

A Summary of the CY 2020 Medicare Physician Fee Schedule (MPFS) and Updates to the Quality Payment Program (QPP)

A SIDE-BY-SIDE COMPARISON OF KEY PROVISIONS FROM THE PROPOSED AND FINAL RULES FOR CY 2020

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Overview

On November 1, 2019 the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2020 Medicare Physician Fee Schedule (MPFS) [final rule](#). This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations.



In addition, CMS issued an interim final rule with comment period (IFC) to establish coding and payment for evaluation and management, observation and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible.

Unless otherwise noted, these regulations are effective on January 1, 2020. According to CMS, comments will be considered ONLY on the aforementioned interim final rule (i.e., “Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine”) if submitted by December 31, 2019. However, CMS does indicate a number of opportunities where the agency is interested in ongoing feedback specific to key policies.

Hart Health Strategies, Inc. has prepared the below “side-by-side” comparison of the proposed and final provisions, including regulatory impact and information collection requirements where pertinent, all with the goal of helping organizations better understand how CMS modified its proposals in response to stakeholder feedback. Page numbers and hyperlinks throughout the summary refer to the public display version of the final rule, which has been posted to our website. A table of contents is also provided to help you more easily navigate the summary. To go directly to a specific section of the rule, please click on the page number listed in the table of contents. To return to the table of contents, use the “Back to Table of Contents” link in the footer of each page.

Provisions of the Final Rule for the PFS

Topic	Proposed Rule	Final Rule
Conversion Factor		
MPFS Conversion Factor	CMS estimated 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 finalized a CY 2020 MPFS conversion factor of \$36.0896 as proposed , a 0.14 percent increase over the CY 2019 MPFS conversion factor (p. 1891). CMS included the specialty impacts of the CY 2020 final rule in Table 119 .
Anesthesia Conversion Factor	CMS estimated 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.	CMS finalized a CY 2020 anesthesia conversion factor of \$22.2016 , which includes a “Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment” of -0.46 percent (p. 1892).
Determination of PE RVUs (p. 17)		
Indirect Practice Expense Per Hour (PE/HR) Data	For newly recognized specialties without available data, CMS proposed the following crosswalks: <ul style="list-style-type: none"> • Medical Toxicology (cross walked to Emergency Medicine) • Hematopoietic Cell Transplantation and Cellular Therapy (cross walked Hematology/Oncology). 	CMS finalized this policy as proposed (p. 21).
Low Volume Codes	<p>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.</p> <p>For CY 2020, CMS proposed to clarify specialty assignment for a list of cardiothoracic services. CMS believed there was a mistake in previously cross walking the codes to cardiac surgery and now proposes to crosswalk them to thoracic surgery.</p>	<p>CMS noted that in its data tables it had inadvertently omitted the column that was meant to be included “specifying if the service-level override was being applied for CY 2020” and stated that they will make the information available in the public use files for the final rule (p. 28).</p> <p>CMS acknowledged comments disagreeing with its proposal (p. 28) including that “for nearly all of the applicable codes, cardiac surgery was the dominant provider in the 2018 Medicare claims data” (p. 29). In response, CMS states that it “<u>did not propose to assign the codes listed . . . to the cardiac surgery specialty. Instead, we proposed to update the incorrect documentation in our expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. The <u>previously finalized assignment of the cardiac specialty to these services has been in place since the CY 2012 rule cycle, and we believe that the expected specialty list should be updated to reflect the correct specialty assignment</u>” (p. 29). (The referenced CY 2012 Final Rule can be found here). CMS finalized the proposal to updated the expected specialty to thoracic surgery for the codes listed in Table 1.</u></p> <p>Additional Codes. CMS received comments requesting expected specialty assignments for a number of other codes for which CMS had not previously made assignments. CMS noted that many of these procedures exceed the 100 claims that trigger the rules associated with low-volume services.</p>

Topic	Proposed Rule	Final Rule
Equipment Costs	<p>Equipment Utilization Rate Assumption. 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 requested stakeholder submission of data to illustrate an alternative equipment utilization rate assumption.</p> <p>Equipment Maintenance. CMS has identified no publicly available datasets on which to reconfigure the equipment maintenance factor. CMS again stated that it will continue to “investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.”</p>	<p>However, CMS stated that it is “adding these codes to the list in the interested of maintaining payment stability, such that if they were to fall below 100 annual services at a future date, then an expected specialty would be assigned (p. 31). <i>The list of codes and expected specialty assignments can be found in Table 2.</i></p> <p>CMS again stated that it seeks submission of data that could support a different utilization rate assumption and states that “a wide-ranging survey or similar study designed to address the subject of equipment utilization rates would be an appropriate tool to investigate this subject in further detail” (p. 44).</p> <p>CMS also states that it does not believe that voluntary submissions of maintenance costs of individual equipment items would be an appropriate data sources for determining costs (p. 45). CMS reiterated its interest in new data sources but acknowledged that it believes that “the 5 percent maintenance factor likely underestimates the true costs of maintaining some equipment and overstates the maintenance costs for other items (p. 45).</p>
Direct PE Inputs for Specific Services	<p>Interest Rates. CMS proposed no changes to equipment interest rates.</p> <p>Standardization of Clinical Labor Tasks. 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> <p>As it did last year, CMS noted that the RUC has mandated use of a new PE worksheet that assists in making recommendations for standardized clinical labor tasks. CMS continued to believe the new worksheet will assist CMS in simplifying and standardizing the clinical labor tasks listed in its direct PE database.</p> <p>Equipment Recommendation for Scope Systems. 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>	<p>CMS stated that it “will consider potential changes to the interest rates used in the equipment cost per minute calculation for possible future rulemaking” (p. 46).</p> <p>CMS made no proposals in this area, but in response to commenter request, CMS stated that it will “separate out the ‘E15: Refined equipment time to conform to changes in clinical labor time’ direct PE refinements and print them in a separate table of refinements (p. 52).</p> <p>Based on input, <i>CMS finalized pricing for the 23 new scope equipment codes (with some modifications) as listed in Table 8 (p. 68).</i> CMS noted that it is “not finalizing changes to the pricing of the group of new scope equipment</p>
	<p><i>Scope Equipment:</i> CMS proposed to add 23 new scope equipment codes. CMS proposed to price the scope equipment items for those codes for which it received pricing information.</p>	

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> • 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. • CMS proposed adopting the workgroup recommendations for which HCPCS codes make use of the new scope equipment items. However, there were 3 instances in which CMS believed the workgroup recommendations did not warrant replacement with the new scope equipment codes: <ul style="list-style-type: none"> ○ CPT 45350 (<i>Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)</i>) ○ CPT 43232 (<i>Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)</i>) ○ CPT 31595 (<i>Larynx nerve surgery</i>)* (Deleted) • CMS did not receive pricing information from the workgroup for 15 other scope equipment items; in these instances, CMS did not propose 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>codes <u>with previously proposed prices</u>” (other than ES092 (<i>See below</i>)) but rather <u>“only newly pricing several scopes that previously lacked pricing”</u> (p. 69). CMS finalizes prices related to 21 HCPCS codes “which are affected by the new scope replacements” in Table 9.</p>
Technical Corrections to Direct PE Input Database and Supporting Files.	<p>CMS received input that there were “clerical inconsistencies” in the direct PE database. CMS proposes to correct these inconsistencies in the direct PE database. These included:</p>	<p>CMS received input that “all codes in the flexible sigmoidoscopy family require a flexible sigmoidoscope in order to perform the procedure.” CMS accepted the information, and CMS finalized the addition of ES085 to CPT 45350 (p. 66).</p>
<ul style="list-style-type: none"> • Deletion of non-facility inputs for <ul style="list-style-type: none"> ○ CPT 43231 (<i>Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination</i>) 	<p>CMS received new pricing information for codes without previous pricing data during the comment period:</p> <ul style="list-style-type: none"> ○ CMS finalized prices for 3 scopes that did not have pricing data: ES072 (rigid scope, otoscopy); ES073 (rigid scope, nasal/sinus endoscopy); and ES078 (non-channeled flexible digital scope, nasopharyngoscopy); however, CMS stated that they “are not finalizing the replacement of any of the old scope equipment codes with these three new scope equipment items for CY 2020, as the commenter did not identify the HCPCS codes in which this replacement would take place” and instead will consider inclusion in the HCPCS codes in which they would be placed in CY 2021 rulemaking (p. 67). ○ CMS finalized pricing for ES092 (non-video flexible scope, laryngoscopy) which increases the direct costs for the 14 HCPCS codes listed at the end of Table 7 (p. 67). <p>CMS finalized this policy as proposed (p. 79).</p>	

- CPT 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)*)
- 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.

Updates to Prices for Existing Direct PE Inputs.

General: CMS proposed updating the name of equipment item EP001 from “DNA/digital image analyzer (ACIS)” to “DNA/Digital Image Analyzer.”

Market-Based Supply and Equipment Pricing Update: 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.” In continuing to update pricing, CMS welcomed feedback from stakeholders “including the submission of additional invoices for consideration.” CMS noted that stakeholders were submitting invoices by February 10th (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 10th or outside of the public comment process . . .”

CMS finalized this policy as proposed (p. 79). CMS also received a request for clarification on “the application of the bilateral adjustment in conjunction with the special rules for multiple endoscopic procedures” (p. 75) as well as clarification specifically about the application to the family of codes in [Table 10](#). CMS replied that the “*manual text states that special rules for multiple endoscopic procedures apply if the procedure is billed with another endoscopy in the same family (i.e., another endoscopy that has the same base procedure). The base procedure for each code with this indicator is identified in the endoscopic base code field. In these situations, we apply the multiple endoscopy rules to a family before ranking the family with other procedures performed on the same day (for example, if multiple endoscopies in the same family are reported on the same day as endoscopies in another family or on the same day as a nonendoscopic procedure). If an endoscopic procedure is reported with only its base procedure, we do not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy*” (p. 75).

CMS stated that it appreciated feedback about items potentially mispriced by StrategyGen, but added that “in the absence of alternative pricing information, we continue to believe that our proposed prices are the most accurate source of data” (p. 93). However, **CMS did finalized changes to the pricing of the following codes:**

- SA022 (*percutaneous neuro test stimulation kit*) (p. 98)
- SD186 (*plasma LDL adsorption column (Liposorber)*) (p. 98)
- SA126 (*Biodegradable Material Kit – PeriProstatic*) (p. 99)
- SA128 (*Rezum delivery device kit*) (p. 99)
- EQ389 (*water thermotherapy procedure generator*) (p. 99)
- SH033 (*fluorescein ink (5 ml uou)*) (p. 100)
- EQ012 (*EECP external counterpulsation system*) (p. 101)

In addition, **CMS finalized the deletion of:**

- SD185 (*plasma antibody adsorption column (Prosorba)*) (p. 99)

CMS welcomed feedback on whether it should make changes to:

Topic	Proposed Rule	Final Rule
	<p><i>Adjustment to Allocation of Indirect PE for Some Office-based Services:</i> 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 proposed to continue its third year transition to this process for allocating indirect PE.</p>	<ul style="list-style-type: none"> ○ SC084 (<i>blood warmer tubing set</i>) (p. 99) <p>Otherwise, CMS finalized the proposed pricing changes as listed in Table 12 other than as detailed above (p. 103).</p> <p>CMS finalized this as proposed (p. 104).</p>
<p>Determination of Malpractice Relative Value Units (RVUs) (p. 106)</p>	<p>Timeline. CMS proposed aligning 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> <p>CY 2020 MP RVU Update. <i>Methodology Changes:</i> CMS proposed the following methodology changes to its calculation of MP RVUs:</p> <ul style="list-style-type: none"> • 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 	<p>CMS finalized this proposal, which means CMS will conduct both the next GPCI and MP RVU updates for implementation in CY 2023 (p. 108).</p> <p>CMS generally finalized its proposals with modifications (as outlined below) (p. 136).</p> <p>CMS finalized this as proposed (p. 111; p. 136).</p> <p>CMS received comments that were critical with how CMS classified “minor” and “major” surgeries; CMS stated that it did not propose “definitions” (p. 112) but then goes on to reiterate that it “set a threshold of a physician work RVU greater than 5.00 to “categorize surgical services as major surgery” (p. 113) for purposes of analysis. CMS did not finalize its proposal to combine major and minor surgery premiums when both are included in rate filings for a specialty nor is it using a wRVU of 5.00 to differentiate between major and minor surgeries (p. 114; p. 136). CMS will maintain its current methodology and “only use major surgery premium data when both minor surgery and major surgery are delineated in the rate filings for a specialty”; CMS will use minor surgery premium data <i>only</i> when minor surgery premium data is all that is available in the filing. CMS also stated that it still maintains its goal of creating a more representative surgical risk factor and that work will be ongoing in future rulemaking (p. 114; p. 137).</p> <p>CMS generally finalized this policy (p. 136). In addition,</p>

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> Utilizing “partial and total imputation” for a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings <p><i>Specialty and Service Risk Group Risk Factors:</i> CMS proposed the specialty risk factors.</p> <p><i>TC-Only Services:</i> 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 proposed assigning a risk factor of 1.00 for TC-Only services in the absence of data for clinicians that furnish TC only services.</p> <p><i>List of Expected Specialties for Low Volume Services:</i> CMS sought comment on the list of expected specialties for low volume codes.</p>	<ul style="list-style-type: none"> CMS received comments on mapping of the <u>electrophysiology</u> risk factor, which included requests for additional details on CMS’ rationale (p. 117). In response, <i>CMS did not finalize its proposal to map all of electrophysiology to a risk factor of 1.89, but rather finalized mapping electrophysiology to the risk factors for cardiology (surgery) and cardiology (no surgery) (p. 119; p. 137).</i> CMS reviewed multiple other comments received regarding the MP RVU update as related to electrophysiology beginning on p. 119. <p>CMS lists the finalized risk factors in Table 14. CMS acknowledged that it received comments about assigning the “lowest physician specialty” risk factor to NPPs for which CMS did not have sufficient premium data. However, <i>CMS finalized its policy of assigning a risk factor of 1.00 (based on the risk factor for allergy and immunology) to NPPs for which it does not have sufficient data (p. 131; p. 137).</i> CMS also acknowledged the request that it should crosswalk the NPPs for which it did not have sufficient data to another NPP specialty for which it did, such as optometry (p. 131). CMS seems to suggest that it is unable to do this because that is not what it had proposed in the rule: “<i>We reiterate that our proposal was to maintain the crosswalk of NPPs for which we had insufficient or no premium data to the lowest physician specialty, not to crosswalk NPPs to the RF of a NPP for which we were able to collect data</i>” (p. 132).</p> <p><i>CMS finalized its proposal (p. 130; p. 137).</i></p> <p>CMS directs stakeholders to its discussion of expected specialties elsewhere in the rule.</p> <p>CMS noted that it has provided additional details on the calculations used in the Final Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule (p. 123).</p>
<p><i>Geographic Practice Cost Indices (GPCIs) (p. 138)</i></p>	<p>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</p>	<p><i>CMS finalized its CY 2020 GPCI update and methodological refinements (p. 164).</i> However, CMS identified that when it performed the data runs for CY 2020 rulemaking, “2016 utilization data had not been replaced with the 2017</p>

Topic	Proposed Rule	Final Rule
	<p>“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.” 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>	<p>utilization data for work and PE GPCIs” (although 2017 data were used for the MP GPCIs); CMS has remedied this and the CY 2020 final rule provisions are now based on 2017 utilization data (p. 158). The final GPCIs for CY 2020 are provided in Addenda E.</p> <p>CMS also mentions that the current GPCI work floor is set to expire on December 31, 2019 (p. 138; p. 139). CMS noted concerns expressed by stakeholders about the expiring GPCI work floor but stated it does not have the authority to extend the work floor without Congressional intervention (p. 151).</p>
<p>Potentially Misvalued Services under the PFS (p. 165)</p>	<p>Public Nomination. CMS reviewed its public nomination process for potentially misvalued codes. CMS reiterated its process used in the past: <i>“We evaluate the supporting documentation submitted with the nominated codes and assess whether the 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.”</i></p> <p>CMS received 3 codes for review via public nomination; CMS is adding one additional code itself for review.</p> <ul style="list-style-type: none"> • Public Nomination #1 & #2: <ul style="list-style-type: none"> ○ CPT 10005 (<i>Fine needle aspiration biopsy; including ultrasound guidance</i>) ○ CPT 10021 (<i>Fine needle aspiration biopsy, without imaging guidance; first lesion</i>) 	<p>CMS again reviewed its public nomination process (p.171).</p> <p>CMS did <u>not</u> finalize the addition of CPT 10005 and 10021 to the list of Potentially Misvalued Services (p. 179).</p>
<p>CMS proposed these codes as potentially misvalued.</p>	<ul style="list-style-type: none"> • Public Nomination #3: <ul style="list-style-type: none"> ○ G0166 (<i>External counterpulsation, per treatment session</i>) 	<p>CMS finalized the addition of G0166 to the list of Potentially Misvalued Services (p. 180). CMS received comments stating that this code is likely under-valued because in the CY 2019 final rule, CMS did not have a complete list of inputs for this PE only code. CMS noted that it will review any recommendations provided by the RUC review and make refinements as part of CY 2021 rulemaking (p. 176) as well as referred readers to its finalized policies for Direct PE inputs related to this code.</p> <p>CMS finalized the addition of CPT 76377 to the list of Potentially Misvalued Services (p. 180).</p>

CMS Nomination. CMS proposed adding the following code as potentially misvalued: 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).

Payment for Medicare Telehealth Services under Section 1834(m) of the Act (p. 183)

CMS did not receive any public requests to add services to the Medicare Telehealth list for FY 2020. However, CMS proposed 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:

- 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)

Given significant support from commenters, ***CMS finalized its proposal to add HCPCS codes G2086, G2087, and G2088 to the Medicare telehealth list beginning in CY 2020.*** (p. 188)

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (p. 191)

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). 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.

CMS finalized and codified in regulation (new section, § 410.67) policies associated with OTPs.

Topic	Proposed Rule	Final Rule
<p>Definitions</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	<p>With support from commenters <i>CMS finalized its proposal to include the five statutorily-required items and services in the definition of OUD treatment services in § 410.67(b), and to include intake activities and periodic assessments required under § 8.14(f)(4) in the definition of OUD treatment services in § 410.67(b).</i> (p. 207)</p> <p>In light of other questions posed by commenters related to toxicology testing, CMS clarified that the reference to toxicology testing in the definition of OUD treatment services includes both presumptive and definitive testing. In addition, CMS clarified that all types of toxicology testing that are used for diagnosing, monitoring and evaluating the progress in treatment at the OTP are included in the definition of OUD treatment services and would be paid under the bundled payment. (p. 203)</p> <p>Finally, CMS will consider comments on additional drugs, items and services to include in the definition of OUD treatment services under its discretionary authority in section 1861(jjj)(1)(F) of the Act as it continues to work on refining this new Medicare benefit in future rulemaking. (p. 206)</p> <p><i>COMMENT: CMS is interested in continued feedback and data on the specific items and services, including their frequency, furnished to beneficiaries by an OTP.</i> (p. 208)</p> <p><i>CMS finalized its proposed definition of “opioid treatment program” at § 410.67(b), as well as the proposed Medicare requirements for OTPs at § 410.67(c).</i> Specifically, in order for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j)</p>

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Bundled Payments for OUD Treatment Services	<p>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.</p>	<p>of the Act, have in effect certification by SAMHSA, and be accredited by an accrediting body approved by SAMHSA. Additionally, CMS finalized its proposal that an OTP must have a provider agreement as required by section 1866(a) of the Act. (p. 221)</p>
	<p>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).</p>	<p>In light of comments, CMS also made changes to § 489.13(a)(2)(i) to align with the provider agreement effective date to the billing effective date under § 424.520(d) or § 424.521(a), as applicable. Absent additional comments on the proposals for the provider agreement requirements in §§ 489.2, 489.10, 489.43, and 498.2., CMS finalized the changes as proposed. (p. 218)</p>
<p>Aspects of the Bundle.</p>	<p><i>Duration of bundle:</i> 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.</p>	<p>CMS finalized its proposal to calculate the full bundled payment rate for services furnished by OTPs by combining the drug component and the non-drug components, and codified the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d). (p. 223)</p>
<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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 	<p>In response to commenters who requested clarification regarding prior authorization, CMS notes that it did not propose, and is not finalizing any prior authorization requirements for services furnished in OTPs, to not restrict access to necessary care. (p. 260)</p>
<ul style="list-style-type: none"> 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 	<p>CMS finalized its proposal to define an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b), but did not finalize any limit on the maximum number of weeks during an overall course of treatment for OUD. (p. 229) CMS also finalized a policy under which the threshold to bill for an episode of care will be that at least one service was furnished to the patient during the week that corresponds to the episode of care. (p. 231) CMS later notes that the threshold to bill a full episode will be that at least one service was furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care, and it finalized this threshold at § 410.67(d)(3). CMS will be monitoring for abuse given this lower threshold for billing for full weekly bundled payment. (p. 233)</p>	
<ul style="list-style-type: none"> 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 	<p>Given commenter concerns, CMS did not finalize partial episodes at this time. However, the agency remains interested in implementing a payment policy for partial episodes at some point in the future. CMS would establish the policies to govern partial episodes through notice and comment rulemaking, and is interested in working with OTPs to explore how such a policy would best be applied. (p. 233)</p>	

during the partial episode, CMS proposes that the code describing a non-drug partial weekly bundle must be used. 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.

Drug and non-drug components: 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. 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. 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

CMS did not receive any comments on non-drug episodes of care, and ***finalized the policies governing the use of non-drug episodes of care in § 410.67(d)(1)(iii).*** (p. [234](#))

CMS finalized its proposal to base the OTP bundled payment rates, in part, on the type of medication used for treatment. These categories reflect those drugs currently approved by the FDA under section 505 of the FFDCa for use in treatment of OUD: that is, methadone (oral), buprenorphine (oral), buprenorphine (injection), buprenorphine (implant), naltrexone (injection)). CMS will codify this policy of establishing the categories of bundled payments based on the type of opioid agonist and antagonist treatment medication in § 410.67(d)(1). (p. [238](#))

CMS finalized its proposal to allow OTPs to bill for an episode of care using the medication not otherwise specified (NOS) code (HCPCS code G2075) in the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of the existing codes. In such cases, the typical or average maintenance dose would be used to determine the drug cost for the new bundle, which contractors would then add to the non-drug component payment amount that corresponds with the relevant payment for drug administration (oral, injectable, or implantable) to determine the total bundled payment for the episode of care. ***CMS also finalized its proposal that pricing would be determined based on the relevant pricing methodology as described in section II.G.3. of this final rule or through invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available, and codified approach for determining the amount of the bundled***

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	<p>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.</p> <ul style="list-style-type: none"> • Non-drug component <ul style="list-style-type: none"> ○ Counseling, Therapy, Toxicology Testing, and Drug 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. <p><i>Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services:</i> 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. CMS seeks comment on the proposed add-on code and the threshold for billing.</p> <p><i>Site of service (telecommunications):</i> 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.</p> <p><i>Coding and payment rates:</i> 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).</p> <ul style="list-style-type: none"> • 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 	<p>payment for episodes of care with new medications in § 410.67(d)(2)(i)(C). (p. 240)</p> <p>CMS did not receive any comments on the pricing of new drugs with a novel mechanism of action, but intends to monitor for the development of such new drugs for the treatment of OUD and may consider this topic further in future rulemaking. (p. 241)</p> <p>CMS did not receive comments on its proposal to include counseling, therapy, toxicology testing, and drug administration in the non-drug component of the bundle, but finalized including intake activities and periodic assessment in the definition of OUD treatment services. (p. 243)</p> <p>CMS finalized its proposal to establish an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished. This add-on payment is codified in the regulations at § 410.67(d)(4)(i)(A). In addition, CMS understands the frequency with which counseling and therapy services are furnished will vary over time for each individual patient and will often decrease over time as a patient stabilizes. (p. 245)</p> <p>CMS finalized its proposal to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services. CMS also finalized its proposal to include substance use counseling and individual and group therapy services furnished via two-way interactive audio-video communication technology in the definition of opioid use disorder treatment service in § 410.67(b). CMS notes that OTP services are not PFS services, therefore, no originating site facility fee (HCPCS code Q3014) applies to OUD treatment services, nor are OTPs authorized to bill for the originating site facility fee. (p. 249)</p> <p>CMS finalized the list of OTP services (including add-on codes for intake activities/periodic assessment/take-home doses of medication) in Table 18 (G2067-G2075), as well as the payment amounts for the drug and non-drugs costs. (p. 252) The full description of these codes start on p. 261.</p> <p>CMS finalized that only an entity enrolled with Medicare as an OTP could bill these codes, and that OTPs are limited to billing only these codes, and may not bill for other codes, such as those paid under the PFS. (p. 263)</p>

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 peer reviewed, 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. 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: 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.

CMS notes that the add-on code describing intake activities should only be billed for new patients (that is, patients starting treatment at the OTP). (p. [253](#)) Additionally, the add-on code describing periodic assessments could be billed for each periodic assessment performed for patients that require multiple assessments during an episode of care, such as patients who are pregnant or postpartum. In order to bill for the add-on code, the services would need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. (p. [254](#)) CMS plans to monitor utilization of the periodic assessment add-on code given program integrity concerns about overutilization, and may consider further refinements in future rulemaking. (p. [255](#))

CMS finalized its proposal to use the typical maintenance dosages to calculate payment rates for the drug component of the weekly bundles (that is, a 100 mg daily dose for methadone, 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) except that the payment rate for the drug component of the oral buprenorphine bundle will be calculated using a typical maintenance dose of 16 mg daily, rather than a 10 mg dose. (p. [268](#))

CMS finalized its proposal to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the "incident to" drugs and to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a drug category or code. CMS codified this policy in the regulations at § 410.67(d)(2)(i)(A). (p. [276](#))

COMMENT: CMS is interested in feedback regarding drug acquisition costs for OTP providers, and in particular any drug acquisitions that exceed these rates after factoring in discounts, rebates, etc., and, if necessary, may revisit the payment methodology for "incident to" OTP drugs in future rulemaking to ensure that OTPs' drug acquisition costs are appropriately reimbursed. (p. [276](#))

CMS finalized its proposal to use ASP-based payment to set the payment rates for the oral drugs and to limit the payment amounts for these drugs to

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	<ul style="list-style-type: none"> ○ 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. <ul style="list-style-type: none"> ▪ 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 Methadone Pricing: Follow TRICARE’s methodology for methadone <p>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.</p> ● 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. 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 	<p>100 percent of the volume-weighted ASP when it is available. (p. 288) When ASP data are not available for the oral drugs used in OTPs, CMS will use the TRICARE rate to set the payment for the drug component of the methadone bundle, and NADAC data to set the payment for the drug component of the oral buprenorphine bundle. The payment methodology for oral drugs is codified at § 410.67(d)(2)(i)(B). (p. 290)</p> <p><u>COMMENT: CMS is interested in feedback regarding drug acquisition costs for OTP providers, and in particular any drug acquisitions that exceed these rates after factoring in discounts, rebates, etc., and if necessary, may revisit the payment methodology for oral OTP drugs in future rulemaking to ensure that OTPs’ drug acquisition costs are appropriately reimbursed.</u> (p. 288)</p> <p><i>CMS finalized a payment rate for the non-drug component that is calculated based on a building block methodology using the Medicare payment rates for similar services furnished in the non-facility setting.</i> (p. 295) <i>CMS also finalized its proposal to adjust the non-drug component rate to account for different administration and dispensing costs of the drug that is used in the episode of care (either oral, injectable, or implantable).</i> (p. 297)</p>

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. 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: 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 cross walked 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),

Consistent with CMS proposal relating to pricing the non-drug component for medication not otherwise specified bundled payments, CMS intends to determine the payment for the non-drug component of the medication not otherwise specified bundle based on whether the drug is oral, injectable, or implantable. This payment would be determined using the building block payment methodology that CMS is adopting to determine the non-drug component of the bundled payments for medications that have the same mode of administration. (p. [301](#))

As a reminder, ***CMS is not finalizing its proposal to create partial episodes at this time, and thus will not be finalizing the proposed methodology for pricing partial episodes.*** (p. [303](#))

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. 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: 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.

As proposed, **CMS created a new place of service code, which will be described as Place of Service code 58 (Non-residential Opioid Treatment Facility – a location that provides treatment for OUD on an ambulatory basis.** POS code 58 should be noted on claims submitted for the HCPCS G codes describing OTP services. (p. [306](#))

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Adjustments to bundled payment rates for OUD treatment services	<p><i>Duplicative payments under Parts B or D:</i> 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.</p>	<p>CMS clarified that its policy on duplicative payments refers to payment for the same medication for the same beneficiary on the same date of service. As such, <i>CMS finalized its proposal that in cases where a payment for drugs used as part of an OTP’s treatment plan is identified as being a duplicative payment because a claim for the same medications for the same beneficiary on the same date of service was paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP.</i> CMS updated the text at § 410.67(d)(5) to reflect this clarification. (p. 313)</p>
	<p>Cost Sharing. 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. CMS welcomes 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.</p>	<p><i>CMS finalized its proposal to set the copayment at zero for a time limited duration to minimize barriers to patient access to OUD treatment services.</i> CMS is interested in setting the copayment at zero for a time limited duration (for example, until such time as the Secretary does not renew the national public health emergency declaration for the continued consequence of the opioid crisis affecting our nation), and intend to address the copayment in future rulemaking. CMS codified this beneficiary cost-sharing amount at § 410.67(e). (p. 317)</p>
	<p>Locality adjustment. <i>Non-drug component:</i> 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.</p>	<p><i>CMS did not propose to apply a geographic locality adjustment to the drug component of the bundled payment rate for OTP services, and given the lack of comments, is finalizing this policy.</i> (p. 318)</p>
<p>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.</p>	<p><i>CMS finalized its proposal to adjust the non-drug component of the OTP bundled payments using the GAF in § 410.67(d)(4)(ii). CMS also finalized that the add-on payment adjustments for non-drug services will be geographically adjusted.</i> (p. 322)</p>	

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Regulatory Impact and Information Collection Requirements	<p>Annual Update. 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.</p> <p><i>Drug component:</i> 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.</p> <p><i>Non-drug component:</i> 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.</p>	<p>CMS finalized its proposal to use the most recently available data from the applicable pricing mechanism finalized for drug pricing to annually update the drug component of the bundled payment. CMS codified this policy at § 410.67(d)(2)(i), which provides that the payment for the drug component of episodes of care will be determined using the most recent data available at the time of ratesetting for the applicable calendar year. (p. 324)</p> <p>CMS finalized its proposal to update the non-drug component of the bundled payment for OUD treatment services based upon the MEI, and codified these policies at § 410.67(d)(4)(iii). While CMS did not explicitly address the application of the annual update to the add-on payment adjustments for non-drug services in the proposed rule, CMS finalized that the add-on payment adjustments for non-drug services will be subject to the annual update as described above. (p. 329)</p> <p>CMS' updated total estimated net Medicare and Medicaid impact, including FFS and Medicare Advantage, over 10 years is \$1,484,000,000. (p. 1092)</p> <p>CMS notes that the burden associated with this policy consists of the time/cost for manufacturers of oral opioid agonist or antagonist treatment medications (that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of OUD) to voluntarily prepare and submit their ASP data to CMS. It does not believe its current estimates need to be changed, however, given the flux in drug manufacturers. (p. 1773)</p>
	<p><i>Bundled Payments Under the PFS for Substance Use Disorders (p. 346)</i></p>	<p>CMS proposes to establish bundled payments for “overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities.”</p> <ul style="list-style-type: none"> To operationalize the bundle, CMS proposes the creation of 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: <ul style="list-style-type: none"> GYYY1 (Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and

Topic	Proposed Rule	Final Rule
	<p>counseling; at least 70 minutes in the first calendar month); CMS proposes a wRVU of 1.70; Proposed direct PE inputs for review in Table 22.</p> <ul style="list-style-type: none"> ○ 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; 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); CMS proposes a wRVU of 0.82; Proposed direct PE inputs for review in Table 22. <ul style="list-style-type: none"> ● 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. ● CMS proposes that in order to report the OUD bundle, a practitioner must first furnish a separately reportable initiating visit, which can be the same initiating visits that serve as initiating visits for CCM and BHI services. ● 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; 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. ● CMS proposes that the billing practitioner or clinical staff must document obtaining beneficiary consent to receive the services, including consent to cost-sharing. ● 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. ● 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 	<p><i>CMS finalized the payment amounts for HCPCS codes G2086, G2087, and G2088 as proposed. CMS also finalized that HCPCS code G2088 can be billed when the total time spent by the billing professional and the clinical staff furnishing the OUD treatment services described by the base code exceeds double the minimum amount of service time required to bill the base code for the month.</i> (p. 359)</p> <p>In response to commenter concerns that the proposed G codes will inappropriately limit access to a variety of evidence-based, non-opioid pain management therapies, CMS said that the bundled codes would not preclude practitioners from furnishing or billing for other non-opioid pain management treatments. (p. 361)</p>

describes diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department setting.”

Physician Supervision for Physician Assistant (PA) Services (p. 365)

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.”

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 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.” 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.”

CMS is finalizing its proposal with modifications (p. 375) to require under §410.74(a)(2) the following:

- ***That a PA must furnish their professional services in accordance with state law and state scope of practice rules for PAs in the state in which the PA’s professional services are furnished. Any state laws or state scope of practice rules that describe the required practice relationship between physicians and PAs, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act.***
- ***For states with no explicit state law or scope of practice rules regarding physician supervision of PA services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the PA’s scope of practice and the working relationships the PA has with the supervising physician/s when furnishing professional services.***

Some notable comments and responses are included below:

- CMS notes that commenters from 20 states provided evidence of changes in their state laws or scope of practice to move away from references to “physician supervision” of PAs, and in some cases replacing it with the term “physician collaboration.” States included: AZ, CA, CO, CN, FL, ID, IL, MA, MI, MO, MT, NV, ND, OR, OK, RI, SC, TX, UT, and VA. Additional commenters from KS, VT, and WI also noted that their states were undergoing similar changes. (p. 368)
- For states where no physician supervision requirements apply, in response to comments that raised concerns about documentation requirements in each individual patient’s medical record rather than documentation at the practice level, CMS clarifies that documentation at the practice which demonstrates the working relationship that PAs have with physicians in furnishing professional services would be adequate. The documentation should describe all services that PAs furnish, not just those outside their scope of practice. (p. 370)
- Some commenters opposed the proposal, suggesting that the proposal failed to meet the statutory requirements for physician

Topic	Proposed Rule	Final Rule
<p><i>Review and Verification of Medical Record Documentation (p. 377)</i></p>	<p>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 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. 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.” 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> <p>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>	<p>supervision in states without physician supervision requirements, and that PAs do not have education tailored to developing the responsibilities to perform all medical services and procedures. In response, CMS acknowledges that the physician supervision requirement remains in effect and states its belief that it is appropriate for the Medicare program to recognize and consider the role of states in regulating medical practice and establishing, upholding, and enforcing their own laws regarding physician supervision. (p. 372)</p> <p>CMS notes that while it expects that its finalized policies may result in increased administrative flexibility for PAs as they furnish services to patients, CMS cannot determine the specific impact of revised policies on practice business plans and demand for certain levels of clinicians. CMS expects that “any emerging trends may be indicative of the current and expanded role of nonphysician practitioners as members of the medical team.” (p. 1902)</p> <p><i>CMS is finalizing its proposal with modifications (p. 389). CMS is explicitly naming PA and NP, CNS, CNM, and CRNA students as APRN students, along with medical students, as the types of students who may document notes in a patient’s medical record that may be reviewed and verified rather than re-documented by the billing professional. CMS is also amending regulations to include CRNAs as a category of APRN for purposes of this policy, and to include CRNA students under the reference to APRN students.</i> CMS lists all regulations to be updated in accordance with this policy on p. 389.</p> <p>Some notable comments and responses are included below:</p> <ul style="list-style-type: none"> • In response to a comment that CRNAs should be included under the CMS proposal since they are included under the nursing industry’s “APRN” umbrella and are also authorized to furnish and bill for E/M services, CMS notes its agreement and, as a result, finalizes the changes noted above related to CNRAs. (p. 383) • Several commenters suggested that CMS be more explicit about the specific types of students and clinicians that would be included under the CMS policy. CMS agrees that additional clarity regarding the specific types of covered students is appropriate. (p. 384) • Some commenters requested clarification about whether multiple students and residents can enter documentation in the medical record on the same day and during the same office visit. CMS responds that it did not propose a limitation on how many members

Topic	Proposed Rule	Final Rule
<p>Care Management Services (p. 390)</p> <p><u>Transitional Care Management (TCM) Services</u></p>	<p>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:</p> <ul style="list-style-type: none"> • 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? 	<p>of the medical team can enter information for a given date or patient encounter and does not believe such a limitation is warranted. (p. 387)</p> <ul style="list-style-type: none"> • In response to questions and comments about the types of clinical support staff who could enter notes in the patients record (including scribes, dieticians, and nutritionists), CMS notes that it proposed broad flexibility for teaching physicians, other physicians, PAs, and APRNs to use their discretion in identifying, for each particular case, the individuals who are serving as members of the medical team, potentially including scribes, dieticians, nutritionists, or other members of their medical team. Although CMS is modifying its proposal to clarify the scope of students that may be considered members of the medical team for the purposes of this documentation policy, CMS intentionally did not propose to specify who can be included as a member of the medical team. (p. 388) • In response to a question asking whether this policy applies to all types of services, including procedures, E/M services, and diagnostic services, CMS concurs. This policy would apply broadly to all types of services of physicians, PAs, and APRNs, regardless of the type of service or the setting in which the service is furnished. (p. 389) <p><i>CMS finalized its proposal to allow concurrent billing of the care management codes currently restricted from being billed with TCM, which includes allowing concurrent billing of TCM with the 14 codes specified in Table 20, as well as CPT codes 99490 and 99491, which CMS identified as codes that also fit this policy. CMS also finalized for both TCM codes the proposed increases in work RVUs and the RUC-recommended direct PE inputs.</i> CMS intends to work with the public and other stakeholders to potentially further refine its billing policies through future notice and comment rulemaking. (p. 397)</p>

Topic	Proposed Rule	Final Rule
Chronic Care Management (CCM) Services	<p>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:</p> <ul style="list-style-type: none"> • 99495: 2.36 • 99496: 3.10 	<p><i>CMS did not finalize its proposal to create HCPCS code GCCC1, given concerns about administrative burden. However, CMS finalized GCCC2 (the add-on for non-complex CCM clinical staff time), henceforth referred to as G2058, because this code addresses what CMS believes is an important gap in the current code set that should be addressed more immediately. CMS finalized the work RVU for G2058, as proposed. (p. 404) CMS will consider potential reevaluation of this code set in the context of any future changes or recommendations that may be made by the CPT Editorial Panel or the RUC. (p. 405) CMS also finalized that HCPCS code G2058 will be reportable a maximum of two times within a given service period for a given beneficiary. (p. 405)</i></p>
	<p>Non-Complex CCM Services by Clinical Staff (CPT 99490, GCCC1, GCCC2). 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.</p>	<p>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.</p>
	<p>Complex CCM Services (CPT 99487, CPT 99489, GCCC3, GCCC4). 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:</p> <ul style="list-style-type: none"> • HCPCS code GCCC3 (instead of CPT 99487) • HCPCS code GCCC4 (instead of CPT 99489) 	<p><i>CMS did not finalize its proposal to create HCPCS codes GCCC3 and GCCC4. Instead, for CY 2020, CMS will continue to recognize CPT codes 99487 and 99489, but with a different care planning element for purposes of billing Medicare. Beginning in CY 2020, for PFS billing purposes for CPT codes 99487 and 99489, CMS will interpret the code descriptor “establishment or substantial revision of a comprehensive care plan” to mean that a comprehensive care plan is established, implemented, revised, or</i></p>

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. 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.

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

monitored. CMS looks forward to reviewing any refinements or other recommendations for these services that may come from the CPT Editorial Panel and the RUC, and will consider such recommendations through our rulemaking process. (p. [409](#))

CMS finalized its proposed changes to the typical care plan for all CCM. (p. [412](#))

With some modification, CMS finalized its PCM proposals. CMS agreed with commenters that the work RVU it proposed for code G2064 (1.28 RVUs) should be valued through a crosswalk to CPT code 99491, thus, it ***finalized an RVU of 1.45 for HCPCS code G2064.*** (p. [418](#))

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.

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

- HCPCS code GPPP1
- HCPCS code GPPP2

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?

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 finalized a requirement that ongoing communication and care coordination between all practitioners furnishing care to the beneficiary must be documented by the practitioner billing for PCM in the patient's medical record. (p. [420](#))

[Table 24](#) shows the elements required for PCM. HCPCS code G2065 will be added to the list of designated care management services for which the agency allows general supervision as described at § 410.26(b)(5).

CMS did not agree with commenters that there will be a duplication of care management between PCM and other care management services, nor overlap between PCM services and HCPCS code GPC1X. However, CMS agreed with commenters that PCM services should not be furnished with other care management services by the same practitioner for the same beneficiary, nor should PCM services be furnished at the same time as interprofessional consultations for the same condition by the same practitioner for the same patient. (p. [427](#)) CMS will monitor billing of these services. (p. [428](#))

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Chronic Care Remote Physiologic Monitoring (RPM) Services	<ul style="list-style-type: none"> • 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. <p>CMS is seeking comment on how best to educate practitioners and beneficiaries on the benefits of PCM services.</p> <p>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:</p> <ul style="list-style-type: none"> • 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). <ul style="list-style-type: none"> ○ CMS proposes a work RVU of 0.50 for this add-on code. <p>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.</p>	<p>CMS finalized the RUC-recommended work RVU 0.61 for CPT code 99458, as well as the RUC-recommended direct PE. In addition, CMS finalized its proposal to designate both CPT code 99457 and CPT code 99458 care management codes as defined in § 410.26(b)(5). (p. 431)</p> <p>CMS plans consider commenter questions related to RPM in future rulemaking. (p. 432)</p>
Comment Solicitation on Consent for Communication Technology-Based	<p>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</p>	<p>CMS finalized a policy to permit a single consent to be obtained, at least annually, for multiple CTBS or interprofessional consultation services. CMS will continue to consider whether a separate consent should be obtained for services that involve direct interaction between the patient and practitioner,</p>

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Services	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.	and those that do not involve interaction such as interprofessional services; and may address this issue in potential future rulemaking. (p. 435)
Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)	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. 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.	As HCPCS codes GCCC1 and GCCC3 are not being finalized for use under the PFS, <i>CMS did not finalize this change for RHCs and FQHCs.</i> Payment for HCPCS G0511 will continue to set based on the average of the national, non-facility payment rates for CPT codes 99490, 99487, 99491, and 99484. (p. 436)
Coinsurance for Colorectal Cancer Screening Tests (p. 437)	<p>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. CMS also states that it is considering adopting such a requirement in the final rule in accordance with the public comments. This includes request for input on:</p> <ul style="list-style-type: none"> • 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 	<p><i>CMS did not finalize any additional notice provisions, but instead, stated that it will “undertake a comprehensive review of all of our outreach materials, such as the Medicare & You Handbook and Medicare Preventive Services, to see if Medicare policies on payment and coverage for screening colonoscopies can be made clearer”</i> (p. 442).</p> <p>CMS noted that they received over 1,600 comments on these provisions (p. 441). CMS stated that comments included recommendations for more frequent coverage of colorectal cancer screening and eliminating coinsurance for diagnostic colonoscopies, which CMS ruled as out of scope (p. 441).</p>
Therapy Services (p. 443)	<p>Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy</p> <p>CMS notes that while it explained and implemented the changes required by section 50202 of the BBA of 2018 (which repealed the Medicare outpatient therapy caps and the therapy cap exceptions process, but retained a targeted medical review process, among other changes) 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</p>	<i>CMS is finalizing these changes as proposed.</i> (p. 446)

Topic	Proposed Rule	Final Rule
Payment for Outpatient PT and OT Services Furnished by Therapy Assistants	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • <u>CQ Modifier</u>: Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant • <u>CO Modifier</u>: Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant. <p>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. 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</p>	<p>No change from proposed rule. Additional background information can be found starting on p. 447.</p>

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<p data-bbox="65 201 302 261">Applying the CQ and CO Modifiers</p>	<p data-bbox="323 139 1136 196">CY 2020, including how the modifiers are applied in different scenarios for different types of services.</p> <p data-bbox="323 201 1150 878">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. 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.</p> <p data-bbox="323 915 1150 1393">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.</p> <p data-bbox="323 1430 1136 1487">CMS acknowledges that application of the 10 percent de minimis standard can work differently depending on the types of services and scenarios</p>	<p data-bbox="1157 201 1913 228"><i>CMS is finalizing its policies with modifications, as detailed below.</i></p> <ul data-bbox="1234 233 2028 1487" style="list-style-type: none"> <li data-bbox="1234 233 2028 553">• <i>Time spent by a PTA/OTA furnishing a therapeutic service “concurrently” or at the same time with the therapist will not count for purposes of assessing whether the 10 percent standard has been met. Instead CMS is finalizing a policy that only the minutes that the PTA/OTA spends independent of the therapist will count towards the 10 percent de minimis standard. CMS is revising regulation text accordingly.</i> CMS intends to provide further detail regarding examples of clinical scenarios to illustrate its final policies regarding the applicability of the therapy assistant modifiers through the cms.gov website. (p. 464) <li data-bbox="1234 558 2028 1105">• <i>CMS is finalizing a revised definition of a service to which the de minimis standard is applied to include untimed codes and each 15-minute unit of codes described in 15-minute increments as a service.</i> CMS will allow the separate reporting, on two different claim lines, of the number of 15-minute units of a code to which the therapy assistant modifiers do not apply, and the number of 15-minute units of a code to which the therapy assistant modifiers do apply. CMS notes that the finalized policy will apply generally in the same way as illustrated in the proposed rule, except for the difference in the minutes of time that are counted toward the 10 percent standard (not counting the minutes furnished together by a therapist and therapy assistant), the application of the 10 percent standard to each billed unit of a time code rather than to all billed units of a timed code, and the billing on two separate claim lines of the units of a timed code to which the therapy assistant modifiers do and do not apply. CMS intends to provide further detail regarding examples of clinical scenarios through the cms.gov website. (p. 466) <li data-bbox="1234 1110 2028 1487">• <i>CMS is not finalizing the proposed documentation requirement to explain in the treatment note the application or non-application of the therapy assistant modifier for each therapy service furnished. CMS is also not finalizing a requirement that the therapy and therapy assistant minutes be included in the documentation.</i> Instead, CMS reminds therapists and therapy providers that correct billing requires sufficient documentation in the medical record to support the codes and units reported on the claim, including those reported with and without an assistant modifier. CMS clarifies that it would expect the documentation to be sufficient to know whether a service was furnished independently by a therapist or a therapist assistant, or was furnished “in part” by a therapist assistant, in

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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.
- Group Therapy: CPT code 97150 (requires constant attendance of therapist or assistant, or both).
- Supervised Modalities: CPT codes 97010 through 97028, and HCPCS codes G0281, G0183, and G0329.
- 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.

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

sufficient detail to determine whether the 10 percent standard was exceeded. ([p. 469](#))

- In response to a comment addressing the correct ordering of modifiers, CMS notes that it recently issued instructions to contractors to reorder modifiers for PT and OT services so that claims with the therapy assistant modifiers are not return. This reordering will be effective for claims containing CQ and CO modifiers with dates of service on and after January 1, 2020. ([p. 471](#))

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). CMS notes that it is not proposing changes to existing documentation requirements in the 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. 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.

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.

Proposed Regulatory Provisions

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

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Therapy KX Modifier Threshold Amounts	<p>otherwise applicable payment amount for the service for dates of service on and after January 1, 2022.</p> <p>Not included in proposed rule.</p>	<p>Under current law, the KX modifier thresholds are updated each year based on the Medicare Economic Index (MEI). They are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest \$10.00.</p> <p>Based on the above calculation, the CY 2020 KX threshold amount is \$2,080 for PT and SLP services combined and \$2,080 for OT services. (p. 471)</p> <p>For CY 2018 through CY 2028, the MR threshold is \$3,000 for PT and SLP services combined and \$3,000 for OT services, as specified by law.</p> <p>Additional detail on how expenses are applied toward these threshold amounts can be found on p. 472.</p>

Valuation of Specific Codes (p. 473)

[Valuation of Specific Codes for CY 2020](#)

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)

Final valuations for the below-noted codes for CY 2020 are available using the links below:

- [Tissue Grafting Procedures](#) (CPT Codes 15769, 15771, 15772, 15773, and 15774)
- [Drug Delivery Implant Procedures](#) (CPT Codes 11981, 11982, 11983, 20700, 20702, 20704, 20701, 20703, and 20705)
- [Bone Biopsy Trocar-Needle](#) (CPT Codes 20220 and 20225)
- [Trigger Point Dry Needling](#) (CPT Codes 20560 and 20561)
- [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 33016, 33017, 33018, and 33019)
- [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 33858, 33859, 33863, 33864, 33871, and 33866)
- [Iliac Branched Endograft Placement](#) (CPT Codes 34717 and 34718)
- [Exploration of Artery](#) (CPT Codes 35701, 35702, and 35703)
- [Intravascular Ultrasound](#) (CPT Codes 37252 and 37253)
- [Stab Phlebectomy of Varicose Veins](#) (CPT Codes 37765 and 37766)
- [Biopsy of Mouth Lesion](#) (CPT Code 40808)

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Transanal Hemorrhoidal Dearterialization (CPT Codes 46945, 46946, and 46948) • Preperitoneal Pelvic Packing (CPT Codes 49013 and 49014) • Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442) • Orchiopexy (CPT Code 54640) • Radiofrequency Neurotomy Sacroiliac Joint (CPT Codes 64451, 64625) • Lumbar Puncture (CPT Codes 62270, 62328, 62272, and 62329) • 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, 64454, and 64624) • 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, 74221, 74240, 74246, and 74248) • 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)

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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, 78830, 78831, 78832, and 78835) • Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001) • Biofeedback Training (CPT Codes 90912 and 90913) • 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 93985 and 93986) • Myocardial Strain Imaging (CPT Code 93356) • Lung Function Test (CPT Code 94200) • Long-Term EEG Monitoring (CPT Codes 95700, 95705, 95706, 95707, 95708, 95709, 95710, 95711, 95712, 95713, 95714, 95715, 95716, 95717, 95718, 95719, 95720, 95721, 95722, 95723, 95724, 95725, and 95726) • 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 98970, 98971, and 98972) • Emergency Department Visits (CPT Codes 99281, 99282, 99283, 99284, and 99285) • Online Digital Evaluation Service (e-Visit) (CPT Codes 99421, 99422, and 94233) • Radiation Therapy Codes (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

Response to Comment Solicitation on Opportunities for Bundled Payments under the PFS (p. 854)

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”). CMS cites several examples of bundled payment models that are being tested by the Center for Medicare and Medicaid Innovation (the Innovation Center). This

CMS received many comments in response to this solicitation. Some expressed general support while urging caution on design and implementation, suggesting that specialty societies and the CPT Editorial Panel are positioned to identify opportunities for bundled payments. Other commenters stated that bundled payments are not within the statutory authority of the PFS. CMS thanked commenters and stated that it will consider this issue further for potential future rulemaking. (p. 856)

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	<p>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. 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>	
<p><i>Payment for Evaluation and Management (E/M) Visits (p. 857)</i></p>	<p><u>Background</u></p> <p>Changes to Coding, Payment, and Documentation for CY 2021 in CY 2019 Final Rule. CMS reviewed its CY 2021 policies that it had finalized during CY 2019 rulemaking:</p> <ul style="list-style-type: none"> • Collapsed payment rate for office and outpatient E/M visit levels 2-4; corollary flexibility to only meet documentation requirements for a level 2 to bill levels 2-4. CMS proposed to rescind these policies. • 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. CMS proposes changes to the add-on codes (see below). • Addition of new extended visit G code (GPR01) (only reportable with office and outpatient E/M visit levels 2-4. CMS proposes to rescind this policy. 	<p>CMS again reviewed the provisions finalized during CY 2019 rulemaking (p. 862).</p> <p><i>CMS finalized these policies as proposed (p. 889)</i>. See additional information below.</p> <p><i>CMS finalized these provisions for CY 2021 as proposed (p. 895)</i>. See additional information below.</p> <p><i>CMS finalized the rescission of GPRO1 (p. 877)</i>.</p> <p><i>CMS finalized its implementation timeline for these provisions for CY 2021 (p. 898)</i>.</p>
<p><u>Policies for CY 2021</u></p>	<p>Documentation and Code Selection. Beginning in CY 2021, CMS proposed adoptions of the new coding, prefatory language, and interpretive guidance framework provided by AMA CPT. 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:</p>	<p><i>CMS finalized its proposal to adopt the MDM guidelines as revised by CPT (p. 870)</i>. CMS acknowledged that some commenters believed further refinement of the MDM guidelines was needed prior to implementation (p. 869). CMS noted that the AMA has stated that it will “undertake educational efforts on its new guidelines (p. 871). CMS received comments that for physicians practicing in multiple sites of service that this could be a burden because they will be using different documentation guidelines for E/M services in different settings (with some suggesting that CMS extend the new guidelines to all sites of service); CMS only responded that it would take this comments into consideration for potential future rulemaking (p. 879).</p> <p><i>CMS finalized that history and physical exam need only be provided and documented “as medically appropriate” (p. 870)</i>.</p>

- History and exam are no longer determinant of code level selection; Number of body systems/areas reviewed and examined under history and exam would no longer apply
- 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)

- 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.

- 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.

CMS finalized its proposal to allow the use of Time or MDM to select the office/outpatient E/M visit level (p. 870). CMS noted that it received comments stated that “the revised office/outpatient E/M code set that would permit code selection based on either MDM or time did not accurately represent MDM activities for urgent care practitioners who report office/outpatient E/Ms in the urgent care setting” and the request that practitioners in the urgent care setting be allowed to continue to use the 1995 or 1997 guidelines (p. 871). CMS responded that allowing the continued use of the 1995 or 1997 guidelines would create additional burden (p. 871).

Split/Shared Services, NPPs, and “Incident To”: CMS received comments and requests for clarification regarding how to count NPP time and physician time when a patient sees both at a single visit (p. 877). This included requests for clarification about CMS’ ‘incident to’ billing policy given that current policy only allows for ‘incident to’ billing for *established* patient visits, but if CMS allows billing for time based on both the physician *and* a QHP for all office and outpatient E/M visits, it would be extending the ‘incident to’ concept to *new* patient visits as well (p. 878). In response, CMS simply stated that it “did not make any proposals specific to split/shared services in the CY 2020 PFS proposed rule” and will consider the comments in future rulemaking (p. 879).

CMS finalized its proposal to adopt CPT 99XXX (p. 873; p. 896). CMS clarified that the code is to be used to report “all prolonged time spent on the date of the primary office/outpatient E/M visit code” and that the “date of the primary visit code” is “the 24 hour period for the *date of service* reported for the primary office/outpatient E/M visit code” (p. 873). CMS reminded stakeholders that “if MDM is used to choose the visit level, time will not be relevant to code selection” (p. 877).

CMS continued to express confusion about whether there is overlap between CPT 99XXX and the use of CPT 99358 and 99359 (p. 875) as well as concern about allowing reporting of CPT 99358 and 99359 with office/outpatient E/M codes given the new reporting guidelines for the office/outpatient E/M codes (p. 876). **CMS also believes that under the new coding framework that CPT 99358 and 99359 are potentially misvalued, in need of revision, and potential challenges to program integrity (p. 877).**

CPT 99202 – 99215 Code Values. CMS proposes to reestablish separate payment levels for levels 2-4. In addition, CMS proposes to accept the RUC-recommended work values for all new and established patient office/outpatient E/M codes. 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.”

Practice Expense. Regarding PE inputs, CMS proposes to remove ED021 (computer, desktop, with monitor) from 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.

Add-on Codes.

Complexity Add-on Code: CMS reviewed the add-on codes it had finalized for CY 2021 (in CY 2019 rulemaking), which it proposed to rescind:

- 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

CMS finalized the proposed values for 99202 – 99215 for CY 2021 ([p. 889](#)). In response to concerns expressed about the process that led to the revaluation, **CMS also noted that it will consider additional information pertaining to valuation of these services submitted prior to February 10, 2020 deadline for consideration in CY 2021 rulemaking** ([p. 886](#)). CMS lists the finalized work RVUs beginning on [p. 880](#) and times in [Table 34](#). In addition, CMS provided [Table 35](#) to compare current time and wRVUs to the CY 2021 values for wRVUs and time.

Global Codes. **CMS finalized that it will not adopt the RUC recommendations to apply the revised office/outpatient E/M values to the global surgery codes** ([p. 905](#); [p. 908](#)).

Budget Neutrality. CMS acknowledged stakeholder concern about the “redistributive impact” of revaluing this code set ([p. 888](#)). CMS stated that it would be premature to finalize a strategy in this rule, but it will consider the comments and address them in future rulemaking ([p. 889](#); [p. 898](#)). CMS also noted that commenters recommended several mechanisms to lessen the immediate impact, including:

- 4 or 5 year phase-in
- Cap increases and/or decreases
- Work with Congress on legislative fix to ensure no negative impact on CY 2021 conversion factor

CMS disagreed with comments that ED021 should remain a direct expense ([p. 886](#)).

CMS reiterated its concern that the new values for the office/outpatient E/M codes “still do not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits” ([p. 889](#)). CMS specifically identified three (3) types of visits that it thinks differ from the “typical office/outpatient E/M service”:

- 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

Topic	Proposed Rule	Final Rule
Global Surgical Packages	<p>office/outpatient evaluation and management visit, new or established))</p> <ul style="list-style-type: none"> 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)) <p>CMS proposed simplifying the complexity add-on coding by consolidating the two add-on codes into a single add on code with a revised descriptor: GPC1X (<i>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)</i>). CMS proposed a wRVU of 0.33 and physician time of 11 minutes (based on CPT 90785 (<i>Interactive complexity (List separately in addition to the code for primary procedure)</i>)). CMS proposed GPC1X could be billed with every level of office and outpatient E/M visit.</p>	<p>(Note: CMS included an impact table of specialty impacts <i>if</i> it had finalized the RUC-recommended E/M values but deleted GCGOX and GPC1X (without the new version of the add-on code) in Table 124).</p> <p>CMS finalized the code descriptor and value for GPC1X as proposed for CY 2021 (p. 895). CMS again stated “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. 891). In response to requests for additional details on CMS’ interpretation of “complex” and “serious,” CMS stated that it looks forward to “continued engagement with the public in the development of guidance” (p. 894).</p> <p>As part of CMS estimates in its Regulatory Impact discussion, CMS stated:</p> <p><i>[W]e assumed that the following specialties would bill HCPCS code GPC1X with 100 percent of their office/outpatient E/M visit codes: family practice, general practice, internal medicine, pediatrics, geriatrics, nurse practitioner, physician assistant, endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonary disease. We want to underscore that this was an assumption regarding which specialties are likely to furnish the types of medical care services that serve as the continuing focal point for all needed health care services or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition and is not meant to be prescriptive as to which specialties may bill for this service. As stated earlier, there are no specialty restrictions for billing HCPCS code GPC1X</i> (p. 1900).</p> <p>CMS finalized that it will <u>not</u> adopt the RUC recommendations to apply the revised office/outpatient E/M values to the global surgery codes (p. 905; p. 908). CMS stated that MedPAC agreed with its decision not to do so (p. 908). CMS acknowledged that most comments received objected to CMS’ failure to extend the E/M code valuation to the global periods (p. 902), including that failure to do so would result in the following negative impacts:</p> <ul style="list-style-type: none"> Disrupt the relativity of the MPFS: CMS responded that “we have questions about the appropriate number of E/M services reflected in the values for global surgery procedures. If the number of E/M

Post-op Visit Claims-Based Reporting. CMS revisited its implementation of a process for collecting data on the number and level of post-op visits (i.e. reporting CPT 99024). CMS also discussed the RAND report that reviewed the claims-based data.

services for global codes is not appropriate, adopting the AMA RUC-recommended values for E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues” (p. 905).

- Create specialty differentials (in violation of statute):
- Violate MACRA section 523(a): CMS states that the statutory requirement is “to use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS” (p. 905). CMS then goes on to state, “Given that the information we have gathered to date as required by section 1848(c)(8)(B)(i) of the Act, as well as the conclusions of past OIG studies, suggests that the values for E/M services typically furnished in global surgery periods are overstated in the current valuations for global surgery codes, we do not believe it would be appropriate to amplify the effects of any such overvaluation by increasing the values of included E/M services while we continue to look into the information and develop appropriate solutions” (p. 905).
- Violate precedent set for previous E/M valuation & Arbitrary Implementation of RUC recommendations: CMS stated that it had extended E/M value updates to globals in the past because it “did not have information to suggest that it might not be appropriate to do so”; and that “there are now important, unresolved questions regarding how post-operative visits included in global surgery codes should be valued relative to stand-alone E/M visit analogues” (p. 904).

In addition to reviewing the statements CMS made in the proposed rule, CMS here also states, “[w]hile the work involved in these post-operative visits is often valued with reference to RVUs for separately-billed E/M visits, bundled post-operative visit RVUs do not directly contribute to a certain number of RVUs to the valuation of procedures with 10- or 90-day global periods” (p. 899).

Reporting Requirement. CMS acknowledged comments challenging the generalizability of the claims data obtained (p. 905). CMS stated that it might consider whether it would be appropriate to require smaller practices to begin complying with the reporting requirement and noted that even though it has statutory authority to penalize practitioners who do not comply with the reporting requirements, the agency has chosen not to do so but that it might “reevaluate this decision if the current reporting rates are insufficient” (p. 906).

Topic	Proposed Rule	Final Rule
<p>Revaluing Office/Outpatient Visits within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services</p>	<p>Globals Survey Data. CMS also reviewed the 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> <p>RAND Report on Recommendations for Revaluation. CMS also discussed a third report by RAND for recommendations on how to revalue procedures based on collected data.</p> <p>CMS cited the values of office/outpatient E/M visits are linked to additional services, including:</p> <ul style="list-style-type: none"> • 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 <p>CMS sought 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 cross walked to the office/outpatient E/M visit codes. In addition, CMS sought 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>	<p>RAND Report. In response to criticism about the report’s conclusions, CMS acknowledged that “the absence of a reported visit does not necessarily mean that a post-operative visit did not occur.” However, CMS went on to state that they have no other way of knowing whether the visit occurred (p. 907). <i>CMS stated that RAND will be issuing a report “in response to each of these methodological concerns” later in 2019 (p. 908).</i></p> <p>CMS did not directly address comments on the RAND report related to survey data. However, CMS thanked stakeholders for comments on the RAND reports and stated that it will take them into consideration in the future. CMS also responded to specialties that were concerned about the agency’s data collection methods by stating, “we welcome submissions on other methods of gathering the data or ways to tabulate the results” (p. 909).</p> <p>CMS did not directly address comments on the RAND report related to potential methods for revaluation. However, CMS thanked stakeholders for comments on the RAND reports and stated that it will take them into consideration in the future. CMS also responded to specialties that were concerned about the agency’s data collection methods by stating, “we welcome submissions on other methods of gathering the data or ways to tabulate the results” (p. 909).</p> <p>CMS thanked commenters for their input (including support for revaluation with some specific recommendations, including for emergency department E/M visits). CMS stated that it will consider the input and recommendations in future rulemaking (p. 912).</p> <p>CMS included specialty-specific CY 2021 impacts of the finalized CY 2021 office and outpatient E/Ms in Table 120. In addition, CMS discussed its burden reduction estimates for its E/M policies beginning on p. 1979.</p>
<p>Regulatory Impact</p>		

Other Provisions of the Final Regulations (p. 913)

Topic

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Changes to the Ambulance Physician Certification Statement Requirement (p. 913)

[Exceptions to Certification Statement Requirement](#)

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;” and subsequently added
- “a certification statement . . . could be obtained from authorized staff should the attending physician be unavailable”

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.

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. 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. 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.” 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.

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.

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

CMS provided clarification that it does not currently require a certification for emergency transport and “did not propose to add such a requirement for emergency ambulance transport” (p. 920). In response to a comment, CMS also clarified that it did not propose to eliminate the certification requirement for hospital-to-hospital transport (p. 921).

CMS finalized its proposals (p. 924). In addition, **CMS finalized recommendations received during the comment period, including (p. 924):**

- Deleting superfluous language it believes is no longer necessary about “certifying medical necessity” since the requirement is included elsewhere
- Adding language to add references to both suppliers and providers and “physician certification statement” and “non-physician certification statement”

CMS finalized its proposal (p. 924). CMS noted that it received a comment asking if “a non-physician certification statement by nursing staff in the emergency department [would be treated] as compliant, if the treating physician is unavailable due to treatment of another patient in the Emergency Department.” CMS responded that specific instances should be

Topic	Proposed Rule	Final Rule
	<p>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>	<p>discussed with the MACs, but that “this scenario could be acceptable” (p. 921).</p> <p><i>CMS declined to add additional staff members at this time</i> (p. 923). However, CMS received recommendations to add the following practitioners (p. 922):</p> <ul style="list-style-type: none"> • Licensed vocational nurses (LVNs) • Advanced practice registered nurses (APRNs) • Paramedics “not functioning as an employee of the ambulance provider or supplier furnishing the ambulance services for which payment is claimed” • Physical therapists • Occupational therapists • Psychologists
<p><i>Establishment of a Medicare Ground Ambulance Services Data Collection System</i> (p. 926)</p> <p>Final Policies for Data Collection Instrument</p>	<p>CMS proposed collecting ground ambulance organization data with a web-based survey that CMS developed specifically for this purpose.</p> <p>Generally, CMS proposed requiring ground ambulance organizations to report on total costs, total revenues, and total utilization.</p> <p>CMS proposed that percent of ground ambulances be sampled from the all strata identified as part of the data collection effort.</p> <p>CMS proposed that the first data collection period will be January 1, 2020 – December 31, 2020.</p>	<p><i>CMS finalized its proposal</i> (p. 944).</p> <p><i>CMS finalized its proposals on what data elements to collect with some modification</i> (p. 951; p. 968; p. 975; p. 982; p. 992; p. 995; p. 1000; p. 1004; p. 1009; p. 1014).</p> <p><i>CMS finalized its proposals regarding sampling</i> (p. 1034).</p> <p><i>CMS finalized its implementation and reporting timeline</i> (p. 1038).</p> <p>CMS noted that it received a number of comments discussing how ground ambulance is only a <i>part</i> of the emergency ecosystem and that CMS should also focus on air ambulance (p. 922). However, CMS replied that the statute does not provide the authority to collect the information on air ambulance as it does for ground ambulance (p. 933).</p> <p>The statute states that these provisions are not subject to the ICR requirements, and therefore, CMS did not set out a burden estimate in the final rule (p. 1774).</p>
<p>Information Collection Requirements</p> <p><i>Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR)</i> (p. 1052)</p>	<p>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</p>	<p><i>CMS finalized its policies as proposed</i> (p. 1056).</p>

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<p>Information Collection Requirements</p> <p>Regulatory Impact</p>	<p>less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks).</p> <p>As such, CMS proposed to expand ICR coverage to include:</p> <ul style="list-style-type: none"> • 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.” 	<p>CMS did not make any burden estimates, specifically because it stated “[w]e do not anticipate the need to use the NCD process to add additional covered conditions in the future” (p. 1775).</p> <p>CMS provides its estimated regulatory impact of these changes beginning on p. 1912. CMS notes that even under the CR coverage rules, less than 1% of beneficiaries with heart failure utilized CR, and that uptake of ICR has been even slower (p. 1913). Based on its claims analysis, CMS states that at an average price of \$120.93, the estimated total cost of adding stable, chronic heart failure to the list of covered conditions for ICR is estimated at \$408,502 annually” (p. 1913).</p>
<p>Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (p. 1057)</p> <p>eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2020</p> <p>Objective 1: Protect Patient Health Information in 2021</p>	<p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p>	<p><i>CMS finalized these policies as proposed. The eCQMs available for Medicaid EPs in 2020 will 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. In 2020, Medicaid EPs will be required to report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically, including at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure).</i> (p. 1062)</p> <p><i>CMS agreed with the commenters that finalizing a 274-day eCQM reporting period only for CY 2020 may cause confusion for Medicaid EPs. Instead, CMS finalized a continuous 90-day eCQM reporting period for all Medicaid EPs in 2020.</i> EPs may select any continuous 90-day period within the calendar year. The reporting period is a minimum, and we encourage EPs to report on a longer period if they are able to do so. Under this policy, EPs may be able to attest to meaningful use as early as April 1, 2020. (p. 1068)</p> <p><i>CMS finalized this policy as proposed</i> (p. 1073).</p>

Medicare Shared Savings Program (p. 1075)

[CMS Web Interface and Claims-based Measures](#)

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, adopted a policy that any future changes to the CMS web interface measures would be proposed and finalized through the QPP rulemaking, and such changes would be applicable to MSSP. 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 the 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: 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:

Under final MIPS policies, no changes are being finalized to the CMS Web Interface measure set for performance year 2020. As a result, ACOs will continue to be responsible for reporting the following measure for performance year 2020 for purposes of MSSP:

- ***ACO – 14 Preventive Care and Screening Influenza Immunization***

As discussed in the proposed rule, ***CMS will maintain the measure with the “substantive” change described in Appendix 1, Table D-A 81 (previously Finalized Quality Measures with Substantive Changes Finalized for the 2022 Payment Year and Future Years) of this final rule. CMS does not believe this change would require that CMS revert the measure to pay-for-reporting for the 2020 performance year.*** CMS has determined that it can create a historical benchmark using data reported for the measure in past years, as updating the numerator instructions that allow the use of the Live Attenuated Influenza Vaccine (LAIV) does not significantly impact the measure. (p. 1079)

Based on the policies being finalized for MIPS, ACOs will not be responsible for reporting the ACO-47 Adult Immunization Status measure (ACO-47) for performance year 2020. (p. 1080)

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- ACO-17 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: 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

For ACO-17, based on comments received, CMS is reverting this measure to pay-for-reporting for performance years starting in 2019, as further detailed on [p. 1082](#), but will revert to pay-for-performance for performance year 2020. ([p. 1083](#))

For ACO-43, CMS is finalizing its proposal that the measure will be pay-for-reporting for 2020 and 2021. ([p. 1085](#))

[Solicitation of Comment on Aligning the MSSP Quality Score with the MIPS Quality Score](#)

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.

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).

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.

Table 40 shows the Shared Savings Program quality measure set for performance year 2020 and subsequent performance years that will result from the finalized policies regarding MIPS. The net result will be a set of 23 measures on which ACOs' quality performance will be assessed for performance year 2020 and subsequent performance years, including 10 patient/caregiver experience of care measures, 4 care coordination/patient safety measures, 6 preventive health measures, and 3 at risk populations measures. ***Table 41 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes.***

CMS details comments and responses to its solicitation throughout this discussion, including as follows:

- Comments in response to the concept of aligning the MSSP quality score with the MIPS quality performance category scoring methodology starting on [p. 1093](#).
- Comments on using the MIPS quality performance category score to assess quality performance for MSSP starting on [p. 1097](#).
- Comments on potentially including Web Interface, the CAHPS for ACO survey, and MIPS claims-based measures for ACOs starting on [p. 1101](#).
- Comments on determining the threshold for minimum attainment in the MSSP using the MIPS APM quality performance category scoring starting on [p. 1105](#).

For most of the topics above, the majority of comments opposed the approaches CMS had detailed.

CMS will consider the feedback it received in the development of future updates and changes to the MSSP quality scoring methodology.

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.

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. 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. 1110)

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.

CMS is finalizing its policies as proposed, as further detailed below.

Topic	Proposed Rule	Final Rule
Expanding the Definition of a Covered Recipient	<p>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.</p>	<p><i>CMS is finalizing its policies as proposed. (p. 1119)</i></p> <p>Highlights from the questions and responses are included below.</p> <ul style="list-style-type: none"> • In response to questions about the definitions of covered recipients, CMS notes that the definitions were delineated within the SUPPORT Act and will be the same across all jurisdictions or regions. CMS will continue to work with stakeholders to determine the challenges the industry may face, including through several routes (e.g. technical assistance, outreach, and the help desk).(p. 1116) • CMS anticipates making updated submission templates available prior to the start of data collection for CY 2021 data. (p. 1117) • CMS discusses its approach for ensuring the integrity of reported data starting on p. 1118.
Nature of Payment Categories	<p>CMS proposes to consolidate accredited/certified and unaccredited/non-certified continuing education programs into a single “medical education programs” category.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>CMS proposes to define “long-term medical supply or device loan” as “the loan of supplies or a device for 91 days or longer.”</p>	<p><i>CMS is finalizing its policies as proposed. (p. 1123)</i></p> <p>In response to comments, CMS notes that it will provide further technical assistance and operational guidance, including through direct outreach, outreach to associations, the issuance of guidance, informational webinar sessions, as well as via the help desk. (p. 1122)</p>
Standardizing Data on Reported Covered Drugs,	<p>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</p>	<p><i>CMS is finalizing its policies as proposed. (p. 1126)</i></p>

Topic	Proposed Rule	Final Rule
<p data-bbox="65 118 300 180">Devices, Biologicals, or Medical Supplies</p> <p data-bbox="65 451 281 578">Information Collection Requirements and Impact Estimates</p>	<p data-bbox="321 118 1178 245">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.</p> <p data-bbox="321 280 1178 407">CMS also proposes to reincorporate language that specifically requires reporting of national drug codes (NDCs) for both research and non-research payments; this provision would be effective 60 days from publishing the final rule.</p>	<p data-bbox="1178 118 2045 375">In response to concerns about the addition of Dis to Open Payments reporting, CMS notes that it looks forward to discussing the details of implementation with stakeholders. CMS will provide guidance, explanations, and examples of how to report Dis, including when there are multiple Dis, on its website and through other outreach efforts, in addition to technical assistance. CMS reminds stakeholders that this DI reporting provision will be effective for data collected beginning in CY 2021 and reported in CY 2022. (p. 1125)</p> <p data-bbox="1178 451 2045 513">In the Information Collection Requirements section, CMS provides its burden estimates for its Open Payment Provisions as follows:</p> <ul data-bbox="1230 516 2045 675" style="list-style-type: none"> • Table 70: Burden to Modify Nature of Payment Categories (total one-time cost of \$675,745) • Table 71: Burden for Changes to Standardize Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies (total one-time cost of 2,440,937) <p data-bbox="1178 711 2045 935">In its Regulatory Impact Analysis, however, CMS estimates a cost of \$10 million per year in increased burden to reporting entities and new covered recipient groups for submitting, collecting, retaining, and reviewing data associated with CMS' expanded definition of "Covered Recipient". CMS also notes that it anticipates minor additional costs for system updates associated with its "nature of payment" categories policy and that it cannot estimate the cost of its policies regarding Standardizing Data Reporting. (p. 1919)</p>

Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy (p. [1127](#))

<p data-bbox="321 1037 1178 1365">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.</p>	<p data-bbox="1178 1037 2045 1070">CMS received a host of comments on this issue, including:</p> <ul data-bbox="1230 1073 2045 1469" style="list-style-type: none"> • Support for the proposed examples (verbal discussion and notation in the chart) • Written materials as a supplement to the verbal discussion • Inclusion of infusion therapy option details, such as effectiveness and out-of-pocket costs • Expansion of professionals that can provide the notification on behalf of the physician • Electronic prompts to beneficiaries • A CMS-developed single, standardized form about infusion therapy options • CMS training program, as well as a CMS web site to search for infusion therapy providers
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Topic	Proposed Rule	Final Rule
		<ul style="list-style-type: none"> • Requirement to discuss only when the drug regimen is available and appropriate for home infusion, and there is a provider available in the area • One streamlined notice at the start of therapy • Only when a new infusion treatment is necessary or if there are changes in the patient’s condition/circumstance that would affect the patient’s choices <p>CMS appreciated commenters’ support and recommendations, which it will take into consideration as it continues developing future policy through notice-and-comment rulemaking effective for home infusion therapy services beginning CY 2021 and for subsequent years. (p. 1130)</p>
<p><i>Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm (p. 1130)</i></p> <p><u>Enrollment of Opioid Treatment Programs</u></p>	<p>See background information under the final rule column.</p> <p>The provisions of this proposed rule would establish requirements that OTPs must meet in order to enroll in Medicare.</p>	<p>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.</p> <p>CMS provides additional details regarding the statutory and regulatory definition (at 42 CFR part 8¹) and requirements for OTPs starting on p. 1131, and additional information on the current Medicare enrollment process starting on p. 1133.</p> <p><i>CMS is finalizing its provisions as proposed with several exceptions (p. 1155)</i>. Exceptions are detailed further below (after highlighted comments).</p> <p>CMS provides comments and responses starting on p. 1146. Highlights are included below:</p> <ul style="list-style-type: none"> • In response to a question, CMS notes that it is in the process of revising Form CMS-855B to include a new category for OTPs. A currently enrolled clinic/group practice will need to separately enroll as an OTP if it wishes to bill for OTP services. (p. 1148) • In response to a question, CMS specifies that OTP facilities will need to enroll, but that physicians and practitioners will not have to enroll as part of the OTP’s enrollment. (p. 1149)

¹ 42 CFR Part 8 addresses Medication Assisted Treatment for Opioid Use Disorders, including requirements for OTPs.

Addition of 42 CFR 424.67 and general OTP requirement to enroll. 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.

Form CMS-855B: In paragraph (b)(1) of 424.67, 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.

- First, in 424.67(b)(1)(i), 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, in 424.67(b)(1)(ii), CMS proposes 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.

Application fee: 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

- CMS acknowledges that OTPs certified and in operation before the enactment of the SUPPORT Act, and therefore modifies its policy to categorize such OTPs at the moderate risk level. ([p. 1151](#))

- ***Section 424.67(b)(1)(i) is expanded to apply to all physicians, other eligible professionals, and pharmacists who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP (regardless of whether the individual is a W-2 employee of the OTP).*** ([p. 1155](#))

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 in 424.67(b)(2).

Categorical risk designation. CMS is proposing to assign newly enrolling OTPs to the high categorical risk level. CMS is proposing four regulatory provisions.

- First, in 424.67(b)(3), CMS is proposing to state that newly enrolling OTP providers will be screened at the high categorical risk level.
- Second, in 424.518(c)(1)(iv), CMS is proposing to add newly enrolling OTPs to the types of providers and suppliers screened at the high categorical risk level.
- Third, at 424.518(b)(1)(xii), CMS is proposing to specify that OTPs that are revalidating their current Medicare enrollment would be screened at the moderate categorical risk level.
- Fourth, at 424.67(d)(1)(iii), 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. CMS is proposing at 424.67(b)(4)(i) 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, at 424.67(b)(4)(ii), CMS proposes that it would not accept a provisional certification for OTP enrollment in Medicare in lieu of full certification.

- ***In 424.67(b)(3), CMS is revising this paragraph to state that applicants must successfully complete the assigned categorical risk level screening required under, as applicable, 424.518(b) and (c). This is intended to accommodate the two levels of screening that CMS is finalizing for newly enrolling OTPs, as discussed below. (p. 1155)***
- ***In 424.518(c)(1)(iv), which outlines providers and suppliers in the high-risk level of categorical screening, CMS is revising this provision to specify that prospective (newly enrolling) OTPs that have not been fully and continuously certified by SAMHSA since October 23, 2018 will be screened at the high-risk level. (p. 1155)***
- ***Proposed 424.518(b)(1)(xii), which stated that revalidating OTPs would be subject to the moderate risk level of categorical screening, will be re-designated as new 424.518(b)(1)(xiii). Prospective OTPs that have been fully and continuously certified by SAMHSA since October 23, 2018 will be included in revised 424.518(b)(1)(xii), to be subject to screening at the moderate category risk level. (p. 1155)***

Besides the changes noted above, CMS is finalizing its OTP enrollment provisions as proposed.

Management employees. CMS is proposing at 424.67(b)(5) 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.

Standards specific to OTPs. CMS proposes the following additional requirements with which OTPs must comply in order to enroll in Medicare:

- At 424.67(b)(6)(i), 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.
- At 424.67(b)(6)(ii), 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).
- At 424.67(b)(6)(iii), 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.

Provider agreement. At 424.67(b)(7)(i), 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, in 424.67(b)(7)(ii), CMS proposes that an OTP'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.

Other applicable requirements. To ensure that the OTP meets all other applicable requirements for enrollment, CMS is proposing at 424.67(b)(8) 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. At 424.67(c), 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 under 424.67.
- 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. At 424.67(d)(1) 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 at 424.67(d)(2) 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, at 424.67(d)(3), CMS is proposing that an OTP may appeal the revocation of its enrollment.

Prescribing individuals. At 424.67(e)(1), 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 also proposes to further clarify in 424.67(e)(2) that all other applicable requirements in 424.67, part 242, and part 8 must also be met.

Relationship to 42 CFR part 8. At 424.67(f), 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. 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).

Information Collection Requirements.

Improper Prescribing. In § 424.535(a)(14), CMS has codified an enrollment revocation reason related to improper prescribing practices, and the introductory text currently refers to situations where 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 in the revocation reason, so CMS would specify the prescribing of “Part B or D drugs.”

Patient Harm. CMS is proposing to add a new revocation reason (424.535(a)(22)) and a new denial reason (424.530(a)(15)) 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.

Information Collection Requirements. CMS provides estimates of the combined burden related to enrollment of OTPs in [Table 72](#), including an average annual cost of \$99,558 per year, and a three-year total cost of \$298,676. CMS also provides additional detail starting on [p. 1920](#).

CMS is finalizing its proposed changes with modifications, as indicated below. (p. 1179)

Improper Prescribing. *Finalized as proposed.*

Patient Harm. *Finalized with the following modifications:*

- ***CMS is removing the following criteria from the patient harm provisions:***
 - ***Required participation in rehabilitation or mental/behavioral health programs.***
 - ***Required abstinence from drugs or alcohol and random drug testing.***
- ***CMS is adding new paragraphs to these provisions that exclude from consideration those actions and orders restricted to: (1) required participation in rehabilitation or mental/behavioral health programs; or (2) required abstinence from drugs or alcohol and random drug testing.***
- ***CMS is removing the criterion that reads: “Any other information that CMS deems relevant to its determination.”***

CMS details comments and responses starting on [p. 1159](#). Highlights are included below:

[Revision and Addition to Denial and Revocation Reasons in §§ 424.530 and 424.535](#)

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- 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.

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.

- In response to comments that CMS’ current improper prescribing revocation authority is improper due to the potential for unfairly targeting specialties and deterring legitimate prescribing, CMS notes that it has been extremely careful in its application of this provision, and stresses that this will not change with its expansion. CMS also notes that it has received no indication that the application of this authority has caused physicians and other eligible professionals to significantly reduce their levels of prescribing or caused barriers to Part D drugs and does not foresee such problems with the addition of Part B drugs. ([p. 1159](#))
- In response to comments that the improper prescribing authority duplicates current safety mechanisms and creates burden, CMS disagrees and notes that only severe cases have triggered this authority, indicating that CMS gives “great deference” to the prescribing decisions of the provider community as a whole. ([p. 1160](#))
- In response to numerous comments opposing the patient harm proposals, CMS notes:
 - Only actions result in patient harm could lead to revocation or denial. ([p. 1161](#))
 - CMS does not believe the authority is overly vague or lacks sufficient guidance since CMS outlines in detail both the types of sanctions or actions that could invoke those provisions and the criteria it would consider. CMS believes these provisions appropriately balance (1) the need for clarity concerning the actions that these provisions cover with (2) the importance of having sufficiently extensive criteria to ensure a fair and exhaustive review of the case. ([p. 1162](#))
 - Only physicians and other eligible professionals impacted by the provisions would be burdened, not other physicians or other eligible professionals. ([p. 1162](#))
 - CMS is cognizant of the relative severity of a Medicare revocation, which is why CMS has historically exercised revocation authority only when the affected party’s behavior is such that revocation is genuinely warranted. ([p. 1162](#))
 - CMS does not believe the revocation provision will impair patient access to health care, considering that only a very small number of physicians would be affected. Should such issues arise after implementation, CMS will consider mechanisms for resolving them. ([p. 1163](#))

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- CMS does not wish to discourage physicians and other eligible professionals from seeking whatever help they may need (e.g. related to drug abuse and alcoholism or other mental/behavioral health issues) and therefore implemented changes as noted above regarding related actions. (p. 1163) CMS notes that the action must be restricted to required participation in a rehabilitation or mental/behavioral health program or abstinence from drugs or alcohol and random drug testing only; if there is another sanction that involves patient harm, CMS could invoke its denial or revocation authority. (p. 1164)
- CMS disagrees that the provisions lack clear standards. CMS notes that if commenters are suggesting that each factor should contain definitive benchmarks, such as a minimum number of patients who were harmed by the conduct in question, CMS does not concur. CMS notes that it must have the discretion to fairly and fully consider the specific facts and circumstances, and establishing threshold could allow bad actors to avoid denial or revocation. (p. 1166)
- CMS recognizes concerns with its consideration of any other information it deems relevant. As a result, CMS will remove this factor. However, CMS notes that it will not affect its continued use of this same factor in several of its other existing denial and revocation reasons, nor will CMS preclude its use in possible future provisions. It is only due to the unique circumstances and potential fact patterns associated with this provision that this criterion is being removed. (p. 1167)
- CMS recognizes the potential for erroneous or unfounded complaints and believes that many of these cases will be detected as such and appropriately dismissed at the state oversight board level. (p. 1168)
- CMS details its statutory authority for establishing these provisions starting on p. 1170.
- CMS does not believe that the functions of protecting patient health, enforcing medical laws, and overseeing physician and practitioner care are exclusive to states. CMS has oversight responsibility for the Medicare program, and while it generally gives deference to state oversight boards, there could be instances where CMS feels compelled to review a matter. (p. 1173)

Topic	Proposed Rule	Final Rule
		<ul style="list-style-type: none"> ○ Actions will be considered through CMS analysis of factors. (p. 1174) ○ CMS, rather than contractors, will typically make patient harm determinations, but CMS does not exclude the possibility that an applicable contractor could make the determination. (p. 1175) ○ Appeal rights will be provided. However, as with all other revocations, affected physicians or other professionals will be unable to review the case during the determination process. (p. 1175) ○ CMS will take action once a state oversight board reports a particular action or order pertaining to patient harm that CMS determines warrant denial or revocation, but if the action or order is later overturned, CMS will take reciprocal action, as appropriate, and rescind the denial or revocation. (p. 1177) <p>CMS discusses its impact estimates for these enrollment denial and revocation provisions starting on p. 1923. CMS estimates combined annual projected savings to the Trust Funds to be \$750,000 annually, or \$7.5 million over 10 years.</p>

Deferring to State Scope of Practice Requirements (p. 1180)

[Ambulatory Surgical Centers](#)

CMS is proposing to revise § 416.42(a), Surgical services, to allow either a physician or an anesthesiologist, as defined at § 410.69(b)², to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed.

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.

CMS is modifying the proposed change at § 416.42(a)(1) to clarify that there are two components to any pre-procedure evaluation and require that, immediately before surgery, a physician must examine the patient to evaluate the risk of the procedure to be performed, and a physician or anesthesiologist must examine the patient to evaluate the risk of anesthesia. A physician may perform both parts of the pre-procedure evaluation. (p. 1185)

CMS notes that approximately 4,000 public comments were submitted on this requirement. CMS notes that majority of commenters supported the change to allow anesthesiologists, in addition to physicians, to evaluate patients before surgery for anesthesia risk. CMS noted that the support comments were predominantly silent in addressing the risk evaluation of the planned surgical procedure. The comments in opposition stated concerns about patient safety, indicating that only physicians possess the medical background to assess the patient in an objective, evidence-based and patient centric way. Based on comments, CMS states that commenters seem to be addressing two specific, separate patient risk evaluations, with an assessment of the surgical

² CMS defines anesthesiologist to include both an anesthesiologist's assistant and a certified registered nurse anesthesiologist.

Topic	Proposed Rule	Final Rule
<p>Hospice</p>	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 	<p>anesthesia risk separate from an evaluation of the patient’s ability to tolerate the overall procedure, the latter of which should remain with the physician. CMS states: “We believe it is beneficial and appropriate to clarify in regulation text the separate evaluations and who must be responsible for them.” CMS later states: “We believe the physician is the appropriate practitioner to perform the clinical assessment for the overall procedure, taking into account underlying patient comorbidities and all aspects of the surgical procedure to be performed to ensure a successful and optimal outcome of the planned procedure in an ASC setting. The physician or anesthetist, in tandem with the physician evaluating the procedure to be performed, would be evaluating the risk of anesthesia and the ability for the patient to tolerate the planned level of anesthesia.” (p. 1184)</p> <p>CMS predicts this change will generate savings of approximately \$17.3 million annually. (p. 1925)</p> <p><i>CMS is finalizing this policy as proposed. (p. 1193)</i></p> <p>Notable comments and responses are included below.</p> <ul style="list-style-type: none"> • In response to some comments that hospices should be allowed to accept orders from PAs employed by or under arrangement with the hospice, CMS expresses its disagreement, indicating that “such piecemeal inclusion without complementary regulations to establish the scope of PA services in hospices may create patient safety and program vulnerabilities.” CMS notes that “it is clear from the comments that a notable portion of the physician assistant and hospice communities view the role of the physician assistant as an acceptable substitute for hospice physicians, which is not in accordance with current statutory provisions. We believe that this disconnect between public perception of the role of the PA and the requirements of statute necessitates rulemaking to clearly set forth what is and is not permissible. We will consider this suggestion for future rulemaking.” (p. 1191) • In response to a comment opposing the idea that attending physicians who are PAs should be limited to prescribing only those medications or therapies that are not related to the terminal prognosis, CMS notes that it did not propose and is not finalizing any such limitations. However, CMS notes that, given the requirements for the hospice interdisciplinary group, “the need for an attending physician outside of the hospice to write orders related to implementing the hospice plan of care should be rare.” (p. 1191) • CMS thanks commenters for submitting information regarding the current and future role of non-physician practitioners (NPPs) without

Topic	Proposed Rule	Final Rule
	<p>supervising physician are located in different offices, such as hospice multiple locations?</p> <ul style="list-style-type: none"> • 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? 	<p>detailing comments, and notes that information will be considered when developing future hospice CoPs related to the role of NPPs. (p. 1192)</p> <ul style="list-style-type: none"> • In response to a question, CMS specifies that if a PA is assigned by a “parent company” to a hospice, then the PA is considered to be an “employee” of the hospice.” (p. 1192) <p>CMS does not believe there are any associated financial impacts for hospices under this policy. (p. 1925)</p>

Advisory Opinions on the Application of the Physician Self-Referral Law (p. 1194)

Revisions

To address concerns from stakeholders and differences between the Physician Self-Referral Law and the Antikickback Statute, CMS made the following proposals:

- CMS proposed 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.”
- CMS proposed 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).
- CMS proposed 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.”
- CMS proposed to modify the time period in which it must issue an advisory opinion after receiving a request from 90 days to 60 days.
- CMS proposed changes to the certifications that must be made as part of the process to state 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

CMS finalized its proposal (p. 1202). CMS specifically stated that it is “not expanding the scope of the advisory opinion process to include hypothetical arrangements or general questions of interpretation” ([p. 1204](#)), but CMS clarified that it will not consider an arrangement “*per se* hypothetical” just because the parties have not yet entered into the arrangement” and provides additional guidance and clarification ([p. 1205](#)).

CMS finalized this proposal (p. 1209).

CMS finalized this proposal (p. 1209).

CMS finalized this proposal (p. 1211; p. 1213).

CMS finalized this proposal (p. 1215).

Topic	Proposed Rule	Final Rule
	<p>comparable officer (or a managing partner if it requested by a corporation).</p> <ul style="list-style-type: none"> • CMS proposed to change the fee structure for requesting an advisory opinion to an hourly fee of \$220. • CMS proposed 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.” • CMS proposed 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. • CMS proposed 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.” • CMS sought 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><i>CMS finalized its proposal with modification</i> (p. 1218). CMS did <u>not</u> finalize a higher hourly fee for expedited review (p. 1217). In addition, in response to commenter concerns, CMS also added, “As we work on operationalizing these reforms to the advisory opinion process, we will consider whether it is feasible to provide requestors with a cost estimate for the review and issuance of an advisory opinion. We will also consider discounting, on a case-by-case basis, the \$220 hourly rate for requestors with demonstrated limited financial resources, such as certain rural providers or small or solo practitioners, or, alternatively, capping the total charges for an advisory opinion” (p. 1218).</p> <p><i>CMS finalized its proposal</i> (p. 1223).</p> <p><i>CMS finalized its proposal</i> (p. 1223).</p> <p><i>CMS finalized its proposal</i> (p. 1223).</p> <p>CMS stated that it received comments suggestion that rescission would be appropriate in the circumstances where there is a “material regulatory change that impacts the conclusions” of an advisory opinion or when a party asks for reconsideration after a negative advisory opinion. Therefore, <i>CMS finalized modification of the regulations to state that “CMS may rescind an advisory opinion if it determines that there is good cause to rescind the opinion”</i> (p. 1224). In addition, <i>CMS finalizes defining “good cause” as “when here is a material change in the law that affects the conclusions reached in an opinion” or “a party that has received a negative advisory opinion seeks reconsideration based on new facts or law”</i> (p. 1225).</p>

CY 2020 Updates to the Quality Payment Program (p. [1228](#))

Topic	Proposed Rule	Final Rule
Definitions	<p>At § 414.1305, CMS proposes to define the following terms:</p> <ul style="list-style-type: none"> • Aligned Other Payer Medical Home Model • Hospital-based MIPS eligible clinician • MIPS Value Pathway <p>CMS also proposes to revise at § 414.1305 the following term:</p> <ul style="list-style-type: none"> • Rural area 	<p>CMS finalized these definitions as proposed (p. 1234).</p> <ul style="list-style-type: none"> • Aligned Other Payer Medical Home Model • Hospital-based MIPS eligible clinician • MIPS Value Pathway • Rural area

MIPS Program Details (p. [1235](#))

[Transforming MIPS:](#) [MIPS Value](#) [Pathways](#)

MVP Framework

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.

To begin implementing MVPs, CMS proposes to define a MIPS Value Pathway at § 414.1305 as a subset of measures and activities, as 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

MVP Framework

CMS finalized a modified proposal to define MVPs at § 414.1305 as “a subset of measures and activities established through rulemaking,” as opposed to “as specified by CMS” to clarify its intention to specify MVPs with stakeholder input to the extent possible (p. [1242](#)).

Note that in this rule, CMS finalized the MVP framework and definition, but will propose and finalize more specific details about participating through this pathway, including specific MVPs, through future rulemaking. CMS still intends to implement MVPs beginning with the 2021 MIPS performance period/2023 MIPS payment year.

In this section, CMS discusses some feedback received and clarifies the following:

- Its intent to develop MVPs in collaboration with stakeholders that align with guiding principles that include simplification and clinician burden reduction.
- Its intent to work with stakeholders to develop MVPs that account for variation in specialty, size, and composition of clinician practices.
- Its intent for MVPs to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a patient population, a specialty or a medical condition, reducing the siloed nature of the current MIPS participation experience.
- Its intent to develop MVPs to connect measures across performance categories.
- Although the MIPS statute requires the use of four performance categories in determining the MIPS composite performance score, CMS is interested in the potential use of measures that could satisfy

these and other details need to be worked out and would be addressed in next year's rulemaking cycle.

more than one performance category within its statutory constraints and welcomes additional stakeholder engagement related to how to best structure and develop MVPs that entail low clinician burden.

- In response to comments in support of implementing MVPs as a voluntary gradual or multi-year pilot, CMS clarified that it has not made any proposals regarding whether participation in MVPs will be mandatory or optional. CMS appreciates that it needs to work diligently with stakeholders to develop and propose policies regarding many aspects of implementation of MVPs in the 2021 MIPS performance period, including the extent of first year implementation or the feasibility of an initial pilot.
- CMS clarifies that a notable change with MVPs is that clinicians would no longer 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 a clinical condition. CMS welcomes ideas from stakeholders for developing MVPs that provide further burden reduction to clinicians.
- CMS acknowledges that a single MVP may not fit the needs of all clinician types and all clinicians in the specialty and would like to work with stakeholders to determine, to the extent possible, the number of MVPs needed for specialists and which measures and activities should be included.
- CMS would like to engage with clinicians in the field and their societies to develop applicable MVPs and foundational population health administrative claims measures that are low burden and meaningful.
- CMS intends to work with stakeholders to determine approaches to maintain equity between MVP and the MIPS participation option, as well as clinicians reporting on different MVPs.
- CMS believes that the integration of population health measures and Promoting Interoperability measures into MVPs provides a degree of standardization across all clinician types.
- Many commenters expressed concerns related to the population health claims-based performance measures that would be selected for use in MVPs. In response, CMS noted that implementation of a foundational population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations can result in MVP measure tracks that provide more uniformity in the program's measures, allow focus on important public health priorities, increase the value of MIPS performance data, and reduce barriers to APM participation. CMS believes that holding all clinicians accountable for the same population health measures will align incentives, reduce clinician

[Estimated Number of Clinicians Eligible for MIPS Eligibility](#)

reporting burden, encourage coordination between clinicians and promote meaningful progress on measures.

- CMS intends to examine concerns regarding population health measure reliability, validity, attribution and risk adjustment and the technical challenges and address them to the extent feasible by working with the measure stewards and clinician experts.
- CMS believes that interoperability is also a foundational element that would apply to all clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. CMS envisions an initial uniform set of Promoting Interoperability measures in each MVP and will consider customizing MVP Promoting Interoperability measures in future years. CMS believes that eligible clinicians could benefit from more targeted approaches that assess the meaningful use of health IT in alignment with clinically relevant MVPs.

Requests for Feedback on MVPs

CMS requested public comments regarding numerous issues involving the MVPs.

Requests for Feedback on MVPs ([p. 1243](#))

CMS received 2,100 comments related to implementation of MVPs. While it did not summarize or respond to these comments in the final rule, it thanks commenters for their responses and may take them into account as it develops future policies for the MVPs.

CMS is also interested in engaging with stakeholders on additional ways to reduce burden in the MIPS program, in addition to what it has solicited comment on for MVPs. CMS intends to continue a dialogue with stakeholders on these important MVP topics and may consider convening public forum listening sessions, webinars, and office hours or using additional opportunities such as the pre-rulemaking process to further understand what is important to clinicians, patients, and stakeholders.

In the Regulatory Impact Analysis section, [Table 122](#) presents the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians for the 2020 MIPS performance period based on 2018 MIPS performance period data and applying the policies for the 2020 MIPS performance period. CMS estimates that in the 2020 performance year, there will be approximately 880,000 MIPS eligible clinicians:

- Approximately 220,000 clinicians would be eligible because they exceed the low volume threshold as individuals and are not otherwise excluded (i.e. “required eligibility”). Note this category is broken down into those who participate and those who do not participate in MIPS.
- About 639,000 MIPS eligible clinicians would not meet the low-volume threshold individually, but are anticipated to submit to MIPS as a group.

[Group Reporting](#)

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.

- An additional 20,644 clinicians would be eligible through the opt-in policy (based on the assumption that 33% of clinicians who exceed at least one but not all low-volume threshold criteria would elect to opt-in to MIPS).

CMS assumed that all Partial QPs would elect to participate in MIPS and included them in its scoring model and eligibility counts.

Limitations to these estimates are discussed starting on [p. 1962](#).

CMS finalized these changes as proposed ([p. 1246](#)).

[MIPS Performance Category Measures and Activities](#) ([p. 1246](#))

[Quality Performance Category](#)

Contribution to Final Score

- 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

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

Contribution to Final Score ([p. 1248](#)).

As a result of ongoing concerns regarding cost measures, particularly cost measure feedback reports, CMS did not finalize these proposals. Therefore, the quality performance category will comprise 45 percent of a MIPS eligible clinician's final score for the 2020 performance year/2022 MIPS payment year. CMS will revisit changes to the quality performance category's weights through future rulemaking and intends on providing additional education and outreach on how eligible clinicians can prepare to meet the incremental shifts in the quality and cost performance category weights ([p. 1250](#)).

Quality Data Submission Criteria ([p. 1250](#))

Submission Criteria for Groups Electing to Report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey ([p. 1250](#)). CMS did not summarize or respond to comments received, but thanked commenters for their responses, which it may take into account as it develops future policies for the CAHPS for MIPS survey.

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 a number of topics, including:

- 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.
- Should a tool be developed to collect information about individual clinicians? Or should this information be kept at the group level only?
- 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).

Data Completeness Criteria. 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 Qualified Clinical Data Registry (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. This revised threshold is based on an analysis of data completeness rates from the 2017 performance period, as described in [Table 35](#).

CMS believes it is important to continue to increase the data completeness threshold, particularly as it observes increased use of electronic methods of reporting, such as EHRs and QCDRs, and is interested in stakeholder feedback on an appropriate incremental approach or other thresholds it should consider.

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,

Data Completeness Criteria ([p. 1251](#)). ***CMS finalized these policies as proposed*** ([p. 1257](#)). CMS reiterated its intention to, through future rulemaking, increase the data completeness threshold to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. [Table 43](#) describes the data completeness requirements by collection type.

In this section, CMS also noted it would take into consideration the suggestion to post measure specifications for both the MIPS quality and QCDR measures earlier than the existing timeframes, especially as CMS continues to increase the data completeness threshold.

In response to requests for clarifications on the data analysis presented in [Table 35](#) of the proposed rule, CMS noted that the data used to support the increase in the data completeness threshold is reflective of all-payer data across all collection types, and is not just reflective of claims.

CMS also finalized the amendment to the regulatory text to emphasize that the data submitted on each measure is expected to be representative of the clinician's or group's performance and free of selection bias ([p. 1259](#)).

accurate, or complete according to § 414.1390(b) or § 414.1400(a)(5), which could result in improper payment.

Selection of MIPS Quality Measures

Call for Measures and Measure Selection Process. 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 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.

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.

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

- **[Table Group A](#)**: Includes new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years.
- **[Table Group B](#)**: 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](#)**: 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](#)**: Includes previously finalized measures with substantive changes for the 2020 performance year.
- **[Table Group DD](#)**: 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 measure Q226: Preventive Care

Selection of MIPS Quality Measures ([p. 1259](#))

Call for Measures and Measure Selection Process ([p. 1260](#)). *CMS finalized its revised requirements for measure stewards. Beginning with the 2020 Call for Measures process, MIPS quality measure stewards will 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 will 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 ([p. 1262](#)).*

In regards to whether CMS should consider realigning the MIPS quality measure update cycle with that of the eCQM annual update process, CMS did not summarize or respond to comments, but thanked the public for its input. CMS may consider this input as it develops future policies for the measure update process.

Quality measures finalized in this rule can be found in [Appendix 1](#):

- **[Table Group A](#)**: *New Quality Measures Finalized for the 2020 MIPS Performance Year/2022 Payment Year and Future Years.*
- **[Table Group AA](#)**: *New Quality Measures Finalized for the 2021 MIPS Performance Year/2023 Payment Year and Future Years*
- **[Table Group B](#)**: *New Specialty Measure Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2020 MIPS Performance Year/2022 Payment Year and Future Years.*
 - CMS clarifies that in the proposed rule, it erroneously indicated that changes were not made to the Pathology, Electro-Physiology Cardiac Specialist, and Interventional Radiology specialty set. CMS clarifies that it actually did propose changes to the Electro-Physiology Cardiac Specialist specialty set (i.e., changes to measure titles) and to the Pathology specialty set (i.e., measures proposed for removal and addition).
- **[Table Group C](#)**: *Previously Finalized Quality Measures Finalized for Removal in the 2020 MIPS Performance Year/2022 Payment Year and Future Years. CMS is removing 42 previously finalized quality measures from the MIPS Program for the 2020 MIPS performance year/2022 payment year and future years. CMS decided NOT to finalize the removal of the following measures, which are discussed in Table C:*
 - **[Q110: Preventive Care and Screening: Influenza Immunization](#)**
 - **[Q111: Pneumococcal Vaccination Status for Older Adults](#)**

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.

- **Q146: Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms**
- **Q178: Rheumatoid Arthritis (RA): Functional Status Assessment**
- **Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use**
- **Q225: Radiology: Reminder System for Screening Mammograms**
- **Q249: Barrett’s Esophagus**
- **Q250: Radical Prostatectomy Pathology Reporting**
- **Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer**
- **Q282: Dementia Functional Status Assessment**
- **Q288: Dementia Education and Support of Caregivers for Patients with Dementia**
- **Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens)**
- **Q396: Lung Cancer Reporting (Resection Specimens)**
- ***As discussed in Table Groups A and C, CMS did not finalize its proposed measure additions and removals for the CMS Web Interface in MIPS ([p. 1265](#)).***
- ***[Table Group D](#): Previously Finalized Quality Measures with Substantive Changes Finalized for the 2020 MIPS Performance Year/2022 Payment Year and Future Years***
- ***[Table Group DD](#): Previously Finalized Quality Measures with Substantive Changes Finalized for the 2019 MIPS Performance Year/2021 Payment Year and Future Years***
- ***CMS finalized changes to measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention as proposed for the 2019 MIPS performance period/2021 MIPS payment year and future years ([p. 1264](#), [p. 2425](#)) CMS will continue to require this measure for groups, APM Entities, and virtual groups reporting through the CMS Web Interface Measure Specifications collection type. However, CMS is redesignating it as “pay-for-reporting” in the Shared Savings Program for performance years starting in 2019, and will exclude it from MIPS scoring for the 2019 MIPS performance period provided it met the data completeness requirement and the measure was reported through the CMS Web Interface Measure Specifications collection type.***

Global and Population-Based Measures. 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 to allow the measure to through the Measures Under Consideration and Measures Application Partnership (MAP) process.

Global and Population-Based Measures ([p. 1266](#)). ***After consideration of comments, CMS did not finalize the inclusion of the population health based All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure, and will seek to propose it through future rulemaking once it is able to consider feedback from the MAP on this measure ([p. 1270](#)).*** CMS cited public concerns about the measure lacking alignment and reliable attribution, and not providing actionable or meaningful feedback to clinicians.

Nevertheless, CMS disagreed with many concerns raised about global and population-based measures, citing the following rationale:

- The purpose of these measures is to encourage systemic health care improvement for the populations being served by MIPS eligible clinicians.
- All MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities.
- While administrative claims-based measures may use a large sample size of data, the data collection is less burdensome than what is used for other collection types, since it is done without any submission required by the clinician or group.
- In regards to concerns about risk adjustment, CMS will continue to evaluate the potential impact of social risk factors on measure performance and to ensure that complex patients, as well as those with social risk factors receive excellent care. CMS will continue to investigate methods to ensure all clinicians are treated as fairly as possible within the program.

Topped Out Measures. CMS has heard from stakeholders that some measures tend to appear topped out or extremely topped out due to a 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.

Topped Out Measures (p. 1270). CMS does not summarize or respond to comments received, but may take them into account as it develops future policies for extremely topped out measures.

CMS also reminds readers that the final determination of which measure benchmarks are subject to the topped out cap in 2020 will not be available until the 2020 MIPS Quality Benchmarks' file is released in late 2019.

Removal of Quality Measures. CMS proposes to remove 55 previously finalized measures from MIPS for the 2020 performance year.

Removal of Quality Measures (p. 1272). *Based on concerns raised, CMS decided not to finalize the removal of 13 measures (particularly some of those measures that are available to non-patient facing clinicians). As such, CMS is removing only 42 quality measures, rather than 55. See [Table Group C for a list of measures finalized for removal in the 2020 MIPS performance year/2022 payment year \(p. 1278\)](#).* Nevertheless, CMS encourages stakeholders to continue to develop measures to not just address measurement gaps, but to also address and replace specialty specific topped out quality measures as it seeks to eventually transition to MVPs.

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 two consecutive CY performance periods.

CMS is interested in what factors should be considered in delaying the removal of measures (e.g., how can it 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 finalized its proposal to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods. 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

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 MIPS eligible clinicians 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.

patient-reported outcome; consideration of the measure in developing MVPs) prior to determining whether to remove the measure (p. 1278).

- CMS clarifies that if the measure has too few reporting clinicians and does not meet the case minimum and reporting volumes, but other considerations favor retaining the measure (e.g., the measure's relevance to sub-specialists), it may consider keeping the MIPS quality measure, with the caveat that the measure steward should have a participation 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.
- In response to concerns about this policy, CMS recognizes the time it takes for measure stewards to develop and invest in quality measures, but also wants to be mindful of the large volume of measures that accrue in its inventory year over year. CMS believes that lowly-reported quality measures do not add value to a clinician's quality improvement strategy, and that having a large volume of measures can increase burden by providing too much choice. It also believes that two consecutive CY performance periods allows for sufficient time to monitor reporting volumes. However, it is open to working with measure stewards to understand the time it takes for measures to achieve increased adoption, and would encourage those measure stewards to submit a participation plan for CMS consideration for measures that have not reached benchmarking thresholds within the 2-year timeframe.

CMS does not summarize or respond to comments received on delaying the removal of measures, but may take them into account as it develops future policies for extremely topped out measures.

CMS also finalized its proposed measure removal criterion 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 (p. 1280).

Request for Information on Potential Opioid Overuse Measure. 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

RFI on Potential Opioid Overuse Measure (p. 1280). CMS does not summarize or respond to comments received, but may take them into account as it considers further development of the Potential Opioid Overuse measure.

Cost Performance Category

(VSAC). CMS seeks to mitigate these usability and feasibility issues by posing various questions to a wider audience of technical implementers to strengthen the potential for measure adoption.

Weight in the Final Score

- 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/2022 payment year;
- CMS proposes at §414.1350(d)(5) to weight the cost category at 25 percent for the 2021 performance year/2023 payment year; and
- CMS proposes at §414.1350(d)(6) to weight the cost category at 30 percent for the 2022 performance year/2024 payment year and all subsequent MIPS payment years.

Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, February 9, 2018) (BBA 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. CMS is required by the statute to weight the cost performance category at 30 percent beginning with the 2022 performance year/2024 MIPS payment year.

Weight in the Final Score

In response to public concerns and to allow clinicians to become more familiar with the feedback process and for CMS to continue to improve feedback reports, CMS did not finalize its proposal to increase the cost category weight for the 2020 performance year/2022 payment year. Instead, it will continue to weight the cost performance category at 15 percent for the 2020 performance year/2022 MIPS payment year and is revising § 414.1350(d)(3) to reflect this.

CMS also did not finalize its proposals to weight the cost category at 25 percent for the 2023 MIPS payment year and at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. CMS will consider the state of the performance feedback that it offers clinicians and expects to propose a weight for the cost performance category for the 2023 MIPS payment year in the CY 2021 PFS proposed rule ([p. 1287](#)).

CMS understands that for many clinicians, cost measures are more difficult to understand than measures and activities in other performance categories. CMS intends to provide clinicians with detailed feedback for all cost measures in July of 2020, reflecting performance from the 2019 MIPS performance period. CMS is committed to improving the feedback experience, including aiming to provide more granular and real-time data, for clinicians to better understand how they can improve their performance on these measures and in turn reduce the cost of care for Medicare beneficiaries. Once clinicians better understand and are more accustomed to reviewing the performance feedback reports on these episode-based and global cost measures, it would then expect to increase the cost performance category weight.

At the same time, CMS believes that the cost measures they are using in MIPS represent the best available measures, and CMS takes care to consider all of the important issues, including attribution and risk adjustment, as part of the measure development process. In regards to reliability, CMS believes its current reliability threshold of 0.4 for measures in the cost performance category is both consistent with other CMS quality programs and ensures moderate reliability, but does not substantially limit participation.

CMS continues to develop more robust and clinician-focused cost measures, including work on developing additional episode-based measures that it may consider proposing for the cost performance category in future years to address additional clinical conditions. CMS also anticipates that it may

Cost Criteria

Attribution. 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, which will be publicly available. CMS believes that presenting the attribution methodology comprehensively along with the rest of the cost measure specifications will minimize complexity.

In the CY 2017 QPP final rule, CMS 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) (81 FR 77175 through 77176). 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. As such, CMS proposes to revise the regulatory text to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician’s performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods.

Episode-Based Measures for the 2020 and Future Performance Period. 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.

continue to use many of the proposed and newly developed episode-based measures within MVPs.

Cost Criteria

Attribution. *CMS finalized its proposal to establish at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure will be attributed according to the measure specifications for the applicable performance period. CMS also finalized its are proposal to revise § 414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician’s performance for purposes of MIPS is assessed as an individual or a group, only applies for the 2017 through 2019 performance periods (p. 1293).*

Episode-Based Measures for the 2020 and Future Performance Period (p. 1294). *After consideration of public comments, CMS finalized its proposal to include the 10 episode-based measures originally proposed, and listed in Table 44, in the cost performance category beginning with the 2020 MIPS performance period with the following modifications, per commenter feedback:*

- *The **Inpatient COPD Exacerbation** measure with the exclusion list expanded to include the recommended lung resection codes, which are listed in the measure’s codes list file available for download on the **MACRA Feedback Page** (p. 1310)*
- *The **Non-Emergent CABG** measure with the removal of CPT code 33406 from the list of episode triggers and addition of the code to the list of exclusions, found in the measure codes list on the **MACRA Feedback page** (p. 1311)*

CMS notes that during field testing of the ten measures episode-based measures, it received 67 responses, including 25 comment letters. A field testing feedback summary report, which details post-field testing refinements added based on the input from the measure-workgroups, is publicly available on the [MACRA Feedback Page](#).

In response to concerns that certain specialties are not yet covered by these measures, CMS noted that it continues to work to develop new episode-based measures and that it expects that future measures may apply to a greater range of specialties and clinical areas. Section 1848(r)(2)(D)(i)(I) of the Act requires CMS to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. CMS aims to find the right balance between the number of fair and reliable measures it can develop and the level of clinician and expert input it can involve in this process.

CMS also recognized stakeholders' requests for an extended development timeline to allow more opportunities for clinicians to provide input on the measures and will consider this feedback for future waves of measure development.

CMS is committed to continuing to increase awareness about the measures both during field testing and through other education and outreach activities. CMS continues to welcome feedback on how the field testing period and the development process can be further refined to increase awareness about the measures.

CMS is also exploring alternative venues to facilitate access to the field test reports in the future. The field test reports from the fall 2018 field testing were available for review through for a period after the field testing period concluded, but removed once the portal was decommissioned. CMS will consider ways the reports can be made available after the field testing period concludes.

In regards to requests for earlier and real-time feedback, CMS noted that the nature of claims-based measures presents considerations that affect the availability of real time feedback. CMS allows at least a 60-day run out to allow for adjustments to claims and ensure data completeness. This, along with episode length for the cost measures must be accounted for in considerations of providing real time feedback early in the beginning of the

performance year. CMS also will continue to explore ways to extend accessibility of materials such as the field test reports, to increase access to information about clinicians' expected performance.

Regarding the use of claims data, section 1848(r)(5) of the Act requires the Secretary, as the Secretary determines appropriate, to use certain claims data to conduct an analysis of resource use. CMS noted that an advantage of using claims data is that it creates no additional reporting burden for clinicians, but CMS will continue to consider incorporating additional data sources, beyond claims, in measure calculations and welcomes feedback on potential alternatives.

CMS also agreed with the importance of cost and quality alignment, and views it as an essential component of episode-based measures. In the course of implementing the framework for MVPs, CMS will consider the relationship between cost and quality.

CMS also clarified that each measure's risk adjustment model employs a common starting point of the CMS-HCC model, but that the measure-specific expert workgroups considered enhancements to the model through the addition of risk factors specifically adapted for each episode group.

CMS is aware of concerns regarding risk adjustment for social risk factors and continues to consider options to account for social risk factors. As part of the standard development and testing process, the measure development contractor conducted analyses to assess the impact of the following social risk factors: income; education; population; employment; race; sex; and dual-eligibility status, which can be found in the measure justification forms for the episode-based measures available for download from the [MACRA Feedback Page](#). Results of these analyses found very little to no effect on the predictive power of the risk adjustment models used when variables for social risk factors were included in the models, compared to using the current models.

CMS also recognized concerns about the perceived issue of double counting costs assigned to the revised Total Per Capita Cost and MSPB clinician measures and the episode-based measures. However, CMS believes that the construction and calculation of the cost measures guards against this possibility. Any given service and its associated cost is only included once per episode per attributed clinician for a given measure. Each cost measure is calculated separately, and then averaged into a single score for the MIPS cost performance category. In the aggregation of a MIPS cost performance category score, the relative impact of a high or low cost service in each cost measure is averaged for a given clinician or clinician group, rather than simply

counted twice, which avoids compounding good or poor results and ensures that clinicians will not be double-penalized or rewarded for a high or low cost service.

Note that all previously established and finalized measures for the cost performance category for the 2020 and future performance periods are summarized in [Table 47](#). The detailed specifications for these measures are available on the [MACRA Feedback page](#). CMS expects to post the measure specifications in final form in the [QPP resource library](#) by the end of the year.

Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes. 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 and input from physician specialty societies and other stakeholders.

Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes. **CMS finalized this proposed revision to the operational list beginning with CY 2020 to include the 10 new care episode and patient condition groups ([p. 1316](#)).**

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.

Revised Cost Measures – Re-evaluation Process for the Total Per Capita Cost and Medicare Spending Per Beneficiary Clinician Measures

Revised Cost Measures – Re-evaluation Process for the Total Per Capita Cost and Medicare Spending Per Beneficiary Clinician Measures ([p. 1316](#))

CMS proposes to modify the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures, currently in use under MIPS, based on stakeholder input and TEP recommendations beginning with the CY 2020 performance year.

- Total Per Capita Cost (TPCC) measure ([p. 1316](#)): **CMS finalized its proposal to include the TPCC measure with the revised specifications as proposed in the cost performance category beginning with the CY 2020 performance period ([p. 1333](#)).**

- Total Per Capita Cost (TPCC) measure: 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

Despite ongoing public concerns about this measure, CMS continues to believe that it provides an important measurement of clinician cost performance. The measure intent to capture broad, overall care plays a significant role in MIPS to complement the more granular information captured by episode-based measures and ensure that there is continuity in clinician incentives throughout a patient’s care

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 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.
- Changing the attribution methodology to more accurately identify clinicians who provide primary care services, by the addition of service category exclusions and specialty exclusions.
- 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. 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.

Additional details about changes to this measure, as well as a comparison to the TPCC cost measure as currently specified, are available in the measure specifications documents available on the [MACRA Feedback page](#).

- MSPB measure: 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;

trajectory. According to CMS, broad, population-based measures provide an important means of measuring healthcare spending as they capture a wide range of patients and, consequently, allow for more comparability between clinicians who are covered by the same measure. This measure also has an important place in cost measurement given that the episode-based measures only apply to a subset of clinicians at this time.

CMS recognized the MAP's reservations about this measure; however, as discussed in the CY 2020 PFS proposed rule (84 FR 40758), CMS believes that it has adequately addressed the mitigating factors outlined by the MAP.

In regards to concerns that this measure includes costs that are outside the reasonable control of a provider, such as drug prices, CMS clarified that the revised measure continues to use payment standardized prices to account for differences in Medicare payments for the same service across Medicare suppliers for all services included in the measure, including for Part B drugs. The measure does not include Medicare Part D costs, as these costs are not yet payment-standardized. However, CMS is currently considering the feasibility of developing a payment standardization for Part D costs to account for factors that are outside the control of clinicians.

In response to concerns that physician assistants (PAs) and nurse practitioners (NPs) that work in collaboration with excluded specialties would still be attributed patient costs based on this methodology, CMS noted it has assessed the frequency of TINs being attributed solely through physician assistants and nurse practitioners, and found that this occurs infrequently.

CMS also clarified that hospitalists, medical oncologists, and radiation specialties, as defined by the CMS provider specialty code, are excluded from the revised TPCC measure, as they are not expected to provide primary care services. Other oncology specialties, including hematology oncology, gynecological oncology, and rheumatology are not excluded from the measure as they are likely to provide primary care services in the form of managing a chronic disease.

CMS also clarified that the measure development contractor performed detailed testing on the revised measure to ensure that all clinicians are measured accurately and fairly, regardless of size, location, or the population they serve.

- 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).
- 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.

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.

CMS further clarified that risk adjustors for dual-eligibility and sex are included in the revised measure. As part of the standard development and re-evaluation processes, the measure development contractor conducted analyses to assess the impact of the following social risk factors-- income, education, employment, race, sex, and dual-eligibility status—which showed that the inclusion of social risk factors in the current risk adjustment model has a minor effect on measure scores.

In response to concerns that clinicians would not be able to track their performance from year to year due to the revisions in the specifications for this measure, CMS noted that clinician performance amongst peers will continue to be measured under the same methodological conditions and assumptions so a clinician’s relative performance would be comparable across iterations of the measure.

CMS also reiterated here that it will continue to consider ways to offer actionable data and feedback on cost measures to clinicians in the future, including the frequency and format of the performance data provided.

- **MSPB measure (p. 1333): After consideration of the public comments, CMS finalized its proposal to include the MSPB Clinician measure with the revised specifications as proposed in the cost performance category beginning with the CY 2020 performance period (p. 1342)**

CMS clarified that the new methodology shifts attribution of episodes towards specialties that are more likely to be involved in managing the course of a patient’s care, whereas the old methodology potentially attributed clinicians who do not provide the overall care management for a beneficiary. CMS also clarified that under the revised measure, an episode can be attributed to multiple clinicians or clinician groups.

CMS also clarified that the MSPB measure currently in use in MIPS and the revised MSPB Clinician measure do not include a specialty adjustment. However, the revised measure has been refined to ensure effective attribution and compare similar clinicians. This is achieved by distinguishing between medical episodes and surgical episodes and risk adjusting for episodes within each major diagnostic category (MDC). These refinements allow for more accurate

comparisons of predicted episode spending as clinicians are compared to other clinicians treating patients with similar characteristics, rather than being compared to all clinicians.

CMS believes it has addressed the concerns raised by the MAP and that these revisions will ensure that the MSPB Clinician measure continues to play an important role in the MIPS cost performance category.

The measure development contractor performed detailed testing on the revised measure to ensure that all providers are measured accurately and fairly, regardless of size, location, or the population they serve. Testing results show similar score distributions for urban and rural clinicians, which indicates that they perform similarly under the revised measure.

Again, all previously established and finalized measures for the cost performance category for the 2020 and future performance periods are summarized in [Table 47](#). The detailed specifications for these measures are available on the [MACRA Feedback page](#). CMS expects to post the measure specifications in final form in the [QPP resource library](#) by the end of the year.

Reliability – Episode-Based Cost Measures. In the CY 2017 QPP final rule (81 FR 77169 through 77170), CMS finalized a reliability threshold of 0.4 for measures in the cost performance category. Since the Lower Gastrointestinal Hemorrhage measure does not meet CMS' reliability threshold for individual reporting, CMS proposes to limit its assessment of this cost measure to clinicians who report as a group or virtual group.

Reliability – Episode-Based Cost Measures. ***After consideration of the comments, CMS finalized its proposal to include the Lower Gastrointestinal Hemorrhage episode-based measure in the Cost performance category only for MIPS eligible clinicians who report as a group or a virtual group. (p. [1346](#))***

[Table 45](#) shows the percent of TINs and TIN/NPIs that meet the 0.4 reliability threshold for each of the ten new episode-based cost measures finalized in this rule for performance year 2020.

One commenter indicated that the reliability is too low at the individual level and requested more details on the range of reliability values by practice size. While CMS has not examined the relationship between practice size and the reliability of the cost measures, it has examined the relationship between case volume and the reliability of cost measures. CMS believes that establishing case minimums that are based on moderate reliability allows it to measure all clinicians and groups that meet those case minimums. CMS will take the recommendation to provide additional reliability figures into consideration when providing future measure testing results and continue to monitor cost performance and reliability for small practices to ensure that the measures continue to accurately and fairly measure their performance.

[Improvement Activities Performance Category](#)

Reliability –Revised Cost Measures. In the CY 2017 QPP final rule (81 FR 77169 through 77170), CMS finalized a reliability threshold of 0.4 for measures in the cost performance category. CMS established a case minimum of 35 episodes for the MSPB clinician measure (81 FR 77171) and a case minimum of 20 beneficiaries for the TPCC measure (81 FR 77170). Given significant changes to these measures, CMS examined the reliability of the two revised measures and found that they 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 did not propose any changes to the case minimums.

Request for Comments on Future Potential Episode-Based Measure for Mental Health. 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.

Small, Rural, or Health Professional Shortage Areas Practices. 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.

Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organization. CMS proposes to remove the references to the four listed accreditation organizations as examples of what is acceptable for recognition as a patient-centered medical home and to remove the reference to the specific accrediting organization for comparable specialty practices.

Improvement Activities Data Submission. 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. Currently, 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.

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.

Reliability –Revised Cost Measures ([p. 1347](#)). CMS did not propose any changes here.

Request for Comments on Future Potential Episode-Based Measure for Mental Health ([p. 1348](#)). While CMS is not summarizing or responding to comments received, it thanks the commenters for their responses, and will consider them in the future.

Small, Rural, or Health Professional Shortage Areas Practices. **CMS finalized this change as proposed** ([p. 1353](#)).

Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organization. **CMS finalized its proposal to remove specific entity name examples** ([p. 1356](#)).

Improvement Activities Data Submission ([p. 1356](#)). In response to feedback that the proposed policy may present challenges for large or multi-specialty groups, **CMS’ finalized a modified version of its proposal that would revise §414.1360(a)(2) to state that beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group’s TIN or virtual group’s TINs, as applicable; and these NPIs must perform the same activity during any continuous 90 days within the same performance year** ([p. 1382](#)).

Instead of requiring clinicians to perform the same activity for the same continuous 90 days, this will allow clinicians flexibility to choose the most appropriate 90-day period while still increasing the number of clinicians required to report. A group could choose to perform an activity for the entire performance year to capture the participation of at least 50 percent of the

group's clinicians. That is, while 50 percent of NPIs in a group must perform the same improvement activity for a continuous 90-day period, they do not need to perform the activity during the same period. For example, some NPIs could perform Practice Improvements for Bilateral Exchange of Patient Information (IA_CC_13) during January while others could perform the same activity in June. In that instance, the group attestation would need to reflect the year-long participation.

Each TIN will need to submit an attestation for each improvement activity selected that at least 50 percent of its NPIs performed the same activity. CMS clarified that if there is an uneven number of clinicians in the group, the group would need to go up to the next whole number to account for 50 percent of the clinicians in the group (e.g., if the group consists of 13 members, then at least 7 clinicians would need to report the same activity).

CMS believes that this revised threshold provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. According to CMS, the common goal of group reporting should be group practice transformation and improved patient outcomes. CMS does not believe that it benefits a group or the patient if only one clinician is undertaking quality improvement efforts because there is not necessarily widespread implementation of the quality initiative.

In response to concerns that this policy would disincentivize specialties from picking improvement activities which are clinically relevant to them, CMS clarified that the improvement activities Inventory has been developed to be applicable to broad groups of clinicians. While the 2020 Inventory will have 20 specialty-specific activities, it will have 85 activities that are broadly applicable to both specialists and general practitioners.

CMS did not agree with concerns that this policy will increase documentation burden and introduce complexity in regards to tracking adherence (for both reporting and audit purposes) in non-employed situations such as with virtual groups and accountable care organizations, or academic medical centers with a very large number of clinicians under one TIN. CMS clarified that data submission for this category remains attestation. It also believes that improvement activities are investments in clinical practice and should not be viewed as costs or reduced revenues.

One commenter expressed concern that imposing a 50 percent threshold would prevent a group from reporting any of the improvement activities at the group level if reporting through a QCDR. The commenter provided an example of a multi-specialty group, which only have four out of ten clinicians reporting through a QCDR due to their scope of clinical practice and availability of relevant QCDR measures. CMS clarified that if an improvement activity is more appropriate for an individual clinician, a group should not be considering it. CMS also clarified that groups reporting to a QCDR that do not meet the 50 percent threshold could: (1) work with the QCDR to have their data submitted for the entire group, not just a subset needed to meet the 50 percent threshold; (2) directly attest to the improvement activity as a group; or (3) submit improvement activities as individuals.

Others raised concerns that this policy does not contemplate common management structures of specialty groups and departments and underestimates the role and impact of a lead quality improvement clinician or committee in a group. CMS disagreed with most of these comments and encouraged 100 percent of the clinicians in a group to participate in the quality improvement action and to complete as many improvement activities beyond the minimum 50 percent required by the MIPS program. In regards to a request that CMS account for organization-level participation where appropriate (e.g. antimicrobial stewardship programs), CMS noted that it has not provided individual versus group differentiation in the Inventory in the past, but that it will take this comment into consideration as it crafts future policies.

One commenter referenced an example in which a group hires an additional fulltime clinician to extend office hours; the group as a whole invested in a new clinician to increase its availability to its patients and should be recognized as such. CMS did not agree that this would demonstrate group level improvement. Another commenter provided an example in which a clinic extended its hours for all of the clinic's patients, regardless of the percentage of clinicians who work the extended hours, and questioned how a group with 20 clinicians would receive improvement activities credit. CMS responded that it understands the realities of clinical practice and believes that improvement activities are broadly applicable.

CMS clarified that this increase in the group threshold will have no impact on the previously finalized 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).

Improvement Activities Inventory

Factors for Consideration in Removing Improvement Activities. CMS proposes to establish the following factors for consideration when proposing the removal of an 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

These factors directly reflect those already finalized for quality measures found in the CY 2019 PFS final rule (83 FR 59765).

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.

CMS anticipates that in future rulemaking, it will continue to increase this threshold. Its future goal would be to have 100 percent of a group performing the same activity during any 90-day period within the same performance year.

Improvement Activities Inventory (p. 1383)

Factors for Consideration in Removing Improvement Activities. ***CMS finalized the seven factors, as proposed, for its consideration when proposing the removal of an improvement activity (p. 1390).*** CMS will take these factors into account, but they are not firm requirements. In addition, commenters will have an opportunity to provide their input during notice-and-comment rulemaking.

In response to feedback, CMS disagreed with concerns that it is removing improvement activities too rapidly. CMS understands that many groups may have made financial investments to perform these improvement activities, but believes that over time, certain activities should be considered for removal to ensure the list is robust and relevant. CMS also believes that having factors to consider in removing improvement activities will provide transparency and alignment with the removal of quality measures.

CMS also disagreed with concerns about measure removal 5, noting that it should be a consideration when removing improvement activities from the MIPS program to lay the groundwork for MVPs.

CMS agreed with commenters that practice improvement should not be a one-size-fits-all process and noted its intention to keep the improvement activities Inventory as broad as appropriate to allow clinicians to apply the activities in a clinically relevant and meaningful manner.

New Improvement Activities and Modifications to and Removal of Existing Improvement Activities (p. 1390). ***In conjunction with its adoption of removal factors, CMS finalized:***

- ***The addition of two new improvement activities for 2020 performance period and future years (see [Appendix 2, Table A](#))***
 - ***[IA BE 25. Drug Cost Transparency \(high weight\)](#)***
 - ***[IA CC 18. Tracking of Clinician's Relationship to and Responsibility for a Patient by Reporting MACRA Patient Relationship Codes \(high weight\)](#)***
- ***Modifications to seven existing improvement activities for 2020 performance period and future years (see [Appendix 2, Table B](#))***
 - ***[IA PSPA 28. Completion of an Accredited Safety or Quality Improvement Program: Added as an example of this activity completion of an accredited CME program related to opioid](#)***

- analgesic risk and evaluation strategy (REMS) to address pain control.*
- **IA_PM_2. Anticoagulant Management Improvements:** *Consolidates this activity with another that is being removed (IA_PM_1) and provides five relevant examples of this activity.*
 - **IA_EPA_4. Additional Improvements in Access as a Result of QIN/QIO TA:** *Consolidates this activity with another that is being removed (IA_CC_3)*
 - **IA_PSPA_19. Implementation of Formal Quality Improvement Methods, Practice Changes, or Other Practice Improvement Processes:** *Consolidates this activity with another that is being removed (IA_PSPA_14) and provides nine relevant examples.*
 - **IA_BE_7. Participation in a QCDR, That Promotes Use of Patient Engagement Tool:** *Consolidates this activity with others proposed for removal related to QCDR participation (IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10) and provides four relevant examples related to patient engagement. Despite requests, CMS did not increase the weight of this activity.*
 - **IA_PSPA_7. Use of QCDR Data for Ongoing Practice Assessment and Improvements:** *Consolidates this activity with others proposed for removal related to QCDR participation (IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10) and provides five relevant examples of activities related to ongoing practice assessment and improvements in patient safety. Despite requests, CMS did not increase the weight of this activity.*
 - **IA_BMH_10. Completion of Collaborative Care Management Training Program:** *Removed reference to the Transforming Clinical Practice Initiative (TCPI) since it ended in September 2019.*
 - **The removal of 15 improvement activities from the Inventory beginning with the 2020 performance period ([see Appendix 2, Table C](#))**
 - **IA_PM_1. Participation in Systematic Anticoagulation Program**
 - **IA_CC_3. Implementation of Additional Activity as a Result of TA for Improving Care Coordination**
 - **IA_PSPA_14. Participation in Quality Improvement Initiatives**
 - **IA_PSPA_5. Annual Registration in the Prescription Drug Monitoring Program**
 - **IA_PSPA_24. Initiate CDC Training on Antibiotic Stewardship**
 - **IA_BMH_3. Unhealthy Alcohol Use**

- [IA BE 11. Participation in a QCDR, That Promotes Use of Processes and Tools That Engage Patients for Adherence to Treatment Plan](#)
- [IA BE 2. Use of QCDR to Support Clinical Decision Making](#)
- [IA BE 9. Use of QCDR Patient Experience Data to Inform and Advance Improvements in Beneficiary](#)
- [IA BE 10. Participation in a QCDR, That Promotes Implementation of Patient Self-action Plans](#)
- [IA CC 6. Use of QCDR to Promote Standard Practices, Tools and Processes in Practice for Improvement in Care Coordination](#)
- [IA AHE 4. Leveraging a QCDR for Use of Standard Questionnaires](#)
- [IA AHE 2. Leveraging a QCDR to Standardize Processes for Screening](#)
- [IA PM 10. Use of QCDR Data for Quality Improvement Such as Comparative Analysis Reports Across Patient Populations](#)
- [IA CC 4. Participation in CMS Transforming Clinical Practice Initiative](#)

CMS Study on Factors Associated with Reporting Quality Measures.

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.

Study on Factors Associated with Reporting Quality Measures. CMS finalized its proposal to end this study and concurrently, remove the incentive under the improvement activity performance category that this study provided for study participants (p. 1393).

CMS plans to finish analysis of collected data by spring 2020, which will show trends and associations of all factors examined. CMS will then shift to implementation of recommendations, which will include feedback to clinicians and stakeholders and educational and outreach work, including webinars. In general, CMS intends to continue to pursue ways to improve outcomes, reduce burden in the collection and reporting of clinician quality measures, and enhance clinical care.

Promoting Interoperability (p. 1394).

In general, as CMS looks toward the future of this category, its goals center on:

- A priority of stability within the performance category after the recent changes made in the CY 2019 PFS final rule while continuing to further interoperability through the use of CEHRT;
- Reducing administrative burden;
- Continued use of 2015 Edition CEHRT;
- Improving patient access to their health information 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](#)

Promoting Interoperability Performance Category Performance Period. 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. [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 – Query of Prescription Drug Monitoring Program (PDMP) Measure. 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.

Promoting Interoperability Performance Category Performance Period. **For the 2021 performance year/2023 MIPS payment year, CMS is finalizing its proposal to add § 414.1320(f)(1) and establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021) ([p. 1397](#)).**

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians ([p. 1398](#)). **Table 48 lists the objectives and measures for the Promoting Interoperability performance category for the 2020 performance period as revised to reflect the final policies established in this final rule as described in the sections below.**

For more information on the 2015 Edition certification criteria required to meet the objectives and measures, CMS refers readers to [Table 43](#) in the CY 2019 PFS final rule (83 FR 59817).

Query of Prescription Drug Monitoring Program (PDMP) Measure ([p. 1398](#)). **CMS finalized its proposal to make the [Query of PDMP](#) measure optional and eligible for 5 bonus points for the Electronic Prescribing objective in CY 2020, and to require a “yes/no” response beginning in CY 2019 ([p. 1403](#)).**

CMS clarified that it does not require the query of the PDMP be performed by the same eligible clinician who prescribes the Schedule II opioid. MIPS eligible clinicians should determine what is most appropriate, in accordance with applicable law, for the medical staff involved in performing the queries based on their own standard operating procedures, guidelines, and preferences.

CMS will continue to work to improve EHR integration with PDMPs as it believes that making the [Query of PDMP](#) measure optional for the long-term would be inconsistent with the recommendations of the [President's Opioid Commission](#). It may propose modifications to this measure in future rulemaking.

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.

Proposed Changes to Measures for the e-Prescribing Objective – Verify Opioid Treatment Agreement Measure. 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.

CMS proposes to redistribute the 20 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. If exclusions are claimed for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure, the combined 40 points associated with both measures would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. Both of these proposals would apply beginning with performance year 2019.

Health Information Exchange Objective – 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

Verify Opioid Treatment Agreement Measure. ***CMS finalized the removal of the Verify Opioid Treatment Agreement measure beginning in CY 2020, as proposed (p. 1406).***

Health Information Exchange Objective.

CMS finalized these redistribution policies as proposed (p. 1408).

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

CMS finalized these modifications as proposed. The revised description of the exclusion will be applicable starting with the 2019 performance period/2021 MIPS payment year (p. 1410).

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.”

Public Health and Clinical Data Exchange Objective – Syndromic Surveillance Reporting.

Public Health and Clinical Data Exchange Objective – Syndromic Surveillance Reporting. In the CY 2018 QPP final rule (82 FR 53674), CMS established the measure description for the Syndromic Surveillance Reporting measure as follows: “The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.” However, in the CY 2019 PFS final rule (83 FR 59798), CMS inadvertently stated that the measure description was as follows: “The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a *non*-urgent care setting” (emphasis added). CMS points out that this was a typographical error and that it did not intend to replace “urgent care” with “non-urgent care” in the measure description.

Scoring Methodology. [Table 42](#) summarizes the proposed scoring methodology for the Promoting Interoperability Measures in performance year 2020.

Scoring Methodology. [Table 49](#) summarizes the scoring methodology for the Promoting Interoperability Measures in performance year 2020, as finalized in this rule.

Additional Considerations

Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists. CMS proposes to continue the existing policy of reweighting the Promoting Interoperability performance category for these types of non-physician practitioner MIPS eligible clinicians for the performance period in 2020, since they may lack experience with the adoption and use of CEHRT.

Additional Considerations

Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists. ***CMS finalized this reweighting policy as proposed (p. 1419).*** CMS clarifies that it 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 Promoting Interoperability performance category, but if they choose to report, they will be scored on the category like all other MIPS eligible clinicians.

Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered Dietitians or Nutrition. CMS proposes to continue the existing policy of

Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered

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. 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. Beginning with the 2020 performance year, a hospital-based MIPS eligible clinician under § 414.1305 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 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. CMS defines a non-patient facing MIPS eligible clinician under § 414.1305 as an individual

Dietitians or Nutrition. **CMS finalized this reweighting policy as proposed (p. 1421).**

Hospital-Based MIPS Eligible Clinicians in Groups. **CMS finalized these revised policies as proposed (p. 1426).**

CMS appreciated a commenter's suggestion that it consider reweighting a group if more than 75 percent of the group qualifies for reweighting for any reason, but declined to adopt it due to the fact that hospital medicine groups may face unique circumstances due to the nature of their practice area that clinicians who practice in non-hospital settings would not experience.

Non-Patient Facing MIPS Eligible Clinicians in Groups: **CMS finalized this revised policy as proposed (p. 1428).**

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. CMS issues Requests for Information (RFI) regarding several issues involving the Promoting Interoperability performance category, including:

- RFI on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category
- RFI on NQF and CDC Opioid Quality Measures
- RFI on a Metric to Improve Efficiency of Providers within EHRs
- RFI on the Provider to Patient Exchange Objective – Immediate Access
- RFI on the Provider to Patient Exchange Objective – Persistent Access and Standards-based API
- RFI on the Provider to Patient Exchange Objective – Available Data
- RFI on the Provider to Patient Exchange Objective – Patient Matching
- RFI on the Integration of Patient-Generated Health Data into EHRs Using CEHRT
- RFI on Engaging in Activities that Promote the Safety of the EHR

Future Direction of the Promoting Interoperability Performance Category (p. 1428). While CMS did not summarize or respond to comments received in response to these RFIs, it thanks commenters for their responses and may take them into account as it develops future policies for the Promoting Interoperability performance category.

[APM Scoring Standard for MIPS Eligible Clinicians](#)

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

No change from proposed rule.

[Participating in MIPS APMs](#)

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

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.

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).

MIPS APM Criteria

CMS updates the list of models expected to satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period as follows: CMS does not include Primary Care First (All Tracks), and instead include the Independence at Home Model. ([p. 1431](#))

Final determinations will still be announced via the QPP website.

- 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.

Quality Performance Category

Allowing MIPS Eligible Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures: 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.

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.

APM Quality Reporting Credit and Exceptions from the Credit: CMS is proposing that APM Entity groups participating in certain 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.

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.

Calculating MIPS APM Performance Category Scores

Quality Performance Category

Allowing MIPS Eligible Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures: ***CMS is finalizing the proposal as proposed to require MIPS quality reporting by MIPS eligible clinicians in MIPS APMs at either the APM Entity, TIN, or individual level. (p. 1435)***

In response to comments expressing concern about the additional reporting burden required to report on quality to both MIPS and their respective APMs, CMS acknowledges that the change in policy may introduce additional burden for some MIPS APM participants. However, CMS anticipates this effect being limited to instances where TINs do not already report separately to MIPS. Additionally, CMS believes any potential burden will be further mitigated by CMS’ proposal to allow APM Entity-level quality reporting for MIPS. (p. 1435)

APM Quality Reporting Credit and Exceptions from the Credit ***CMS is finalizing the policy to assign an APM Quality Reporting Credit of one-half of the quality performance category score under the APM scoring standard for APM Entity groups participating in MIPS APMs where quality data cannot be used for MIPS purposes. (p. 1439)*** CMS clarifies that this proposal was intended to apply specifically to those MIPS APMs that do not utilize MIPS measures and data collection types. (p. 1437)

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.

CMS is finalizing its exceptions to the policy as proposed. (p. 1440)

Additional Reporting Option for APM Entities: 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.

Additional Reporting Option for APM Entities:
CMS is finalizing this policy as proposed. (p. 1441)

Bonus Points and Caps for the Quality Performance Category: 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, 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.

Bonus Points and Caps for the Quality Performance Category:
CMS is finalizing this policy as proposed. (p. 1442)

Special Circumstances: 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, 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 uncontrollable circumstances policy that CMS previously established for other MIPS eligible clinicians to MIPS eligible

Special Circumstances:
CMS is finalizing this policy as proposed. (p. 1444)

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 the CMS proposal pertains to reporting on MIPS quality measures.

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.

Excluding Virtual Groups from APM Entity Group Scoring. 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

Excluding Virtual Groups from APM Entity Group Scoring
CMS is finalizing this policy as proposed. ([p. 1447](#))

group scores. 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. 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 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 after a maximum number of MIPS performance years
- Sunsetting the APM Quality Reporting Credit for non-Advanced APMs
- Sunsetting the APM Quality Reporting Credit for APM Entities in One-Sided Risk Tracks
- Retain different APM Quality Reporting Credits for Advanced APMs and MIPS APMs, 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

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.

Regulation Text

Not addressed in the proposed rule.

Performance Category Scores

Request for Comment on APM Scoring Beyond 2020. CMS received public comments with general support for finding new ways to continue to reward APM participation without giving APM participants an undue advantage within MIPS, without specific support or opposition to any potential approach discussed in the proposed rule. CMS continues to seek input from the stakeholder community as it continues to consider these and other policies that may be included in future rulemaking. ([p. 1445](#))

MIPS APM Performance Feedback

No change from proposed rule. ([p. 1447](#))

Regulation Text

Due to a clerical error, CMS notes that the regulation text corresponding with the proposals discussed in this section on the APM Scoring Standard was omitted from the publication of the proposed rule. Based on several factors, CMS believes stakeholders understood the proposed policy and CMS’ intent to codify it. As such, *CMS is finalizing the proposed policies, as explained above, including amending 414.1370(g)(1).* ([p. 1449](#))

Performance Category Scores

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

Assigning Quality Measure Achievement Points – Scoring Measures Based on Achievement. CMS proposes to amend § 414.1380(b)(1)(i) to extend the 3-point floor through the 2020 MIPS performance year 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.

Assigning Quality Measure Achievement Points – Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements. CMS proposes to amend § 414.1380(b)(1)(i)(A)(1) so that for the 2020 performance year, clinicians will continue to 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.

Assigning Quality Measure Achievement Points – Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment. CMS proposes at § 414.1380(b)(1)(ii) (84 FR 40790) that, beginning with the CY 2020 performance period, for each measure that has a benchmark that CMS determines has the potential to incentivize 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 also proposed 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.

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. 1450)

Scoring Measures Based on Achievement. **CMS finalized this change as proposed (p. 1453).** CMS notes here that as it moves towards the MVP framework, it anticipates revisiting and possibly removing the 3-point floor in future years.

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements. **CMS finalized this policy as proposed (p. 1456).**

CMS recognized concerns regarding the assignment of 3 points to measures without a benchmark and will take them into consideration in the future. At the same time, for many new measures, CMS anticipates that a benchmark will be able to be created which will allow for up to 10 points.

CMS envisions that the progression of the MIPS program under the MVP framework will allow it to remove some of the scoring complexity associated with the MIPS program and that the removal of caps and bonuses could be part of the framework.

A summary of **Quality Performance Category Scoring Policies for the CY 2020 Performance Period** is provided in [Table 50](#).

Modifying Benchmarks to Avoid the Potential for Inappropriate Treatment. **CMS finalized these policies as proposed, including the decision to apply the flat percentages to the following two measures:**

- **MIPS #1: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%); and**
- **MIPS #236: Controlling High Blood Pressure (p. 1467).**

CMS reiterates that it will 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

According to CMS, 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 compliance. CMS will 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, it anticipates using the modified benchmarks for the Medicare Part B claims and the MIPS CQM collection types.

Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure. 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, such as narrative questions, are added to the survey.

Incentives to Report High-Priority Measures. 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.

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. 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. CMS proposes to continue for the 2020 MIPS performance year its previously established improvement scoring policy, which is to compare the MIPS eligible 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

In response to a request that CMS apply the flat percentage benchmarks to “topped out” measures, CMS noted that it would not be appropriate to apply this standard broadly and that it believes it is important that to take a performance-based approach to scoring, such that its benchmarks are based on a distribution of scores.

CMS is interested in working with stakeholders to better understand alternative methods for setting benchmarks in these instances and would consider revising this policy through future rulemaking.

CMS also may consider in future years revisiting flat percentage benchmarks as it transforms MIPS through the implementation of the MVP framework.

CMS reminds readers that these two measures have additional denominator exclusions for the 2020 MIPS performance year and future years, which are detailed in Appendix 1, [Table Group D](#).

Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure (p. 1467). CMS did not summarize feedback received, but will consider it for future rulemaking.

Incentives to Report High-Priority Measures. **CMS finalized these proposals (p. 1471).**

Incentives to Use CEHRT to Support Quality Performance Category Submissions. **CMS finalized this proposal (p. 1473).** CMS reiterates here that it envisions that the progression of the MIPS program under the MVP framework will allow it to remove some of the scoring complexity associated with the MIPS program, including the removal of bonuses.

Improvement Scoring for the MIPS Quality Performance Category Percent Score. **CMS finalized this proposal (p. 1474).**

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. 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.

Calculating the Final Score.

Complex Patient Bonus for the 2022 MIPS Payment Year. 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.

Final Score Performance Category Weights

Reweight Performance Categories due to Data that are Inaccurate, Unusable, or Otherwise Compromised. CMS proposes at § 414.1380(c)(2)(i)(A)(9), and (c)(2)(i)(C)(10) that beginning with the 2018 MIPS performance period/2020 MIPS payment year, it will 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

Facility-Based Measurement Scoring Option for the Quality and Cost Performance Categories for the 2022 MIPS Payment Year. **CMS finalized this proposal** ([p. 1477](#)).

For informational purposes, CMS provided in [Table 51](#) 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.

Calculating the Final Score ([p. 1480](#)).

Complex Patient Bonus for the 2022 MIPS Payment Year. **CMS finalized this proposal** ([p. 1486](#)).

CMS provides an updated analysis in [Table 52](#) to support its decision to continue the complex patient bonus. This analysis relies on data submitted for the 2018 MIPS performance period as an input to estimate the 2020 MIPS performance period final scores. However, since the analysis resulted in inconsistent findings, CMS intends to revisit the size and structure of the complex patient bonus through future rulemaking.

CMS understands that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. However, it is not aware of data sources for indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. CMS will evaluate additional options in future years based on any updated data or additional information— including the Office of the Assistant Secretary for Planning and Evaluation (ASPE) report findings— to better account for social risk factors while minimizing unintended consequences and consider these as it moves forward.

Final Score Performance Category Weights ([p. 1487](#))

Reweight Performance Categories due to Data that are Inaccurate, Unusable, or Otherwise Compromised. **CMS finalized these policies as proposed** ([p. 1501](#)).

If a MIPS eligible clinician with compromised data requests reweighting under this policy, CMS would consider both the timing of when the clinician learned the data were compromised and the state of the data to determine whether reweighting is appropriate.

of the associated MIPS payment year. CMS proposes that the term agent 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 also would amend § 414.1380(c)(2)(i)(C) 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 solicits comment on this proposal and possible alternatives for balancing efforts to allow reweighting 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.

CMS clarifies that reweighting under this policy 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 believes that its policy could apply in cases where a clinician's data are rendered inaccurate, unusable, or otherwise compromised due to changes in hospital contracts that are outside the control of the clinician or its agents. In cases where MIPS eligible clinicians undergo transitions in hospital contracts, CMS encourages MIPS eligible clinicians to work with their contracting hospital to obtain data, including in cases where the MIPS eligible clinician may terminate a contract or may initiate a new contract.

CMS also notes that when it learns of circumstances that suggest MIPS data are inaccurate, unusable or otherwise compromised, it will aim to provide information to the MIPS eligible clinicians whose data may have been compromised on an ongoing and timely basis.

Finally, CMS reminds readers that it previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 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 reweighting due to compromised data, he or she would receive a final score equal to the performance threshold.

Redistributing Performance Category Weights

2020 performance/2022 payment year: [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 (i.e., 15 percent) to the Quality performance and a portion of the Cost category weight (i.e., 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);

Redistributing Performance Category Weights

2020 performance/2022 payment year: ***CMS finalized its redistribution policies for the 2020 performance year/2022 MIPS payment year at § 414.1380(c)(2)(ii)(D) as proposed with a few modifications. Since CMS also finalized in this rule different weights for the Quality and Cost categories than what it proposed, it modified the numerical amounts of weight that it will redistribute to account for these different weights for Quality and Cost, as shown in [Table 55](#). In addition, in response to stakeholder concerns, in the scenario when only the Improvement Activities and Cost performance categories are scored, CMS will provide a weight of 50 percent for each performance category, as shown in [Table 55](#) (p. 1507).***

Over time, CMS wants to redistribute more weight to the Cost and Promoting Interoperability performance categories, and less to the quality performance category, to have better alignment between the Cost and Quality performance categories and due to CMS' focus on interoperability.

- 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.
- 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.

2021 performance/2023 payment year: [Table 48](#) includes proposed redistribution policies for the 2021 performance/2023 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.

2022 performance/2024 payment year: [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.

Establishing the Performance Threshold. 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.

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 to be codified at § 414.1405(b)(7) and (8), respectively. CMS believes these proposals would provide for a gradual and incremental transition toward a performance threshold that

2021 performance/2023 payment year: ***After consideration of public comments, CMS did not finalize performance category weights for the 2023 MIPS payment year. Therefore, it is no longer finalizing redistribution weights for the Cost and Quality performance categories for the 2023 MIPS payment year*** ([p. 1511](#)).

2022 performance/2024 payment year: ***After consideration of public comments, CMS did not finalize performance category weights for the 2024 MIPS payment year. Therefore, it is no longer finalizing redistribution weights for the Cost and Quality performance categories for the 2024 MIPS payment year*** ([p. 1511](#)).

Establishing the Performance Threshold. ***CMS finalized its proposal to set the performance threshold at 45 points for the 2020 MIPS performance year/2022 payment year, codified at § 414.1405(b)(7), and at 60 points for the 2021 MIPS performance year/2023 MIPS payment year, codified at § 414.1405(b)(8)*** ([p. 1532](#))

The performance thresholds for the first 3 years of MIPS are presented in [Table 58](#).

Since the publication of the CY 2020 PFS proposed rule, CMS now has the actual final score data for the 2018 performance year/2020 payment year with which to estimate the mean and median. CMS estimates the mean of the actual final scores for the 2020 payment year at 86.91 points and the median at 99.63 points although these values may change after the completion of targeted reviews and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised.

[MIPS Payment Adjustments](#)

must be set at the mean or median final score for a prior period in Year 6 of the MIPS program (i.e. the 2022 performance year).

CMS recognizes that using final scores from the early years of MIPS has numerous limitations and may not be similar to the distribution of final scores for the 2022 performance year. As such, 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.

CMS refers readers to [Table 59](#) for potential values for estimating the performance threshold for the 2024 MIPS payment year based on the mean or median final score from prior periods. CMS has updated this table from the CY 2020 PFS proposed rule (see [Table 51](#)) to include the actual final score data for the 2020 payment year. CMS has also updated this table to include an estimate of the mean and median for the 2022 payment year from its Regulatory Impact Analysis in this final rule as this estimate incorporates the newly available data for the 2020 payment year.³ As illustrated in [Table 59](#), CMS found that the mean and median final scores for the 2020 payment year are higher than the values for the 2019 payment year and higher than CMS' original estimate from the CY 2020 PFS proposed rule which had an estimated mean of 80.30 and median of 90.91 (84 FR 40802); however, CMS also estimated the final scores for the 2021 payment year will be lower than the values for both the 2019 and 2020 payment years.

CMS considered all data and commenter concerns and has decided to take a conservative approach for estimating the 2024 MIPS payment year performance threshold. CMS continues to believe that 74.01 points is an appropriate estimate for a performance threshold for the 2024 MIPS payment year. The mean of 74.01 points for the 2019 MIPS payment year is the lowest of the two actual mean scores available and falls between CMS' projections for mean final scores for the 2021 and 2022 MIPS payment years illustrated in [Table 59](#). CMS believes the policy changes across MIPS payment years, in conjunction with the projected decrease in mean and median final scores from the 2020 MIPS payment year, justifies using the mean from the 2019 MIPS payment year (74.01 points) as the estimated performance threshold for the 2024 MIPS payment year.

However, CMS may revisit the performance threshold for the 2023 payment year in future rulemaking if it receives additional data that changes its estimate of the performance threshold for the 2024 payment year

CMS also believes that the proposed performance thresholds of 45 points and 60 points for the 2022 and 2023 MIPS payment years, respectively, are appropriate because they would represent a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, as required by the statute.

CMS does not believe that keeping the performance threshold at 30 points or increasing the performance threshold by 5 or 10 points would as effectively

³ For a complete description of the data sources and methodology for the projected 2022 MIPS payment year final scores, please refer to the [Regulatory Impact Analysis](#) of this final rule.

incentivize the delivery of high quality care for the 2022 MIPS payment year. It also would not provide as much of a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year.

CMS appreciates the unique challenges faced by MIPS eligible clinicians that are in specialty practices, including pathologists, audiologists, physical therapists, and ASC-based and hospital-based MIPS clinicians. CMS believes that there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold and be successful in MIPS including policies that adjust the quality performance category scores to account for the number of available quality measures.

Starting on p. 1551, CMS provides updated examples with the policies finalized for the 2022 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score above the performance threshold of 45 points based on its final policies.

[Table 123](#), in the Regulatory Impact Analysis section of this rule, shows the impact of MIPS payment adjustments in 2022 based on 2020 performance, by practice size and based on whether clinicians are expected to submit data to MIPS:

- 92.5 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments in 2022 based on 2020 performance.
- 45.3 percent of MIPS eligible clinicians are expected to receive a positive adjustment with an exceptional payment adjustment.
- Over 80 percent of clinicians in small practices (1-15 clinicians) that submit data to MIPS would receive a positive or neutral adjustment. However, a smaller proportion of clinicians in small practices (1-15 clinicians) who participate in MIPS are estimated to receive a positive or neutral payment adjustment compared to larger sized practices.
- Among those who CMS estimates would not submit data to MIPS, 89 percent are in small practices (15,993 out of 18,017 clinicians who do not submit data)

Additional Performance Threshold for Exceptional Performance. CMS proposes to set the additional performance threshold for the 2022 MIPS payment year at 80 points and to set the additional performance threshold for the 2022 MIPS payment year at 85 points.

Since, under section 1848(q)(6)(F)(iv) of the Act, funding is available for exceptional performance only through the 2024 MIPS payment year, which is the sixth year of the MIPS program, CMS believes it is appropriate to further incentivize clinicians whose performance meets or exceeds the

Additional Performance Threshold for Exceptional Performance. After consideration of public comments and more recent data discussed in the Regulatory Impact Analysis of this final rule (also summarized below), CMS did not finalize its proposal to set the additional performance threshold at 80 points for the 2022 MIPS payment year, and instead, finalized the additional performance threshold at 85 points for the 2022 MIPS payment year. CMS finalized the additional performance threshold at 85 points for the 2023 MIPS payment year as proposed. It is codifying the additional

additional performance threshold for the fourth and fifth years of the MIPS program.

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 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.

performance threshold for the 2022 MIPS payment year and for the 2023 MIPS payment year at § 414.1405(d)(6) (p. 1544).

CMS believes that an increase of 10 points from the additional performance threshold of 75 points for the 2021 MIPS payment year is a reasonable increase for the 2022 MIPS payment year and would further incentivize continued care improvement by high performing clinicians that have invested in quality care and are exceptional performers in MIPS.

CMS clarifies that an additional performance threshold of 80 points and 85 points would each require a MIPS eligible clinician to participate and perform well in multiple performance categories. In addition, 80 points and 85 points are at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target.

CMS also notes that a higher additional performance threshold could increase the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the funds available are distributed over fewer clinicians that score at or above the higher additional performance threshold.

[Table 123](#), in the Regulatory Impact Analysis section of this rule, shows the impact of MIPS payment adjustments in 2022 based on 2020 performance, including the following estimate:

- 45.3 percent of MIPS eligible clinicians are expected to receive a positive adjustment with an exceptional payment adjustment.

As further discussed in the Regulatory Impact Analysis, CMS estimates that the number of MIPS eligible clinicians receiving an additional payment adjustment with the additional performance threshold at 80 points and 85 points is 533,069 and 390,354 MIPS eligible clinicians, respectively, representing a decrease in the number of MIPS eligible clinicians that would receive an additional payment adjustment by 142,715 clinicians. The estimated 390,354 MIPS eligible clinicians expected to receive the additional payment adjustment when the additional performance threshold is set at 85 points is about 44 percent of the MIPS eligible population compared to 61 percent of the MIPS eligible population if the additional performance threshold were to be set at 80 points. CMS also estimates that the maximum payment adjustment (for a MIPS eligible clinician with a final score of 100 points) would increase from 4.5 to 6.2 percent. However, this projection is only an estimate and may change based on the distribution of actual final scores ([p. 1539](#), [p. 1976](#))

Limitations to these estimates are discussed starting on [p. 1962](#).

Examples of Adjustment Factors. CMS provides a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on its proposed policies for the 2022 MIPS payment year.

Examples of Adjustment Factors ([p. 1544](#)). CMS updated this figure and table based on its finalized policies.

[Figure 1](#) provides an illustrative *example* of how various final scores will 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 for the 2022 MIPS payment year. In [Figure 1](#), the applicable percentage is 9 percent for the 2022 MIPS payment year. Because the performance threshold is 45 points, CMS anticipates that more clinicians will receive a positive adjustment than a negative adjustment, that the scaling factor will be less than 1, and that the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points will be less than 9 percent. [Figure 1](#) also illustrates an example of the slope of the line for the linear adjustments for the 2022 MIPS payment year, but it can change considerably as new information becomes available. Again, this example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

[Table 60](#) illustrates the changes in payment adjustments based on the final policies for the 2020 and 2021 MIPS payment years, and the policies for the 2022 and 2023 MIPS payment years discussed in this final rule, as well as the statutorily-required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

In the Regulatory Impact Analysis section of the rule, CMS estimates that for the 2020 performance year/2022 payment year, \$433 million would be redistributed through budget neutrality and that \$500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The model further estimates that the maximum positive payment adjustments are 6.2 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. However, this projection is only an estimate and may change based on the distribution of actual final scores for clinicians with final scores at or higher than the additional performance threshold and the associated Medicare payments ([p. 1539](#), [p. 1948](#)).

[Targeted Review
and Data Validation
and Auditing](#)

Targeted Review

Who is Eligible to Request a Targeted Review. 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

Targeted Review

Who is Eligible to Request a Targeted Review. **CMS finalized this revision as proposed** ([p. 1557](#)).

qualified registry, health IT vendor, or QCDR), may submit a request for a targeted review.

Timeline for Targeted Review Requests. 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.

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;

Timeline for Targeted Review Requests. **CMS finalized this revision as proposed** ([p. 1560](#)).

Denial of Targeted Review Requests. **CMS finalized this revision as proposed** ([p. 1562](#)).

Requests for Additional Information. **CMS finalized this clarification** ([p. 1564](#)).

- 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. 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.

Notification of Targeted Review Decisions. **CMS finalized this proposal** ([p. 1566](#)).

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.

Scoring Recalculations. **CMS finalized this proposal** ([p. 1567](#)).

Data Validation and Auditing

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).

Data Validation and Auditing ([p. 1567](#))

In response to public requests, CMS will consider publishing the aggregate findings of previous audits surrounding cherry-picked data in connection with future educational efforts.

A commenter requested clarification on whether CMS would not conclude a clinician was cherry-picking data if it submitted data on a single patient in order to receive the minimum point threshold for a quality measure. CMS clarified that existing policy takes into consideration that MIPS eligible clinicians may submit data in accordance with CMS data submission requirements on a single measure. CMS believes that even in the context of submitting data on a single patient in order to receive the minimum point threshold, the patient selected should be representative.

[Third Party Intermediaries](#)

Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries. 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 (i.e., quality; improvement activities; and Promoting Interoperability), 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. 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.

Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries ([p. 1570](#)). **CMS finalized its proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400. Specifically, it finalized changes to § 414.1400(a)(2) to state that beginning with the 2023 MIPS payment year [2021 performance year], QCDRs and qualified registries must be able to submit data for all of the MIPS performance categories identified in the regulation, and Health IT vendors must be able to submit data for at least one such category** ([p. 1580](#)).

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.

Commenters raised concerns that this could shift costs and burden of administering the MIPS program onto physicians via their specialty societies and would require QCDRs to perform services that were not part of the original quality program, which could result in many QCDRs electing to reevaluate their decisions to seek approval to submit MIPS data. CMS clarified that although this may cause an increase in burden, its intent is to ensure that the QCDRs and qualified registries that are approved in the program are of

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) or (5) or §414.1380(c)(2)(i)(C)(1)-(7) or § 414.1380(c)(2)(i)(C)(9).

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.

the highest quality and can be used as reliable resources to support quality reporting on behalf of eligible clinicians and groups.

Since the 2017 QPP final rule (81 FR 77366 and 81 FR 77384) states that QCDRs and qualified registries must audit a subset of data prior to submission for all performance categories that the QCDR or qualified registry is submitting data on, some commenters voiced concern about having to audit and validate Promoting Interoperability data and improvement activities and noted that some QCDRs may incur additional costs from EHR vendors who may charge fees for providing additional necessary reports. CMS understands that this policy will require the minority of existing QCDRs and qualified registries who do not support all three performance categories to take on additional efforts and resources to support the remaining performance categories. Although some EHR vendors may charge for reports, CMS believes that the costs will be minimal because CEHRT includes the capability to calculate the Promoting Interoperability measures and the reports that must be generated. In addition, the use of [health information exchanges](#) is an option for transmitting data.

CMS clarifies that under its current data validation processes, as described in the CY 2017 QPP final rule (81 FR 77368 through 77369) and (81 FR 77384 through 77385), QCDRs and qualified registries are required to provide information on their sampling methodology. For example, it is encouraged that 3 percent of TIN/NPIs submitted be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients (with a maximum sample of 50 patients)). CMS would expect that this review of patient medical records would be done to validate that the pertinent quality actions were done for measures and activities done by the clinician and group. In addition, validation guidance clarifications can be found within the improvement activities validation document at the [MIPS Data Validation Document](#) link. With regards to auditing whether improvement activities have been completed by a clinician or group, it is important for a third party intermediary to validate that an action has been done through review of medical records or other forms of documentation that will indicate that the quality action and/or improvement activity has been completed ([p. 1592](#)).

CMS noted that a majority of existing qualified registries and QCDRs already support all three performance categories, citing that from 2017 to 2018, the number of clinicians who have used their QCDR/qualified registry for submitting all three performance categories rose from approximately 24 percent to 36 percent. CMS believes that under this revised policy, more

MIPS eligible clinicians may want to use this method as a burden reduction on data submission since it will allow QCDRs and qualified registries to become one-stop-shops for reporting. Overall, CMS believes the added benefit this policy provides to clinicians outweighs concerns about the small number of qualified registries and QCDRs that are not able to comply.

CMS expressed appreciation for comments that health IT vendors should be held to the same standards as QCDRs and qualified registries, and may consider this feedback in future rulemaking.

CMS clarified that this policy requires that QCDRs and qualified registries support all three performance categories, but does not require that an eligible clinician or group to report all three performance categories through a QCDR or qualified registry. CMS also clarified that the 2021 self-nomination period begins on July 1, 2020 and ends on September 1, 2020, which gives QCDRs sufficient time to incorporate this reporting into their workflows.

CMS also finalized its proposal to amend § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability, [this requirement applies] if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may 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***
- ***§ 414.1380(c)(2)(i)(A)(5) [i.e., NPs, PAs, CRNAs, and CNSs] or***
- ***§ 414.1380(c)(2)(i)(C)(1) through (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] (p. 1580).***

In response to requests for clarification on the percentage of participants that would have to be exempt, CMS clarified that a third party could be excepted from this requirement if ***all*** [emphasis added] of the third party intermediary’s MIPS eligible clinicians, groups or virtual groups fall under the cited reweighting policies. A QCDR or qualified registry cannot be excepted from this requirement and must be able to submit data for the Promoting Interoperability performance category so long as it supports ***any*** [emphasis added] clinician, group or virtual group that uses CEHRT and is not identified as eligible for reweighting of the Promoting Interoperability performance category.

Approval Criteria for Third Party Intermediaries. To prevent disruptions in participation, CMS proposes to adopt two additional criteria for approval at § 414.1400(a)(4) to ensure continuity of services to MIPS eligible clinicians, groups, and virtual groups that utilize the services of third party intermediaries:

- 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.
- At § 414.1400(a)(4), to add a new paragraph (vi) to establish that a condition of approval is for a 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 transition plan.

If CMS determines that a third party intermediary has ceased to meet either of these proposed criteria for approval, CMS may take remedial action or terminate the third party intermediary in accordance with § 414.1400(f).

Approval Criteria for Third Party Intermediaries. CMS finalized at § 414.1400(a)(4), as proposed, 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 (p. 1584).

CMS also finalized at § 414.1400(a)(4) to add paragraph (vi) with modification to be consistent with other sections of the regulations. Instead of requiring the third party intermediary to support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary, CMS finalized 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 third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan (p. 1584).

CMS clarified that:

- In instances where a clinician or group is leaving a third party intermediary on its own volition, a transition plan, while encouraged, is not required from a QCDR or a qualified registry.
- Third party intermediaries are not required to support the transition of MIPS eligible clinicians, groups, or virtual groups to an alternate collection type for measures on which no data has been collected.
- For QCDR measures, supporting the transition to an alternate collection type may not be feasible in every case.
- While CMS understands that sometimes issues arise outside of a registry's direct control, impacting a registry's ability to provide services, it believes that a transition plan should be required regardless of the reason that the third party intermediary is discontinuing services.

CMS appreciated a recommendation that it develop a "CMS-approved transition advisory plan," but disagrees and instead believes it is appropriate to provide flexibility to the third party intermediaries to craft a transition plan for its review and approval. According to CMS, the strategy utilized in transitioning clients off a QCDR or qualified registry's platform should be left to the QCDR or qualified registry to determine, based on their unique circumstances.

Qualified Clinical Data Registries

Qualified Clinical Data Registries (p. 1585)

QCDR Approval Criteria

Requirement for QCDRs to Support All Three Performance Categories Where Data Submission is Required. See earlier discussion on Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries.

QCDR Approval Criteria

Requirement for QCDRs to Support All Three Performance Categories Where Data Submission is Required. ***CMS finalized these proposals with technical modifications for clarity and consistency with existing regulatory provisions (p. 1592).*** For a summary of these finalized policies, see earlier discussion on [Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries](#), including requirements related to the auditing of such data.

As discussed in the 2017 QPP final rule (81 FR 77363 through 77364), although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to use QCDRs to report on applicable measures for the quality performance category, the statute does not specifically address use of QCDRs for the other MIPS performance categories. Although CMS previously could have limited the use of QCDRs to assessing only the quality performance category, CMS believes it would be less burdensome for MIPS eligible clinicians if it expands QCDRs' capabilities.

Based on CMS's review of existing 2019 QCDRs, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting all three performance categories. In 2017, 73 percent (approximately 83 QCDRs) and in 2018, 73 percent (approximately 110 QCDRs) have supported all three performance categories.

Responding to requests that it delay this policy and coordinate with the updates to standards that may be included in the 21st Century Cures Act final rule, CMS noted that it does not believe that those proposals will have a significant impact on the ability of QCDRs to report measures for the Promoting Interoperability category. However, when the 21st Century Cures Act final rule is published, CMS will determine if additional modifications are necessary.

Responding to a request for clarification regarding the number of measures from each performance category that will be required for approval, CMS encourages third parties to support the minimum number of measures and activities to support the Promoting Interoperability performance category as discussed in § 414.1375 (83 FR 59798 through 59817) and Improvement Activities performance category as discussed in the CY 2017 QPP final rule (81 FR 77185, in order to offer a complete reporting experience to eligible clinicians and groups. Note that QCDRs and qualified registries are required to support the minimum number of measures to meet the reporting requirements of the Quality performance category, as described in the CY 2017 QPP final rule (81 FR 77368).

Requirement for QCDRs to Engage in Activities that will Foster Improvement in the Quality of Care. The definition of QCDR at § 414.1305(2) currently reads: 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 to include the QCDR's approved quality improvement services in the qualified posting for each approved QCDR.

Enhanced Performance Feedback Requirement. 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 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.

Requirement for QCDRs to Engage in Activities that will Foster Improvement in the Quality of Care. ***Due to concerns about the need for more specificity surrounding these policies, CMS is not finalizing these proposals at this time.*** However, CMS continues to believe they are important and will consider proposing this requirement in subsequent future rulemaking, and encourages QCDRs to prepare for such ([p. 1599](#)).

CMS did not intend on the policy being vague, unclear, or arbitrary, but intended to provide flexibility to the QCDR as to the type of improvement service they may offer. In response to concerns, CMS also clarified that the services offered would not be used to rank the QCDRs in any way, but to serve as a helpful resource for clinicians and groups.

CMS appreciates suggestions that it provide a minimum threshold of the type of service that needs to be provided, and may consider this feedback for future rulemaking. CMS may also, in the future, consider requirements that would require that the QCDRs describe the activities they are proposing to support as a part of their self-nomination application, as well as the ability of the QCDR to provide this service to all the clinicians and groups it supports for a given performance period.

Enhanced Performance Feedback Requirement. ***CMS finalized these proposals with technical modifications*** (since CMS is not finalizing § 414.1400(b)(2)(iii), discussed in the previous section, the previously proposed § 414.1400(b)(2)(iv) will now become § 414.1400(b)(2)(iii)) ([p. 1603](#)).

CMS understands that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and clarifies that these comparisons 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.

In regards to the exception that could apply if a QCDR does not receive the data from their clinician until the end of the performance period, CMS clarifies that it would depend on the QCDRs to let CMS know as soon as possible when there are issues that arise that would cause a delay in providing performance feedback.

CMS did not summarize or respond to feedback on requiring clinicians who utilize a QCDR to submit data prior to the close of the performance period, but will take these comments into consideration as it develops future policies for QCDRs.

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.

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

Measure Considerations

- Previously Finalized QCDR Measure Considerations: CMS proposes to codify a number of previously finalized QCDR measure considerations (83 FR 59902). In response to stakeholder concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, CMS proposes to amend § 414.1400 by adding § 414.1400(b)(3)(iv) to codify 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.
- QCDR Measure Availability: 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.

QCDR Measures

Measure Considerations

- Previously Finalized QCDR Measure Considerations: **CMS finalized its decision to codify these QCDR measure considerations as proposed (p. 1607)**. In general, CMS clarifies that the newly finalized QCDR measure considerations and requirements for approval apply to all QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures for the 2021 performance period and future years. CMS will not be grandfathering in previously approved QCDR measures.
- QCDR Measure Availability: **CMS also finalized its proposal that it 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 (p. 1613)**. CMS is trying to address scenarios in which a QCDR measure is approved, but the QCDR measure owner does not allow any outside QCDRs to use their QCDR measure. CMS' overall intent is to move away from having duplicative measures in the program, simply because QCDRs are unwilling to license their QCDR measures to one another.

To clarify, a QCDR measure is available when the QCDR measure owner is willing to allow other QCDRs to borrow their QCDR measure with the appropriate permissions and/or licensing. CMS leaves measure license user agreements (including fees), expectations, and terms between the measure owner and borrower.

In response to concerns regarding inappropriate or inconsistent implementation, incorrect understanding of measure specifications, and lack of standardized data methods resulting in inaccurate benchmarking by the borrowing QCDR, CMS would expect that a QCDR measure licensure agreement would include the QCDR measure owner's terms of use, which could include implementation criteria to ensure that the measure is programmed and collected in a way that is consistent with what the QCDR measure owner intends. CMS believes that QCDRs approved for 2020 and future years should be able to comprehend and adhere to a preferred standardized data methodology due to their measure experience.

For QCDR measure owners that come to find that a borrowing QCDR does not meet the terms of the licensing agreement prior to granting permission to borrowing the measure, CMS would expect QCDR measure owners to be able to provide evidence to justify instances where their measure was made available but ultimately could not be borrowed by another QCDR. CMS would consider these on a case-by-case basis.

CMS also believes that QCDR measure owners should be given a chance to respond to instances where there is alleged blocking of the use of a QCDR measure. CMS requests that QCDRs keep documentation to support their claim as to why a QCDR measure licensing agreement could not be reached/why a given QCDR should not be allowed to use their QCDR measure. CMS will review information on why the QCDR measure was not made available to another QCDR on a case-by-case basis.

In instances where CMS finds that QCDRs are blocking the use of their QCDR measure from other QCDRs without any evidence that proves the borrowing QCDR is unable to meet the QCDR measure owner's terms, CMS will likely approve another similar QCDR measure over this one.

- QCDR Measure Addresses a Measurement Gap: 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.
- QCDRs Measures Meeting Benchmarking Thresholds: 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. As described in the CY 2017 QPP final rule (81 FR 77277 through 77282), for benchmarks to be developed, a measure must have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size criteria.

- QCDR Measure Addresses a Measurement Gap: ***CMS also finalized, as proposed, its policy to give greater consideration to measures for which a QCDR conducted an environmental scan and sought to identify measure gaps prior to measure development (p. 1615).*** CMS clarifies that the performance gap may be identified by data submitted to the registry on the given measure or through current clinical study citations (within the past 5 years). A health care survey would not provide sufficient evidence of a performance gap. CMS also notes that a measure that is considered to have a performance gap would not be considered topped out, as described in the CY 2017 QPP final rule (81 FR 77282 through 77283).
- QCDRs Measures Meeting Benchmarking Thresholds: ***CMS also finalized its proposal to, beginning with the 2020 performance period, 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 (p. 1622).*** CMS reminds QCDRs to be aware of which measures are considered low-reported, since measures that do not meet benchmarking thresholds result in a 3- point floor, as described in the CY 2017 QPP final rule (81 FR 77282).

CMS recognized concerns that this policy could create hardships for specialties to participate in MIPS and deter QCDRs from investing in the development and maintenance of measures. Nevertheless, it believes that maintaining low-reported measures in the program over multiple years is counterintuitive to the Meaningful Measurement Initiative and indicative of metrics that are not of interest to the majority of clinicians within a given specialty. At the same time, CMS is aware of instances in which measures may be low-reported due to being highly sub-specialized and refers readers to the section below titled, [QCDR Measures—Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds](#), for a discussion on 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.

Some commenters felt the 2-year period was insufficient for some measures to achieve acceptable numbers of adoption or for EHR vendors to complete data integration to support the measure. CMS responded that since QCDRs will be required to test their measures

prior to self-nominating them, as finalized in in the next section of this rule, it is assumed that the QCDR would have considered the time it takes for data integration from an EHR prior to testing the measure to ensure that measure is feasible. If a QCDR cannot timely complete the data integration process for a QCDR measure, it should delay self-nominating that QCDR measure until it is implementable. QCDR measures should not be submitted for consideration until they are fully developed and tested, including the ability to be supported by EHR vendors. CMS also believes this issue is mitigated by the policy finalized in the next section of this rule, which would require QCDRs to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure during the self-nomination period. According to CMS, this would allow QCDRs to demonstrate whether the measure is implementable and data collection on the metric is possible.

Measure Requirements.

- Previously Finalized Requirements Considerations Codified as Requirements: Beginning with the 2020 performance period, CMS proposes to change both of the following considerations into requirements and to codify these requirements by amending § 414.1400 to add § 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
- Linking QCDR Measures to Cost Measures, Improvement Activities, and MVP: 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

Measure Requirements.

- Previously Finalized Requirements Considerations Codified as Requirements: ***CMS finalized its decision to codify these two considerations as requirements for QCDRs, beginning with the 2020 performance period (p. 1623).***
- Linking QCDR Measures to Cost Measures, Improvement Activities, and MVP: ***CMS finalized its proposal with clarification that QCDRs are required to link their measure to at least one performance category as feasible (i.e., not all 3). Thus, CMS is amending § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures as feasible to at least one of the following at the time of self-nomination: (a) cost measure; (b) improvement activity; or (c) an MVP. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, CMS would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations as discussed earlier (p. 1629).***

CMS clarified that a link can be established if, for example, the associated measures and activities address the same clinical condition or disease. CMS will require the QCDR to provide a narrative with their QCDR measure specification that identifies the

- Completion of QCDR Measure Testing: CMS also proposes, at § 414.1400(b)(3)(v)(C), that beginning with the 2021 performance period, all QCDR measures must be fully developed, with completed testing at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. All QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the [CMS Blueprint for the CMS Measures Management System](#) and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. In the discussion, CMS also refers to the National Quality Forum (NQF) guides for measure testing criteria as standards that illustrate differences in the testing process based on measure type.

other measures and activities that relate, and explain why they believe there is a link. CMS plans to provide education to QCDRs to ensure that they adequately understand this requirement.

CMS notes that if a QCDR measure cannot be linked to a cost measure because the specialty isn't reflected in the cost measures, then the QCDR would indicate there are no cost measures to link in their QCDR measure submission for us to note as a part of our review.

- Completion of QCDR Measure Testing: ***CMS finalized these testing requirements as proposed, beginning with the 2021 performance period (p. 1637).*** 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, CMS is unable to determine the financial impact of this policy on QCDRs beyond the likelihood of it being more than trivial ([p. 1956](#)).

Critics of this proposal felt it could delay the creation and submission of new measures by a number of months or even years; would be cost prohibitive for many QCDRs; may result in some QCDRs electing to cease measure development or no longer participating in the MIPS program; could lead to increased licensing fees or participation fees for clinicians; and that it removes the ability for clinicians to report on measures that are not in the CMS measure inventory. While CMS understands the increased time and cost burdens associated with measure testing, it believes the benefits of completed measure testing far outweigh the burdens of it. CMS also reminds readers that it has signaled through previous rulemaking cycles (83 FR 59901 through 59902) its intent to raise the bar for QCDR measures.

CMS also disagreed with the comment that this policy is contrary to Congress' intent for QCDRs to serve as testbeds for more robust and creative measures as there is no reference in section 1848(q) of the Act to QCDRs serving as "testbeds" for such measures.

CMS also disagreed that having real-world access to EHR data is comparable to that of measure testing data or that requiring collection of 12 months of data on a QCDR measure could replace measure testing.

Other clarifications about these new requirements include:

- All QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures will be expected to meet these new QCDR measures requirements and considerations to be approved for the 2021 performance period and future years. CMS will not be grandfathering in previously approved QCDR measures.
- CMS has not proposed timeframes for measure testing. The testing process will depend on the measure type, for example, a measure that is specified as an eCQM measure has additional steps that it undergoes when compared to other measure types. CMS defers to QCDR measure owners as the experts in their specialty. If a QCDR believes that they need more than one year is needed to ensure a measure is statistically appropriate, reliable, and to complete measure testing at the clinician level, then they should delay self-nominating the QCDR measure until testing is completed.
- CMS will not accept trial testing in place of fully completed testing data at the clinician level.
- The requirement to collect data on a QCDR measure prior to self-nomination (see next section) is separate from the requirement to fully test the measure.
- CMS does not currently require QCDR measures to be NQF endorsed in order to be approved for use in the program. However, it believes in utilizing the existing NQF testing standard without variation, to avoid inconsistencies that may result from substandard results.

CMS reminds the public that it provides support through webinars, and resources through the [Measure Management System](#). To sign up for these webinars, email MMSsupport@battelle.org.

- Collection of Data on QCDR Measures: 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. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable, whether data collection on the metric

- Collection of Data on QCDR Measures: ***CMS finalized the QCDR measure data collection policies as proposed (p. 1641).***

Despite various concerns raised about this requirement and the impact it would have on QCDRs and QCDR measures, CMS believes that the benefits of this policy outweigh the burdens. In response to requests for delayed implementation of this policy, CMS stated its belief that the 2021 performance period start date would allow for sufficient time needed for planning and budgeting.

is possible, and data collected could be used to demonstrate that there is a performance gap. CMS suggests QCDRs collect data on as many months as possible, but encourages 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 since this will also likely increase the chance that the measure will be able to be benchmarked.

Duplicative QCDR Measures: 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 one 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).

CMS reiterated here that QCDRs should not be using the MIPS program as a test-bed for measure development, particularly since this is a pay-for-performance program and clinician's performance on measures have impacts on their payments.

CMS also clarified that while it encourages QCDRs to collect data for 12 months prior to submitting the measure for its consideration, it understands there may be instances where less than 12 months of data may be available.

- Duplicative QCDR Measures: ***CMS finalized this policy as proposed (p. 1649).***
After the close of the self-nomination period, CMS will review QCDR self-nomination applications, identify similar QCDR measures for harmonization, and then notify the relevant QCDRs through the Self-Nomination Portal that their QCDR measures have been identified for measure harmonization. In this communication, CMS will include its reasons as to why harmonization is appropriate, including where it believes duplication exists, points of contact from the other identified QCDRs, and information regarding provisional approval for the given year.

As part of the QCDR measure review process, CMS will review all new QCDR measures submitted at the time of self-nomination and compare them to previously approved QCDR measures. In instances where there are no significant differences and the specification of the new measure is duplicative of an existing measure, CMS would reject the new measure and recommend the QCDR seek permission to use the existing approved QCDR measure. In instances where there is overlap, and both measures cover a similar clinical concept, but with differing quality actions or patient populations, CMS will request measure harmonization. In instances where QCDRs cannot or refuse to collaborate to harmonize their measures, CMS will select and approve the most robust QCDR measure and reject any duplicative ones.

CMS clarified that QCDR measures are reviewed to identify similarities and differences in areas that include (but are not limited to): clinical concept being measured, quality action (e.g., screening versus screening and follow-up), patient population, clinical setting (place of service), and the clinician type eligible to report on the measure. With regards to ensuring that harmonization will only occur when clinically appropriate, CMS noted that it does review

clinical appropriateness when requesting harmonization; however, it relies on the QCDRs to indicate, as a part of their QCDR measure reconsideration, when and why they believe harmonization is not appropriate.

In response to a request that CMS consider the level of rigor in evidence or testing process between QCDRs with two similar measures, CMS noted it would be difficult to do so since, for the 2020 performance period and previous years, it has not required measure testing.

In response to a suggestion that an existing measure with baseline performance should not be rejected in favor of a new measure without prior data collection or baseline performance, CMS believes that the data collection requirement for QCDR measures, beginning with the 2021 performance period, will mitigate this concern. Nevertheless, in instances where one measure completely overlaps another's clinical concept, but includes a more robust quality action, CMS' preference would be to select the more robust QCDR measure (regardless of a given QCDR measure's history within the program).

CMS also clarified that while a QCDR's relevant expertise in the specialty is given some consideration in the context of measure harmonization decisions, it would not be the deciding factor as several QCDRs may have overlapping expertise. CMS would expect that QCDRs would develop QCDR measures reflective of their area of clinical experience and strength, and continuously engage in discussions with the QCDRs regarding the clinical aspects of their QCDR measures through QCDR measure preview calls and QCDR measure reconsideration calls. It is at these meetings where QCDRs are given the opportunity to present and rationalize the need for quality metrics around the topic at hand.

CMS disagrees with commenters that specialty societies should be involved in evaluating QCDR measures for which they are not the owners of. Although they may be experts, CMS believes conflicts of interest may arise when the specialty society themselves have their own QCDR and are then allowed to evaluate QCDR measures from another QCDR of the same specialty.

Measure Rejections. 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

Measure Rejections. ***CMS finalized these policies as proposed. Specifically, if finalized that all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes***

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 two consecutive years (i.e., do not have a minimum of 20 individual clinicians or groups who reported the measure to

on September 1st) to determine whether they are appropriate for the program. Beginning with the 2020 performance period, CMS will reject QCDR measures with consideration of, but not limited to, the factors proposed (p. 1656).

As a part of its QCDR measure removal process, CMS does give consideration to the availability of other specialty-specific measures, particularly outcome or high priority measures, available in the MIPS program prior to flagging any given measure for removal. In addition, performance data provided in the QCDR measure self-nomination demonstrating that a performance gap still exists will be taken into consideration prior to a final decision.

While CMS’ general preference is to have more outcome measures in the program, it does understand a need for process measures, particularly for non-patient facing clinicians. In instances where the outcome related metrics are limited or topping out, CMS encourages non-patient facing specialties to develop measures that address a high priority area (such as patient experience or care coordination) when it is not feasible to develop outcome measures. In addition, CMS will take into consideration performance gap information that is provided by a QCDR that demonstrates a process measure is not topped out.

CMS also clarifies here that a “robust” measure refers to measures with the most vigorous quality action or guidance or as a descriptor to describe strong, vigorous, or thoroughly vetted components of a measure. CMS also refers readers to the [CMS Blueprint](#) where it has similarly defined “robust.”

In instances where QCDRs may disagree with their QCDR measure rejection, they may request a reconsideration call to discuss their position with CMS.

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).

Measure Review Process. 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).

Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds. 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.

Measure Review Process. ***CMS finalized this policy as proposed (p. 1661).***

Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds. ***CMS finalized this policy as proposed (p. 1664).***

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

Requirement to Support All Three Performance Categories Where Data Submission is Required. 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) or (5) or §414.1380(c)(2)(i)(C)(1)-(7) or § 414.1380(c)(2)(i)(C)(9).

Enhanced Performance Feedback Requirement. CMS proposes revise the current § 414.1400(c)(2) to reclassify at paragraph (c)(2)(i) that beginning with the 2022 MIPS payment year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. CMS also 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 specific 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 as a part of the performance feedback given at least 4 times a year. 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)).

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).

Remedial Action and Termination of Third Party Intermediaries. Third parties intermediaries have an affirmative obligation to certify that the data they submit on behalf of a MIPS eligible clinician, group or virtual

Qualified Registries

Requirement to Support All Three Performance Categories Where Data Submission is Required. **CMS finalized its proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400** ([p. 1670](#)).

See similar finalized policies and discussion of stakeholder comments related to [QCDRs](#).

Enhanced Performance Feedback Requirement. **CMS finalized these requirements as proposed** ([p. 1675](#)).

CMS did not summarize or respond to comments on potentially requiring clinicians to submit data to a qualified registry throughout the performance period, but will take this feedback into consideration as it develops future policies for qualified registries.

Remedial Action and Termination of Third Party Intermediaries
CMS finalized these changes in regulation as proposed ([p. 1686](#)).

group are true, accurate and complete to the best of its knowledge. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as "cherry-picking," results in data submissions that are not true, accurate or complete. A third party intermediary that submits a certification under § 414.1400(a)(5) in connection with the submission of data it knows are cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS determined that third party intermediary knowingly submitted data that are not representative of the clinician's or group's performance and certified that the submitted data were true, accurate and complete, CMS would have multiple grounds to impose remedial action or termination under existing regulation.

In this rule, CMS proposes two changes to the regulations to more expressly emphasize CMS enforcement authority to impose remedial action or termination under existing regulation. First, CMS proposes to clarify that remedial action and termination provisions at § 414.1400(f)(1) are triggered if CMS determines that a third party intermediary submits a false certification under paragraph (a)(5). Second, 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 clarified here that third party intermediaries should be able to track the eligibility status of the clinicians and groups they support MIPS reporting for, particularly as it pertains to MIPS eligible, voluntary participation, and opt-ins. If a third party intermediary submits data that misstate whether a clinician is non-eligible, a Qualified APM Participant, or other APM participant, then the third party intermediary has submitted data that are inaccurate. If CMS determines a third party intermediary is misrepresenting the status of its clinicians, it would anticipate seeking a corrective action plan from the third party intermediary to address these deficiencies.

If a submission meets applicable program requirements, such as a submission of data on a single patient to meet a minimum threshold, a third party intermediary may be able to accurately certify that the data it is submitting are true, accurate and complete even if the data does not meet the data completeness threshold for an individual eligible clinician. Data submissions that do not meet appropriate data completeness thresholds will not receive an error message from the system, and will be scored according to the scoring regulations at § 414.1380.

In response to concerns that specialty society clinical data registries do not have the capacity to tell whether a group has specifically submitted false or incomplete data, CMS stated that it is the responsibility of the third party intermediary to validate data prior to submission to CMS and to ensure that the data it submits are true, accurate, and complete to the best of its knowledge. Further, it should be a joint responsibility of the eligible clinician and the third party intermediary to ensure that data submitted to CMS is true and reflective of their scope of practice, while avoiding selection bias.

Regulation Text Changes. To more completely and accurately reference the data available for public reporting on Physician Compare, CMS proposes to amend § 414.1395 by adding paragraph (a)(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 by adding paragraph (a)(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 by adding paragraph (a)(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. Section 1848(q)(9)(D) of the Act requires the Secretary to periodically post on Physician Compare aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. As such, 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). CMS clarifies that some aggregate MIPS data is already publicly available in other places, such as via the [Quality Payment Program Experience Report](#).

Quality. 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

Regulation Text Changes. *CMS finalized these changes to the regulatory text as proposed* ([p. 1689](#)).

Final Score, Performance Categories, and Aggregate Information. *CMS finalized its proposal to publicly report aggregate MIPS data beginning with Year 2 data (CY 2018 data, available starting in late CY 2019), as technically feasible* ([p. 1692](#)).

CMS reiterated that it will statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare to ensure these data are understood and interpreted accurately. In addition, CMS will work to ensure all data publicly reported on Physician Compare is accurate. CMS also clarifies that aggregate data will reflect MIPS eligible clinicians and groups collectively and will not be specialty-specific.

Quality ([p. 1692](#)). While CMS did not summarize or respond to comments, it will take them into account as it develops future policies for public reporting on Physician Compare.

website. CMS will consider stakeholder feedback before proposing any policies in future rulemaking.

Facility-based Clinician Indicator. 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.

Facility-based Clinician Indicator. *CMS finalized these policies as proposed (p. 1699).* CMS again clarified that it will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare, including either on profile pages or the downloadable database and to provide the appropriate context and explanatory text for Medicare patients and caregivers.

[Overview of the APM Incentive \(p. 1700\)](#)

[Terms and Definitions](#)

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 another 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).

CMS is finalizing this proposal. (p. 1702)

[Advanced APMs](#)

Bearing Financial Risk for Monetary Losses. 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

Bearing Financial Risk for Monetary Losses.

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.

Excluded Items and Services under Full Capitation Arrangements. 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?

CMS is finalizing its proposal to amend the definition of expected expenditures without modification. ([p. 1710](#)) Regulation text is at 414.1415(c)(5).

In response to concerns that the proposed definition could lead to a current Advanced APM no longer meeting the expected expenditure nominal amount standard, and therefore no longer being an Advanced APM, CMS notes that while that is possible, all Advanced APMs for CY 2019 that satisfy the current generally applicable nominal amount standard by meeting the expected expenditure nominal amount standard would continue to do so under the proposed amended definition of expected expenditures. ([p. 1710](#))

Excluded Items and Services under Full Capitation Arrangements.

CMS notes that all commenters were supportive of excluding certain items and services from the definition of full capitation arrangements for the purposes of the advanced APM financial risk criterion. They asserted that the exclusion of certain services from the definition of full capitation arrangements for purposes of the Advanced APM financial risk criterion would provide the ability to tailor different APMs to meet the needs of different payers and provider types. The commenters also identified specific items and services such as hospice care, emergency care, or specific high cost pharmaceuticals. CMS notes that it will take these comments into consideration as it considers possible proposals in future rulemaking. ([p. 1712](#))

[Qualifying APM Participant \(QP\) and Partial QP Determinations](#)

- 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?

Application of Partial QP Status. 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. 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. 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

Application of Partial QP Status. *CMS is not finalizing the proposed policy.* (p. [1716](#)).

After making its proposal, CMS further investigated system requirements and determined that it would not be able to modify its system to implement the proposed policy, if finalized. CMS will review and consider public comments received, continue to seek stakeholder feedback, and if appropriate, propose policies pertaining to Partial QPs in future rulemaking. (p. [1715](#))

CMS includes burden estimates as follows:

- [Table 106](#) provides estimated burden for Partial QP elections
- [Table 107](#) provides the change in estimated burden for Partial QP elections

QP Performance Period. *CMS is finalizing its proposed policies without modification.* (p. [1721](#))

In response to comments expressing concern about the short window of time between the termination from the Advanced APM and the reporting deadlines required for reporting to MIPS, CMS notes that it has consistently maintained that participants in Advanced APMs may be considered MIPS eligible clinicians and that they may need to report to MIPS, depending on whether they attain QP or Partial QP status. CMS encourages individual eligible clinicians who are advanced APM participants to check their QP or Partial QP status throughout the year online, and to communicate with their APM Entities in case there are any changes at the APM Entity Level that may affect whether they will need to report to MIPS. (p. [1720](#))

[All-Payer
Combination Option](#)

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.

Aligned Other Payer Medical Home Models. CMS reiterates its proposal discussed above to add the defined term “Aligned Other Payer Medical Home Model.”

As noted in the discussion on terms and conditions, CMS is finalizing without modification its proposal to define the term “Aligned Other Payer Medical Home Model.” ([p. 1733](#))

In response to comments, CMS provides a rationale for not expanding the term to include other payer payment arrangements that are not aligned with a CMS multi-payer model on [p. 1732](#).

Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models. Under current regulations, an Other Payer Advanced APM is another 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 to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models.

Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models.
CMS is finalizing its proposal that the CEHRT criterion at 414.1402(b) and the use of quality measures criterion at 414.1402(c) will apply to any Aligned Other Payer Medical Home Model for which CMS will make an Other Payer Advanced APM determination. ([p. 1734](#))

CMS discusses its proposal to apply the 50 eligible clinician limit later in the rule.

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 also addresses the applicable financial risk and nominal amount standards in this discussion later in the rule.

Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status. 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, to be effective January 1, 2020, for applications for the 2021 QP Performance Period. 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 the Remaining Other Payer process that CMS finalized in the CY 2019 PFS final rule.

Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status.

CMS is finalizing its proposals without modification. ([p. 1735](#))

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.

Bearing Financial Risk for Monetary Losses

Aligned other Payer Medical Home Model Financial Risk and Nominal Amount Standards: 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 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, based on failure to meet or exceed one or more specified performance standards. CMS also proposes that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models.

Generally Applicable Other Payer Advanced APM Nominal Amount Standard

Marginal Risk: 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.

Expected Expenditures: 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.

Bearing Financial Risk for Monetary Losses.

Aligned other Payer Medical Home Model Financial Risk and Nominal Amount Standards:

CMS is finalizing its proposals without modification. (p. 1739)

In response to concerns about applying the 50 eligible clinician limit, CMS notes that, as a general principle, CMS aligns policies pertaining to the Advanced APM and the Other Payer Advanced APM criteria to the extent feasible and appropriate. (p. 1739)

Generally Applicable Other Payer Advanced APM Nominal Amount Standard

Marginal Risk: ***CMS is finalizing its proposal without modification (p. 1744).*** CMS provides an example of how the average marginal risk rate would be calculated in [Table 65](#).

Expected Expenditures: ***CMS is finalizing its proposal without modification (p. 1749).*** In response to concerns around burden, CMS clarifies that demonstrating compliance with this requirement should require only a minimal amount of analysis, if any, on the part of the payer or clinicians. (p. 1749)

Excluded Items and Services under Full Capitation Arrangements: 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?

Excluded Items and Services under Full Capitation Arrangements: CMS notes that it appreciates the comments submitted and will take them into consideration for any potential future rulemaking on this issue. ([p. 1751](#))

[Information Collection Requirements and Impact Estimates](#)

CMS adjusts currently approved burden estimates based on updated projections for the 2020 MIPS performance period. See below tables for details.

- [Table 108](#): Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process
- [Table 109](#): Change in Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process
- [Table 110](#): Estimated Burden for the Submission of Data for All-Payer QP Determinations
- [Table 111](#): Change in Estimated Burden for the Submission of Data for All-Payer QP Determinations

Overall, CMS estimates that between 210,000 and 270,000 eligible clinicians will 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 \$535 and \$685 million for the 2022 payment year. ([p. 1928](#))

CMS lists the APMs that are expected to be Advanced APMs for the 2020 QP Performance Period ([p. 1929](#)), 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); and
- Medicare Shared Savings Program (Track 2, Basic Track Level E, and the Enhanced Track)

Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS codes G2082 and G2083) (p. [1762](#))

On March 5, 2009, the U.S. Food and Drug Administration (FDA) approved Spravato (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). After reviewing the Spravato Prescribing Information, Medication Guide, and REMS requirements, CMS concluded that effective and appropriate treatment of TRD with esketamine requires discrete services of a medical professional, meaning those that may furnish and report E/M services under the PFS, both during an overall course of treatment and at the time the drug is administered.

To avoid delays in beneficiary access and to facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, ***CMS is creating two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For CY 2020, CMS is establishing RVUs for these services that reflect the relative resource costs associated with the evaluation and management (E/M), observation and provision of the self-administered esketamine product using HCPCS G codes.***

CMS has historically established coding and payment on an interim final basis for truly new services when it is in the public interest to do so. Like most other truly new services, CMS expects diffusion of this kind of treatment into the market will take place over several years, even though we expect some people to benefit immediately. Consequently, the expected impact on other PFS services is negligible for 2020, and CMS will consider the public comments received on this interim final policy as it considers finalizing coding or payment rules for this treatment beginning in 2021.

The HCPCS G-codes are described as follows:

- HCPCS code G2082: Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.
- HCPCS code G2083: Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation.

For the overall E/M and observation elements of the services, ***CMS is incorporating the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212. CMS is also incorporating CPT codes 99415 and 99416, which include direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner. Finally, CMS is incorporating the wholesale acquisition cost (WAC) data from the most recent available quarter for the cost of the provision of the self-administered esketamine. For HCPCS code G2082, CMS is using a price of \$590.02 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, CMS is using a price of \$885.02 for the supply input describing 84 mg of esketamine (supply code SH110).***

COMMENT: In the future, CMS anticipates using ASP or WAC data, but seeks comments on how to best establish input prices for the esketamine product, as well as other potential self-administered drugs that necessitate concurrent medical services, under PFS ratesetting. In addition to seeking comment on the interim final values for HCPCS codes G2082 and G2083, CMS also seeks comment on the assigned work RVUs, work times, and direct PE inputs.

Topic	Proposed Rule	Final Rule
Waiver of Proposed Rulemaking for Provisions	CMS finds that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the urgent need of some Medicare beneficiaries for effective treatment for TRD, a serious and life-threatening condition. CMS is providing a 60-day public comment period.	