quality measures for a given MVP could assess quality outcomes associated with these activities. CMS invites comment on these concepts, as well as other suggestions for how the Promoting Interoperability performance category can be better integrated into MVPs.

#### Transitioning to MVPs

- CMS is interested in feedback on approaches to accelerate the development and implementation of MVPs, as well as any comments on the optimal timeline for transition.
- CMS intends to transition to MVPs beginning with the 2021 MIPS performance period/2023 MIPS payment year. What practice level operational considerations does it need to account for in the timeline for implementing MVPs?

#### Adjusting MVPs for Different Practice Characteristics ([p. 740](#))

##### Small and Rural Practices ([p. 740](#))

Under current quality performance category submission requirements, the same number of measures and activities are reported regardless of group size, which may impose a high burden on small practices, given their very limited resources to address program requirements. Another challenge for small and rural group practices is the lack of a sufficient case mix to report measures that can be reliably scored, which makes the use of a set of administrative claims-based quality and cost measures especially challenging. CMS recognizes that MVP policies

may need to account for these challenges. As CMS moves towards MVPs, it will be evaluating other policies (such as eligibility requirements, including the low-volume threshold, submission requirements, and scoring) for further modification. CMS also intends to adopt policies that reduce barriers for small practices transitioning into APMs where available.

**CMS requests the following comments on policies to support small practices:**

- **How should CMS structure the MVPs to provide flexibility for small and rural practices and reduce participation burden? What MVP related policies could best assist small and/or rural groups when submitting measures and activities? Should CMS have alternate measures and activities submission requirements for small and/or rural practices? For example, should small and/or rural practices be allowed to report fewer measures and activities within an MVP?**
- **How can CMS mitigate challenges small and/or rural practices have in reporting? What types of technical assistance would be most helpful to help small and/or rural practices to have successful participation in MVPs?**
- **How can CMS reduce barriers to small and/or rural groups to transitioning into APMs, such as lack of information on performance on quality and cost measures and limited resources?**
- **What approaches could help small practices transition to MVPs?**

**Multispecialty Practices Participation in MVPs (p. 742)**

At § 414.1305, a group is defined as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. Section 1848(q)(1)(D)(ii) of the Act requires that the MIPS process for assessing group practices must, to the extent practicable, reflect the range of items and services furnished by the MIPS eligible clinicians in the group practice involved. CMS recognizes that multispecialty groups, especially those groups with a large number of clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. CMS also acknowledges ongoing requests from stakeholders to 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.<sup>26</sup>

CMS is interested in using the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. CMS believes this approach could address stakeholder concerns about reporting on meaningful measures, which are related to their practice without adding undue operational and data collection burden associated with creating identifiers for sub-groups. Under this approach, multispecialty groups would report on multiple assigned or selected MVPs, where assignment or selection of MVPs would be proposed in future rulemaking, at the group level. Depending on how the MVPs are then combined and scored at the group level, this may eliminate the need for groups to create sub-TIN identifiers and apply eligibility criteria at the sub-TIN level. If CMS requires reporting on more than one MVP, it may consider putting a cap on the number of MVPs, measures, and activities to ensure there is no undue burden for multispecialty practices.

**CMS seeks comment on its consideration of a requirement in future years that multiple specialty types within a group report relevant MVPs to provide more comprehensive information for patients:**

- **Can CMS use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. For example, would it better for multispecialty groups to report and be scored on multiple MVPs to offer patients a more**

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<sup>26</sup> In the CY 2018 QPP final rule (82 FR 53593), CMS stated that in future rulemaking it intended 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. However, in the CY 2019 PFS final rule (83 FR 597420), CMS did not propose any changes due to operational challenges.

**comprehensive picture of group practice performance or for multispecialty groups to create sub-groups which would break the overall group into smaller units which would independently report MVPs? How should CMS balance the need for information for patients on clinicians within the multispecialty practice with the clinician burden of reporting?**

- **What criteria should be used to identify which MVPs are applicable to multispecialty groups? For example, should it be based on the number or percentage of clinicians from the same specialty in the group? Should a group be able to identify which clinicians will report which MVP?**
- **Should there be a limit on the number of MVPs that could be reported by a multispecialty group?**
- **What mechanisms should be used to assess a group's specialty composition to determine which MVPs are applicable? For example, would groups need to submit identifying information to assure that measure MVPs aligned with the number or percent of clinicians of different specialties within a group? Is there information (such as specialty as identified in PECOS or the specialty reported on claims) CMS could leverage to ensure the appropriateness of MVPs for groups?**
- **Later in this rule, CMS seeks comment on whether to align Shared Savings Program quality reporting requirements and quality scoring methodology with MIPS. As MIPS transitions to MVPs and addresses multispecialty practices, what MVP policies should be applied to MIPS APM participants?**

#### **Incorporating QCDR Measures into MVPs (p. 745)**

CMS continues to believe that participation in QCDR quality improvement programs is a strong sign of a commitment to quality and improvement. At the same time, while this environment has encouraged a flexible approach to quality improvement, CMS believes it has also contributed to confusion and lack of consistency in measurement as the list of MIPS measures is greatly outpaced by the number of QCDR measures. CMS believes that a smaller and more focused set of quality measures assembled into an MVP, integrated with cost measures and improvement activities, will better serve the program by reducing the complexity of identifying how to participate in the program for clinicians, improving CMS' ability to compare clinicians, and improving beneficiaries' ability to identify high quality practices. According to CMS, a proliferation of measures that are different for every modest variation in practice is contrary to such a goal.

#### **CMS requests comments on policies for how QCDR measures would be used in MVPs:**

- **Should QCDR measures be integrated into MVPs along with MIPS measures, or should they be limited to specific MVPs consisting of only QCDR measures? How does CMS continue to encourage clinicians to use QCDRs under MVPs?**

#### **Scoring MVP Performance (p. 747)**

CMS anticipates that its basic approach to scoring measures and activities would remain stable with MVPs (e.g., both quality and cost measures would be scored using a scale of 0 to 10 and performance assessed by comparing to a benchmark, using the current approach to calculate benchmarks). However, CMS may propose scoring changes in future rulemaking. For quality measures, CMS anticipates, when possible, that MVPs would use a single benchmark for each measure and that all clinicians and groups in the MVP would be compared against the same standard. In addition, CMS would no longer need special scoring policies and bonuses to incent selection of certain measures because clinicians would be required to report all measures and activities in the MVP. Finally, CMS could align improvement scoring for quality and cost performance measures, because clinicians would use a stable set of measures, allowing for comparison year-to-year at the measure level. CMS believes the standardized sets of measures in MVPs would enable it to smoothly integrate new measures and collect data to develop robust benchmarks before scoring these measures on performance.

Since small practices will continue to face challenges with meeting case minimums that allow reliable scoring of quality measures, scoring policies will need to taken into account that not all measures reported by small practices can be scored based on the case mix available for reporting.

CMS anticipates that the underlying scoring framework for Improvement Activities and Promoting Interoperability measures would not change with the introduction of the MVP framework. However, scoring policies may be developed as more details of the implementation of MVPs are developed.

***CMS seeks feedback on the following scoring policies:***

- ***What scoring policies can be simplified or eliminated with the introduction of MVPs? For example, CMS may consider eliminating scoring available for 2021 MIPS performance period providing a 3-point floor for each submitted measure that can be reliably scored (83 FR 59842). Additionally, it may consider eliminating the scoring bonuses available for the 2021 MIPS performance period for submitting high-priority measures and use of CEHRT to support quality performance category submissions (83 FR 59850 to 59852). Are there other scoring policies that could be simplified or eliminated?***
- ***CMS would also consider proposing scoring policies to evaluate MVPs holistically, making sure that scoring across MVPs is equitable and that clinicians are not unfairly advantaged by reporting a specific MVP. CMS seeks feedback on scoring policies that will help it create level comparability across MVPs. Are there approaches it should take to create equity across MVPs and across clinician types, for example, that regardless of the number of measures and activity, no single MVP would “outperform” others? For example, should there be an MVP adjustment added to the performance category scores?***
- ***How should CMS score multispecialty groups reporting multiple MVPs? Should scores be consolidated for a single group score or scored separately (and with separate MIPS payment adjustments) for specialists within the group? Alternatively, should CMS have an aggregate score for the multispecialty group?***

**MVP Population Health Quality Measure Set ([p. 749](#))**

CMS plans to increase the use of global and population based administrative claims-based quality measures and outlines a proposal to add at least one additional administrative claims-based quality measure starting in the 2021 MIPS performance period later in this section.

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures, for purposes of the MIPS quality performance category. Currently, the MIPS program has one administrative claims-based quality measure, the all-cause readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum (81 FR 77300).

CMS believes increasing the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of required condition and specialty specific measures would reduce the burden associated with quality reporting, help improve patient outcomes, and increase alignment with APMs and other payer performance measurement. It also has heard from some stakeholders that it should drive quality measurement towards a set of population-based outcome measures. At the same time, CMS recognizes that the use of an administrative claims-based quality measure set would entail certain tradeoffs:

- These measures historically have been applicable to primary care clinicians, with less relevance for some specialists;
- They have been limited to Medicare fee for service patients, excluding other payer patients, and therefore, have not provided a picture of a clinician’s entire practice and patient base; and
- They require a large sample to produce reliable results, which presents challenges in a clinician program that allows for participation by individuals and groups with relatively few patients in a specific measure denominator.

CMS is working on multiple fronts to find the best and most appropriate measures for the MIPS program:

- CMS is working with measure stewards on technical specifications to ensure the measures are reliable and broadly applicable to MIPS eligible clinicians, and it intends to have the measures reviewed by a consensus-based entity (e.g., the National Quality Forum (NQF) Measure Applications Partnership (MAP)).
- CMS is also looking at the use of administrative claims-based quality measures in other programs and models to identify examples of measures that could be included as MIPS measures:
  - The Shared Savings Program currently has a measure ACO–38 All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions, that CMS is in the process of adapting and testing for the MIPS program, and later in this rule proposes to add this measure to MIPS in 2021.
  - CMS is reviewing other measures that it could propose in future rulemaking for MIPS, such as a measure similar to the ACO – 43 Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91), which is currently used in the Shared Savings Program, but recently underwent substantive changes.
  - CMS is also reviewing two risk adjusted utilization measures that are included in the CPC+ Model Quality and Utilization Measure Set for the 2019 Performance Period for potential inclusion in the MIPS program: the HEDIS® Acute Hospital Utilization (AHU) measure (this is the inpatient hospital utilization measure in CPC+ Model that was updated by NCQA in 2018); and the HEDIS® Emergency Department Utilization (EDU).<sup>27</sup> These measures assess the risk-adjusted ratio of observed-to-expected acute inpatient and observation stay discharges during the measurement year reported by surgery, medicine and total among members 18 years of age and older. These measures are currently specified for health plans, but CMS intends to work with the measure steward, NCQA, for appropriateness for the MIPS program.

Clinicians have raised concerns in response to previously proposed administrative claims-based quality measures regarding measure reliability and applicability, case size, attribution, risk adjustment, application at the clinician or group level, and degree of actionable feedback for improvements (81 FR 77130 through 77136). Clinicians have also called for the examination of potential sociodemographic status risk adjustment for administrative claims-based quality measures. CMS clarifies that it is proposing to continue the complex patient bonus in MIPS and would continue to assess the need for and effectiveness of such a scoring adjustment to ensure fair performance comparisons between clinicians.

**CMS requests comments on the following topics related to the use of a population health quality measure set:**

- **In addition to the quality measures described above, are there specific administrative claims-based quality measures that CMS should consider, including, but not limited to, any that assess specialty care that are specified and/or tested at the clinician/group practice level?**
- **CMS would like to balance the desire for quality measures specific to a clinical practice with a reduction in administrative burden for submission. Should administrative claims-based quality measures be used to replace some of the reporting requirements in the quality performance category? For example, if two additional administrative claims-based quality measures were added to MVPs should it reduce the required quality measures by 1 measure for each of the MVPs?**
- **In addition to testing, what other information or methods should be used to mitigate concerns about administrative claims-based quality measure reliability, applicability, and degree of actionable feedback for clinician performance improvement? What concerns should be prioritized?**

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<sup>27</sup> The Acute Hospital Utilization and Emergency Department Utilization measures and specifications were developed by the National Committee for Quality Assurance (“NCQA”) under the Performance Measurements contract (HHSM -500-2006-00060C) with CMS and are included in HEDIS® with permission of CMS.

### Clinician Data Feedback ([p. 755](#))

CMS recognizes the critical need for data feedback and intends to provide enhanced clinician driven data feedback and analysis under the future MVP approach. CMS is interested in whether clinicians would benefit from receiving feedback on administrative data available to CMS, such as information on the services that their patients receive or information on the clinician's volume of services in comparison to their peers to determine if the clinician is an outlier. Clinicians may also benefit from timely actionable clinical data feedback from registries, and CMS proposes to enhance data feedback requirements for QCDRs and registries [later in this rule](#).

#### **CMS seeks comments on the following topics related to clinician feedback:**

- **CMS would like to provide meaningful clinician feedback on administrative claims-based quality and cost measures. As clinicians and groups move towards joining APMs, is there particular data from quality and cost measures that would be helpful?**
- **Would it be useful to clinicians to have feedback based on an analysis of administrative claims data that includes outlier analysis or other types of actionable data feedback? What type of information about practice variation, such as the number of procedures performed compared to other clinicians within the same specialty or clinicians treating the same type of patients, would be most useful? What level of granularity (e.g., individual clinician or group performance) would be appropriate?**
- **CMS understands the need for timely data feedback and seeks comments on clinician data feedback timing needs.**

### Enhanced Information for Patients ([p. 756](#))

#### **Patient Reported Measures ([p. 756](#))**

CMS intends to incorporate more patient reported outcomes and care experience measures into MVPs. The agency wants to learn how patient reported information is being effectively used in the field and cites some current approaches to gathering such information. CMS recognizes current limitations with the availability of patient reported measures. For example, they are often specific to a clinical condition or procedure, and there are currently no such measures applicable to the majority of clinicians in the MIPS program.

#### **CMS requests comments on the best ways to enhance the patient voice in MVPs:**

- **What patient experience/satisfaction measurement tools or approaches to capturing information would be appropriate for inclusion in MVPs? How could current commercial approaches for measuring the customer experience outside of the health care sector (for example, single measures of satisfaction or experience) be developed and incorporated into MVPs to capture patient experience and satisfaction information?**
- **What approaches should CMS take to get reliable performance information for patients using patient reported data, in particular at the individual clinician level? Given the current TIN reporting structure, are there recommendations for ensuring clinician level specific information in MVPs? Should clinicians be incentivized to report patient experience measures at the individual clinician level to facilitate patients making informed decisions when selecting a clinician, and, if so, how?**
- **How should patient-reported measures be included in MVPs? How can the patient voice be better incorporated into public reporting under the MVP framework, in particular at the individual clinician level?**

[Later in this rule](#), CMS also discusses initiatives to expand the information collected in the CAHPS for MIPS survey.

#### **Publicly Reporting MVP Performance Information ([p. 758](#))**

Currently, all MIPS quality measure information is displayed on Physician Compare clinician and group profile pages at the individual quality measure level. User testing with patients and caregivers has shown that

performance on certain individual quality measures is particularly useful for selecting clinicians for their healthcare needs. However, testing has also shown that patients and caregivers are interested in a single overall rating called a “value indicator” for a clinician or group when making comparisons across groups or clinicians. To date, a “value indicator” to compare the performance of a clinician or group has not been possible since clinicians can select from an inventory of measures and are not all reporting on the same quality measures. However, CMS believes that MVPs, in which clinicians of a particular specialty are held accountable for a uniform set of quality and cost measures, would better allow for such comparisons.

**CMS seeks input on approaches to publicly reporting MVP performance information:**

- **What considerations should be taken into account if it publicly reports a value indicator, as well as corresponding measures and activities included in the MVPs?**
- **If CMS develops a value indicator, what data elements should be included? For example, should all reported measures and activities be aggregated into the value indicator?**
- **How would a value indicator, based on information from MVPs, be useful for patients making health care decisions?**
- **What methods of displaying MVP performance information should CMS consider other than its current approach to using star ratings for quality measure information on clinician profile pages?**
- **What factors should be considered to ensure publicly reported MVP information is comparable across relevant clinicians and groups?**

The [Public Reporting on Physician Compare section](#) of this rule includes additional considerations for publicly reporting these types of information such as a value indicator, patient narratives, and patient reported outcome measures.

**Group Reporting (p. 761)**

CMS has noticed that previously established policies for group reporting with regard to the Promoting Interoperability performance category (81 FR 77214 through 77216, 82 FR 53687) are not reflected in the regulation text for group reporting at §§ 414.1310(e)(2)(ii) and for virtual groups at § 414.1315(d)(2). In the CY 2017 Quality Payment Program final rule (81 FR 77215), CMS stated that to report as a group for the Promoting Interoperability performance category, the group will need to aggregate data for all of the individual MIPS eligible clinicians within the group for whom they have data in CEHRT.

***In an effort to more clearly and concisely capture its existing policy for the Promoting Interoperability performance category, CMS proposes to revise §§ 414.1310(e)(2)(ii) and 414.1315(d)(2) to state that individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.***

***Similarly, CMS proposes to revise § 414.1315(d)(2) to state that solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.***

**MIPS Performance Category Measures and Activities (p. 762)**

Quality Performance Category ([p. 762](#))

Contribution to Final Score ([p. 763](#))



CMS previously finalized that the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year and 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

Section 1848(q)(5)(E)(i)(I) of the Act, as amended by the Bipartisan Budget Act, 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 second through fifth years, the Quality category percentage shall be adjusted so that the total percentage points of the adjustment equals the total number of percentage points by which the cost performance category performance percentage is less than 30 percent for the respective year. By the 2022 performance year, both the Quality and Cost category shall represent 30 percent of the MIPS composite score. With this authority, CMS proposes the following:

- ***CMS proposes at § 414.1330(b)(4) that the quality category will comprise 40 percent of a clinician's final score for the 2020 MIPS performance year/2022 payment year;***
- ***CMS proposes at § 414.1330(b)(5) that quality will comprise 35 percent of a clinician's final score for the 2021 performance year/2023 payment year; and***
- ***CMS proposes at § 414.1330(b)(6) that quality will comprise 30 percent of clinician's final score for the 2022 performance year/2024 payment year.***

#### **Quality Data Submission Criteria ([p. 765](#))**

Submission Criteria for Groups Electing to Report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey ([p. 765](#))

CMS is not proposing any changes to the established submission criteria for the CAHPS for MIPS Survey. However, it seeks comment on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level. In regards to narratives, user testing has shown that patients and caregivers regularly request more information from patients like themselves in their own words. CMS believes patient narratives about their health care experiences can provide a valuable complement to standardized survey scores. Including data at the individual level is also of interest to CMS since it has heard this is valuable to patients and caregivers in making decisions related to their health care. [Later in this rule](#), CMS seeks comments on adding patient narratives to the Physician Compare website in future rulemaking.

***CMS seeks comments on seven domains identified in the [President's Management Agenda—OMB Circular No. A-11 section 280—Managing Customer Experience and Improving Service Delivery](#), which discusses how customer experience should be measured in the federal government, and if additional elements, questions, or context should be added to the current CAHPS for MIPS survey. CMS also seeks comment on whether these domains should be used to measure individual clinicians if a new instrument was developed.***

***In preparation for future rulemaking, CMS also seeks comment on:***

- ***Measures that would expand the information collected in the CAHPS for MIPS survey, including a question regarding the patients' overall experience and satisfaction rating with a recent health care encounter. Several versions of the CAHPS survey, including the CAHPS Clinician & Group Survey 3.0, do have a question regarding the patients' rating of a clinician (additional information is available [here](#)).***
- ***Method for collecting this type of information from patients and caregivers and if a web, paper, phone, or email-based survey would be preferred? Currently the CAHPS for MIPS survey is only administered through paper and phone-based methods.***
- ***Should a tool be developed to collect information about individual clinicians? Or should this information be kept at the group level only? Currently patient experience data is only available through the CAHPS for MIPS survey, and this survey does not collect information on individual***

**clinicians. CMS notes that patient experience measures provide a more objective assessment of health care quality, since satisfaction may change frequently based on subjective expectations.**

- **Should this data be collected at a pilot level first, provided that such an approach is consistent with our statutory authority, so that CMS learns from this data before fully implementing broader across the program? If so, CMS seeks comments regarding the framework and implementation criteria of a pilot.**
- **CMS seeks comment on the value of using narrative questions (i.e., inviting patients to respond to a series of questions in free text responding to open ended questions and describing their experience with care in their own words). CMS would build on work done by AHRQ to develop a [Narrative Elicitation Protocol](#), which is a set of open-ended questions that prompt patients to tell a clear and comprehensive story about their experience with a clinician. [Later in this rule](#), CMS seeks comment on how the free text questions might be scored as part of the QPP.**

#### Data Completeness Criteria ([p. 769](#))

For MIPS performance years 2017 and 2018, the data completeness threshold was finalized and retained at 50 percent. CMS then increased the threshold to 60 percent for performance year 2019. In this rule, ***CMS proposes to amend § 414.1340 to increase the data completeness criteria to 70 percent for the 2020 performance year. As such, MIPS eligible clinicians and groups submitting data on QCDR measures, MIPS CQMs, and eCQMS must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2020 MIPS performance period. Those submitting Part B claims measures must submit data on 70 percent of applicable Part B patients.***

CMS believes it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. Based on an analysis of data completeness rates from data submission for the 2017 performance period, as described in [Table 35](#), CMS believes that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold.

**CMS believes it is important to continue to increase the data completeness threshold and is interested in stakeholder feedback on an appropriate incremental approach or other thresholds it should consider.** For instance, CMS also considered a higher threshold, such as 80 percent, but was concerned this would be considered burdensome to clinicians.

In response to concerns about perceived opportunities to selectively submit MIPS data that are unrepresentative of a clinician or group's performance (i.e., "cherry-picking"), ***CMS proposes to further amend § 414.1340 to add a new subsection (d) to clarify that if quality data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete according to § 414.1390(b) or § 414.1400(a)(5).*** CMS believes this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance.

[Table 36](#) describes the data completeness requirements by collection type. CMS is not proposing any changes to the sampling requirements for Web Interface and CAHPS for MIPS survey measures.

#### Selection of MIPS Quality Measures ([p. 772](#))

##### Call for Measures and Measure Selection Process ([p. 772](#))

CMS discusses the current Annual Call for Measures process and notes its intent to continue to submit future MIPS quality measures to a consensus-based entity, as appropriate, and consider the recommendations provided as part of the comprehensive assessment of each measure considered for inclusion in MIPS. CMS also summarizes here the set of factors that stakeholders should consider when submitting quality measures for

possible inclusion in MIPS. ***In addition to these previously finalized considerations, CMS proposes that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards would be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process.***

***CMS also seeks comment as to whether it should consider realigning the MIPS quality measure update cycle with that of the eCQM annual update process.*** The current cycle of measure updates to MIPS quality measures is separate from the [eCQM annual update process](#). If the update cycles were to align, quality measure specifications updates would be gathered earlier in the year, which may pose an issue when considerations need to be given for things like updates to clinical guidelines and changes in NQF endorsement status.

***Proposed changes to quality measures can be found in Appendix 1:***

***Table Group A of Appendix 1: Includes new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years are found in of this rule.***

***Table Group B of Appendix 1: Includes proposals for modifications to existing specialty sets and new specialty sets. CMS notes that all specialty set recommendations submitted for consideration earlier in the year were vetted, and those recommendations that CMS agreed with are being proposed in this rule. Since CMS did not propose any changes to the following specialty measure sets, they are not included in this rule: Pathology, Electrophysiology Cardiac Specialist, and Interventional Radiology.***

***Table Group C of Appendix 1: Includes quality measures proposed for removal in the 2020 performance year and future years. CMS proposes to remove 55 previously finalized quality measures, including 1 measure from the CMS Web Interface.***

***Table Group D of Appendix 1: Includes previously finalized measures with substantive changes for the 2020 performance year.***

***Table Group DD of Appendix 1: Includes previously finalized quality measures with substantive changes proposed for the 2019 performance year and future years. Here, CMS only proposes to update the Web Interface numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention measure. For the 2018 MIPS performance period, CMS is excluding the Web Interface version of this measure from MIPS eligible clinicians' quality scores. Note that changes to the MIPS Web Interface measures would also be applicable to ACO quality reporting under the Medicare Shared Savings Program.***

***Global and Population-Based Measures ([p. 778](#))***

As discussed earlier in regards to the MVP framework, Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the quality performance category. CMS believes that all MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities. CMS also has heard from stakeholders that it should drive quality measurement towards a set of population-based outcome measures to publicly report on quality of care. According to CMS, the use of administrative claims based measures will reduce reporting burden since they are calculated based on data available from clinicians' billings on Medicare Part B claims and do not require separate data submission to CMS.

In [Table Group AA of Appendix 1](#) of this proposed rule, ***CMS proposes the inclusion of a population health-based quality measure, the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure, beginning with the 2021 MIPS performance period.*** The delayed implementation would allow CMS time to work through operational factors, such as allowing for time for the measure to go through the Measures Under Consideration and Measures Application Partnership (MAP) process that is typically applied for all MIPS quality measures.

#### Topped Out Measures (p. 780)

CMS refers readers to the CY 2018 QPP final rule (82 FR 53637 through 53640), where it finalized the 4-year timeline to identify topped out measures, after which it may propose to remove the measures through future rulemaking. CMS also refers readers to the 2019 MIPS Quality Benchmarks' file that is located in the [QPP resource library](#) to determine which measure benchmarks are topped out for 2019 and would be subject to the scoring cap if they are also identified as topped out in the 2020 MIPS Quality Benchmarks' file. Note that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2020 MIPS Quality Benchmarks' file is released in late 2019.

In the CY 2019 PFS final rule (83 FR 59761 through 59763), CMS finalized that once a measure has reached extremely topped out status (e.g., a measure with an average mean performance within the 98th to 100th percentile range), CMS 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. However, CMS would also consider retaining the measure if there are compelling reasons as to why it should not be removed (e.g., 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).

CMS has heard from stakeholders that some measures tend to appear topped out or extremely topped out due to clinicians' ability to select measures they expect to perform well on, and because of this, the data CMS receives is not actually representative of how clinicians perform across the country on these metrics. For this reason, ***CMS seeks comment on whether it should increase the data completeness threshold for quality measures that are identified as extremely topped out, but are retained in the program due to the limited availability of quality measures for a specific specialty. CMS also seeks comment on potential alternative solutions in addressing extremely topped out measures.***

In addition, in the CY 2019 PFS final rule (83 FR 59761 through 59763), CMS also finalized its policy to exclude QCDR measures from the topped out measure timeline. 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.

#### Removal of Quality Measures (p. 782)

*\*Note that the proposals in this section apply to traditional MIPS measures; separate proposals impacting QCDR measures are discussed [later](#) in this summary.*

CMS refers readers to the CY 2019 PFS final rule (83 FR 59763 through 59765) for details on the previously established criteria to remove measures. In addition to previously established measure removal criteria, CMS has observed instances where MIPS quality measures have had low reporting rates year over year, and have made it difficult for some MIPS quality measures to achieve a benchmark. As a result, these measures have resulted in clinicians receiving no more than 3 points for each measure.

CMS believes low reported measures can point to the fact that the measure concept does not provide meaningful measurement to most clinicians. As such, ***CMS proposes to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2***

**consecutive CY performance periods.** CMS believes the 2 year period is appropriate to monitor reporting volumes since any newly finalized measure would need more than 1 CY performance period in order to observe measure reporting trends. CMS will factor in other considerations (such as, but not limited to: the robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome) prior to determining whether to remove the measure, with the caveat that the measure steward should have a plan in place (prior to approval of the measure) to encourage reporting of the measure, such as education and communication or potentially measure specification changes.

**CMS proposes to remove 55 previously finalized measures from MIPS for the 2020 performance year.** See [Table Group C of Appendix 1](#) for a list of quality measures and rationales for removal.

Stakeholders have also expressed the need for more notice before a measure is removed. **CMS is interested in what factors should be considered in delaying the removal of measures. For example, CMS has not heard concerns from stakeholders that selection bias may be impacting low reporting rates and is interested if this is something it should consider, and how it could determine when low-reporting is due to selection bias versus instances where the measure is not a meaningful metric to the majority of clinicians who would have reported on the measure otherwise.**

**CMS also seeks comment on whether it should delay the removal of a specific quality measure by a year and why.**

Finally, it has come to CMS' attention that certain MIPS measure stewards have limited or prohibited the use of their measures by third party intermediaries, such as QCDRs and qualified registries. These limitations may lead to inadvertent increases in burden both for the MIPS eligible clinicians who rely on third party intermediaries and for third party intermediaries themselves. In addition, these limitations may adversely affect CMS' ability to benchmark the measure or the robustness of the benchmark. Thus, **CMS proposes to adopt an additional removal criterion, specifically, that it may consider a MIPS quality measure for removal if it determines it is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians** (CMS describes this in the introduction of this section as "instances where the measure steward or owner refuses to enter into a user agreement with CMS."

[Request for Information on Potential Opioid Overuse Measure \(p. 784\)](#)

To address concerns associated with long-term, high-dose opioids, CMS developed an eQIM titled: [Potential Opioid Overuse](#). The [Potential Opioid Overuse](#) measure captures the proportion of patients aged 18 years or older who receive opioid therapy for 90 days or more with no more than a 7-day gap between prescriptions with a daily dosage of 90 morphine milligram equivalents (MME) or higher. It is intended to report the extent of long-term, high-dose opioid prescribing with the goal of improving patient safety by reducing the potential for opioid-related harms and encouraging the use of alternative pain management. The measure was field tested in 2017, which indicated that this measure is important, feasible, reliable, valid, and usable.

Through interviews primarily with EHR vendors, CMS has identified potential challenges for implementing the Potential Opioid Overuse measure. For example, vendors expressed concerns about the feasibility of accurately capturing some of the medication-specific data elements within the measure, such as medication start and end dates and times, because these are not consistently captured during typical workflows. Also, the human readable CQL-based specification is more than 200 pages long in order to accommodate a library providing more information on opioid medications than is currently available to export for the Value Set Authority Center (VSAC). **CMS seeks to mitigate these usability and feasibility issues by gathering information from a wider audience of technical implementers to strengthen the potential for measure adoption. CMS invites public comment the following questions:**

- **Would you select this measure to support your quality measure initiatives? Why?**

- **Would you implement this measure in its current state? Why?**
- **How can we improve the usability of this measure?**
- **This measure performs medication calculations, to calculate MME, which helps compare different opioids and opioid dosages. Are there any workflow, mapping, or other implementation factors to consider related to the required medication related data elements needed to perform the MME calculations in this measure? Specifically related to: Use of the opioid data library, which clearly lists the required medication information directly in the measure specification; Use of medication end dates, to calculate medication durations; Use of coded medication frequencies, such as “3 times daily” or “every 6 hours,” required to calculate daily medication dosages.**
- **Are there any other foreseeable challenges to implementing this measure?**

### Cost Performance Category ([p. 787](#))

#### Weight in the Final Score ([p. 787](#))

Section 51003(a)(1)(C) of the Bipartisan Budget Act of 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. In the CY 2019 PFS final rule, CMS established that the weight of the cost performance category is 15 percent of the final score for the 2019 performance year (83 FR 59765 through 59766). Taking stakeholder feedback into account, CMS proposes a steady increase in the weight of the Cost category to allow clinicians to adequately prepare for the 30 percent weight while gaining experience with the new cost measures:

- ***CMS proposes at § 414.1350(d)(4) that the cost performance category would make up 20 percent of a MIPS eligible clinician’s final score for the 2020 MIPS performance year;***
- ***CMS proposes at §414.1350(d)(5) to weight the cost category at 25 percent for performance year 2021; and***
- ***CMS proposes at §414.1350(d)(6) to weight the cost category at 30 percent for performance year 2022 and all subsequent MIPS payment years.***

**CMS invites comments on whether it should consider an alternative weight for the 2022 and/or 2023 MIPS payment years.** CMS considered maintaining the weight of the cost performance category at 15 percent for the 2020 and 2021 performance years since it is still introducing new cost and clinicians are still gaining familiarity and experience with these new measures. However, since CMS is required by statute to weight the cost performance category at 30 percent beginning with the 2022 performance year, it is concerned about this significant transition.

### Cost Criteria ([p. 790](#))

#### Attribution ([p. 792](#))

CMS previously adopted the following attribution methodologies:

- **Total per Capita Cost** measure: beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries used in the Shared Savings Program.
- **Medicare Spending Per Beneficiary (MSPB)** measure: an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period
- **Acute Inpatient Medical Condition episode-based measure**: an episode is attributed to each MIPS eligible clinician who bills inpatient 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
- **Procedural episode-based measures**: an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

***In this rule, CMS proposes to change its approach to proposing attribution methodologies for cost measures by including the methodology in the measure specifications.*** For example, CMS has reevaluated the Total Per Capita Cost and MSPB measures and the revised measures proposed in this rule include substantial changes to the attribution methodology. In prior rulemaking, CMS discussed the attribution methodologies for the cost performance category measures in the preamble and included those methodologies in the regulation text. ***However, for the 2020 performance period and going forward, CMS will address attribution as part of the measure logic and specifications.*** The attribution methodology for each cost performance category measure can be found in the measure specifications, which are available for review and public comment [here](#) during the public comment period for the proposed rule, and will be available in final form in the [QPP Resource Library](#) after the final rule is published.

CMS also previously established a final policy to attribute cost measures at the TIN/NPI level, regardless of whether a clinician’s performance for purposes of MIPS is assessed as an individual (the TIN/NPI level) or as part of a group (the TIN level). ***Similar to the attribution methodology for cost measures, CMS proposes to include the level of attribution for each cost performance category measure in the measure specifications for the 2020 performance year and going forward.***

CMS believes this approach is preferable because it would reduce complexity for MIPS eligible clinicians and other stakeholders by presenting the attribution methodology with the rest of the cost measure specifications, ensure non-substantive changes could be implemented without undertaking rulemaking, and align with the approach taken for measures in the quality performance category.

Episode-Based Measures for the 2020 and Future Performance Periods (p. 795)

***Following the successful field testing and review through the MAP process, CMS proposes to add the following 10 episode-based measures as cost measures for the 2020 performance period and future performance periods:***

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

*\*This measure is being proposed only for groups, as discussed below.*

To develop and gather input on these 10 measures, a CMS contractor convened 10 clinical subcommittees composed of more than 260 clinicians affiliated with 120 specialty societies. As with the measures finalized in the CY 2019 PFS final rule (83 FR 59767), the 10 episode-based measures proposed for 2020 also were reviewed by a standing TEP. Further details about the measure development process can be found [here](#). Additional documents, including a field testing feedback summary report and measure justification forms containing test results for each of the measures, can be found [here](#). Detailed specifications for each of the 10 proposed episode-based measures are available for direct download [here](#). More information about the attribution methodology for each measure is available in section A.2 of the methodology documentation.

CMS clarifies that in these episodes, it defines cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts.

Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes ([p. 799](#)) Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders. ***In this section, CMS proposes to revise the operational list beginning with CY 2020 to include the 10 new care episode and patient condition groups, which serve as the basis for the new cost measures proposed in this rule.*** The proposed revisions to the operational list are available [here](#).

Revised Cost Measures ([p. 801](#))

Re-evaluation Process for the Total Per Capita Cost and Medicare Spending Per Beneficiary Clinician Measures ([p. 802](#))

***CMS proposes to modify the Total Per Capita Cost and Medicare Spending Per Beneficiary measures, currently in use under MIPS, based on stakeholder input beginning with the CY 2020 performance year.*** In this section is additional information about the TEP and workgroups that contributed to the refinement of these measures, as well as links to reports summarizing this work and field-testing.

- Total Per Capita Cost Measure ([p. 803](#)): Modifications to this measure address the following concerns about the current version of this measure:
  - The measure's attribution methodology assigned costs to clinicians over which the clinician has no influence, such as costs occurring before the start of the clinician-patient relationship.
  - The attribution methodology did not effectively identify primary care relationships between a patient and a clinician and could potentially attribute beneficiaries to a clinician not responsible for the beneficiaries' primary care.
  - The measure did not account for the shared accountability of clinicians and that attributing costs to a single clinician or clinician group could cause fragmentation of care.
  - The beneficiary risk factors were determined one year prior to the start of the performance period, which would preclude the risk adjustment methodology from reflecting the more expensive treatment resulting from comorbidities and/or complications that might arise during the performance period.

Proposed changes that address these concerns include:

- ***Changing the attribution methodology to more accurately identify a beneficiary's primary care relationships.*** A primary care relationship is identified by a candidate event, defined as the occurrence of an E/M service such as an established patient assisted living visit or an outpatient visit (i.e., the E/M primary care service), paired with one or more additional services indicative of general primary care (e.g., routine chest X-ray, electrocardiogram, or a second E/M service provided at a later date). The candidate event initiates a year-long risk window from the E/M primary care service. Only the portion of the risk window that overlaps with the performance



period, which is divided into 13 four-week blocks called beneficiary-months, is attributable to a clinician for a given performance period. For example, if the risk window were initiated during one MIPS performance period and ends in the following MIPS performance period, only the beneficiary-months that occur during the earlier MIPS performance period would be attributed to the clinician/clinician group to calculate the measure for that particular MIPS performance period. Within an attributed TIN, only the clinician with the TIN/NPI combination performing the highest number of candidate events is attributed the beneficiary-months, since this TIN/NPI combination is deemed to have the most substantive relationship with the beneficiary. More specific examples are provided in this section and in the specifications.

***Changing the attribution methodology to more accurately identify clinicians who provide primary care services, by the addition of service category exclusions and specialty exclusions.*** Specifically, candidate events are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (e.g., global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (e.g., podiatry, dermatology, optometry, ophthalmology). This measure would continue to adjust for specialty to account for variation in cost across clinician specialties and in clinician groups with diverse specialty compositions.

***Changing the risk adjustment methodology to determine a beneficiary's risk score for each beneficiary-month using diagnostic data from the year prior to that month rather than calculating one risk score for the entire performance period using diagnostic data from the previous year.*** This methodology would better account for any changes in the health status of the beneficiary for the duration of a primary care relationship and during the performance period. ***CMS also proposes to add an institutional risk model to improve risk adjustment for clinicians treating institutionalized beneficiaries.***

***Changing the measure to evaluate beneficiaries' costs on a monthly basis rather than an annual basis.*** The performance period during which costs are assessed is divided into 13 beneficiary-months, mentioned earlier, allowing for the measure and the risk adjustment model to reflect changes in patient health characteristics at any point throughout the performance period.

The revised Total per Capita Cost measure underwent MAP review during the 2018-2019 cycle. In December 2018, the MAP Clinician Workgroup gave the preliminary recommendation of 'conditional support for rulemaking,' with the condition of NQF endorsement, but in January 2019, the MAP Coordinating Committee reversed the Clinician Workgroup's preliminary recommendation and provided a final recommendation of "do not support for rulemaking with potential for mitigation" (more details on these mitigating factors is available [here](#)). CMS considered removing the current version of this measure and not proposing a revised measure, but chose against this out of concern that a substantial portion of clinicians would be left with only the MSPB measure, that fewer than half of all clinicians in MIPS meet the case minimum for the MSPB clinician measure, that only a handful of episode-based measures have been developed to date, and that no other cost measure addresses primary care. While CMS recognizes and value the MAP's expressed concerns about the revised measure, CMS believes it has adequately addressed the mitigating factors through the information it has made publicly available (including testing results in the measure justification forms available [here](#)) and discussions with stakeholders at the MAP.

Further details about these proposed changes to the measure, as well as a comparison to the Total Per Capita Cost measure as currently specified, is available in the measure specifications documents available [here](#).

- Medicare Spending Per Beneficiary Clinician Measure (p. 809). Modifications to this measure address the following concerns about the current version of this measure:
  - The attribution methodology did not recognize the team-based nature of inpatient care;
  - The attribution based on the plurality of Part B service costs during index admission could potentially attribute episodes to specialties providing expensive services as opposed to those providing the overall care management for the patient; and
  - The measure captured costs for services that are unlikely to be influenced by the clinician's care decisions.

Proposed changes that address these concerns include:

- ***Changing the attribution methodology to distinguish between medical episodes (where the index admission has a medical MS-DRG) and surgical episodes (where the index admission has a surgical MS-DRG)***. A medical episode is first attributed to the TIN billing at least 30 percent of the inpatient E/M services on Part B physician/supplier claims during the inpatient stay. The episode is then attributed to any clinician in the TIN who billed at least one inpatient E/M service that was used to determine the episode's attribution to the TIN. A surgical episode is attributed to the surgeon(s) who performed any related surgical procedure during the inpatient stay, as determined by clinical input, as well as to the TIN under which the surgeon(s) billed for the procedure. The list of related surgical procedures MS-DRGs may be found in the measure codes list for the revised measure [here](#). This revised methodology accounts for the team-based nature of care provided when managing medical conditions during an inpatient stay and allows for attribution to multiple clinicians to ensure that all clinicians involved in a beneficiary's care are appropriately attributed/
- ***To account for the more limited influence clinicians' performance has on costs when compared with hospitals, CMS proposes to add service exclusions to remove costs that are unlikely to be influenced by the clinician's care decisions***. Specifically, CMS would exclude unrelated services specific to groups of MS-DRGs aggregated by major diagnostic categories (MDCs) (e.g., orthopedic procedures for episodes triggered by MS-DRGs under Disorders of Gastrointestinal System (MDC 06 and MDC 07)).
- ***CMS also proposes to modify the measure title from Medicare Spending Per Beneficiary (MSPB) to Medicare Spending Per Beneficiary clinician (MSPB clinician) to distinguish it from measures with similar names in use in other CMS programs***.

Further details about these proposed changes, including a comparison to the current version of this measure, is available [here](#). A measure justification form containing testing results for this measure with the proposed revisions can be downloaded [here](#).

#### Reliability (p. 812)

##### *Episode-Based Cost Measures*

CMS examined the reliability of the proposed 10 episode-based measures at its established case minimums and found that all meet the reliability threshold of 0.4 for the majority of groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. All of the proposed measures meet this standard at the individual clinician level as well, with the exception of the Lower Gastrointestinal Hemorrhage episode-based measure. [Table 38](#) lists these results.

***Since the Lower Gastrointestinal Hemorrhage measure does not meet CMS' reliability threshold for individual***

**reporting, CMS proposes to CMS proposes to limit its assessment of this cost measure to clinicians who report as a group or virtual group.**

#### *Revised Cost Total Per Capita Cost and Medicare Spending Per Beneficiary Measures*

CMS examined the reliability of the three revised measures and found that the measures meet CMS' reliability threshold of 0.4 for the majority of clinicians and groups at the existing case minimums, as shown in [Table 39](#). Based on this analysis, CMS is not proposing any changes to the case minimums, which we previously finalized as 35 for the [MSPB clinician measure](#), and 20 for the [Total Per Capita Cost measure](#).

#### Request for Comments on Future Potential Episode-Based Measure for Mental Health (p. 815)

**CMS seeks to expand the range of procedures and conditions captured by episode-based cost measures and seeks comment on the potential future use of a new Psychoses/Related Conditions episode-based measure.**

This acute inpatient medical condition episode-based measure evaluates costs for the treatment of inpatient psychoses and related conditions and, according to CMS, was developed through the same process involving extensive expert clinician input as other measures proposed in this rule. Additional details about this measure are discussed in this section. Specifications are available [here](#).

#### Summary of Previously Established and Proposed Measures for the Cost Performance Category for the 2020 and Future Performance Periods (p. 819)

[Table 40](#): Lists Cost Measures for the 2020 Performance Period and Future Performance Periods

#### Improvement Activities Performance Category (p. 821)

##### **Small, Rural, or Health Professional Shortage Areas Practices (p. 821)**

In the CY 2018 QPP final rule (82 FR 53581 through 53582), CMS changed the definition of rural area to mean ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available. ***CMS inadvertently references the incorrect file name in the current definition and proposes to modify the definition of rural area at § 414.1305 to mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.***

To be clear, CMS has been using the more appropriate FORHP eligible ZIP code file in all previous three years of MIPS. The definition of "rural" in MIPS is based on the rural definition developed by HRSA's FORHP which may be found [here](#). The FORHP defines all non-Metro counties as rural and uses an additional method of determining rurality called the Rural-Urban Commuting Area (RUCA) codes. The FORHP eligible ZIP codes are available in a file located [here](#).

##### **Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organizations (p. 823)**

In the CY 2017 QPP final rule (81 FR 77179 through 77180), CMS finalized an expanded definition of what is acceptable for recognition as a certified-patient-centered medical home or comparable specialty practice. The finalized criteria include:

- Whether the practice has received accreditation from one of four accreditation organizations that are nationally recognized: (1) the Accreditation Association for Ambulatory Health Care; (2) the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home; (3) the Joint Commission Designation; or (4) the Utilization Review Accreditation Commission (URAC).
- The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

- The criteria for being a nationally recognized accredited patient-centered medical home are that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home.

***CMS proposes to remove the references to the four listed accreditation organizations in order to be recognized as patient-centered medical homes and to remove the reference to the specific accrediting organization for comparable specialty practices.*** It was and is not CMS' intention to limit patient-centered medical home or comparable specialty practice accreditation organizations to those listed.

#### **Improvement Activities Data Submission ([p. 824](#))**

In the CY 2017 QPP final rule (81 FR 77181), CMS clarified that if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period, the group may report on that activity. In addition, CMS specified that all MIPS eligible clinicians reporting as a group would receive the same score for the improvement activities performance category if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period. In the CY 2018 QPP proposed rule (82 FR 30053), CMS sought feedback on whether CMS should establish a minimum threshold of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (TIN) to receive credit in the improvement activities performance category in future years.

***In this rule, CMS proposes to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent beginning with the 2020 performance year and future years.*** If finalized, this change would have no impact on policy that eligible clinicians participating in an APM will receive full points for the improvement activities performance category as discussed in the CY 2017 QPP final rule (81 FR 77258 through 77260). CMS believes a 50 percent threshold is appropriate because by Year 4 (2020 performance year) of the QPP, clinicians should be familiar with the improvement activities category; selected activities should be adopted throughout much of the practice in order to improve clinical practice, care delivery, and outcomes; and that increasing this threshold will not present additional complexity and burden for a group since there are range of activities to choose from. CMS also considered higher (100 percent) and lower (25 percent) thresholds, but decide 50 percent was both achievable and appropriate and aligns with the threshold for the number of practice sites that must be recognized for a TIN to receive full credit as a patient-centered medical home.

***CMS also proposes that at least 50 percent of a group's NPIs must perform the same activity for the same continuous 90 days in the performance period beginning with the 2020 performance year.*** CMS believes this would facilitate improvement in clinical practice within a TIN.

To be clear, other submission requirements would remain the same. In other words, each TIN would need to submit an attestation for each improvement activity selected that at least 50 percent of its NPIs performed the same activity for the same continuous 90 days in the performance period.

#### **Improvement Activities Inventory ([p. 828](#))**

##### Factors for Consideration in Removing Improvement Activities

***CMS proposes to establish the following factors for consideration when proposing the removal of as improvement activity:***

- ***Factor 1: Activity is duplicative of another activity;***
- ***Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice;***
- ***Factor 3: Activity does not align with current clinical guidelines or practice;***
- ***Factor 4: Activity does not align with at least one meaningful measures area;***

- **Factor 5: Activity does not align with the quality, cost, or Promoting Interoperability performance categories;**
- **Factor 6: There have been no attestations of the activity for 3 consecutive years; or**
- **Factor 7: Activity is obsolete**

CMS believes that having factors to consider in removing improvement activities would provide transparency and alignment with the factors for removal of quality measures. CMS understands that many practices may have made financial investments to perform these activities, but believes that over time, certain improvement activities should be considered for removal to ensure the list is robust and relevant. CMS will fully examine each activity prior to removal and notes that the removal factors are not firm requirements, but considerations it will take into account when making these decisions.

#### New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

**CMS proposes to remove 15, modify seven, and add two new improvement activities for the 2020 performance period and future years, contingent on the proposed removal factors being finalized.** Some of these changes aim to consolidate duplicative activities.

**CMS also proposes to add two new improvement activities for the 2020 performance period and future years. See [Appendix 2](#) for a list of these proposed changes.**

#### **CMS Study on Factors Associated with Reporting Quality Measures ([p. 832](#))**

Starting in CY 2017, this annual study, which aimed to evaluate clinical improvement activities and measurement among a range of practice types to examine clinical quality workflows and data capture, was slated for a minimum period of 3 years. CMS believes by the end of 2020, it will have accrued the minimum data needed for the analysis to achieve the study goals. Therefore, **CMS proposes to end this study and concurrently, remove the incentive under the improvement activity performance category that this study provided for study participants.**

CMS next plans to analyze the data gathered over the 3 study years and to make recommendations to improve outcomes, reduce burden, and enhance clinical care. It plans to finish this analysis by Spring 2020. CMS will conduct outreach and education to inform the public of this analysis. CMS will then shift its focus to implementation of recommendations.

#### Promoting Interoperability ([p. 835](#))

##### **Background ([p. 835](#))**

Section 1848(q)(2)(A) of the Act includes the meaningful use of Certified Electronic Health Record Technology (CEHRT) as a performance category under the MIPS.

##### **Goals of Proposed Changes to the Promoting Interoperability Performance Category ([p. 836](#))**

The general goals of CMS' proposals related to this category are:

- A priority of stability within the performance category after the recent changes made in the CY 2019 PFS final rule (83 FR 59785 through 59820) while continuing to further interoperability through the use of CEHRT;
- Reducing administrative burden;
- Continued use of the 2015 Edition CEHRT;
- Improving patient access to their EHRs so they can make fully informed health care decisions; and
- Continued alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate

### **Promoting Interoperability Performance Category Performance Period ([p. 836](#))**

As finalized in the CY 2019 PFS final rule, for the 2020 MIPS performance year, the performance period for the Promoting Interoperability performance category is 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 2021 performance year, CMS proposes to maintain this criteria by establishing a performance period of a minimum of a continuous 90-day period within CY 2021, up to and including the full calendar year.***

### **Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians ([p. 837](#))**

***[Table 41](#) lists the objectives and measures for the Promoting Interoperability category for the 2020 performance period as revised to reflect the proposals made in this rule and summarized below.***

#### **Proposed Changes to Measures for the e-Prescribing Objective ([p. 837](#))**

Beginning with the MIPS performance period in 2019, CMS adopted two new measures for the e-Prescribing objective that are based on electronic prescriptions for controlled substances:

1. Query of Prescription Drug Monitoring Program (PDMP), which is optional and available for bonus points for 2019 (83 FR 59800 through 59803); and
2. Verify Opioid Treatment Agreement (83 FR 59803 through 59806).

Per the discussion below, CMS proposes changes to these measures. The main catalyst for these proposals was stakeholder feedback, but also passage of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-271), which may significantly affect the maturation, requirements, and use of PDMPs and State networks upon which the Query of PDMP measure is dependent.

#### ***Query of Prescription Drug Monitoring Program (PDMP) Measure ([p. 839](#))***

When CMS made this measure optional for 2019, it also allowed for flexibility to query the PDMP in any manner allowed under their State law. However, CMS received substantial feedback from health IT vendors and specialty societies that this flexibility presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it, and that it is premature to require this measure in 2020. In addition, there is considerable variation among state PDMP programs as many only operate within a state and are not linked to larger systems. Furthermore, there are challenges posed by the current lack of integration of PDMPs into the EHR workflow and wide variation in whether PDMP data can be stored in the EHR.

***In response to this feedback, CMS proposes to make the Query of PDMP measure optional and eligible for 5 bonus points for the Electronic Prescribing objective in CY 2020. In the event that CMS finalizes this proposal, the e-Prescribing measure would be worth up to 10 points in CY 2020.***

***CMS also proposes to remove the numerator and denominator for the Query of PDMP measure and instead require a “yes/no” response beginning in CY 2019.*** CMS proposes this change to reduce clinician burden since there are currently not standards-based interfaces between CEHRT and PDMPs and clinicians must manually track the number of times that they query a PDMP outside of CEHRT. A “yes” response would indicate that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. Since this measure would be optional, there are no exclusions.

***CMS welcomes comments on future timing for requiring a measure that includes EHR PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder especially in relation to the requirements of the SUPPORT Act.***

Overall, CMS envisions a future state where PDMP data is integrated into the clinical workflow and where clinicians do not have to access multiple systems to find and reconcile the information. CMS clarifies that ONC is currently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. As mentioned earlier, the SUPPORT Act also includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers. These provisions and other efforts, including a collaboration between the ONC and CDC, are discussed in more detail in this section. CMS also anticipates working closely with the Drug Enforcement Administration (DEA) on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances, which may include the definition of a value set related to such measures.

#### *Verify Opioid Treatment Agreement Measure (p. 847)*

In the CY 2019 PFS final rule (83 FR 59803 through 59806), CMS finalized the Verify Opioid Treatment Agreement measure as optional in both CYs 2019 and 2020. Since that time, CMS has received feedback from stakeholders that this measure has presented significant implementation challenges and an increase in burden, and does not further interoperability. Concerns include: a lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid treatment agreements and how this impacts verifying whether there is an agreement; how to calculate 30 cumulative days of opioid prescriptions in a 6-month period; concerns over which medications should be used to determine the 30-cumulative day threshold; and concern that CMS' lack of definition and standards around what would constitute an opioid treatment agreement has created an unintended burden.

***Since the challenges described above result in a measure that is vague, burdensome to measure and does not necessarily offer a clinical value to the health care providers or support the clinical goal of supporting opioid use disorder (OUD) treatment, CMS proposes to remove the Verify Opioid Treatment Agreement measure beginning in CY 2020.***

#### *Health Information Exchange Objective (p. 849)*

*Proposed Modification of the Support Electronic Referral Loops by Sending Health Information Measure*  
***CMS proposes to redistribute the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed, beginning with performance year 2019.*** CMS had previously finalized an exclusion for this measure, but had not proposed a redistribution policy.

#### *Modification of the Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure*

In the CY 2019 PFS final rule, CMS established the following exclusion for this measure: "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" (83 FR 59812). CMS is concerned this language could be read to create two different sets of exclusion criteria—receiving fewer than 100 transitions of care or referrals; or having fewer than 100 encounters with patients never before encountered— which was not its intention. CMS' intention was that a combination of the two criteria must occur fewer than 100 times during the performance period for the exclusion to be applicable to a MIPS eligible clinician.

***To clarify this exclusion, CMS proposes to revise the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion, beginning with the 2019 performance year, to read: "Any MIPS eligible clinician who receives transitions of care or referrals or has patient***

**encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.”** For example, during the performance period, if a clinician received 50 transitions of care, 50 referrals, and 50 patient encounters in which they have never before encountered the patient, the total sum of 150 would be above the threshold of fewer than 100 times, and therefore the clinician would not be eligible for this exclusion.

#### Scoring Methodology ([p. 857](#))

***Table 42 summarizes the proposed scoring methodology for the Promoting Interoperability measures in performance year 2020.*** Note that the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

#### Additional Considerations ([p. 858](#))

##### Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists ([p. 858](#))

CMS previously established a policy for performance periods 2017, 2018 to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. This policy was instituted to 1) recognize that these types of MIPS eligible clinicians may lack experience with the adoption and use of CEHRT and 2) the fact that CMS has little evidence as to whether there are sufficient measures applicable to these types of clinicians under the Promoting Interoperability category since many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program. Under current policy, CMS 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 category, but if they choose to report, they will be scored on the Promoting Interoperability category like all other MIPS eligible clinicians.

***CMS proposes to continue the existing policy of reweighting the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians for the performance period in 2020.*** CMS analyzed data from 2017, and concluded that it is unable to determine at this time whether the Promoting Interoperability measures specified for the 2020 performance period are applicable and available for NPs, PAs, CRNAs, and CNSs. However, as more data beyond this first year become available, CMS plans to reevaluate the measures and consider how it could ensure that there are sufficient measures applicable and available for these types of MIPS eligible clinicians.

##### Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered Dietitians or Nutrition ([p. 860](#))

In the CY 2019 PFS final rule, CMS decided to apply the same policy it adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 - 2019 to these new types of MIPS eligible clinicians for the performance period in 2019.

***CMS proposes to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dietitians or nutrition professionals for the performance period in 2020.***

##### Hospital-Based MIPS Eligible Clinicians in Groups ([p. 861](#))

CMS defines a hospital-based MIPS eligible clinician under § 414.1305 as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of services identified by the Place of Service (POS) codes as an inpatient hospital (POS 21), on campus outpatient hospital (POS 22), off campus



outpatient hospital (POS 19), or emergency room (POS 23) setting, based on claims for the MIPS determination period (81 FR 77238 through 77240, 82 FR 53686 through 53687, 83 FR 59727 through 59730). A MIPS eligible clinician who is a hospital-based MIPS eligible clinician will be assigned a zero percent weight for the Promoting Interoperability category, and the points associated with the Promoting Interoperability category will be redistributed to another performance category or categories. However, if a hospital-based MIPS eligible clinician chooses to report on the Promoting Interoperability measures, they will be scored on the Promoting Interoperability category like all other MIPS eligible clinicians.

For groups reporting on the Promoting Interoperability category, CMS previously stated that group data should be aggregated for all MIPS eligible clinicians within the group (81 FR 77214 through 77216, 82 FR 53687). This includes those MIPS eligible clinicians who may qualify for a zero percent weighting of the Promoting Interoperability category due to circumstances such as a significant hardship or other type of exception, hospital-based or ASC-based status, or certain types of non-physician practitioners. CMS established at § 414.1380(c)(2)(iii) that for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability category to be reweighted, all (i.e., 100 percent) of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting (82 FR 53687, 83 FR 59871). However, CMS has heard from several stakeholders that this policy sets a threshold that is too restrictive.

***In response, CMS proposes to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. CMS proposes that, beginning with the 2020 performance year, a hospital-based MIPS eligible clinician means an individual 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 as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. CMS believes the 75 percent threshold is appropriate since it is consistent with the thresholds for groups in the definitions of facility-based MIPS eligible clinician and non-patient facing MIPS eligible clinicians.***

***CMS also proposes to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician (or the definition of a non-patient facing MIPS eligible clinician, as proposed in the next section).***

#### Non-Patient Facing MIPS Eligible Clinicians in Groups (p. 863)

CMS defines a non-patient facing MIPS eligible clinician under § 414.1305 as an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician. A MIPS eligible clinician who is a non-patient facing MIPS eligible clinician will be assigned a zero percent weight for the Promoting Interoperability category, and the points associated with that category will be redistributed to another performance category or categories (81 FR 77240 through 77243, 82 FR 53680-53682, 83 FR 59871). However, if a non-patient facing MIPS eligible clinician chooses to report on the Promoting Interoperability measures, they will be scored on the category like all other MIPS eligible clinicians. This policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

***In an effort to more clearly and concisely capture its existing policy for non-patient facing MIPS eligible clinicians, CMS proposes to revise § 414.1380(c)(2)(iii) to also account for a group or virtual group that meets***

*the definition of a non-patient facing MIPS eligible clinician under § 414.1305, such that the group or virtual group only has to meet a threshold of more than 75 percent.*

**Future Direction of the Promoting Interoperability Performance Category ([p. 865](#))**

CMS seeks input on the future direction of this category through multiple RFIs:

RFI on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category ([p. 865](#))

**CMS seeks comment on potential new measures for OUD prevention and treatment that could be included in future years of the Promoting Interoperability category and that include the following characteristics:**

- **Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;**
- **Leverage the capabilities of CEHRT where possible, including: near-automatic calculation and reporting of numerator, denominator, exclusions and exceptions to minimize manual documentation required of the provider; and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;**
- **Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD-10 or CPT;**
- **Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider;**
- **Are applicable to all clinicians (e.g., clinicians participating as individuals or as a group, or clinicians located in a rural area, designated health professional shortage area (HPSA), designated medically-underserved area (MUA), or urban area);**
- **Could potentially align with other MIPS performance categories; and**
- **Are represented by a measure description, numerator/denominator or yes/no attestation statement, and possible exclusions**

RFI on NQF and CDC Opioid Quality Measures ([p. 867](#))

**CMS seeks public comment on the development of potential measures for consideration for the Promoting Interoperability category that are based on existing measures, including the opioid quality measures endorsed by the National Quality Forum (NQF) and the CDC Quality Improvement (QI) opioid measures discussed below. CMS believes that the clinical actions identified within these measures can be supported by the standards and functionalities of certified health IT. At the same time, it recognizes that modifications to the NQF and CDC measures may be necessary to make the measures as applicable as possible to all participants and seeks comment on any modifications that would be necessary. In addition, there is some overlap between these measures, and CMS seeks comment on whether there are ways in which the two sets of measures could be correlated to support potential new measures. Finally, CMS seeks comment on which measures might best advance the implementation and use of interoperable health IT and encourage information exchange between care teams and with patients.**

- **NQF Quality Measures:** The following three NQF-endorsed quality measures, stewarded by the Pharmacy Quality Alliance (PQA), evaluate patients with prescriptions for opioids in combination with benzodiazepines, at high-dosage, or from multiple prescribers and pharmacies. These three measures were also recommended by the MAP for inclusion on the December 2018 Measures Under Consideration List for the Medicare Shared Savings Program.
  - Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)

- [Use of Opioids from Multiple Providers in Persons Without Cancer \(NQF #2950\)](#)
- [Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer \(NQF #2951\)](#)

Additional information regarding each measure can be found using [NQF's Quality Positioning System](#).

- **CDC Quality Improvement (QI) Opioid Measures.** The CDC developed 16 QI opioid measures to align with the recommendations in the "[CDC Guideline for Prescribing Opioids for Chronic Pain](#)" and to improve opioid prescribing. These measures are found in Appendix B of the CDC document "[Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain](#)." These measures address treatment guidelines for both initial/short term prevention and treatment practices (e.g., #2: [Check PDMP Before Prescribing Opioids](#); #4: [Evaluate Within Four Weeks of Starting Opioids](#)), as well as long-term treatment and outcomes (e.g., # 11: [Check PDMP Quarterly](#); #12: [Counsel On Risks and Benefits Annually](#)). The data sources from these measures include State PDMP data or the practice EHR data field. CMS notes that the CDC and the Agency for Healthcare Research and Quality are also developing electronic clinical decision support tools which can provide real-time clinical decision support (CDS) for some of the best practices included in the Implementing the CDC Prescribing Guideline document.

***CMS seeks comment on which of the 16 CDC QI opioid measures have value for potential consideration for the Promoting Interoperability category. CMS also seeks comment on whether it should consider a different type of measurement concept for OUD prevention and treatment, such as reporting on a set of cross-cutting activities and measures to earn credit in the Promoting Interoperability category (e.g., set of one clinical decision support, the related CDC QI opioid measure, and a potentially relevant clinical quality measure). While the CDC quality measures could be implemented for the Quality category, they are highlighted as under consideration for the Promoting Interoperability category as they have been linked in the CDC work to the use of clinical decision support artifacts through health IT).***

#### RFI on a Metric to Improve Efficiency of Providers within EHRs (p. 872)

Despite the benefits of EHRs, research also points to variable results from the implementation of health IT across practice settings, suggesting health IT adoption is not a universal remedy for inefficient practice. Stakeholders continue to describe ways in which the potential benefits of EHRs have not been fully realized, pointing to non-optimized electronic workflows and poor system design that can increase rather than reduce administrative burden, contributing to physician burnout.

In 2017, the NQF released "[A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy](#)," which included a discussion of measure concepts of productivity and efficiency, which can result from the use of health IT. For example, the report identifies a measure concept for the "percentage of reduction of duplicate labs and imaging over time." However, CMS recognizes that there are challenges associated with tying such measures of economic efficiency to a single factor such as electronic workflow improvements. In November 2018, ONC released the draft report "[Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs](#)," which describes a variety of factors that may contribute to EHR-related burden, and provides draft recommendations for how HHS and other stakeholders may be able to address these factors.

**With these recommendations in mind, CMS seeks feedback on a potential metric to evaluate health care provider efficiency using EHRs under the Promoting Interoperability Program. Specific questions include:**

- **What are useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be**

linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or “yes/no” reporting, and exclusions.

- What do stakeholders believe may be hindering their ability to achieve greater efficiency (e.g., product, measures, CMS regulations)? Please, provide examples.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could we reward health care providers for adoption and use of these technologies?
- What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could CMS measure and reward health care providers for uptake of more efficient electronic workflows?
- Could CMS successfully incentivize efficiency? What role should CMS play in improving efficiency in the practice of medicine? The underlying goal is to move to a more streamlined, efficient, easier user experience, whereby providers can input and access a patient’s data in a reliable, timely manner. CMS seeks feedback on the best way(s) to get there.

RFI on the Provider to Patient Exchange Objective ([p. 875](#))

In the CY 2019 PFS proposed rule (83 FR 35932), CMS introduced a potential future Promoting Interoperability concept that explored creating a set of priority health IT activities that could serve as alternatives to the traditional Promoting Interoperability Program measures. One such activity that CMS requested comment on was a health IT activity in which MIPS eligible clinicians could obtain credit in the Promoting Interoperability category if they maintain an “open API,” or standards-based API, which allows patients to access their health information through a preferred third-party application.

ONC’s 21st Century Cures Act proposed rule (84 FR 7424 through 7610) includes new proposals that focus on how certified health IT can use APIs to allow health information to be accessed, exchanged, and used without special effort. For instance, ONC has proposed to adopt a new criterion for a standards-based API that would replace the existing API criterion with one that requires the use of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard. ONC has proposed to make the standards-based API criterion part of the 2015 Edition base EHR definition, which would ensure that this functionality is ultimately included in the CEHRT definition required for participation in the Promoting Interoperability Program. If finalized, ONC has proposed that health IT developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products.

CMS’ Interoperability and Patient Access proposed rule (84 FR 7610 through 7680) would also require certain health plans and payers to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer.

#### *Immediate Access*

The existing [Provide Patients Electronic Access to Their Health Information](#) measure specifies that the MIPS eligible clinicians provide the patient timely access to view online, download, and transmit his or her health information, and further specifies that patient health information must be made available to the patient within 4 business days of its availability to the MIPS eligible clinicians. **Recognizing the importance of patients having access to their complete health information, including clinical information from the MIPS eligible clinicians’ CEHRT, and appreciating the new technical flexibility a standards-based API provides, CMS seeks comment on whether MIPS eligible clinicians should make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the MIPS eligible clinician in their CEHRT. It also seeks comment on the barriers to more immediate access to patient information, and**

**whether there are specific data elements that may be more or less feasible to share no later than one business day. Finally, CMS seeks comment as to when implementation of such a requirement is feasible.**

#### *Persistent Access and Standards-based API.*

In ONC's 21st Century Cures Act proposed rule (84 FR 7481 through 7484) there is a proposal regarding requirements around persistent access to APIs, which would accommodate a patient's routine access to their health information without needing to reauthorize their app and re-authenticate themselves. The existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information (e.g., the measure only specifies that access must be "timely"). **CMS seeks comment on whether the Promoting Interoperability performance category measure should be updated to accommodate this proposed technical requirement for persistent access. Also, if ONC's proposal for a FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability Program for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?**

#### *Available Data*

In the 21st Century Cures Act proposed rule (84 FR 7424 through 7610), ONC has proposed to adopt a new 2015 Edition certification criterion for the Electronic Health Information (EHI) export. The purpose of this criterion is to provide patients and health IT users the ability to securely export the entire EHR for a single patient, or all patients, in a computable, electronic format, and facilitate receiving the health IT system's interpretation, and use of the EHI using the existing technology of developers. **Building on these proposals, CMS seeks comment on alternative measures under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR:**

- **Do stakeholders believe that incorporating this alternative measure will be effective in encouraging the availability of all data stored in health IT systems?**
- **In relation to the Provider to Patient Exchange objective as a whole, how should a measure focused on using the proposed total EHI export function in CEHRT be scored?**
- **If this certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?**
- **In the long term, how do stakeholders believe such an alternative measure would impact burden?**
- **If stakeholders do not believe this will have a positive impact on burden, in what other way(s) might an alternative measure be implemented that may result in burden reduction? Please be specific.**
- **Which data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?**

#### **CMS also poses some general questions related to health IT activities:**

- **Do stakeholders believe that CMS should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long term care, behavioral health, and home and community-based services to promote better care coordination for patients with chronic conditions and complex care needs? If so, what criteria should CMS consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability Program?**
- **What criteria should CMS employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the program?**

- **Are there additional health IT activities CMS should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?**

#### *Patient Matching*

Per Congress’s guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a unique patient identifier (UPI). **Similar to the CMS and ONC Interoperability proposed rules, CMS seeks comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. CMS also seeks comment on how it may leverage our authority to provide support to those working to improve patient matching.**

- **Do stakeholders believe that CMS and ONC patient matching efforts impact burden? Please, explain.**
- **If stakeholders believe that patient matching is leading to increased burden, what suggestions might stakeholders have to promote interoperability securely and accurately, without the requirement of a UPI, that may result in burden reduction? Please, be specific.**

**CMS notes that it intends to use comments it receives for the development of policy and future rulemaking.**

#### RFI on the Integration of Patient- Generated Health Data into EHRs Using CEHRT (p. 884)

Increasingly affordable wearable devices, sensors, and other technologies capture patient-generated health data (PGHD), providing new ways to monitor and track a patient's healthcare experience between medical visits, which could help improve care management and patient outcomes, potentially resulting in increased cost savings. Although many types of PGHD are being used in clinical settings today, the continuous collection and integration of patients’ health-data into EHRs to inform clinical care has not been widely achieved across the health care system.

In the 2015 Edition Health IT Certification Criteria final rule (80 FR 62661; 45 CFR 170.315(e)(3), ONC finalized a criterion for patient health information capture functionality within certified health IT that allows a user to identify, record, and access information directly and electronically shared by a patient. CMS also finalized a PGHD measure requiring health care providers to incorporate patient generated health data or data from a nonclinical setting into CEHRT (80 FR 62851). However, CMS removed this measure in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41663 through 41664), due to concerns that the measure was not fully health IT-based and could include paper-based actions. CMS also points to a 2018 white paper released by ONC, “[Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024](#),” which describes key challenges, opportunities and enabling actions for different stakeholders, including clinicians, to advance the use of PGHD.

**In light of these activities and findings, CMS is interested in ways that the Promoting Interoperability Program could adopt new elements related to PGHD that represent clearly defined uses of health IT, are linked to positive outcomes for patients, and advance the capture, use, and sharing of PGHD.** CMS clarifies that a future program element related to PGHD would not necessarily need to be implemented as a traditional measure requiring reporting of a numerator and denominator, as a way to potentially reduce the reporting burden.

**Specific questions include:**

- **What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.**
- **Should the Promoting Interoperability Program explore ways to include bonus points for health care providers engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?**

- **Should providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?**
- **Should the Promoting Interoperability Program explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?**

CMS believes the bi-directional availability of data, meaning that both patients and their health care providers have real-time access to the patient's EHR, is critical. This includes patients being able to import their health data into their medical record and have it be available to health care providers. **CMS welcomes input on how it can encourage and enable health care providers to advance capture, exchange, and use of PGHD.**

RFI on Engaging in Activities that Promote the Safety of the EHR (p. 888)

Recognizing that risks to patient safety are one of the unintended consequences that may result from implementation of EHRs, **CMS seeks comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, CMS seeks feedback on ways that the Promoting Interoperability category may reward MIPS eligible clinicians for engaging in activities that can help to reduce errors and other patient safety issues associated with EHR implementation.**

**For instance, CMS requests comment on a potential future change to the performance category under which MIPS eligible clinicians would receive points towards their Promoting Interoperability category score for attesting to performance of an assessment based on one of the [ONC SAFER Guides](#).** The SAFER Guides are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs in nine different areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry, Test Results Reporting and Follow-Up, and Clinician Communication. According to CMS, each of the SAFER Guides is based on the best evidence available, including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems. A number of EHR developers currently utilize the SAFER Guides as part of their health care provider training modules. CMS might consider offering points towards the Promoting Interoperability category to MIPS eligible clinicians who attest to conducting an assessment the [High Priority Practices](#) and/or the [Organizational Responsibilities](#) SAFER Guides, which cover many foundational concepts from across the guides. Alternatively, CMS might consider awarding points for review of all nine of the SAFER Guides. **CMS also invites comments on alternatives to the SAFER Guides, including appropriate assessments related to patient safety, which should also be considered as part of any future bonus option.**

**APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs (p. 891)**

Overview (p. 891)

In the CY 2017 QPP rule, CMS finalized the APM scoring standard, which is designed to reduce reporting burden for participants in MIPS 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. CMS previously established that:

- The MIPS performance period applies for the APM scoring standard.
- The MIPS final score calculated for the APM entity is applied to each MIPS eligible clinician in the APM Entity
- The MIPS payment adjustment is applied at the TIN/NPI level for each MIPS eligible clinician in the APM Entity group
- The MIPS final score under the APM scoring standard is comprised of the four MIPS performance categories, which are weighted as follows:
  - Quality: 50 percent

- Cost: 0 percent
- Improvement activities: 20 percent
- Promoting interoperability: 30 percent

### MIPS APM Criteria ([p. 891](#))

CMS established 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 on quality measures and cost/utilization; 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.

CMS also clarified that that CMS considers whether each distinct track of an APM meets the criteria 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. CMS also clarified that it considers 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.

Based on the MIPS APM criteria, CMS expects that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period:

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

Final CMS determinations of MIPS APMs for the 2020 MIPS performance period will be announced via the [QPP website](#).

### Calculating MIPS APM Performance Category Scores ([p. 893](#))

#### Quality Performance Category ([p. 893](#))

CMS discusses previously finalized policies to (1) require MIPS eligible clinicians in MIPS APMs to submit data on APM quality measures for purposes of MIPS and (2) a policy to reweight the quality performance category to zero percent in certain cases, but CMS also notes that it did not anticipate that the quality performance category would need to be reweighted regularly. After several years of implementation of the APM scoring standard, CMS has found that for participants in certain MIPS APMs, it often is not operationally possible to collect and score performance data on APM quality measures for purposes of MIPS because these APMs run on episodic or yearly timelines that do not always align with the MIPS performance periods and deadlines for data submission, scoring, and performance feedback. CMS now believes it is necessary to consider new approaches to quality performance category scoring, as detailed below.



Allowing MIPS Eligible Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures ([p. 894](#))

***CMS proposes to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures beginning with the 2020 MIPS performance period. Under this proposal, CMS would allow MIPS eligible clinicians in MIPS APMs to receive a score for the quality performance category either through individual or TIN-level reporting based on the generally applicable MIPS reporting and scoring rules for the quality performance category. CMS would use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity. Each MIPS eligible clinician in the APM Entity group would receive one score, weighted equally with that of the other MIPS eligible clinicians in the APM Entity group, and CMS would calculate one quality performance category score for the entire APM Entity group. If a MIPS eligible clinician has no quality performance category score—if the individual’s TIN did not report and the individual did not report—that MIPS eligible clinician would contribute a score of zero to the aggregate APM Entity group score.*** This approach similar to the established policy for the Promoting Interoperability performance category under the APM scoring standard.

***CMS would use only scores reported by an individual MIPS eligible clinician or a TIN reporting as a group; CMS would not accept virtual group level reporting because a virtual group level score is too far removed from the eligible clinician’s performance on quality measures for purposes of the APM scoring standard.***

***CMS requests comment on this proposal.***

APM Quality Reporting Credit ([p. 895](#)) and Exceptions from the Credit ([p. 896](#))

***CMS is proposing that APM Entity groups participating in MIPS APMs receive a minimum score of one-half of the highest potential score for the quality performance category, beginning with the 2020 MIPS performance period.*** CMS compares this proposal with the statutory provision that provides APM participants a minimum score of one-half of the highest potential score for the improvement activities performance category and further details its rationale on [p. 896](#).

***To the extent possible, CMS would calculate the final score by adding to the credit any additional MIPS quality score received on behalf of the individual NPI or the TIN. All quality category scores would be capped at 100 percent.*** For example, if the additional MIPS quality score were 40 percent, that would be added to the 50 percent credit for a total of 90 percent; if the quality score were 70 percent, that would be added to the 50 percent credit and because the result is 120 percent, the cap would be applied for a final score of 100 percent.

***CMS requests comment on this proposal.***

Additionally, ***CMS would not apply the APM Quality Reporting Credit to the APM Entity group’s quality performance score for those APM Entities reporting only through a MIPS quality reporting mechanism according to the requirements of their APM, such as the Medicare Shared Savings Program, which requires participating ACOs to report through the CMS Web Interface and the CAHPS for ACOs survey measures.*** In these cases, no burden of duplicative reporting would exist, and there would not be any additional unscored quality measures for which to give credit.

In the case where an APM Entity group is in an APM that requires reporting through a MIPS quality reporting mechanism under the terms of participation in the APM, should the APM Entity group fail to report on required quality measures, the individual eligible clinicians and TINs that make up that APM Entity group would still have the opportunity to report quality measures to MIPS for purposes of calculating a MIPS quality performance

category score, potentially subject to limitations.<sup>28</sup> However, as in these cases no burden of duplicative reporting would exist, they would remain ineligible for the APM Quality Reporting credit.

#### Additional Reporting Option for APM Entities (p. 897)

CMS recognizes that some APM Entities may have a particular interest in ensuring that MIPS eligible clinicians in the APM Entity group perform well in MIPS, or in reducing the overall burden of joining the entity. Likewise, CMS recognizes that some APMs, such as the CMS Web Interface reporters already require reporting on MIPS quality measures as part of participation in the APM. Therefore, ***CMS is proposing that, in instances where an APM Entity has reported quality measures to MIPS through a MIPS submission type and using MIPS collection type on behalf of the APM Entity group, CMS would use that quality data to calculate an APM Entity group level score for the quality performance category.*** CMS believes this approach best ensures that all participants in an APM Entity group receive the same final MIPS score while reducing reporting burden to the greatest extent possible. ***CMS requests comment on this proposal.***

#### Bonus Points and Caps for the Quality Performance Category (p. 898)

CMS previously finalized policies to include bonus points in the performance category score calculation when scoring quality at the APM Entity group level. Because these adjustments would, under the proposals discussed later in this proposed rule<sup>29</sup>, already be factored in when calculating an individual or TIN-level quality performance category score before the quality scores are rolled-up and averaged to create the APM Entity group level score, ***CMS believes it would be inappropriate to continue to calculate these adjustments at the APM Entity group level in the case where an APM Entity group's quality performance score is reported by its composite individuals or TINs. However, in the case of an APM Entity group that chooses to or is required by its APM to report on MIPS quality measures at the APM Entity group level, CMS would continue to apply any bonuses or adjustments that are available to MIPS groups for the measures reported by the APM Entity and to calculate the applicability of these adjustments at the APM Entity group level. CMS requests comment on this proposal.***

#### Special Circumstances (p. 898)

In prior rulemaking, with regard to the quality performance category, CMS did not include MIPS eligible clinicians who are subject to the APM scoring standard in the automatic extreme and uncontrollable circumstances policy or the application-based extreme and uncontrollable circumstances policy that CMS established for other MIPS eligible clinicians. However, as discussed above,<sup>30</sup> CMS is proposing to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures and be scored for the MIPS quality performance category based on the generally applicable MIPS reporting and scoring rules for the quality performance category. In light of this proposal, ***beginning with the 2020 MIPS performance period/2022 MIPS payment year and only with regard to the quality performance category, CMS proposes to apply the application-based extreme and uncontrollable circumstances policy and the automatic extreme and***

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<sup>28</sup> The language here is not clear and reads as follows: ***"In the case where an APM Entity group is in an APM that requires reporting through a MIPS quality reporting mechanism under the terms of participation in the APM, should the APM Entity group fail to report on required quality measures, the individual eligible clinicians and TINs that make up that APM Entity group would still have the opportunity to report quality measures to MIPS for purposes of calculating a MIPS quality performance category score as finalized in they would in any Other MIPS APM in accordance with § 414.1370 (g)(1)(ii)."***

<sup>29</sup> CMS refers to "section[s] III.J.3.d.(1)(b) of this proposed rule". However, based on the discussion, it appears that CMS may be referencing its proposal to Allow MIPS Eligible Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures, on p. 894 of the proposed rule and discussed [above](#).

<sup>30</sup> CMS refers to "III.J.3.c.(5)(c)(i)(c) of this proposed rule". However, based on the discussion, it appears that CMS may be referencing its proposals in the section "Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures" and discussed [above](#).

***uncontrollable circumstances policy that CMS previously established for other MIPS eligible clinicians to MIPS eligible clinicians participating in MIPS APMs who are subject to the APM scoring standard and would report on MIPS quality measures as proposed. CMS would limit the proposed application of these policies to the quality performance category because our proposal pertains to reporting on MIPS quality measures.***

Under the previously established policies, MIPS eligible clinicians who are subject to extreme and uncontrollable circumstances may receive a zero percent weighting for the quality performance category in the final score. With respect to how reweighting would apply in individual versus group reporting scenarios when the individual qualifies for a zero percent weighting, CMS proposes the following:

- TIN level reporting, where one or more - but not all – MIPS eligible clinicians qualify for reweighting:
  - ***CMS would not apply the zero percent weighting to the qualifying MIPS eligible clinician.***
  - ***The TIN would still report on behalf of the entire group, although the TIN would not need to report data for the qualifying MIPS eligible clinician.***
  - ***All MIPS eligible clinicians in the TIN who are participants in the MIPS APM would count towards the TIN’s weight when calculating the aggregated APM Entity score for the quality performance category.***
- TIN level reporting, where all MIPS eligible clinicians qualify for reweighting:
  - ***The TIN would not be required to report on the quality performance category and would be assigned a weight of zero when calculating the aggregated APM Entity’s quality performance category score***
- Individual level reporting (solo practitioner, group reports at individual level):
  - ***The individual would not be required to report on the quality performance category and would be assigned a weight of zero when calculating the aggregated APM Entity’s quality performance category score***

***If quality performance data were reported by or on behalf of one or more TIN/NPIs in an APM Entity group, a quality performance category score would be calculated for, and would be applied to, all MIPS eligible clinicians in the APM Entity group. If all MIPS eligible clinicians in all TINs of an APM Entity group qualify for a zero percent weighting of the quality performance category, the quality performance category would be weighted at zero percent of the MIPS final score.***

***CMS welcomes comments from the public in this discussion of how best to address the technical infeasibility of scoring quality for many of our MIPS APMs, and whether the above described policy or some other approach may be an appropriate path forward for the APM entity group scoring standard in CY 2020.***

***CMS requests comment on this proposal.***

#### ***Excluding Virtual Groups from APM Entity Group Scoring ([p. 901](#))***

Due to concerns that virtual groups could be used to calculate APM Entity group scores, CMS has excluded virtual group MIPS scores when calculating APM Entity group scores. Previously, CMS has effectuated this exclusion through the use and application of terms defined in § 414.1305, specifically, “APM Entity,” “APM Entity group,” “group,” and “virtual group.”

To improve clarity around the exclusion of virtual group scores in calculating APM Entity group scores, ***CMS now is proposing to effectuate this exclusion more explicitly, by amending § 414.1370(e)(2) to state that the score calculated for an APM Entity group, and subsequently the APM Entity, for purposes of the APM scoring standard does not include MIPS scores for virtual groups.***

### [Request for Comment on APM Scoring Beyond 2020 \(p. 901\)](#)

**CMS is seeking comment on potential policies to be included in next year's rulemaking to further address the changing incentives for APM participation under MACRA**, noting its interest in continuing to shift eligible clinicians into MIPS APMs and Advanced APMs.

CMS notes that the QP threshold will be increasing in future years, potentially resulting in larger proportions of Advanced APM participants being subject to MIPS under the APM scoring standard. At the same time the MIPS performance threshold will be increasing annually, gradually reducing the impact of the APM scoring standard on participants' ability to achieve a neutral or positive payment adjustment under MIPS.

**CMS discusses some options it is considering with respect to the application of the APM Quality Reporting Credit for APM Entities, including variations thereof, as follows:**

- **Sunsetting the APM Quality Reporting Credit for APM Entities (p. 902) after a maximum number of MIPS performance years**
- **Sunsetting the APM Quality Reporting Credit for non-Advanced APMs (p. 902)**
- **Sunsetting the APM Quality Reporting Credit for APM Entities in One-Sided Risk Tracks (p. 902)**
- **Retain different APM Quality Reporting Credits for Advanced APMs and MIPS APMs (p. 903), for example based on the level of risk in the MIPS APM**

**CMS seeks comments and suggestions on other ways in which CMS could modify the APM scoring standard to continue to encourage MIPS eligible clinicians to join APMs, with an emphasis on encouraging movement toward participation in two-sided risk APMs that may qualify as Advanced APMs.**

### [MIPS APM Performance Feedback \(p. 904\)](#)

CMS discusses challenges providing feedback to MIPS eligible clinicians scored under the APM scoring standard, and provides an update regarding the availability of feedback to ACO participant TINs. More information is available on [p. 904](#).

### [MIPS Final Score Methodology \(p. 905\)](#)

As CMS transform MIPS through the MIPS Value Pathways (MVP) Framework discussed earlier in this rule, it may propose modifications to its scoring methodology in future rulemaking in an effort to develop a methodology that emphasizes simplicity and that is understandable for MIPS eligible clinicians. For example, it anticipates revisiting and removing policies such as 3-point floor, bonus points, and assigning points for measures that cannot be scored against a benchmark through future rulemaking. As CMS proposes to transform the MIPS program through MVPs, its goal is to incorporate ways to address these issues without developing special scoring policies.

### [Performance Category Scores \(p. 905\)](#)

**Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures (p. 905)**

**Assigning Quality Measure Achievement Points (p. 906)**

- Scoring Measures Based on Achievement.  
***For the 2020 MIPS performance year, CMS proposes to again apply a 3-point floor for each measure that meets the data completeness criteria (generally, 70 percent for 2020), meets the case minimum requirement of at least 20 cases, and can be reliably scored against a benchmark based on the***

**baseline period.**<sup>31</sup> However, as CMS moves towards the proposed MVPs, it notes it could possibly remove the 3-point floor in future years.

- Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements. ***For the 2020 performance year, CMS again proposes that clinicians will receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.***

[Table 43](#) includes a summary of the proposed scoring policies for the CY 2020 MIPS performance period.

- Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment ([p. 910](#)) ***CMS proposes that, beginning with the CY 2020 performance period, for each measure that has a benchmark that CMS determines has the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the performance-based benchmarking methodology. More specifically, rather than develop benchmarks based on the distribution of scores, CMS would base them on flat percentages such that any performance rate at or above 90 percent would be in the top decile and any performance rate above 80 percent would be in the second highest decile, and this would continue for the remaining deciles.***

CMS selected the 90 percent threshold out of concern that if the top decile was originally below 90 percent, using the flat percentages would actually raise the level up to 90 percent and therefore provide a stronger incentive to provide inappropriate care in order to get the top score. ***CMS seeks comment on whether it should use a different criteria.***

CMS also notes that this policy would align with the Shared Savings Program, which uses flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure. However, the Shared Savings Program uses this method to avoid penalizing high ACO performance; in the case of MIPS, CMS would apply the flat percentages to ensure that the benchmark does not result in inappropriate and potentially harmful patient treatment.

***CMS would rely on CMS medical officers to determine whether certain measure benchmarks may have unintended consequences that put patients at risk and whether the measure benchmark should move to a flat percentage. The assessment will take into account all available information, including from the medical literature, published practice guidelines, and feedback from clinicians, groups, specialty societies, and the measure steward. Before applying the flat percentage benchmarking methodology to any recommended measure, CMS would propose the modified benchmark for the applicable MIPS payment year through rulemaking.***

***CMS has identified two measures for which it believes it needs to apply benchmarks based on flat percentages to avoid potential inappropriate treatment:***

- ***MIPS #1: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%); and***
- ***MIPS #236: Controlling High Blood Pressure***

CMS believes these measures lack comprehensive denominator exclusions and risk-adjustment or risk-stratification, which can lead to the possible over treatment of patients in order to meet numerator

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<sup>31</sup> CMS previously established that measures with a benchmark based on the *performance period* (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year.

compliance. For these two measures, CMS would not know which benchmarks and their associated collection types are impacted until it runs its analysis; however, based on the benchmarks for the 2019 MIPS performance period, CMS would anticipate using the modified benchmarks for the Medicare Part B claims and the MIPS CQM collection types.

**CMS seeks comment on future actions it should take to help determine which measures to apply the flat percentage benchmarking to (e.g., convening a technical expert panel). It also seeks comment on whether it should consider different methodologies for the modified benchmarks** (e.g., excluding the top decile or increasing the required data completeness for the measure to a very high level- such as 95 to 100 percent- and use performance period benchmarks rather than historical benchmarks).

***Separately, CMS proposes to revise the text at § 414.1380(b)(1)(ii) to provide exceptions and to clarify the requirement that benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.***

#### Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure (p. 914)

CMS is not proposing any changes to the scoring of the CAHPS for MIPS survey measure. However, ***CMS requests comment on future approaches to scoring the CAHPS for MIPS survey measure if new questions are added to the survey.*** CMS is considering expanding the information collected in the CAHPS for MIPS survey measure, including the addition of narrative questions that would invite patients to respond to a series of questions in free text, such as responding to open ended questions and describing their experience with care in their own words. CMS clarifies that it would work with stakeholders on user testing before proposing any such methodology in future rulemaking.

#### Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria (p. 916)

CMS is not proposing any changes to this policy.

#### Incentives to Report High-Priority Measures (p. 916)

***CMS proposes to maintain the cap on measure points for reporting high priority measures for the 2020 MIPS performance year—i.e., the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.***

In the CY 2019 PFS final rule (83 FR 59851), CMS finalized technical updates to more clearly and concisely capture previously established policies in the section, but inadvertently added that a high priority measure must have a benchmark. This was not intended to be a policy change. ***CMS proposes to clarify through the regulatory text that in order for a measure to qualify for high priority bonus points it must meet case minimum and data completeness and not have a zero percent performance. The measure does not need to have a benchmark.***

#### Incentives to Use CEHRT to Support Quality Performance Category Submissions (p. 917)

***CMS proposes to continue to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2020 MIPS performance year.***

#### Improvement Scoring for the MIPS Quality Performance Category Percent Score (p. 918)

***CMS proposes to continue it previously established improvement scoring policy for the 2020 MIPS performance year.*** More specifically, CMS will compare the clinician's quality performance category achievement percent score for the 2020 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent for the 2019 MIPS performance period.

## **Facility-Based Measurement Scoring Option for the Quality and Cost Performance Categories for the 2022 MIPS Payment Year** ([p. 920](#))

In the CY 2019 PFS proposed rule (83 FR 35962 through 35963), CMS requested comments on a number of issues, including whether it should expand the facility-based scoring option to other facilities and programs in future years, particularly the end-stage renal disease (ESRD) and post-acute care (PAC) settings. CMS appreciates comments received, but is not proposing an expansion to other facility types as part of this rule. However, it may consider addressing this issue in future rulemaking.

In the CY 2019 PFS final rule, CMS established at § 414.1380(e)(2)(i)(C) that a MIPS eligible clinician is facility-based if the clinician can be attributed, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. For purposes of clarity, ***CMS proposes to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period.*** This does not constitute a change in policy.

For informational purposes, CMS also provides in [Table 44](#) a list of the measures included in the FY 2021 Hospital VBP Program measure set that will be used in determining the quality and cost performance category scores for the CY 2020 MIPS performance period/2022 MIPS payment year. The FY 2021 Hospital VBP Program has adopted 12 measures (83 FR 41454 through 41455). The performance period for these measures varies depending on the measure, and some measures include multi-year performance periods.

## **Scoring the Improvement Activities Performance Category** ([p. 922](#))

CMS refers readers to the proposed changes to this category [discussed earlier](#).

## **Scoring the Promoting Interoperability Performance Category** ([p. 923](#))

CMS refers readers to the proposed changes to this category [discussed earlier](#).

## **Calculating the Final Score** ([p. 924](#))

### **Complex Patient Bonus for the 2022 MIPS Payment Year** ([p. 924](#))

***CMS proposes to continue the complex patient bonus as previously finalized (i.e., up to five points added to the final score) for the 2020 MIPS performance year.*** Although CMS intends to maintain the complex patient bonus as a short-term solution, it does not believe it has sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS.

Section 1848(q)(1)(G) of the Act requires CMS to consider, on an ongoing basis, risk factors in its scoring methodology for MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185) and, as appropriate, other information. ASPE completed its first report in December 2016. Its second report is expected in October 2019, as required by the IMPACT Act, and will build on the analyses included in initial report and may provide additional insight for a long-term solution to addressing risk factors in MIPS.

In the CY 2018 QPP final rule (82 FR 53771 through 53776), when considering approaches for a complex patient bonus, CMS reviewed evidence to identify how indicators of patient complexity have an impact on performance under MIPS, as well as availability of data to implement the bonus. Specifically, CMS identified two potential indicators for complexity: medical complexity as measured through Hierarchical Condition Category (HCC) risk scores; and social risk as measured through the proportion of patients with dual eligible status. CMS has updated its earlier analysis (available at: 82 FR 53776) and the preliminary results are shown in [Table 45](#). Table 45 illustrates the average estimated MIPS final scores for individual MIPS eligible clinicians who submitted at

least 6 measures and for group reporters, stratified by the average HCC risk score and dual eligible ratio quartiles. Overall, the analysis of preliminary data shows a consistent relationship between the dual eligible ratio quartiles and the average MIPS final scores only for individuals, where the average MIPS final score decreases as the quartile increases. CMS found slight differences in the average HCC risk score and dual eligible ratio quartiles for groups, but virtually no difference for average HCC risk score for individuals. However, CMS has only one year of data and recognizes that more recent data, including information from ASPE, may bring different results.

**Final Score Performance Category Weights (p. 929)**

Table 46 summarizes the weights proposed for each performance category for the 2020 MIPS performance/2022 payment year through the 2022 performance/2024 payment year.

**TABLE 46: Proposed Weights by MIPS Performance Category for the 2022 through 2024 MIPS Payment Years**

Performance Category	2022 MIPS Payment Year (Proposed)	2023 MIPS Payment Year (Proposed)	2024 MIPS Payment Year (Proposed)
Quality	40%	35%	30%
Cost	20%	25%	30%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

Reweighting Performance Categories due to Data that are Inaccurate, Unusable, or Otherwise Compromised (p. 930)

*CMS proposes, beginning with the 2018 MIPS performance period/2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who it determines has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if CMS learns the relevant information prior to the beginning of the associated MIPS payment year. CMS also would amend the regulatory text to clarify that this new policy would not be voided by the submission of data for the Promoting Interoperability performance category as is the case with other significant hardship exceptions.*

*If CMS determines that a MIPS eligible clinician’s data were compromised and the conditions for reweighting are met, it proposes to notify the clinician of this determination through the performance feedback that it provides under section 1848(q)(12) of the Act if feasible, or through routine communication channels for the QPP.*

CMS further clarifies the timing set forth in this proposal. If CMS determines a MIPS eligible clinician has submitted compromised data for a performance category during the associated payment year or at a later point, the MIPS eligible clinician would not qualify for reweighting under this proposal, instead for the performance categories with compromised data the clinician’s performance category score would be zero and the scoring weight for the category would not be redistributed.

For purposes of this reweighting policy, reweighting would take into account both what control the clinician had directly over the circumstances and what control the clinician had indirectly through its agents. The term agent is intended to include any individual or entity, including a third party intermediary as described in § 414.1400, acting on behalf of or under the instruction of the MIPS eligible clinician. CMS believes that reweighting is not appropriate if a clinician could exert influence over a third party intermediary or another party to prevent or



remediate compromised data and does not do so. However, it is appropriate in certain circumstances that may be within the control of the clinician's third party intermediary if the clinician cannot alter that party's conduct (e.g., if a clinician's third party intermediary could correct the clinician's compromised data and despite requests from the clinician the third party intermediary chose not to do so).

Factors relevant to whether the circumstances were outside the control of the clinician and its agents include: whether the affected MIPS eligible clinician or its agents knew or had reason to know of the issue; whether the affected MIPS eligible clinician or its agents attempted to correct the issue; and whether the issue caused the data submitted to be inaccurate or unusable for MIPS purposes.

CMS' determination of whether reweighing will be applied under this policy will take into account any information known to the agency, and CMS will consider the information obtained on a case-by-case basis for reweighing. Information would be provided to CMS through routine communication channels for the QPP, as well as other relevant information sources of which it is aware.

**CMS solicits comment on this proposal and possible alternatives for balancing efforts to allow reweighing in circumstances in which clinicians are not culpable for compromised data while maintaining financial incentives for clinicians, third party intermediaries and other parties to prevent and correct compromised data. More specifically, CMS seeks comment on:**

- **The factors presented above to determine whether the circumstances were outside the control of the clinician and its agents, and whether there are additional factors CMS should consider to determine if there should be reweighing based on compromised data;**
- **Whether there are other factors it should consider when adopting a timeline for reweighing due to compromised data and whether the period should be broader (i.e., not limited to prior to the beginning of the associated MIPS payment year);**
- **Whether there are other incentives for MIPS eligible clinicians to alert CMS to concerns about compromised data; and**
- **Whether and how this proposal should apply to circumstances in which a MIPS eligible clinician or one or more of its agents becomes aware of potential data issues prior to submission of data.**

CMS emphasizes that this proposed reweighing policy is solely intended to mitigate the potential adverse financial impact of compromised data on the MIPS eligible clinician; a determination under this proposed policy that data are compromised due to circumstances outside of the control of the MIPS eligible clinician and its agent and therefore that reweighing will occur for that clinician does not indicate and should not be interpreted to suggest that a third party intermediary or other individual or entity could not be held liable for the compromised data.

CMS also requests that third party intermediaries, to the extent feasible, inform MIPS eligible clinicians if the third party intermediary believes their data may have been compromised. CMS also encourages these third parties to provide CMS with a list of or other identifying information for all MIPS eligible clinicians who may have been affected by such issues, so that CMS may evaluate the circumstances in a timely manner. CMS also encourages MIPS eligible clinicians to contact the agency and self-identify if they believe they have compromised data; they should not rely solely on a third party intermediary to do so.

Finally, CMS reminds readers that it previously finalized 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 77326 through 77328 and 82 FR 53778 through 53779). Therefore, if a MIPS eligible clinician is scored on fewer than two performance categories as a result of reweighing due to compromised data, he or she would receive a final score equal to the performance threshold.

Redistributing Performance Category Weights ([p. 936](#))

**Table 47** summarizes performance category redistribution policies proposed for the 2020 performance/2022 payment year. CMS proposes similar redistribution policies to its policies finalized for the 2019 performance year (83 FR 59876 through 59878), with some modifications:

- **CMS adjusted its redistribution policies to account for a Cost category weight of 20 percent for the 2020 performance year;**
- **In scenarios when the Cost category weight is redistributed while the Promoting Interoperability performance category weight is not, CMS would redistribute a portion of the Cost category weight (15 percent) to the Quality performance and a portion of the Cost category weight (5 percent) to the Promoting Interoperability performance category to better emphasize the importance of interoperability. CMS currently redistributes all of the Cost category weight to the quality performance category (83 FR 59876 through 59878);**
- **CMS does not believe it would be appropriate to redistribute weight from the other performance categories to the Cost category for the 2020 MIPS performance year, except in scenarios in which the only other scored performance category is the Improvement Activities category since CMS is proposing substantial changes to some of the cost measures and clinicians need more time to adjust to these measures.**
- **Beginning with the 2020 performance year, CMS proposes to not redistribute performance category weights to the improvement activities performance category in any scenario because this category only assesses whether a MIPS eligible clinician completed certain activities rather than variation in performance.**
  - CMS clarifies that in situations where the weights of both the Quality and Promoting Interoperability categories are redistributed, Cost would be weighted at 85 percent and improvement activities would be weighted at 15 percent. CMS believes this would help to reduce incentives to not report measures for the quality category in circumstances when a clinician may be able to report but chooses not to do so.
  - When the Quality and Cost performance categories are each weighted at zero percent, CMS would weight the Improvement Activities category at 15 percent and weight the Promoting Interoperability performance category at 85 percent in alignment with this policy and to emphasize interoperability.

**Table 48** includes proposed redistribution policies for the 2021 performance/2023 payment year.

- **CMS believes it would be appropriate to begin redistributing weight to the Cost category beginning with the 2021 performance/2023 payment year since MIPS eligible clinicians will have had more experience being scored on cost measures. Starting with the 2021 payment year, CMS would redistribute performance category weights so that the quality and cost performance categories are almost equal. For simplicity, it would redistribute the weight in 5- point increments. If the redistributed weight cannot be equally divided between quality and cost in 5-point increments, CMS would redistribute slightly more weight to quality than cost.**

**Table 49** includes proposed redistribution policies for the 2022 performance/2024 payment year.

- **CMS would continue to redistribute weight to the Promoting Interoperability performance category, but it would ensure that if the Quality and Cost categories are scored, they would have a higher weight than the Promoting Interoperability performance category.** For example, beginning with the 2022 performance year, if the Improvement Activities category is the only performance category to be reweighted to zero percent, Quality and Cost would be 40 and 35 percent, respectively, and CMS would not increase the weight of the Promoting Interoperability performance category (weighted at 25 percent) so that it would not exceed the weight of the quality or cost performance categories.

## ***MIPS Payment Adjustments (p. 943)***

### ***Establishing the Performance Threshold (p. 943)***

To determine a performance threshold to propose for the fourth year of MIPS (2020 MIPS performance period/2022 MIPS payment year) and the fifth year of MIPS (2021 MIPS performance period/2023 MIPS payment year), CMS is again relying 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, which allows the Secretary to 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 with respect to the sixth year (i.e., the 2022 performance year, at which point the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary).

[Table 51](#) presents potential values for estimating the performance threshold for the 2022 performance year based on the mean or median final score from prior periods. CMS considered using the actual final scores for the 2018 performance year; however, final scores were not available in time for CMS to use for purposes of this proposed rule (although it intends to include these results in the final rule if available). CMS believes the data points based on actual data from the 2017 MIPS performance period would be appropriate to use in projecting the estimated performance threshold for the 2022 performance year. However, after it analyzes the actual final scores for 2018, if it sees the mean or median final scores significantly increasing or decreasing, it would consider modifying its estimation of the performance threshold for the 2022 performance year accordingly.

In this rule, CMS is choosing the mean final score of 74.01 points for the 2017 performance year as its estimate of the performance threshold for the 2022 performance year because it represents a mean based on actual data; is more representative of clinician performance because all final scores are considered in the calculation; is more achievable for clinicians, particularly for those that are new to MIPS; and is a value that falls generally in the middle of potential values for the performance threshold referenced in [Table 51](#). CMS notes that this is only an estimation, provided in accordance with 1848(q)(6)(D)(iv) of the Act.

***CMS seeks comment on whether and how it should use the release of additional MIPS data to update its estimates.*** CMS understands that using final scores from the early years of MIPS has numerous limitations and may not be similar to the distribution of final scores in year 6 since eligibility and scoring policies changed in the initial years of the program. CMS will propose the actual performance threshold for the 2022 MIPS performance year in future rulemaking.

***Based on these analyses, CMS proposes a performance threshold of 45 points for the 2020 performance year and a performance threshold of 60 points for the 2021 performance year.*** CMS views these increases as consistent with the increase in the performance threshold from the 2018 performance year (15 points) to the 2019 performance year (30 points) and believes it provides a gradual and incremental transition to the performance threshold it will establish for the 2022 performance year, which it currently estimates to be 74.01 points.

***CMS seeks comment on whether it should adopt a different performance threshold in the final rule if it determines that the actual mean or median final scores for the 2018 performance year are higher or lower than its estimated performance threshold for the 2022 performance year of 74.01 points. For example, if the actual mean or median final score for 2018 is closer to 85 points, should CMS finalize a higher performance threshold than currently proposed? Or if the mean or median values are lower, should it finalize a lower performance threshold? Should the increase from year-to-year be more gradual? CMS seeks comment on alternative numerical values for the performance threshold for both the 2020 and 2021 performance years.***

### [Additional Performance Threshold for Exceptional Performance \(p. 951\)](#)

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. 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; 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. 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 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act. Funding is available for additional MIPS payment adjustment factors only through the 2022 performance/2024 payment year, which is the sixth year of the MIPS program.

CMS is again relying 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, which allows the Secretary to 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 with respect to the sixth year (i.e., the 2022 performance year, at which point the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary).

***CMS proposes to set the additional performance threshold for the 2020 MIPS performance year at 80 points and to set the additional performance threshold for the 2021 MIPS performance year at 85 points.*** These values are higher than the 25th percentile of the range of the possible final scores above the proposed performance threshold for the 2020 and 2021 MIPS performance years, which is explained in more detail in this section. As discussed earlier, for the initial 5 years of MIPS, CMS is relying on the discretion afforded by the special rules authorized under the Bipartisan Budget Act of 2018, which also apply for purposes of establishing an additional performance threshold for a year. As such, CMS proposes to again decouple the additional performance threshold from the performance threshold.

Alternatively, for the 2020 performance year, CMS considered whether the additional performance threshold should remain at 75 points or be set at a higher number, for example, 85 points. For the 2021 performance year, CMS also considered whether the additional performance threshold should remain at 80 points, as proposed, or whether a different numerical value should be adopted. ***CMS seeks comments on its proposals and alternative considerations.***

***CMS also seeks comment on how the distribution of the additional MIPS payment adjustments across MIPS eligible clinicians may impact exceptional performance by clinicians participating in MIPS.*** For example, the distribution of the additional MIPS payment adjustments could result in a higher additional MIPS payment adjustment available to fewer clinicians or could result in a lower additional MIPS payment adjustment available to a larger number of clinicians.

### [Example of Adjustment Factors \(p. 956\)](#)

[Figure 1](#) 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 proposed for the 2022 MIPS payment year in this proposed rule. In [Figure 1](#), the performance threshold is 45 points. The applicable percentage is 9 percent for the 2020 performance/2022 payment year. In this example, CMS anticipates that more clinicians will receive a positive adjustment than a negative adjustment, that the scaling factor would be less than 1, and that the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent. In this example, CMS also estimates that the scaling factor for the MIPS payment adjustment factor is 0.203. Thus, MIPS eligible clinicians with a final

score equal to 100 would have a MIPS payment adjustment factor of 1.823 percent (9 percent x 0.2026) (note: this is prior to adding the exceptional performance adjustment). The example scaling factor for the additional MIPS payment adjustment factor is 0.395. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.95 percent (10 percent x 0.395). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be  $1 + 0.0182 + 0.0395 = 0.0578$ , for a total positive MIPS payment adjustment of 5.78 percent.

CMS notes that the slope of the line for the linear adjustments presented in this example could change considerably as new information becomes available and that 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 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 52](#) illustrates the changes in payment adjustments based on the final policies for 2018/2020 and 2019/2021, and the proposed policies for 2020/2022 and 2021/2023 discussed in this proposed rule, as well as the statutorily required increase in the applicable adjustment percent.

CMS also provides examples to demonstrate scenarios in which MIPS eligible clinicians exceed the proposed performance threshold of 45 points based on policies proposed for the 2020 performance/2022 payment year:

- [Example 1/Table 53](#): MIPS eligible clinician in small practice submits 5 Quality measures via claims (performing at the median level—i.e, 6 achievement points each); submits 1 medium-weight Improvement Activity; significant hardship approved for Promoting Interoperability category; Cost category score of 50 percent; complex patient bonus of 3 points; qualifies for small practice bonus of 6 points. *\*Because the clinician does not meet full participation requirements, he/she does not qualify for improvement scoring.* In this example, the clinician would receive a final score of 59.5 points and exceed the performance threshold.
- [Example 2/Table 54](#): MIPS eligible clinician in a non-small practice participates in MIPS as a group and scores 75 percent for Quality (achievable through multiple scenarios), 50 percent for Cost, 100 percent for Promoting Interoperability and 100 percent for Improvement Activities. The group also qualifies for a complex bonus of 3 points. In this example, the final score of 83 points would exceed the performance threshold and the additional exceptional performance threshold and thus, qualify for the exceptional performance bonus.
- [Example 3/Table 55](#): An individual MIPS eligible clinician that is non-patient facing and not in a small practice receives performance category scores of 50 percent for Quality (achievable through multiple scenarios); 50 percent for Cost; did not submit Promoting Interoperability measure and qualifies for automatic re-weighting of the category; and 50 percent for 1 medium-weighted Improvement Activity. The clinician also qualifies for a complex bonus of 3 points.

### [Targeted Review and Data Validation and Auditing \(p. 966\)](#)

#### [Targeted Review \(p. 966\)](#)

##### **Who is Eligible to Request a Targeted Review**

In the CY 2017 QPP final rule, CMS established that MIPS eligible clinicians and groups may submit a targeted review request and that these submissions could be with or without the assistance of a third party intermediary (81 FR 77353). To minimize burden on clinicians, CMS believes it is important to allow designated support staff and third party intermediaries to submit targeted review requests on their behalf. ***To expressly acknowledge the role of designated support staff and third party intermediaries in the targeted review process, CMS proposes to revise § 414.1385(a)(1) to state that a MIPS eligible clinician or group (including their designated***

**support staff), or a third party intermediary as defined at § 414.1305 (e.g., a qualified registry, health IT vendor, or QCDR), may submit a request for a targeted review.**

MIPS eligible clinicians and groups (including their designated support staff) can request a targeted review by logging into the [QPP website](#) and, after reviewing their performance feedback, submitting a request for targeted review. An authorized third party intermediary that does not have access to their clients' performance feedback still would be able to request a targeted review on behalf of their clients. CMS will share an URL link to the Targeted Review Request Form with these designated entities.

### **Timeline for Targeted Review Requests**

In the CY 2017 QPP final rule (81 FR 77358), CMS finalized that MIPS eligible clinicians and groups have a 60-day period to submit a request for targeted review, which begins on the day CMS makes available the MIPS payment adjustment factor and ends on September 30 of the year prior to the MIPS payment year or a later date specified by CMS. During the first year of targeted review for MIPS, CMS allowed MIPS eligible clinicians and groups 90 days, with an additional 14-day extension, to submit a targeted review request. In response to feedback, in December 2018, CMS also made available revised performance feedback to clinicians and groups who filed a targeted review request.

***In this rule, CMS proposes to revise § 414.1385(a)(2) to state that all requests for targeted review must be submitted during a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors, and to state that the targeted review request submission period may be extended as specified by CMS. This change would apply beginning with the 2019 performance period.*** CMS anticipates that by limiting the targeted review period to 60 days, it would be able to make available the revised performance feedback during October of the year prior to the MIPS payment year, which would be approximately 2 months earlier than the first year of targeted review.

### **Denial of Targeted Review Requests**

During the first year of targeted review, CMS received many targeted review requests that were duplicative and continues to seek opportunities to limit burden and improve the efficiency of its processes. ***Therefore, CMS proposes to revise § 414.1385(a)(3) to state that a request for a targeted review may be denied if:***

- ***The request is duplicative of another request for targeted review;***
- ***The request is not submitted during the targeted review request submission period; or***
- ***The request is outside of the scope of targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year.***

Notification will be provided to the individual or entity that submitted the targeted review request as follows:

- If the targeted review request is denied; there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group.
- If the targeted review request is approved; in this case, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

### **Requests for Additional Information**

***CMS proposes to add § 414.1385(a)(5) to state that a request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS's request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period.***

***Documentation can include, but is not limited to:***

- ***Supporting extracts from the MIPS eligible clinician or group's EHR;***

- **Copies of performance data provided to a third party intermediary by the MIPS eligible clinician or group;**
- **Copies of performance data submitted to CMS;**
- **QPP Service Center ticket numbers;**
- **Signed contracts or agreements between a MIPS eligible clinician/group and a third party intermediary.**

#### **Notification of Targeted Review Decisions**

In the CY 2017 QPP final rule (81 FR 77358), CMS finalized that decisions based on the targeted review are final, and there is no further review or appeal. **To align with policies regarding the auditing of entities submitting MIPS data, CMS also proposes to add § 414.1385(a)(8) to state that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.**

#### **Scoring Recalculations**

**CMS proposes to add § 414.1385(a)(6) to state that if a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to the measures, activities, performance categories, and final score, as well as the MIPS payment adjustment factors.**

#### **Data Validation and Auditing ([p. 971](#))**

CMS clarifies here that a clinician or group that submits a certification under § 414.1390(b) in connection with the submission of data they know is cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, it may subject the MIPS eligible clinician or group to auditing in accordance with § 414.1390(a) and in the case of improper payment a reopening and revision of the MIPS payment adjustment in accordance with § 414.1390(c).

#### **Third Party Intermediaries ([p. 973](#))**

CMS proposes several changes to its previously established policies regarding third party intermediaries, as summarized below.

#### **Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries ([p. 973](#))**

Current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); Improvement Activities; and Promoting Interoperability. **In response to stakeholder feedback for a more cohesive participation experience, CMS proposes to amend § 414.1400(a)(2) to state that beginning with the 2021 performance period and for all future years, for the MIPS performance categories identified in the regulation, QCDRs and qualified registries must be able to submit data for each category, and Health IT vendors must be able to submit data for at least one category.**

#### **CMS solicits feedback on the benefits and burdens of this proposal, including whether the requirement to support all three identified categories of MIPS performance data should extend to health IT vendors.**

CMS also recognizes the need to create an exception to allow QCDRs and qualified registries that only represent MIPS eligible clinicians that are eligible for reweighting under the Promoting Interoperability performance category. **Thus, CMS proposes to revise § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability category, this requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) (physical therapists, occupational therapists,**

*qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) or (5) (i.e., NPs, PAs, CRNAs, and CNSs) or §414.1380(c)(2)(i)(C)(1)-(7) (i.e., hardship exemptions, extreme/uncontrollable circumstances, non-patient facing, hospital-based, and ASC-based) or § 414.1380(c)(2)(i)(C)(9) (i.e., small practice clinicians). CMS anticipates using the self-nomination vetting process to assess whether the QCDR or qualified registry is subject to its proposed requirement to support reporting the Promoting Interoperability performance category.*

**CMS solicits comments on this proposal, including the scope of the proposed exception from the Promoting Interoperability reporting requirement for certain types of QCDRs and qualified registries. Specifically, it solicits comment on whether it should more narrowly tailor, or conversely broaden, the proposed exceptions for when QCDRs and qualified registries must support the Promoting Interoperability performance category.**

#### Approval Criteria for Third Party Intermediaries ([p. 976](#))

CMS has experienced instances where a third party intermediary withdraws mid-performance period, which impacts the clinician or group's ability to participate in the MIPS program, through no fault of their own. CMS proposes two changes to help prevent these disruptions.

- CMS proposes at § 414.1400(a)(4) to add a new paragraph (v) to establish that a condition of approval for a third party intermediary is for the entity to agree to provide services for the entire performance period and applicable data submission period.
- CMS proposes at § 414.1400(a)(4) to add a new paragraph (vi) to establish that a condition of approval is for third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved a transition plan.

#### Qualified Clinical Data Registries (QCDRs) ([p. 977](#))

CMS refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012, which requires the Secretary to establish requirements for an entity to be considered a QCDR and a process to determine whether or not an entity meets such requirements. CMS also refers readers to section 1848(m)(3)(E)(i), (v) of the Act, the CY 2019 PFS final rule (83 FR 60088), and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries and QCDR approval criteria.

#### QCDR Approval Criteria ([p. 977](#))

Requirement for QCDRs to Support All Three Performance Categories Where Data Submission is Required ([p. 978](#))

As noted above, the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); Improvement Activities; and Promoting Interoperability.

***Beginning with the 2021 performance period and for future years, CMS proposes to require QCDRs to support three performance categories: Quality, Improvement Activities, and Promoting Interoperability. CMS proposes to amend § 414.1400(a)(2) to state beginning with the 2021 performance period and for all future years, for the MIPS performance categories [listed above], QCDRs must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category: Quality (except for data on the CAHPS for MIPS survey); Improvement Activities; and Promoting Interoperability. A third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies.***



Based on CMS's review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting all three performance categories.

Requirement for QCDRs to Engage in Activities that will Foster Improvement in the Quality of Care (p. 981)

The definition of QCDR at § 414.1305(2) currently states that beginning with the 2020 performance year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and 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. ***To clarify this definition, CMS proposes to add § 414.1400(b)(2)(iii) that beginning with the 2023 MIPS payment year (2021 performance year), the QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. CMS would require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. CMS intends on including the QCDR's approved quality improvement services in the qualified posting for each approved QCDR.***

CMS clarifies that quality improvement services may be broad, and do not necessarily have to be specific towards an individual clinical process (e.g., for the QCDR to provide reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria; or if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide). To be clear, these QCDR quality improvement services would be separate and apart from any activities that are reported on under the improvement activities performance category.

Enhanced Performance Feedback Requirement (p. 983)

Currently, CMS requires QCDRs to provide timely performance feedback at least 4 times a year on all of the MIPS performance categories that the QCDR reports to CMS (82 FR 53812). However, CMS sees value in providing more timely feedback. In the QCDR performance feedback currently being provided to clinicians and groups, CMS has heard from stakeholders that not all QCDRs provide feedback the same way—some QCDR feedback contains information needed to improve quality, whereas other QCDR feedback does not supply such information due to the data collection timeline.

***Therefore, CMS proposes a change so that QCDRs structure feedback in a similar manner. CMS proposes a new paragraph at § 414.1400(b)(2)(iv), beginning with the 2023 MIPS payment year [2021 performance year], to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. CMS solicits comment on other exceptions that may be necessary under this requirement.*** CMS understands that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realizes the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to.

***CMS also proposes to strengthen the QCDR self-nomination process at § 414.1400(b)(1) to add that beginning with the 2023 MIPS payment year [2021 performance year], QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year.***

The current performance period begins January 1 and ends on December 31, and the corresponding data submission deadline is typically March 31. CMS has heard from QCDR stakeholders that in some instances, clinicians wait until the end of the performance period to submit data to the third party intermediary, who are

then unable to provide meaningful feedback to their clinicians 4 times a year. **CMS seeks comment for future rulemaking on whether it should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the performance period (i.e., December 31). CMS also seeks comment for future rulemaking on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback to the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.**

#### **QCDR Measures (p. 986)**

Through education and outreach, CMS has heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and believes the proposals summarized below will help to ensure that the measures made available in MIPS are meaningful to a clinician's scope of practice.

#### **QCDR Measure Considerations (p. 987)**

All new and previously approved QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). The QCDR measure review process occurs after the self-nomination period closes on September 1. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639).

***Here, CMS proposes to codify a number of previously finalized QCDR measure considerations (83 FR 59902). CMS proposes to amend § 414.1400 by adding § 414.1400(b)(3)(iv) to include the following previously finalized QCDR measure considerations for approval:***

- ***Preference for 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 of care coordination.***
- ***Measures that address the domain for patient and caregiver experience.***
- ***Measures that address efficiency, cost, and resource use.***

To clarify, these factors would be codified as measure *considerations*. Later in this section, CMS also proposes to change the following previously finalized considerations into *requirements*:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

***CMS also proposes to amend § 414.1400 to add paragraph (b)(3)(iv)(H) to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.*** CMS previously finalized a policy beginning with the 2018 performance period, that allows QCDRs to seek permission from another QCDR to use an existing and approved QCDR measure. CMS generally encourages QCDR measure owners to permit other QCDRs to report their measures on behalf of MIPS eligible clinicians for purposes of MIPS. To the extent that QCDR measure owners limit the availability of their measures, such limitations may adversely affect a QCDR's ability to benchmark the measure, the robustness of the benchmark, or the comparability of MIPS eligible clinicians' performance results on the measure.

***CMS also proposes to amend § 414.1400 to add § 414.1400(b)(3)(iv)(I) to state that it would give greater consideration to measures for which QCDRs:***

- a) **Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy PQRS program; and**
- b) **Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.**

**Finally, CMS proposes to amend § 414.1400 to add paragraph (b)(3)(iv)(J) to state that beginning with the 2020 performance period, CMS will place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods [see discussion below].** Those that do not, may not continue to be approved. Later in this section, CMS also discusses how QCDRs may create participation plans for existing approved QCDR measures that have failed to reach benchmarking thresholds, in order to be reconsidered for future use.

This proposal responds to observed instances, over the first 2 years of MIPS, where QCDR measures have been approved for continued use in the program, but have had low reporting volumes, below the case minimum and reporting volume thresholds required for a measure to be benchmarked within the program.

QCDR Measure Requirements (p. 992)

**Beginning with the 2020 performance period, CMS proposes to change both of the following considerations into requirements and proposes to amend § 414.1400 by adding § 414.1400(b)(3)(v) to include the following:**

- **Measures that are beyond the measure concept phase of development**
- **Measures that address significant variation in performance**

**Beginning with the 2021 performance period and future years, CMS also proposes that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination:**

- **Cost measures (as proposed in this rule);**
- **Improvement Activities (as found in [Appendix 2](#)); or**
- **CMS developed MVPs (under the pathway framework, for example, a surgery specific QCDR should be able to correlate their surgery-related QCDR measure to an MVP, such as the Major Surgery pathway).**

CMS understands that not all measures may have a direct link. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, it would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements defined above.

**CMS also proposes, at § 414.1400(b)(3)(v)(C), that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.** CMS references the [CMS Blueprint for the CMS Measures Management System](#) in defining this process. CMS also notes that the testing process for quality measures is dependent on the measure type (e.g., a measure that is specified as an eQIM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards, which further illustrate these differences based on measure type.

This proposal responds to public comments received, and CMS's priority to ensure that all measures available in MIPS are reliable and valid, thereby reducing reporting burden on eligible clinicians and groups. While CMS understands this proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, it is unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial.

**Furthermore, CMS proposes to require QCDRs to collect data on the potential QCDR measure. For a QCDR measure to be considered for use in the program, beginning with the 2021 performance period and future years, CMS proposes to amend § 414.1400 to add paragraph (b)(3)(v)(D) that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on.** CMS suggests QCDRs collect data on as many months as possible, but strongly encourage QCDRs to collect data for 12 months prior to submitting the QCDR measure at the time of self-nomination, since quality reporting requires 12 months of data and this will also likely increase the chance that the measure will be able to be benchmarked.

This proposal is meant to discourage situations in which QCDRs have attempted to use the MIPS Program to “test” out measure concepts without concrete evidence that there is a measurement performance gap. In addition, CMS has identified some current QCDR measures in the program that have continuously low reporting rates, which affects the ability to meet benchmarking criteria. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable and data collection on the metric is possible. In addition, the data collected on the QCDR measure prior to self-nomination, could be used to demonstrate that there is a performance gap and need for measurement.

**Finally, CMS proposes to amend § 414.1400 to add paragraph (b)(3)(v)(E) to state beginning with the 2022 MIPS payment year [2020 performance period], CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years.** If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure(s) as discussed in the next section. CMS clarifies that QCDRs could address the duplication by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. CMS would not approve duplicative QCDR measures if QCDRs choose not to address the areas of duplication with other approved QCDR measures identified by CMS during the previous year’s QCDR measure review period.

#### QCDR Measure Rejections (p. 999)

CMS proposes QCDR measure rejection criteria that generally align with finalized removal criteria for MIPS quality measures in the CY 2019 PFS final rule (83 FR 59763 through 59765). **Specifically, CMS proposes to amend § 414.1400 to add paragraph (b)(3)(vii) to state that beginning with the 2020 performance period, it would reject QCDR measures with consideration of, but not limited to, the following factors:**

- **QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.**
- **QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.**
- **QCDR measures that are duplicative or identical to quality measures used under the legacy PQRS program, which have been retired.**
- **QCDR measures that meet the “topped out” definition as described at § 414.1305 and in the CY 2017 QPP final rule (81 FR 77282 through 77283). If a QCDR measure is topped out and rejected, it may be reconsidered for the program in future years if the QCDR can provide evidence through additional data and/or recent literature that a performance gap exists and show that the measure is no longer topped out during the next QCDR measure self-nomination process.**
- **QCDR measures that are process-based, with considerations to whether the removal of the process measure impacts the number of measures available for a specific specialty.**
- **Whether the QCDR measure has potential unintended consequences to a patient’s care (e.g., the measure disqualifies a patient from receiving oxygen therapy or other comfort measures).**

- **Considerations and evaluation of the measure’s performance data, to determine whether performance variance exists.**
- **Whether the previously identified areas of duplication have been addressed as requested.**
- **QCDR measures that split a single clinical practice or action into several QCDR measures (e.g., splitting a measure into multiple measures based on a particular body extremity, such as improvement in toe pain- the 5th toe, and a separate measure for the 2nd toe).**
- **QCDR measures that are “check-box” with no actionable quality action (e.g., a QCDR measure that measures that a survey has been distributed to patients).**
- **QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years (i.e., do not have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size of 20 applicable cases).**
- **Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.**
- **QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.**
- **QCDR measures that focus on rare events or “never events” in the measurement period (e.g., a fire in the operating room).**

QCDR Measure Review Process (p. 1001)

Currently, QCDR measure approvals are on a year-to-year basis (82 FR 53811), from September to December once self-nomination occurs. **To help reduce yearly self-nomination burden and address stakeholder feedback (83 FR 59898 through 59901), CMS proposes to amend § 414.1400 to add paragraph (b)(3)(vi) to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at CMS’s discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described above. However, as part of this proposal, upon annual review, CMS may revoke the second year’s approval if a QCDR measure approved for 2 years is:**

- **Topped out (see § 414.1305, in the CY 2017 QPP final rule (81 FR 77282 through 77283));**
- **Duplicative of a more robust measure;**
- **Reflects an outdated clinical guideline;**
- **Requires measure harmonization; or**
- **The QCDR self-nominating the QCDR measure is no longer in good standing, as described in the CY 2018 Quality Payment Program final rule (82 FR 53808).**

CMS clarifies that for QCDRs not in good standing, it would not remove a measure mid-year; rather, the measure’s 2-year approval would be revoked during annual review after 1 year and the QCDR’s measures would no longer qualify for multi-year approval in the future.

Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds (p. 1003)

Earlier in this rule, CMS discusses how QCDR measures that fail to meet benchmarking thresholds after being in the program for 2 consecutive calendar years may not continue to be approved in the future. However, CMS understands that there are instances where measures that are low-reported may still be considered important to a respective specialty. **Therefore, beginning with the 2020 performance period, it proposes to amend § 414.1400 to add paragraph (b)(3)(iv)(J)(aa) to state in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist’s practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR’s detailed plans and changes to encourage**

**eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.**

As examples, a QCDR measure participation plan could include one or more of the following:

- Development of an education and communication plan.
- Update the QCDR measure's specification with changes to encourage broader participation, which would require review and approval by CMS.
- Require reporting on the QCDR measure as a condition of reporting through the QCDR.

To be clear, implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period, as CMS considers many factors in whether to approve QCDR measures. At the following annual review of QCDR measures, CMS would analyze the measure's data submissions to determine whether the QCDR measure participation plan was effective (meaning, reporting volume increased, thereby increasing the likelihood of the QCDR measure being benchmarked). If the data does not show an increase in reporting volume, CMS may not approve the QCDR measure for the subsequent year.

#### Qualified Registries ([p. 1004](#))

##### **Requirement to Support All Three Performance Categories Where Data Submission is Required ([p. 1004](#))**

Similar to the proposal for QCDRs, ***beginning with the 2021 performance period and for future years, CMS proposes at § 414.1400(a)(2) to require qualified registries to support all three performance categories: Quality (except for data on the CAHPS for MIPS survey); Improvement Activities; and Promoting Interoperability with an exception. For the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dietitians or nutrition professionals) or (5) (i.e., NPs, PAs, CRNAs, and CNSs) or §414.1380(c)(2)(i)(C)(1)-(7) (i.e., hardship exemptions, extreme/uncontrollable circumstances, non-patient facing, hospital-based, and ASC-based) or § 414.1380(c)(2)(i)(C)(9) (i.e., small practice clinicians).*** As part of this proposal, CMS would require qualified registries to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination.

##### **Enhanced Performance Feedback Requirement ([p. 1006](#))**

***Additionally, CMS proposes to add a new paragraph, § 414.1400(c)(2)(ii), beginning with the 2023 payment year [2021 performance year], to require that qualified registries provide the following as a part of the performance feedback given at least 4 times a year: feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. If the qualified registry does not receive the data from their clinician until the end of the performance period, this will preclude the qualified registry from providing feedback 4 times a year, and the qualified registry could be excepted from this requirement. CMS seeks comment on other exceptions that may be necessary.***

***Furthermore, CMS proposes to strengthen the qualified registry self-nomination process at § 414.1400(c)(1) to add that beginning with the 2023 MIPS payment year [2021 performance year], qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)).***

The current performance period begins January 1 and ends on December 31, and the corresponding data submission deadline is typically March 31. CMS has heard from qualified registry stakeholders that in some instances, clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. **CMS seeks comment for**

**future rulemaking on whether it should require MIPS eligible clinicians, groups, and virtual groups who utilize a qualified registry to submit data throughout the performance period, and prior to the close of the performance period (i.e., December 31). CMS also seeks comment for future rulemaking on whether clinicians and groups can start submitting their data starting April 1 to ensure that the registry is providing feedback to the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.**

#### Remedial Action and Termination of Third Party Intermediaries ([p. 1009](#))

Among other provisions, § 414.1400(a)(5) specifically obligates each third party intermediary to certify that all data it submits to CMS on behalf of a MIPS eligible clinician, group or virtual group is true, accurate and complete to the best of its knowledge. However, based on experience with third party intermediaries thus far, CMS has concerns that certain third party intermediaries may not fully appreciate their existing compliance obligations or the implications of non-compliance.

CMS refers readers to CY 2019 PFS final rule (83 FR 59908 through 59910) for the discussion of the evolution of policies regarding remedial actions and termination of a third party intermediary. The agency's enforcement authority as codified in § 414.1400(f) broadly extends to include instances of willful misconduct by the third party intermediary, as well as other instances in which a third party intermediary inadvertently submits data with deficiencies, and errors that render the data "inaccurate, unusable or otherwise compromised." To facilitate a more fulsome understanding on when inadvertent conduct could trigger an enforcement action against a third party intermediary, the current regulatory text in § 414.1400(f)(3) provides that the threshold for "inaccurate, unusable or otherwise compromised" may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary.

***To provide further clarification, CMS proposes to add the phrase "including but not limited to" to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data.***

CMS anticipates that this and other proposed revisions in this rule will emphasize to third party intermediaries the sanctions they may face from CMS if they submit improper data to CMS. In addition, CMS notes that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data.

#### Public Reporting on Physician Compare ([p. 1014](#))

##### Background ([p. 1014](#))

For previous discussions on the background of Physician Compare, CMS refers readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 QPP final rule (81 FR 77390 through 77399), the CY 2018 QPP final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), and the [Physician Compare Initiative Website](#).

##### **CMS proposes to publicly report on Physician Compare:**

- ***Aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible; and***
- ***An indicator on the profile page or in the downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as technically feasible.***

These proposals are summarized below.

### Regulation Text Changes (p. 1014)

To more completely and accurately reference the data available for public reporting on Physician Compare, CMS proposes to amend § 414.1395(a) by adding paragraph (1) stating that CMS posts on Physician Compare, in an easily understandable format: (i) information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and (ii) the names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs. CMS also proposes to amend § 414.1395(a) by adding paragraph (2) stating that CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. Finally, CMS proposes to amend § 414.1395(a) by adding paragraph (3) stating that the information made available under § 414.1395 will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

### Final Score, Performance Categories, and Aggregate Information (p. 1015)

***In accordance with section 1848(q)(9)(D) of the Act, CMS proposes to publicly report on Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible, and to codify this proposed policy at § 414.1395(a).*** Although CMS previously finalized a policy to periodically post aggregate information on the MIPS, as technically feasible, for all future years, CMS had not proposed or finalized in rulemaking a specific timeframe for doing so. CMS clarifies that the aggregate data publicly reported would be inclusive of all MIPS eligible clinicians. CMS also notes that some aggregate MIPS data is already publicly available in other places, such as via the QPP Experience Report.

### Quality (p. 1017)

CMS is not making any proposals regarding publicly reporting quality performance category information. **However, it seeks comment on the value of collecting and publicly reporting information from narrative questions and other PROMs, as well as publishing a single "value indicator" reflective of cost, quality and patient experience and satisfaction with care for each MIPS eligible clinician and group, on the Physician Compare website. CMS will consider stakeholder feedback before proposing any policies in future rulemaking.**

Physician Compare website user testing has repeatedly shown that Medicare patients and caregivers greatly desire narrative reviews, quotes and testimonials by their peers, and a single overall "value indicator," reflective for each MIPS eligible clinician and group, and would expect to find such information on the Physician Compare website already, based on their experiences with other consumer-oriented websites. CMS currently does not display any narrative patient satisfaction information on Physician Compare or any single overall value indicator for MIPS eligible clinicians and groups (except MIPS performance category and final scores); currently all performance information on Physician Compare is publicly reported at the individual measure level.

CMS clarifies that to be publicly reported on Physician Compare, patient narrative data would have to meet CMS's public reporting standards, described at § 414.1395(b), and reviewed in consultation with the Physician Compare Technical Expert Panel, to determine how and where these data would be best reported on Physician Compare. CMS also clarifies that if it proposes to publicly report patient narratives in future rulemaking, it will address all related patient privacy safeguards consistent with section 10331(c) of the Affordable Care Act, which requires that information on physician performance and patient experience is not disclosed in a manner that violates the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a) with regard to the privacy individually identifiable health information, and other applicable law.



### **Promoting Interoperability ([p. 1019](#))**

Although CMS is not making any proposals regarding publicly reporting Promoting Interoperability category information, it refers readers to the Interoperability and Patient Access proposed rule, published in the March 4, 2019 Federal Register (84 FR 7646 through 7647), where it proposed to include an indicator on Physician Compare for the eligible clinicians and groups that submit a “no” response to any of the three prevention of information blocking attestation statement. These statements contain specific representations about a clinician’s implementation and use of CEHRT and are intended to verify that a MIPS eligible clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. In the event that these statements are left blank, that is, a “yes” or a “no” response is not submitted, the attestations would be considered incomplete, and we would not include an indicator on Physician Compare. CMS would post this indicator on Physician Compare, either on the profile pages or the downloadable database, as feasible and appropriate, starting with the 2019 performance period data available for public reporting starting in late 2020. CMS notes that addressing comments on this proposed policy is outside the scope of this proposed rule.

### **Facility-based Clinician Indicator ([p. 1020](#))**

CMS established at § 414.1380(e) a facility-based measurement scoring option under the MIPS quality and cost performance categories for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year.

***CMS proposes to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as technically feasible. CMS also proposes to provide a link to facility-based measure-level information for such MIPS eligible clinicians on Hospital Compare, as technically feasible. CMS proposes to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible.***

CMS also considered displaying hospital-based measure-level performance information on Physician Compare profile pages, including scores for specific measures and the hospital overall rating. However, it opted instead for the proposal above due to concerns about duplication with Hospital Compare; interpretability by Physician Compare website users expecting to find clinician-level, rather than hospital-level, information; and operational feasibility. Additionally, CMS believes its proposed approach is consistent with consumer testing findings that Medicare patients and caregivers find value in information on the relationships clinicians and groups may have with facilities where they perform services.

### **Overview of the APM Incentive ([p. 1023](#))**

#### ***Terms and Definitions ([p. 1024](#))***

***CMS proposes to add a new term “Aligned Other Payer Medical Home Model” and define it to mean a payment arrangement (not including a Medicaid payment arrangement) operated by an other payer that formally partners with CMS in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:***

- The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16

Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

- Empanelment of each patient to a primary clinician; and
- At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; Risk-stratified care management; Coordination of care across the medical neighborhood; Patient and caregiver engagement; Shared decision-making; and/or Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

### **Advanced APMs (p. 1026)**

#### **Bearing Financial Risk for Monetary Losses (p. 1028)**

##### **Expected Expenditures (p. 1028)**

CMS provides background on its approach for defining financial risk starting on [p. 1028](#). CMS notes that it previously established a definition of expected expenditures to mean the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, ‘expected expenditures’ means the episode target price.

However, CMS notes its concern that the definition of expected expenditures may lead to the total risk under a benchmark-based nominal amount standard to not always be sufficient to ensure that the level of average or likely risk under an Advanced APM is actually more than nominal. CMS notes, for example, that the level of expected expenditures reflected in an APM’s benchmark or episode target price could be set in a manner that would substantially reduce the amount of loss an APM entity would reasonable expect to bear. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is “essentially illusory.”

**Therefore, CMS is proposing to amend the definition of expected expenditures to define expected expenditure as follows: For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the expected Medicare Parts A and B expenditures for a participant in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for Advanced APM determinations.**

CMS notes that in general, expected expenditures are expressed as a dollar amount, and may be derived for a particular APM from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, CMS recognizes that expected expenditures under an APM often are risk-adjusted and trended forward. **For the purposes of this proposed definition of expected expenditures, CMS would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the APM.**

CMS is also proposing a similar amendment to the definition of expected expenditures applicable to the Other Payer Advanced APM criteria [later in the rule](#). **CMS seeks comment on this proposal.**

##### **Excluded Items and Services under Full Capitation Arrangements (p. 1032)**

CMS previously finalized a capitation standard which provides that full capitation arrangements meet the Advanced APM financial risk criterion. CMS also finalized that the capitation standard only applies to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all

items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As CMS has begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, CMS has noticed that some payment arrangements that are submitted as capitation arrangements include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, and out-of-network emergency services. In reviewing these exclusion lists, CMS believes that it may be appropriate for CMS to allow certain capitation arrangements to be considered “full” capitation arrangements even if they categorically exclude certain items or services from payment through the capitation rate. **As such, CMS is seeking comment on:**

- **What categories of items and services might be excluded from a capitation arrangement that would still be considered a full capitation arrangement?**
- **Whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services?**
- **What percentage of the total cost of care such exclusions typically account for under what is intended to be a “full” global capitation arrangement?**
- **How non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements?**
- **Whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under the full capitation standard for Other Payer Advanced APMs?**

### **Qualifying APM Participant (QP) and Partial QP Determinations (p. 1034)**

#### **Application of Partial QP Status (p. 1035)**

CMS has previously finalized a policy to apply Partial QP status at the NPI level across all TIN/NPI combinations (similar to its policy for QP status). However, CMS notes that it no longer believes it should apply Partial QP status at the NPI level across all TIN/NPI combinations. CMS details its rationale starting on [p. 1036](#), noting that the MIPS exclusion does not always provide a net positive outcome across an individual clinician’s TIN/NPI combinations when compared to the APM Incentive Payment that QPs receive, and that it may prevent some clinicians from receiving a positive MIPS payment adjustment for other TIN/NPI combinations – and that it may deterring clinicians from participating in Advanced APMs. ***Therefore, CMS is proposing that beginning with the 2020 QP performance period, Partial QP status would apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status, and to make corresponding changes to regulation text. This means that any MIPS election for a Partial QP would only apply to the TIN/NPI combination through which Partial QP status is attained. CMS seeks comment on this proposal.***

#### **QP Performance Period (p. 1038)**

CMS previously finalized policies 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, that CMS will make QP determinations at three separate snapshot dates, and that an eligible clinician is not a QP or Partial QP for a year if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period. Additionally, CMS finalized that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP or Partial QP thresholds based on participation in the remaining non-terminating APM Entities.

However, currently under the terms of some Advanced APMs, APM Entities can terminate their participation in the Advanced APM while bearing no financial risk after the end of the QP Performance Period for the year (August 31). Under current regulations, an APM Entity's termination after that date would not affect the QP or Partial QP status of all eligible clinicians in the APM Entity. CMS believes that allowing those eligible clinicians to retain their QP or Partial QP status without having borne financial risk under the Advanced APM through which they attained QP or Partial QP status is not aligned with the structure and principles of the QPP. CMS states that a critical aspect of Advanced APMs is that participants must bear more than a nominal amount of financial risk under the model. If an APM Entity terminates participation without financial accountability, the APM Entity has not borne more than a nominal amount of financial risk.

***Therefore, CMS proposes to revise regulations to state that, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP or Partial QP for the year if: (1) the APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or (2) the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. In addition, CMS is proposing to revise regulations to state that, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if: (1) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.***

***CMS proposes similar regulation text revisions to apply the same policies regarding termination without bearing financial risk to determinations for Partial QP status.***

***CMS seeks comment on these proposals.***

#### ***All-Payer Combination Option (p. 1043)***

CMS provides an overview of the All-Payer Combination Option starting on [p. 1043](#), including policies CMS has finalized addressing this option. CMS notes that, in this section of the proposed rule, CMS discusses its proposal to define the term Aligned Other Payer Medical Home Model and its proposals regarding bearing financial risk for monetary losses – specifically the Medicaid Medical Home Model financial risk standard and the definition of expected expenditures. CMS also discusses its request for comment on whether certain items and services should be excluded from the capitation rate for its definition of full capitation arrangements. A summary of these proposals is included starting on [p. 1065](#).

#### ***Aligned Other Payer Medical Home Models (p. 1049)***

***CMS reiterates its proposal discussed above to add the defined term “Aligned Other Payer Medical Home Model.”*** CMS notes that this proposed definition includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. CMS discusses its rationale for proposing such a definition, including its decision to exclude Medicaid payment arrangements and its decision to limit this definition to other payer payment arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models, starting on [p. 1050](#).

***CMS seeks comment on this proposal.***

**Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models ([p. 1052](#))**

Under current regulations, an Other Payer Advanced APM is an other payer arrangement that meets the Other Payer Advanced APM criteria. ***Accordingly, CMS proposes that the Other Payer Advanced APM CEHRT criterion and the use of quality measures criterion would apply to any Aligned Other Payer Medical Home Model for which CMS would make an Other Payer Advanced APM determination. Further, CMS proposes to require Aligned Other Payer Medical Home Models to comply with the 50 eligible clinician limit<sup>32</sup> to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models.***

Regarding the applicable financial risk and nominal amount standards, consistent with the financial risk and nominal amount standards applicable to Medical Home Models and Medicaid Medical Home Models, ***CMS proposes that the Aligned Other Payer Medical Home Model financial risk and nominal amount standards would be the same as the Medicaid Medical Home Model financial risk and nominal amount standards. CMS is also proposing corresponding amendments to regulation text.*** CMS believes that this proposal is appropriate because the same expectation of ability to bear a more than nominal amount of financial risk applies to participants in these models as Medical Home Models and Medicaid Medical Home Models because the arrangements are already aligned and the participants are the same.

**Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status ([p. 1053](#))**

***CMS proposes that payers may submit other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Payer Initiated Process.*** This proposal would be effective January 1, 2020 for the 2021 performance year. In the CY 2019 PFS final rule, CMS finalized a process for Remaining Other Payers to submit other payer arrangements for CMS determination of Other Payer Advanced APM status. Other payers would be required to submit their other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, using this Remaining Other Payer process.

***CMS proposes that APM Entities and eligible clinicians can submit other payer arrangements for CMS to determine whether they are Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Eligible Clinician Initiated Process.***

***CMS seeks comment on these proposals.***

**Bearing Financial Risk for Monetary Losses ([p. 1053](#))**

**Aligned Other Payer Medical Home Model Financial Risk and Nominal Amount Standards ([p. 1055](#))**

With respect to requirements for bearing risk, CMS has previously established Medical Home Model financial risk and nominal amount standards and Medicaid Medical Home Model financial risk and nominal amount standards, but CMS notes that none of these standards apply to arrangements with other payers for the purposes of Other Payer Advanced APM determinations. Consistent with CMS' proposal to define the term Aligned Other Payer Medical Home Model, ***CMS is proposing to conform financial risk and nominal amount standards for Aligned Other Payer Medical Home models with those that apply for Medicaid Medical Home***

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<sup>32</sup> Under current regulations, if an APM Entity participating in a Medical Home Model or a Medicaid Medical Home Model is owned and operated by an organization with 50 or more eligible clinicians whose Medicare billing rights have been reassigned to the TIN(s) of the organization(s) or any of the organization's subsidiary entities, then the generally applicable financial risk and nominal amount standards apply, rather than the respective Medical Home Model or Medicaid Medical Home model financial risk and nominal amount standards.

**Models.** CMS is also proposing to state that both model types require the direct payment by the APM Entity to the payer, which means either the other payer or the Medicaid agency. CMS also proposes that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models. CMS seeks comment on these proposals.

#### Generally Applicable Other Payer Advanced APM Nominal Amount Standard ([p. 1056](#))

CMS previously finalized that for a other payer payment arrangement to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least 4 percent of the expected expenditures. CMS also 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. CMS defines expected expenditures for Other Payer Advanced APM criteria as the Other Payer Advanced APM benchmark, except for episode payment models, for which it is defined as the episode target price.

- **Marginal Risk ([p. 1057](#)).** CMS discusses its rationale for including a marginal risk requirement to ensure strong financial risk components for Other Payer Advanced APMs, and also notes that CMS has applied the marginal risk policy by requiring that a payment arrangement must meet exceed the marginal risk rate of 30 percent at all levels of total losses. CMS notes that it has encountered some other payer arrangements that include strong financial risk components and exceed the 30 percent marginal risk requirement at the most common levels of losses, but that also employ marginal risk rates below 30 percent at much higher levels of losses, thereby precluding them from Other Payer Advanced APM status. ***CMS proposes to provide that, in the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate requirement of 30 percent. Exceptions for large losses and small losses that currently apply would be retained. CMS provides an example of how the average marginal risk rate would be calculated in [Table 58](#).*** CMS provides its rationale starting on [p. 1059](#). ***CMS seeks comment on this proposal.***
- **Expected Expenditures ([p. 1060](#)).** Consistent with its proposal [described above](#) to redefine expected expenditures for Advanced APMs, ***CMS proposes to update the definition of expected expenditures as it applies to Other Payer Advanced APM criteria. Specifically, CMS would clarify that for the purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expected expenditures for a participant in the absence of the payment arrangement. If expected expenditures (i.e. benchmarks) under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures would not be considered when CMS assesses financial risk under the payment arrangement for Other Payer Advanced APM determinations. As with Advanced APM criteria, CMS clarifies that it would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the payment arrangement. CMS seeks comment on this proposal.***
- **Excluded Items and Services under Full Capitation Arrangements ([p. 1064](#)).** As discussed under the [above discussion](#) of Advanced APM criteria, CMS believes it may be appropriate to allow certain capitation arrangements to be considered “full” capitation arrangements even if they categorically exclude certain services from payment through the capitation rate. ***Therefore, CMS seeks comment on the following:***
  - ***How other payers define or determine what, if any, exclusions are reasonable in a given capitation arrangement?***
  - ***Whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or***

- reasons for excluding those categories of services and why such items or services are excluded?*
- *How non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements?*
  - *Whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under a full capitation arrangement?*

#### **Quality Payment Program Technical Revisions ([p. 1067](#))**

This section includes certain proposed technical revisions to the regulations to correct several technical errors and to reconcile the text of several of regulations with the final policies CMS adopted through notice and comment rulemaking. These proposed revisions are technical in nature and do not change any substantive policies for the QPP.

## Collection of Information Requirements ([p. 1070](#))

As part of the Paperwork Reduction Act (PRA), CMS is required to solicit comments on the below issues specific to relevant information collection requests (ICRs):

- The need for the information collection and its usefulness in carrying out the proper functions of its agency.
- The accuracy of its burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Its efforts to minimize the information collection burden on the affected public, including the use of automated collection techniques.

## ICRs Regarding Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) ([p. 1070](#))

CMS proposes to use the ASP payment methodology to set the payment rates for the “incident to” drugs and ASP-based payment to set the payment rates for the oral product categories, which stems from manufacturers’ voluntarily-submitted ASP data. CMS is not proposing any revisions to the burden estimates at this time, but will consider revisions depending on changes in voluntary submissions from oral OUD drug manufacturers, manufacturer consolidations, and new Part B drug and biological manufacturers.

## ICRs Regarding the Open Payments Program – “Nature of Payment” Categories ([p. 1075](#)) and Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies ([p. 1077](#))

CMS’ proposal to modify the nature of payment categories require updates to the existing ICR. CMS estimates that reporting entities would need to make minor, one-time updates to their data collection processes (because they expect to report a transaction with one of the new categories), as well as updates to their submission processes. Despite this CMS does not anticipate any ongoing added burden beyond what is already approved under the existing ICR.

CMS proposes modifications to its existing ICR given applicable manufacturers and GPOs will need to accommodate the reporting of device identifiers (DIs). While CMS anticipates that some entities may be capturing this information already, the agency welcomes feedback regarding the potential burden associated with its proposal and the extent to which DIs are already tracked. CMS expects that larger companies would incur more burden as they likely have more complex systems and more records to report.

## ICRs Regarding Medicare Enrollment of Opioid Treatment Programs ([p. 1079](#))

CMS proposes to modify its existing ICR to accommodate the enrollment of OTPs, which 1,900 will likely be eligible over the next 3 years. A copy of the draft OTP supplement will be available on-line, and CMS welcomes public comment on: (1) its contents; (2) the usefulness of the data to be captured thereon; and (3) the anticipated burden of completion. The impact of CMS’ proposal to require the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP, as well as collecting an application fee at the time of enrollment, is discussed [below](#).

## Information Collection Requirements associated with MIPS and Advanced APMs ([p. 1082](#))

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs, and the ICRs reflect proposals in this rule, as well as previously finalized policies in the two prior years. According to CMS, two MIPS ICRs show an increase in burden due to proposed changes in policies: QCDR self-nomination applications and Call for Quality Measures.

**QCDR:** CMS increased its estimate of the time required to submit a QCDR measure by 1.5 hour due to



the proposal to require QCDRs to identify a linkage between their QCDR measures to related cost measures, Improvement Activities, and MIPS Value Pathways starting with the 2021 self-nomination period (+1 hour); and the proposal to require QCDR measure stewards to submit measure testing data as part of the self-nomination process for each QCDR measure (+0.5 hours). CMS also increased its estimate of the time required for a QCDR to submit their self-nomination by 0.25 due to the proposal to require QCDRs to include a description of the quality improvement services they intend to support.

**Call for Quality Measures:** CMS increased its estimate of the time required to nominate a quality measure for consideration by 1 hour due to the proposal to require that MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement activities and provide rationale for the linkage.

The remaining changes to currently approved burden estimates are adjustments to reflect better understanding of the impacts of policies finalized in previous rules, as well as the use of updated data sources available at the time of publication of this proposed rule.

CMS' participation estimates are reflected in Tables 69, 70, and 71 for the quality performance category, Table 87 for the Promoting Interoperability performance category, and Table 92 for the improvement activities performance category. However, CMS cautions readers that the accuracy of its estimates have been impacted by their ability to predict the number of voluntary reporters and the number of QPs now that more AAPMs are available.

CMS notes that proposed changes to certain ICRs for Advanced APMs are limited to adjustments based on projections for the CY 2020 MIPS performance period.

[Table 64](#) presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. CMS also explains that policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule and continued in this proposed rule create some additional data collection requirements not listed in Table 64. A list of these additional data collection are [listed here](#).

### **ICRs Regarding Third-Party Intermediaries (p. 1092)**

The burden associated with qualified registry self-nomination, QCDR self-nomination and measure submission, and the CAHPS for MIPS survey vendor applications follow.

**Qualified registries:** This rule would adjust the number of self-nomination applications based on current data and due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR and minimum participation requirements. The adjustments would increase CMS' total burden estimates while keeping its burden per response estimates unchanged. See table [65](#) and [66](#) for more detail.

**Qualified Clinical Data Registries:** This rule would increase CMS' minimum total burden estimate and increase the maximum total burden estimate based on the above. CMS' per response estimates for the simplified and full self-nomination processes would increase, as well. See tables [67](#) and [68](#) for details. Of note, CMS states that it may not approve QCDR measures if they are not broadly available. CMS also states it is not accounting for QCDR measure licensing costs as part of its burden estimates at this time, but may consider doing so in the future if data are available. CMS also explains that, in instances in which multiple, similar QCDR measures exist that warrant approval, it may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. CMS encourages QCDRs to harmonize measures or significantly differentiate

measures that are similar, but notes it cannot account for these costs in its burden estimates given significant variation that is likely in either scenario. CMS notes that a significant reduction in burden will come as a result of 2-year QCDR measure approvals.

### **ICRs Regarding Quality Data Submission (p. 1114)**

This rule would adjust the number of respondents based on current data, thus increase total burden estimates, although per response estimates remain unchanged.

Using participation data from the 2017 MIPS performance period combined with the estimate of QPs for the 2020 performance period, CMS estimates a total of 833,243 clinicians will submit quality data as individuals or groups in the 2020 MIPS performance period, a decrease of 131,003 clinicians when compared to its estimate of 964,246 clinicians in the CY 2019 PFS final rule. These will be updated should more current data become available.

CMS explains that estimating the burden associated with the submission of quality performance category data has limitations given clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. The burden will largely depend on the collection type selected, although CMS does assume, on average, each clinician will submit 6 quality measures.

More details can be found in this section, as well as in the following tables

- ◆ [Table 69: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type](#)
- ◆ [Table 70: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type](#)
- ◆ [Table 71: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians](#)
- ◆ [Table 72: Summary of Quality Measures for the 2020 MIPS Performance Period](#)
- ◆ [Table 73: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type](#)
- ◆ [Table 74: Change in Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type](#)
- ◆ [Table 75: Estimated Burden for Quality Performance Category: Clinicians \(Participating Individually or as Part of a Group\) Using the MIPS CQM/QCDR Collection Type](#)
- ◆ [Table 76: Change in Estimated Burden for Quality Performance Category: Clinicians \(Participating Individually or as Part of a Group\) Using the MIPS CQM/QCDR Collection Type](#)
- ◆ [Table 77: Estimated Burden for Quality Performance Category: Clinicians \(Submitting Individually or as Part of a Group\) Using the eCQM Collection Type](#)
- ◆ [Table 78: Change in Estimated Burden for Quality Performance Category: Clinicians \(Participating Individually or as Part of a Group\) Using the eCQM Collection Type](#)
- ◆ [Table 79: Estimated Burden for Quality Data Submission via the CMS Web Interface](#)
- ◆ [Table 80: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface](#)
- ◆ [Table 81: Estimated Burden for Group Registration for CMS Web Interface](#)
- ◆ [Table 82: Change in Estimated Burden for Group Registrations for the CMS Web Interface](#)

### **ICRs Regarding the Nomination of Quality Measures (p. 1139)**

CMS estimates the burden associated with its annual call for quality measures. Details about CMS' estimates are in the tables below.

- ◆ [Table 83: Estimated Burden for Call for Quality Measures](#)
- ◆ [Table 84: Change in Estimated Burden for Call for Quality Measures](#)

### **ICRs Regarding Promoting Interoperability Data (p. 1142)**

CMS proposes some adjustments to its estimates based on updated data and analysis, and its PI policies. More details can be found in the following tables.

- ◆ [Table 85: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories](#)
- ◆ [Table 86: Change in Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories](#)
- ◆ [Table 87: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians](#)
- ◆ [Table 88: Estimated Burden for Promoting Interoperability Performance Category Data Submission](#)
- ◆ [Table 89: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission](#)

### **ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures (p. 1152)**

CMS proposes to adjusted currently approved burden estimates based on data from the 2018 MIPS performance period. More details can be found in the following tables.

- ◆ [Table 90: Estimated Burden for Call for Promoting Interoperability Measures](#)
- ◆ [Table 91: Change in Estimated Burden for Call for Promoting Interoperability Measures](#)

### **ICRs Regarding Improvement Activities Submission (p. 1154)**

CMS proposes to adjusted currently approved burden estimates based on more recent data. See the below tables for more details.

- ◆ [Table 92: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians](#)
- ◆ [Table 93: Estimated Burden for Improvement Activities Submission](#)
- ◆ [Table 94: Change in Estimated Burden for Improvement Activities Submission](#)

### **ICRs Regarding the Nomination of Improvement Activities (p. 1159)**

CMS adjusted its currently approved burden estimates based on data from the 2018 MIPS performance period. More details can be found in the tables below.

- ◆ [Table 95: Estimated Burden for Nomination of Improvement Activities](#)
- ◆ [Table 96: Change in Estimated Burden for Nomination of Improvement Activities](#)

### **Quality Payment Program ICRs Regarding Partial QP Elections (p. 1161)**

CMS proposes to adjust currently approved burden estimates based on updated projections for the 2020 MIPS performance period. More can be found in the tables below.

- ◆ [Table 97: Estimated Burden for Partial QP Election](#)
- ◆ [Table 98: Change in Estimated Burden for Partial QP Election](#)

### **ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process and Eligible Clinician Initiated Process (p. 1163)**

CMS proposes to adjust currently approved burden estimates based on updated projections for the 2020 MIPS performance period. See below tables for details.

- ◆ [Table 99: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process](#)
- ◆ [Table 100: Change in Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process](#)
- ◆ [Table 101: Estimated Burden for the Submission of Data for All-Payer QP Determinations](#)
- ◆ [Table 102: Change in Estimated Burden for the Submission of Data for All-Payer QP Determinations](#)

## ICRs Regarding Voluntary Participants Election to Opt-Out of Performance Data Display on Physician Compare ([p. 1168](#))

CMS proposes to adjust currently approved burden estimates based on data from the 2018 MIPS performance period. See the tables below for more details.

- ◆ [Table 103: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare](#)
- ◆ [Table 104: Change in Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare](#)

## Summary of Annual Quality Payment Program Burden Estimates ([p. 1170](#))

[Table 105](#) summarizes this proposed rule's burden estimates for the Quality Payment Program, while [Table 106](#) provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule.

## Regulatory Impact Analysis ([p. 1776](#))

### Overall Impact ([p. 1176](#))

CMS estimates that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. CMS notes that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the Small Business Administration standards, and that there are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. CMS estimates that the rule generates \$3.46 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon.

### Changes in Relative Value Unit (RVU) Impacts and Other PFS Impacts ([p. 1180](#))

#### Resource-based Work, PE, and MP RVUs ([p. 1180](#))

**CMS estimates the CY 2020 PFS conversion factor to be 36.0896**, which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) and a 0 percent update adjustment factor specified for CY 2020 under section 1848(d) of the Act. **CMS estimates the CY 2020 anesthesia conversion factor to be 22.2774**, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments. [Table 108](#) and [Table 109](#) present how CMS calculated the proposed PFS and Anesthesia conversion factors for 2020.

[Table 110](#) shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in the table. Column F shows the shows the estimated CY 2020 combined impact on total allowed charges of all the RVU changes by specialty.

The most widespread specialty impacts of the proposed RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers, neurology, emergency medicine, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed increases in value for particular services following the recommendations from the American medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review, increased

payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services.

The estimated impacts for several specialties, including ophthalmology and optometry, reflect decreases in payments relative to payment to other physician specialties as a result of revaluation of individual procedures reviewed by the AMA's RUC and CMS. The estimated impacts for other specialties, including vascular surgery, reflect decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 1 percent reduction for CY 2020 is only applicable to approximately 17 percent of the Medicare payment to these entities.

CMS reminds stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The impacts are averages and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under "downloads" on the [CY 2020 PFS proposed rule website](#). CMS selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties.

#### **[Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for CY 2021 \(p. 1186\)](#)**

CMS provides an impact of its [proposed changes to E/M coding and payment for CY 2021](#) for illustrative purposes. [Table 111](#) illustrates the estimated specialty level impacts CMS calculated associated with implementing the RUC-recommended work values for the office/outpatient E/M codes, as well as the revalued HCPCS add-on G-codes for primary care and certain types of specialty visits in 2020, rather than delaying until 2021.

Overall, those specialties that bill higher level established patient visits, such as endocrinology or family practice, see the greatest increases as those codes were revalued higher relative to the rest of the office/outpatient E/M code set. Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits. Other specialty level impacts are primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set and the relative increases to the particular office/outpatient E/M codes predominantly billed by those specialties. CMS notes that any potential coding changes and recommendations in overall valuation for new and existing codes between the CY 2020 proposed rule and the CY 2021 final rule could impact the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, CMS does not believe it can estimate with any degree of certainty what the impact of potential changes might be. CMS also notes, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

#### **[Effects of Proposed Changes Related to Telehealth \(p. 1189\)](#)**

CMS is [proposing to add three new codes](#), HCPCS codes GYYY1, GYYY2, and GYYY3, to the list of Medicare telehealth services for CY 2020. Although CMS expects these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, CMS estimates there will only be a negligible impact on PFS expenditures from these

additions.

### **Other Provisions of the Proposed Regulation ([p. 1189](#))**

CMS provides its impact estimates of other proposals starting on the pages noted below.

- [Effects of Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs \(OTPs\) \(\[p. 1189\]\(#\)\)](#). The total estimated Part B net impact, including FFS and Medicare Advantage, of CMS' proposal to cover OUD treatment services beginning on or after January 1, 2020 over 10 years is \$1,024,000,000.
- [Changes to the Ambulance Physician Certification Statement Requirement \(\[p. 1191\]\(#\)\)](#)
- [Medicare Ground Ambulance Services Data Collection System \(\[p. 1191\]\(#\)\)](#)
- [Intensive Cardiac Rehabilitation \(\[p. 1198\]\(#\)\)](#). CMS estimates that the total cost of adding stable, chronic heart failure to the list of covered conditions for ICR is estimated at \$408,502 annually. CMS is not able to accurately quantify the number of entities that would seek approval as CR or ICR programs.
- [Medicaid Promoting Interoperability Program Requirements for Eligible Professionals \(\[p. 1200\]\(#\)\)](#)
- [Medicare Shared Savings Program \(\[p. 1203\]\(#\)\)](#)
- [Open Payments \(\[p. 1204\]\(#\)\)](#). CMS' initial estimate is that there will be approximately \$10 million dollars per year in increased burden to reporting entities and the new covered recipient groups for submitting, collecting, retaining, and reviewing data. Modifications to the "Nature of Payment" Categories are anticipated to require minor additional costs. Costs for the addition of a device identifier data element cannot be estimated.
- [Medicare Enrollment of Opioid Treatment Programs \(\[p. 1205\]\(#\)\)](#)
- [Deferring to State Scope of Practice Requirements – Ambulatory Surgery Centers \(\[p. 1207\]\(#\)\)](#). CMS predicts a savings of approximately \$17.3 million under its proposal to allow an anesthetist, in addition to a physician, to perform the required pre-surgical risk and evaluation examination, but acknowledges uncertainty and invites public comment on its assumptions.
- [Deferring to State Scope of Practice Requirements – Hospice \(\[p. 1208\]\(#\)\)](#). CMS does not believe that there are any associated financial impacts for hospices under its proposal to accept orders for drugs from physician assistants.

### **Changes Due to Updates to the Quality Payment Program ([p. 1208](#))**

CMS presents the overall and incremental impacts to the expected QPs and associated APM incentive payments. CMS notes that final data sets including data from the second performance period were not available in time to incorporate into this analysis. CMS intends to use data from the CY 2018 MIPS performance period in the final rule.

### **Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs ([p. 1209](#))**

CMS estimates that there are 12,000 providers within 5 percent of performance year 2020 QP thresholds in Advanced APMs who could potentially benefit from participation in Other Payer Advanced APMs. CMS estimates that its proposal to amend the marginal risk standard to use an average marginal risk rate, when the marginal risk rate varies, could potentially benefit 500-100 eligible clinicians.

Overall, CMS estimates that between 175,000 and 225,000 eligible clinicians would become QPs, therefore be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year. CMS estimates that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs would be between approximately \$500 and \$600 million for the 2022 payment year. These estimates include qualification based on the Medicare Only Option and the All-Payer Combination Option.

CMS lists the APMs that are expected to be Advanced APMs for the 2020 QP Performance Period, including:

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

### **Estimated Number of Clinicians Eligible for MIPS Eligibility (p. 1213)**

[Table 113](#) presents the estimated MIPS eligibility status and the associated PFS allowed charges for the 2020 MIPS performance period after using QPP Year 1 data and applying the proposed policies for the 2020 MIPS performance period. After taking into account various assumptions regarding group versus individual participation and opt-in decisions, CMS estimates that there will be 818,391 MIPS eligible clinicians for the 2020 MIPS performance period, accounting for \$68 billion in allowed PFS charges.

### **Estimated Impacts on Payments to MIPS Eligible Clinicians (p. 1219)**

CMS' impact analysis looks at the total effect of the proposed MIPS policy changes on the MIPS final score and payment adjustment for CY 2020 MIPS performance period/CY 2022 MIPS payment year. The estimated payment impacts presented in this proposed rule reflect averages by practice size based on Medicare utilization. CMS does not provide estimates by specialty. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems that would not be affected by MIPS payment adjustment factors. CMS notes that it is unable to assess performance for virtual groups as an entity due low participation for the 2019 performance period (fewer than 10 virtual groups). CMS details its methodology for calculating impacts starting on [p. 1220](#), including its assumptions for the quality performance category score ([p. 1221](#)); cost performance category score ([p. 1223](#)); facility-based measurement scoring ([p. 1224](#)); the promoting interoperability performance category score ([p. 1226](#)); the improvement activities performance score ([p. 1228](#)); the complex patient bonus ([p. 1228](#)); the final score ([p. 1229](#)); and the MIPS payment adjustment ([p. 1229](#)). CMS discusses assumptions and limitations of its estimates starting on [p. 1243](#).

Using the assumptions noted above, CMS' model estimates that \$586 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 5.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. [Table 114](#) shows the impact of the payments by practice size and whether the clinicians are expected to submit data to MIPS. [Table 114](#) also shows that 87.3 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. CMS notes that some clinicians who do not submit data to MIPS may receive final scores above zero through performance on the cost performance category, which does not require separate data submission to MIPS. Among those who CMS estimates would not submit data to MIPS, 90 percent are in small practices (16,116 out of 17,954 clinicians). CMS plans to update these numbers in the final rule.

## **Potential Costs of Compliance with the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians ([p. 1233](#))**

### ***Potential Costs of Compliance with Promoting Interoperability Performance Category ([p. 1233](#))***

CMS is not changing its burden assumptions to account for its proposal to allow clinicians and groups to satisfy the optional bonus Query of PDMP measure by submitting a “yes/no” attestation. CMS does not have information with which to estimate the number of clinicians who may pursue the option of relying on a QCDR or qualified registry to support the three performance categories of quality, improvement activities, and promoting interoperability.

### ***Potential Costs of Compliance with Improvement Activities Performance Category ([p. 1234](#))***

CMS generally anticipates that most of its IA proposals would not increase burden. As a result of ending and removing the Study on Factors Associated with Reporting Quality Measures, CMS estimates a reduction in burden of 100 hours and \$20,286.

### ***Potential Costs of Compliance for Third Party Intermediaries ([p. 1236](#))***

While CMS expects that some third-party intermediaries may incur additional costs under its proposals, CMS notes that it is unable to determine the impact of several of its proposals, including transitioning from allowing QCDRs and qualified registries to report across three performance categories to requiring it; requiring QCDRs to provide educational services and lead quality improvement initiatives; requiring QCDRs to complete measure development and testing at the clinician level prior to submission to CMS and complete data; requiring measure harmonization; and allowing submission of a QCDR measure participation plan. Likewise, CMS is unable to estimate an impact for other proposals that may reduce burden, including 2-year approval of QCDR measures. CMS does not anticipate a significant increase in cost or effort for additional performance feedback requirements proposed. CMS notes that across all QCDRs, the aggregate financial impact would be zero under its proposals regarding QCDR measure licensure. CMS estimates a 1 hour per QCDR measure impact for its requirement for QCDRs to identify a linkage between their QCDR measures to other measure/activity types.

## **Alternatives Considered ([p. 1244](#))**

### **Alternatives Considered Related to Medicare Coverage for OUD Treatment Services Furnished By OTPs ([p. 1245](#))**

CMS discusses several alternatives considered for its proposals for OUD treatment services furnished by OTPs, including:

- Alternatives for pricing oral medications ([p. 1245](#))
- Alternatives for the update factor ([p. 1246](#))

### **Alternatives Considered Related to Payment for E/M Services ([p. 1246](#))**

CMS notes that it considered a number of alternatives to its proposals for office/outpatient E/M visits effective January 1, 2021. CMS notes that it considered the following alternatives:

- An alternative in which CMS adopted the RUC’s recommended values but excluded the two HCPCS add-on G-codes that it finalized in the CY 2019 final rule. The specialty level impacts for this alternative are displayed in [Table 115](#). The specialties that benefitted the most from this alternative, such as Endocrinology and Rheumatology, are those that primarily bill levels 3-5 established patient office/outpatient E/M visits as those visit levels had the greatest increases in valuation among the overall office/outpatient E/M code set.
- An alternative in which CMS proposed refinements to the RUC recommendations for two of the CPT codes (99212 and 99214 – levels 2 and 4 for established patients). The refinements CMS considered are shown in [Table 116](#), and the specialty level impacts are shown in [Table 117](#). Specialties like dermatology and family practice, who frequently bill the two codes, experience more modest increases relative to other alternatives.



- An alternative that reflected CMS refinements to the CPT codes identified above, but that also included the consolidated, redefined and revalued HCPCS add-on G Code GPC1X. [Table 118](#) reflects specialty level impacts.

**Alternatives Considered for the Quality Payment Program (p. 1254)**

CMS considered alternatives with performance thresholds of 35 and 50, respectively, with the proposed additional performance threshold of 80, as discussed starting on [p. 1254](#). CMS also considered alternatives with additional performance thresholds of 75 and 80, using a performance threshold of 45, as discussed starting on [p. 1255](#).

**Additional Burden and Burden Reduction Estimates (p. 1257)**

CMS discusses burden reduction estimates for the E/M services proposals starting on [p. 1257](#), including CMS' analysis of burden reduction estimates provided by the AMA. CMS notes that its proposals are consistent with CMS' goal of burden reduction and align with the policy principles that underlay what CMS finalized in the CY 2019 PFS final rule. The AMA's estimates of burden reduction and other materials related to the CPT and RUC efforts are available on the [AMA website](#).

CMS estimates that the total cost of reviewing this rule is \$13.4 million.

\* \* \* \* \*