hfma
healthcare financial management association

Physician Fee Schedule Final Rule and Interim Final Rule for 2020
Summary Part I - [CMS-1715-F and IFC]

Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; 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; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule

On November 1, 2019, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2020[1] and other revisions to Medicare Part B policies. Policies in the final and interim final rule will generally go into effect on January 1, 2020, unless otherwise specified. The final and interim final rule is scheduled to be published in the November 15, 2019 issue of the *Federal Register*.

The 60-day comment period for the interim final rule ends at close of business on December 31, 2019.

HPA is providing a summary in two parts. Part I covers sections I through III.J of the final rule and the interim final rule. This includes payment policies under the PFS; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; establishment of an Ambulance Data Collection System; 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. The interim final rule covers policies related to the administration of esketamine. Part II will cover the updates to the Quality Payment Program (QPP).

Table of Contents for Summary Part I (Sections I through III.J and IV of the Final Rule and the Interim Final Rule)

[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

I. Introduction

The final rule updates the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities. The final rule includes policies, for implementation in 2021, the AMA RUC-recommended values for the office/outpatient E/M codes. The final rule also finalizes policies related to care management services, including the Principal Care Management (PCM) service.

The final rule includes policies to implement section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) which authorizes a new Medicare benefit for opioid use disorder (OUD) treatment services furnished by Opioid Treatment Programs (OTPs). The new statutory provision defines OUD treatment services and OTPs and establishes a bundled payment for OUD treatment services. The final rule also includes policies to implement section 50203(b) of the Balanced Budget Act (BBA) of 2018 which requires ground ambulance providers of services and suppliers to submit cost and other information.

The conversion factor (CF) for 2020 is $36.0896, which reflects the 0.00 percent update adjustment factor specified under the BBA of 2018 and a budget neutrality adjustment of 0.14 percent (2019 conversion factor of $36.0391*1.00*1.0014). The 2020 anesthesia conversion factor is $22.2016, which reflects the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for anesthesia specialty.

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. CMS attributes specialty impact changes to increases/decreases in value for particular services based on recommendations from the AMA RUC Committee and CMS review, updates to supply and equipment pricing for certain codes, and the continued implementation of the adjustment to indirect PE allocation for some office-based services (primarily behavioral health specialties).

On a specialty-specific basis, CMS estimated that the combined impact of the finalized policies range from an increase of 4 percent for clinical social worker, increase of 3 percent for clinical psychologist, increase of 2 percent for podiatry, to a decrease of 4 percent for ophthalmology, a decrease of 3 percent for diagnostic testing facility, and a decrease of 2 percent for cardiac surgery, neurology, optometry, and vascular surgery.

II. Provisions of the Final Rule for PFS

A. Background

Since January 1, 1992, Medicare has paid for physician services under section 1848 of the Act, "Payment for Physicians' Services." The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP) for each service. These relative values are adjusted for geographic cost variations, as measured by geographic practice cost indices (GPCIs). The summation of these relative values or relative value units (RVUs) are multiplied by a conversion factor (CF) to convert them into a payment rate. This background section discusses the historical development of work, practice expense, and malpractice RVUs, and how the geographic adjustment and conversion factor are used to determine payment. The basic formula is the following:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU MP x GPCI MP)] x CF

B. Determinations of Practice Expense (PE) Relative Value Units (RVUs)

1. Practice Expense Methodology

CMS summarizes the history of the development of PE RVUs, the steps involved in calculating direct and indirect cost PE RVUs, and other related matters.

For 2020, CMS makes note of several issues in this section.

CMS has incorporated the available utilization data for two new specialties: medical toxicology and hematopoietic cell transplantation and cellular therapy.[2] CMS finalizes its proposal to use proxy practice expense per hour (PE/HR) values for these new specialties by crosswalking the PE/HR from specialties that furnish similar services in the Medicare claims data. Medical toxicology will use PE/HR data from emergency medicine, and hematopoietic cell transplantation and cellular therapy will use PE/HR data from hematology/oncology. The relevant PE/HR data can be found in the 2020 PFS Final Rule PE/HR file published on CMS' website.[3]

CMS finalizes its proposal, with modifications, to clarify the expected specialty assignment for a series of low volume cardiothoracic services that had been incorrectly assigned a crosswalk to the cardiac surgery specialty instead of thoracic surgery. CMS finalizes the 91 affected codes for which CMS proposed to change its expected specialty to thoracic surgery are show in Table 1 in the final rule (page 27 of the display copy). In response to a comment, CMS added 112 codes that generally fell into two categories – codes with a restricted coverage statue ("R") or codes that exceed 100 services in the claims data, and thus did not meet its criteria for low volume status CMS. CMS states that it added the codes to the list in the interest of maintaining payment stability, such as if they were to fall below 100 annual services at a future date, then an expected specialty would be assigned. CMS also changed the expected specialty for CPT code 96571 changing it to Pulmonary Disease.

The complete list of expected specialties assignments for individual low volume services (2,194 codes) can found on CMS' website.[4] CMS is following its approach finalized in 2018. Under this approach, CMS uses the most recent year of claims data to determine which codes are low-volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). Instead of assigning specialty mix based on the specialties reporting the services in the claims data, CMS assigns an expected specialty based on input from the RUC and other stakeholders. Services for which the specialty is automatically assigned based on previous policies (such as "always therapy" services) are unaffected by the list of expected specialty assignments. These service-level overrides also apply for both PE and MP calculations.

With respect to the formula for calculating equipment cost per minute, CMS notes that it currently uses an equipment utilization rate assumption of 50 percent for most equipment (90 percent for expensive diagnostic imaging equipment as required by statute). Stakeholders have suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce this rate. As it has stated in the past, CMS continues to believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate. CMS welcomes submission of data that

[2] These became recognized Medicare specialties in 2018.
[3] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-PEHR.zip
[4] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Specialty-Assignment.zip. CMS applied the override to 1,657 of the codes in 2020.

would justify an alternative equipment utilization rate. In addition, CMS also notes that the annual maintenance factor used in the equipment calculation may not be precisely 5 percent for all equipment. In the absence of an auditable, robust data source, CMS does not believe it has sufficient information to justify a variable maintenance factor, though it continues to investigate ways of capturing such information.

2. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. CMS believes this will increase the transparency of the information used to set PE RVUs, facilitate the identification of exceptions to the usual values, provide greater consistency among codes that share the same clinical labor tasks, and improve relativity of values among codes. In addition, CMS notes the advantage that as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

CMS notes, as in previous years, that it will continue to display two versions of the Labor Task Detail public use file to facilitate rulemaking for 2020: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

b. Equipment Recommendations for Scope Systems

CMS states that during its routine reviews of direct PE input recommendations, it has regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. It has been exploring this issue since 2017 and has repeatedly expressed its desire to standardize the description of scopes and its pricing. In 2019, CMS delayed proposals for any further changes to scope equipment until 2020, so that it could incorporate feedback from a RUC workgroup: the Scope Equipment Reorganization Workgroup.

The Scope Equipment Reorganization Workgroup submitted detailed recommendations to CMS for consideration for 2020, describing 23 different types of scope equipment, the HCPCS associated with each scope type, and invoices for scope pricing. Using this information, CMS proposed to establish 23 new scope equipment codes (Table 6 in the final rule). For the eight new scope items where invoices were submitted for pricing, CMS proposed to replace the existing scopes with the new scope equipment. In response to comments, CMS received additional invoices and comments that clarified the relationship between former scope equipment codes and the newly created scope equipment codes. Table 8 from the final rule and reproduced below shows the final 2020 new scope equipment code and pricing. CMS welcomes additional invoices in future cycles to establish individual pricing for these codes and continues to welcome more data to help identify pricing for the remaining 7 scope equipment codes that lack invoices.

CMS also modified the description of some equipment items; for example, changed the name of the ES071 scope from "rigid scope, hysteroscopy" to "rigid scope, channeled, hysteroscopy." It also finalizes a price of $6,795 for the ES071 scope based on the pricing data submitted, and finalized the replacement of the existing "endoscope, rigid, hysteroscopy" (ES009) scope with the new ES071 scope equipment.[5]

Table 8: Final CY 2020 New Scope Equipment Codes			
CMS Code	**Scope Equipment Description**	**Proposed Price**	**Finalized Price**
ES070	rigid scope, cystoscopy		
ES071	rigid scope, channeled, hysteroscopy		$6,795.00
ES072	rigid scope, otoscopy		$2,333.98
ES073	rigid scope, nasal/sinus endoscopy		$3,004.75
ES074	rigid scope, proctosigmoidoscopy		
ES075	rigid scope, laryngoscopy	$3,966.08	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy		
ES078	non-channeled flexible digital scope, nasopharyngoscopy		$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy		
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51	$21,485.51
ES081	channeled flexible digital scope, cystoscopy		
ES082	channeled flexible digital scope, hysteroscopy		
ES083	channeled flexible digital scope, bronchoscopy		
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy		$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy		$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound		$0.00
ES092	non-video flexible scope, laryngoscopy	$5,078.04	$5,105.97

Based on recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, CMS finalizes its proposal, with modification, to make this scope replacement for about 100 codes in total (see Table 7 in the final rule). In response to comments, CMS made scope replacement for an additional 21 codes (See Table 9 in the final rule).

[5] This results in a slight increase in the equipment pricing for this item, as the ES009 equipment scope code was previously priced at $6,295.62. The CPT codes affected by this replacement are CPT codes 58555, 58562, and 58565, as well as CPT code 58563 which is the only other code that previously employed the ES009 scope.

c. Technical Corrections to Direct PE Input Database and Supporting Files

For 2020, CMS finalizes its proposals to correct several clerical inconsistencies and make some technical corrections to the direct PE input database:

- CMS finalizes its proposal to remove the non-facility direct PE inputs for CPT codes 43231 and 43232. Based on feedback from gastroenterology specialty societies and its own assessment, these services are never performed in the non-facility setting.

- CMS finalizes its proposal for a series of CPT codes describing nasal sinus endoscopy surgery that these codes should be subject to the special rules for multiple endoscopic procedures instead of the standard multiple procedure payment reduction beginning in 2020. Table 10 in the final rule lists the 27 nasal sinus endoscopy codes subject to the special rules for multiple endoscopy procedures. These would apply if any of these procedures are billed together for the same patient on the same day. CMS also finalizes its proposal that CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)) would be the base procedure. If an endoscopy procedure is reported together with is base procedure, CMS does not pay separately for the base procedure.

  Several commenters requested clarification regarding the application of the bilateral adjustment in conjunction with the special rules for multiple endoscopic procedures. CMS refers readers to the 1992 PFS final rule where this policy was established (56 FR 59515) and to Pub. 100-04, Medicare Claims Processing Manual, Chapter 23.[6] CMS also disagreed with a comments that the nasal endoscopy family differs significantly from other colonoscopy families where the special rule for multiple endoscopic procedures has long been in place.

d. Updates to Prices for Existing Direct PE Inputs

For 2020, CMS finalizes its proposal to update the prices of one supply and one equipment item in response to public submission of invoices. These items included the supply item: Urolift Implant and implantation device (SD291) and the equipment item: CDP-computerized dynamic posturography system (EQ002). CMS also updated the pricing for the ER097 gamma camera system based on the submission of invoices, and because these invoices were submitted as part of a revaluation or comprehensive review of a code family, this updated pricing will be fully implemented immediately for 2020. See Table 29 in the final rule for details on the updated prices, CPT codes affected, and number of services impacted. CMS also updated pricing for existing supply and equipment codes based on additional invoice submissions its received based on the market-based supply and equipment pricing update, as described below.

---

[6] This 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, CMS applies 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, CMS does not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy.

CMS notes that to be included in a given year's proposed rule, it generally needs to receive invoices by February (February 10th deadline in 2020). CMS notes it will, of course, consider invoices submitted during the comment period following the publication of the proposed rule or during other times as part of its annual process.

For 2020, CMS also discussed two additional issues: (1) market-based supply and equipment pricing update and (2) adjustment to allocation of indirect PE for some office-based services (third year of the adjustment).

(1) Market-Based Supply and Equipment Pricing Update

In 2019, CMS initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs for supply and equipment pricing.[7] These supply and equipment inputs had not been systematically examined since 2004-2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. CMS finalized these pricing recommendations with changes to about 70 supply and equipment codes based on comments and feedback.

Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, CMS finalized a policy to phase in its use of the new direct PE input pricing over a 4-year period. CMS implemented this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for 2019, one third of the difference between the 2019 price and the final price is implemented for 2020, and one half of the difference between the 2020 price and the final price is implemented for 2021, with the new direct PE prices fully implemented for 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 11 in this rule (reproduced below).

Table 11: Example of Direct PE Pricing Transition		
Current Price	$100	
Final Price	$200	
Year 1 (2019) Price	$125	1/4 difference between $100 and $200
Year 2 (2020) Price	$150	1/3 difference between $125 and $200
Year 3 (2021) Price	$175	1/2 difference between $150 and $200
Final (2022) Price	$200	

CMS highlights two instances where it will continue to fully implement prices with no transition. This includes (1) new supply and equipment codes for which it establishes prices during the transition years (2019, 2020 and 2021) based on the public submission of invoices, and (2) existing supply and equipment codes, when it establishes prices based on invoices that were submitted as part of a revaluation or comprehensive review of a code or code family

[7]CMS used its authority under section 1848(c)(2)(M) of the Act, as added by the Protecting Access to Medicare Act of 2014 (PAMA) that allows the Secretary to collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS.

CMS highlights two other instances where it phases-in any new or updated pricing over the remaining years of the 4-year transition period. This includes (1) existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which its establishes prices based on invoices submitted by the public, and (2) any updated pricing on very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. CMS notes that it continues to welcome feedback from stakeholders, including the submission of additional invoices for consideration.

For 2020, CMS received invoice submissions for about 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. Based on the review of the invoices, CMS proposed to update the prices of these supply and equipment items. In most cases, CMS found alignment between the prior research carried out by the StrategyGen contractor and the submitted invoice. In those cases, CMS averages the prices from the previous market research and the newly submitted invoices. In other cases, the invoices appeared to be outliers and CMS continues to use its existing pricing. In some instances, CMS adopts the use of the invoice prices as more representative than its 2019 research and pricing.

In response to comments, CMS received additional invoices and suggestions for pricing changes. In several instances, commenters did not support the proposed pricing, but did not submit additional invoices or other pricing data that could be used to support such a change. In other cases, commenters submitted invoices, and CMS incorporated price changes for these items. This includes, among others, the following items,

- CMS updated the supply price of the percutaneous neuro test stimulation kit (SA022) supply from $114.52 to $413.24 based on a review of 481 paid invoices. CMS also agreed with commenters that the proposed price had failed to incorporate all of the components of the test kit. CMS phases in these price changes; the equipment price used in the PE calculations for 2020 for this item is $366.83.
- CMS updated the price of the "plasma LDL adsorption column (Liposorber)" (SD186) from $752.40 to $1,118.06 based on a commenter's submission of all U.S. customer invoices from a three month period.

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period is available on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Market-Based-Supply.zip.

(2) Adjustment to Allocation of Indirect PE for Some Office-Based Services

As background, CMS allocates indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting, and thus indirect PE RVUs allocated to these services are higher

in the nonfacility setting than in the facility setting. In cases where direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting. In 2018, CMS finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services (mostly behavioral health services). CMS refers readers to the 2018 PFS final rule (FR 52999 through 53000) for a discussion of this revised methodology. CMS first began implementing this modification in 2018, the first year of a 4-year transition.

For 2020, CMS finalizes its proposal to continue with the third year of the transition of this adjustment to the standard process for allocating indirect PE. There are 48 codes affected by this policy, and the list is available on CMS' website.[8]

C. Determination of Malpractice Relative Value Units (MP RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and MP expense. By way of background, the resource-based formula to determine the MP for a given service is comprised of three major components: (1) specialty's risk factor, (2) specialty weight—or the mix of practitioners providing the service—compared to all other specialties, and (3) work value for the service.[9] In 2015, CMS implemented the third comprehensive five-year review and update of MP RVUs, which updated each specialty's risk factor based upon updated insurance premium data. In 2016, CMS finalized a policy to conduct annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data) and to adjust MP RVUs for intensity and complexity (using the work RVU or clinical labor RVU). CMS also finalized a policy to modify the specialty mix assignment methodology by using an average of the 3 most recent years instead of the most recent year of data.

In 2018, CMS proposed to use the MP premium data (collected as part of the GPCI update) to update the specialty risk factors used in the calculation of MP RVUs prior to the next 5-year update (2020). After consideration of comments and differences it observed in raw rate filings and how those data were categorized to conform to the specialty risk factors, CMS did not finalize its proposal.

For 2020, CMS is conducting the statutorily required 3-year review of the GPCIs, which coincides with the statutorily required 5-year review of the MP RVUs. CMS notes that the MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of the MP RVUs. CMS would like to align these updates given the common source of data.

[8] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Alt-Methodology-Indirect-PE.zip

[9] The specialty risk factors are intended to capture differences in the risk of professional liability and the cost of malpractice claims faced by different specialties. The specialty weight and work value for a given service allows for differences in the risk of professional liability and cost of malpractice claims to be allocated to a particular service.

Thus, CMS finalizes its proposal to review, and if necessary, update the MP RVUs at least every 3 years, similar to its review and update of the GPCIs. CMS did not receive any specific comments on this proposal. CMS would conduct the next statutorily-mandated review and update of both the GPCI and MP RVU for implementation in 2023.

For 2020, CMS also finalizes its proposal, with minor modifications, to implement the fourth comprehensive review and update of MP RVUs. In brief, CMS makes the following changes:

- CMS finalizes its proposal to download and use a broader set of filings from the largest market share insurers in each state, beyond those listed as "physician" and "surgeon" to obtain a more comprehensive data set.
- CMS is not finalizing its proposal to combine minor and major surgery premiums when both are delineated on rate filings for a specialty nor is it finalizing its proposal to use a physician work RVU of 5.00 as a threshold to identify surgical services as major or minor surgery. Instead, CMS finalizes a policy to develop risk factors by maintaining the current methodology to only use major surgery premium data when both minor surgery and major surgery are delineated on rate filings for a specialty, and to use the minor surgery premium data when it is the only premium type in the rate filings for a specialty.
- CMS also finalizing a policy to map risk factors for cardiac electrophysiology to the risk factor for cardiology (surgery) and cardiology (no surgery). It finalizes its proposal to assign the risk factor of the lowest physician specialty (allergy/immunology) to TC-only services, which is a risk factor of 1.00.
- CMS finalizes a policy to maintain assigning the current risk factor of the lowest physician specialty (allergy/immunology), which is a risk factor of 1.00 to nonphysician practitioner specialties.
- CMS also finalizes its proposal to include an additional column on the anticipated low volume specialty list which specifies if a service was identified as a low volume service for 2020, indicating if the service-level override was being applied for 2020.
- Lastly, CMS finalizing its proposal to treat excluded specialties in a consistent manner for the purposes of calculating MP RVUs.

The detailed methodology for the revision and summary of comments received is discussed below.

2. Methodology for the Revision of Resource-based Malpractice RVU

a. General Discussion

CMS calculated the MP RVUs using updated malpractice premium data obtained from state insurance filings. The methodology CMS finalized for the 2020 review and update largely parallels the approach CMS used in the 2015 update. CMS is incorporating several methodological refinements as described below, largely to ensure that as much data are used in the calculations, as possible. CMS uses four data sources in their calculation of MP RVUs: malpractice premium data in effect as of December 31, 2017; 2018 Medicare payment and utilization data; higher of the 2020 work RVUs or the clinical labor portion of the direct PE RVUs; and 2019 GPCIs.

Malpractice premium data were obtained from the insurers with the largest market share in each state and was collected from all 50 states and the District of Columbia. Malpractice premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies.
Premium data were included for all physicians and nonphysician practitioner specialties, and all risk classifications that were available in the rate filings.

b. Methodological Refinements
CMS finalized certain methodological improvements that will expand the specialties and the amount of filings data used to develop the risk factors. In previous updates, CMS excluded premium data from a large number of states (at least 35) because not all specialties had distinct premium data in the rate filings.

For the 2020 update, CMS proposed the following methodological improvements, two of which CMS finalized, as proposed.

(1) Downloading and using a broader set of filings from the largest market share insurers in each state, beyond those listed as "physician" and "surgeon" to obtain a more comprehensive data set. Commenters were supportive of this change, and CMS finalized, as proposed.

(2) Combining minor surgery and major surgery premiums to create the surgery service risk group. In the previous update, only premiums for major surgery were used in developing the surgical risk factor. Commenters expressed concern with the method CMS used to classify surgeries as either minor or major, stating it was arbitrary and inconsistent with other CMS policy and that, in general, such definitions should be developed with a consensus methodology among physician specialties. In consideration of comments, CMS is not finalizing this proposed methodological refinement nor is it finalizing its proposal to use physician work RVU of 5.0 as a threshold to categorize surgical services as major or minor. Instead, CMS will continue to use its current approach that only uses major surgery premium data when both major and minor are delineated in the rating filings, and to use minor surgery premium data, only when minor surgery premium data are delineated in the rate filings for purposes of developing surgical risk factors.

(3) Utilizing partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings. CMS provides an example of how it would impute data for a specialty that is not listed on the insurer's rate filing. For example, if the sleep medicine specialty is not listed on the insurer's rate filing, then the insurer's rate filing for general practice would be matched to the CMS specialty of sleep medicine. CMS believes that these improvements would allow it to utilize as much of the information from the filings as possible instead of discarding that information. While some commenters disagreed with this approach and the proposed specialty mappings, CMS reiterated its desire to create a more comprehensive data set and finalized its proposal, without modification.

CMS also received additional comments, several of which addressed why the specialty of cardiac electrophysiology should remain mapped to the risk factor for cardiology (surgery) and cardiology (no surgery). Several commenters noted that it would not make sense for services like

pacemaker implantation that include placing transvenous wires inside the heart or catheter ablations to treat cardiac arrhythmias inside the heart to receive a non-surgical PLI risk factor. Upon additional review of the submitted comments, CMS is not finalizing its proposal to map cardiac electrophysiology to a risk factor of 1.89, and instead is finalizing the mapping of risk factors for cardiac electrophysiology to the risk factor for cardiology (surgery) and cardiology (no surgery).

c. Steps for Calculating Malpractice RVUs

CMS calculation of the MP RVUs follows the same conceptual specialty-weighted approach used in the 2015 update, along with the methodological improvements. The specialty-weighted approach for the MP RVUs for a given service is based on a weighted average of the risk factors of all specialties furnishing the service. CMS describes the five steps used for calculating the MP RVUs and the changes from the last update.

Step 1: Compute a preliminary national average premium for each specialty

CMS maps insurance rate area malpractice premiums for each specialty to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2013-2017 American Community Survey (ACS) 5-year estimates). This calculation is then divided by the average MP GPCIs across all counties for each specialty to yield a normalized national average premium for each specialty.

Step 2: Developing Distinct Service Risk Groups

CMS determined that there was sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 16 specialties (there were 10 such specialties in the 2015 update). Three of these specialties (general practice, family practice, and OB//GYN) were delineated into surgical, non-surgical, and surgical with obstetrics. All other specialties were assigned a single risk factor that was applied to all services performed by these specialties. These specialties are listed in Table 13 in the final rule (reproduced below, with modification).

Table 13: Specialties Subdivided into Service Risk Groups

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), **Cardiology Electrophysiology (21)**, Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93)
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16)

Note: The specialty of cardiology electrophysiology was not listed in Table 13 in the final rule, but CMS finalized this change based on comments received, as thus was included here for completeness and accuracy.

Step 3: Calculate a risk factor for each specialty

CMS calculates a risk factor for each specialty that reflects the relative differences in national average premiums between specialties. These risk factors are calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the

lowest premium (allergy and immunology). CMS calculates separate risk factors for specialties with multiple service risk groups (i.e., surgical and non-surgical).

CMS assigns a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor. This is the same approach CMS used in the 2015 update.

Table 14 in the final rule shows the risk factors by specialty type and service risk group.[10] CMS notes that it has refined the nomenclature and uses "All" in the table to mean that all services performed by that specialty receive the same risk factor.

Step 4: Calculate malpractice RVUs for each CPT/HCPCS code.
In this step, CMS calculates malpractice RVUs for each CPT/HCPCS code. Using 2018 utilization data, CMS identifies the percentage of services furnished by each specialty for each code. This percentage is then multiplied by each respective specialty's risk factor (as calculated in step 3). The products for all specialties from these calculations are added together to derive the weighted malpractice costs across all specialties furnishing that service. This service specific risk factor is then multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service.

CMS continues to use service level overrides to determine the specialty for low volume procedures for both PE and MP calculations, as finalized in the 2018 PFS final rule (82 FR 53000-53006). The list of codes and expected specialties is available on its website.[11]

Step 5: Rescale for budget neutrality
The final step ensure applies a budget neutrality adjustment. In this adjustment, CMS includes all specialties in its calculation.

The resource based MP RVUs are shown in Addendum B, which is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html

Estimates of the impact on payment can be found in the Regulatory Impact Section (section VI of this final rule and summary). Overall, the impact of these changes was minimal at the specialty level, though changes could be larger for certain services. Emergency medicine is expected to obtain a 1 percent increase in Medicare payments based on the MP RVU changes, and several specialties (chiropractor, dermatology, gastroenterology, neurosurgery, and oral/maxillofacial surgery) are expected to see a 1 percent decrease.

[10] This table is also available for download at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Malpractice-Risk-Factors.zip
[11] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Specialty-Assignment.zip

D. Geographic Practice Cost Indices (GPCIs)

1. GPCI Update

As required by statute,[12] CMS is required to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components: work, PE, and MP. At least every 3 years, CMS is required to review and, if necessary, adjust the GPCIs.[13] If more than 1 year has elapsed since the last date of the last previous GPCI adjustment, the adjustment would be half of the adjustment that otherwise would be made.

Since the previous GPCI update was implemented in 2017 and 2018, CMS finalizes its proposal to phase in 1/2 of the latest GPCI adjustment in 2020. For 2020, CMS the updated GPCI values were based on calculations done by a contractor. More details can be found in the contractor's report "Final Report for the CY 2020 Update of the GPCIs and MP RVUs for the Medicare Physician Fee Schedule."[14]

Each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below.

- The work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average. CMS calculates the work GPCIs using wage data for seven professional specialty occupation categories,[15] adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. By statute, there is a 1.5 work GPCI floor for services furnished in Alaska.[16] CMS finalizes its proposal to use updated BLS Occupational Employment Statistics (OES) data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

- The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. The PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). CMS does not vary the medical equipment, supplies, and other miscellaneous index among physician localities (based on the rationale of a national market) assigning a value of 1.0 to each PFS

[12] Section 1848(e)(1)(A) of the Act.
[13] Section 1848(e)(1)(C) of the Act
[14] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-Final-Report.pdf
[15] CMS does not use physician wages in calculating the work GPCIs as this potentially introduces some circularity since Medicare payments contribute to overall physician wages.
[16] Section 1848(e)(1)(G). In addition, section 1848(e)(1)(E) provides for a 1.0 floor for the work GPCIs, which expired at the end of 2017 and was extended by the BBA of 2018 through 2019. The work GPCIs do not reflect this 1.0 floor since this provision has not been extended for 2020, as of publication of this final rule.

locality. CMS also used updated BLS OES data (2014 through 2017) to calculate the employee wage component and purchased service index of the PE GPCI.

- The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). CMS notes that the 2020 MP GPCI update reflects premium data presumed in effect as of December 30, 2017.

CMS finalizes its proposals to continue using the current cost share weights for determining the PE GPCI values and locality GAFs (last revised in 2014). The GPCI cost share weights for 2020 are displayed in Table 15 in the final rule (reproduced below).

Table 15: Cost Share Weights for 2020 GPCI Update

Expense Category	Current Cost Share Weight	Cost Share Weight
Work	50.866%	50.866%
Practice Expense	44.839%	44.839%
- Employee Compensation	16.553%	16.553%
- Office Rent	10.223%	10.223%
- Purchased Services	8.095%	8.095%
- Equipment, Supplies, Other	9.968%	9.968%
Malpractice Insurance	4.295%	4.295%
Total	100.000%	100.000%

With respect to the PE GPCI floor for frontier states, there are no changes in the states identified as Frontier States for 2020.[17] The qualifying states are: Montana, Wyoming, North Dakota, South Dakota, and Nevada. In accordance with statute, CMS would apply a 1.0 PE GPCI floor for these states in 2020.

In calculating GPCIs for the U.S. territories, CMS currently uses two distinct methodologies—one for Puerto Rico and the Virgin Islands, and a second approach for the Pacific Islands (Guam, American Samoa, and Northern Marianas Islands). As finalized in the 2017 PFS final rule, CMS assigns the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. For the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands), CMS assigns the Hawaii GPCI values for each of the three GPCIs.

2. Calculation of GPCIs in California

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modifies the fee schedule areas used for payment purposes in California beginning in 2017. The statute requires

[17] In general, a frontier state is one in which at least 50 percent of the counties are "frontier counties," which are those that have a population per square mile of less than 6.

that fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined and that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure, although for payment the actual number of localities under the MSA-based structure is 32.[18] CMS refers readers to the 2017 PFS final rule (81 FR 80267) for a detail discussion of this issue.

Those fee schedule areas that were in the rest-of-state locality (as of 2013) and locality 3 (Marin, Napa, and Solano counties) are part of a transition area as defined by statute (section 1848(e)(6)(D) of the Act). As such, GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. These areas will fully transition to MSA-based locality structure in 2022.

Section 1848(e)(6)(C) of the Act also establishes a hold harmless for transition areas beginning with 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas and thus subject to the hold harmless provision. For purpose of calculating budget neutrality, CMS uses an approach consistent with its implementation of the GPCI floor provisions.

3. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of the proposed rule, CMS identified two technical refinements to the methodology that it states yield improvement over the current method. CMS finalizes both improvements.

- CMS finalizes its proposal to weight by total employment when computing county median wages for each occupation code to take into account that occupation wage can vary by industry within a county.
- CMS also finalizes its proposal to use a weighted average when calculating the final county-level wage index—removes the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data.

4. Summary of Comments

Commenters expressed various concerns related to the GPCI methodology. A few commenters expressed concern, for example, over the expiring work GPCI floor of 1.0. CMS notes in response, that this floor is established by statute and is set to expire on December 31, 2019, and thus, CMS does not have the authority to extend this floor beyond that date. Another commenter expressed concern that the GPCIs in Hawaii do not account for the unique costs of providing medical services in this state. In particular, the commenter stated that the high costs of shipping equipment play a major part in the high cost of health care in Hawaii and the PE values should reflect that additional costs. CMS notes that it had previously attempted to locate date sources

[18] The total number of physician localities is 112 payment localities – 34 statewide areas (one locality for the entire state) and 75 localities in the other 16 states.

specific to geographic variation in shipping costs and found no comprehensive national data source for this information. It encourages commenters and other stakeholders to submit data supporting this assertion for consideration in future rulemaking.
Commenters also brought two issues to CMS' attention that resulted in corrections in the final rule. First, several commenters note consistent discrepancies in county rent indices delineated in the county-level public use file for New England states as compared to the rest of the country. CMS acknowledged that it identified an issue with the data in New England where the raw data values were defined at the sub-county areas in New England but were summarized to the county-level in the development of the 2020 GPCI values. CMS corrected this issue in the final rule but notes that the corrected mapping had virtually no effect on the resulting work, PE, and MP GPCIs and the GAFs. Second, a commenter indicated that CMS did not accurately implement the California MSA-based structure in the 2020 PFS proposed rule consistent with the methodology finalized in 2017 based on the statutory requirements. CMS agrees with the commenters that there were issues with the calculation of the GPCI values reflected in the 2020 PFS proposed rule for California. CMS made errors in how it aggregated data to the MSA-based localities and a programming error that led to issues in establishing accurate transition values and applying the hold harmless provision. Correcting these issues led to GAFs that are higher in all but three of the 32 payment localities in California. CMS also acknowledged that it inadvertently used the 2016 utilization data in the calculation of the work and PE GPCIs (instead of the 2017 utilization data), which it has corrected in the final rule.

5. GPCI Update Summary

The 2020 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to the final rule. This is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html

E. Potentially Misvalued Services under the Physician Fee Schedule

1. CY 2020 Identification and Review of Potentially Misvalued Services

a. Public Nominations
Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the RVUs for these services.

In the 2012 PFS final rule (76 FR 73058), CMS finalized a process for the public to nominate potentially misvalued codes.[19] The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. CMS reviews the information and in the following year's PFS proposed rule, publishes a list of nominated codes and indicates whether it is proposing the code as a potentially misvalued code. CMS finalizes its list of potentially misvalued codes in the final rule.

[19] CMS notes that since 2009, the annual potentially misvalued code review and Five-Year Review process has resulted in the review of about 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs

CMS received three submissions that nominated codes for review under the potentially misvalued code initiative.

- CPT code 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and CPT code 10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion). The commenter raised several concerns with these codes. For example, the commenter disagreed with the one-third reduction from its previous physician time and the 5 percent reduction in the work RVU for CPT 10021 stating that there was a change in intensity. CMS notes, in response, that these codes were recently reviewed within a family of 13 similar codes and refers the readers to its discussion in the 2019 PFS final rule (83 FR 59517). In response to comments, CMS states its belief that refinements to the valuations for these services continue to be valid, as no compelling information has been presented.

- HCPCS code G0166 (External counterpulsation, per treatment session). This code was also reviewed in the 2019 PFS final rule (83 FR 59578) and the work and direct PE inputs, as recommended by the AMA RUC, were finalized by CMS. The commenter states its concern that the PE inputs did not reflect the total resources required to deliver the service. CMS states that it will review the new data and prior public comments received on this code. With respect to this code, CMS states in response to comments that it will review the AMA RUC's forthcoming recommendations and will consider any refinements through its rulemaking process for 2021.

CMS also nominated one code for review.

- CPT code 76377 (3D rendering w/interpretation post process). CMS highlights that a similar code (CPT code 76376) was recently reviewed by the AMA RUC at the April 2018 meeting. While the specialty societies argued that the two codes are different because they are utilized by different patient populations, CMS views both codes to be similar enough that CPT code 76377 should be reviewed to maintain relativity in the code family. One commenter did not necessarily agree that code 76377 was necessarily similar to code 76375, as it has different clinical indications, different patients, different complexities in work as well resources and equipment. CMS notes in its reply that it will make a determination of their similarities.

In summary, CMS is including CPT code 76377 and HCPCS code G0166 on its final list of potentially misvalued codes for 2020. CMS is not including CPT codes 10005 and 10021 on its final list of potentially misvalued codes for 2020.

b. Other Comments

Another commenter provided information to CMS that stated the work involved in furnishing services represented by the office/outpatient evaluation and management (E/M) code set (CPT code 99201-99215) have changed sufficiently to warrant reevaluation. CMS notes, in response, that it agrees in principle, that these codes may not be correctly valued and notes the changes it has made in examining these codes. This has included change to E/M payment and documentation requirements implemented in the 2019 PFS final rule, as well as other changes.

CMS refers readers to section II. P of this final rule where it discusses these codes in detail.

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

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services from the Medicare telehealth list. CMS assigns requests to two categories: Category 1 and Category 2. Category 1 services are similar to services that are currently on the telehealth list. Category 2 services are not similar to services on the telehealth list and CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part. Requests to add services must be submitted and received by February 10, 2020 to be considered for the next rulemaking cycle. Additional information for submitting a request is available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

CMS did not receive any requests from the public for additions to the Medicare Telehealth list for 2020. CMS proposed to add three HCPCS G-codes related to treatment for opioid use disorder - new services being proposed in this year's rule – which it believes are sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Specifically, CMS believes that the psychotherapy portions of the bundled codes are similar to the psychotherapy codes described by CPT codes 90832 and 90853, which are currently on the list. CMS notes that it does not need to consider whether the non-face-to-face aspects of these HCPCS G-codes are similar to other telehealth services as the care coordination aspects of these codes are commonly furnished remotely using telecommunication technology, and do not require the patient to be present in-person with the practitioner when they are furnished.

CMS finalized its proposal to add the face-to-face portions of these three services to the list:

- HCPCS code G2086: 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.
- HCPCS code G2087: 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.
- HCPCS code G2088: 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 believes that the addition of these codes will complement the existing policies related to flexibilities in treating SUDs under Medicare telehealth. The majority of commenters supported its proposal to add these codes to the Medicare telehealth list.

G. Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

CMS finalizes its proposals (with several modifications described below) to implement section 2005 of the SUPPORT Act. Under section 2005, a new Medicare benefit for OUD treatment services furnished by OTPs was authorized for services beginning January 1, 2020. The SUPPORT Act defines opioid use disorder treatment services and opioid treatment programs, establishes a bundled payment for opioid use disorder treatment services and includes OTPs as Medicare providers for the purposes of furnishing opioid use disorder treatment services.

As proposed, CMS adds new section 42 CFR §410.67 to incorporate those SUPPORT Act provisions into Medicare rules. Finalized provisions define OUD treatment services and OTPs and establish a methodology for determining Medicare payment for OTP services.

Under regulations that existed prior to the SUPPORT Act, OTPs are able to obtain federal accreditation and certification if they meet certain standards including providing OUD treatment services that are consistent with the Substance Abuse and Mental Health Services Administration (SAMSHA) standards described in 42 CFR §8.12.

2. Definitions

Opioid use disorder treatment services (§410.67(b)). CMS finalizes the following items as proposed in its definition for OUD treatment services:

A. Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) for use in treatment of opioid use disorder.
B. Dispensing and administration of such medications, if applicable.
C. Substance use counseling by a professional to the extent authorized under State law to furnish such services including counseling services and individual and group therapy services furnished via a two-way interactive audio-video communication consistent with Medicare's telehealth benefit.
D. Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law.
E. Toxicology testing.

CMS sought comments on other items and services currently covered under Medicare Part B that should be added to this definition. In response commenters' recommendations, CMS adds two new services to the finalized definition of OUD treatment services:

F. Intake activities including the initial medical examination as required under 42 CFR §8.12(f)(2) and initial assessment services required under §8.12(f)(4). CMS notes in the preamble that these activities include preparation of a treatment plan.
G. Periodic assessments as required under 42 CFR §8.12(f)(4).

In response to questions about the mental health professionals who may furnish counseling and therapy services, CMS notes that the statute permits OUD treatment to be provided by "a professional to the extent authorized under State law to furnish such services." As a result, the final rules do not limit reimbursement for these services to only those professionals who are permitted to bill Medicare directly. Instead professionals providing OUD treatment services can include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists if authorized to do so under state law.

In response to comment, CMS clarifies that the reference to toxicology testing at §410.67(b)(5) includes both presumptive and definitive testing and incorporates all types of toxicology testing used for diagnosing, monitoring and evaluating the progress in OUD treatment. CMS notes that other toxicology tests unrelated to OUD at an OTP may be paid separately under the CLFS if reasonable and necessary and would not be part of the bundle for OUD treatment services.

CMS explains that the FDA has so far approved three drugs for the treatment of opioid dependence: buprenorphine, methadone, and naltrexone. It describes the properties and usual dosages for each. It sought comment on how medications that may be approved by the FDA in the future should be considered and included in the definition of OUD treatment services. In response to a suggestion, CMS notes that it will consider comments relating to authorizing additional drugs in future rulemaking.

Likewise, in response to a long list of additional services that commenters recommended be included in the OUD treatment services definition, CMS declines to add more at this time, but notes that as it gains experience with this benefit, it will consider additional changes.

Opioid Treatment Program (§410.67(b)). CMS adopts, as proposed, the definition for an opioid treatment program. The definition (1) incorporates existing SAMSHA regulations defining those services at 42 CFR §8.2 and (2) includes the following additional requirements for OTPs to participate in the Medicare program. An OTP must:

- Be enrolled in the Medicare program;
- Be certified by SAMSHA;
- Be accredited by an accrediting body approved by SAMHSA; and
- Have a Medicare provider agreement in place.

Under existing SAMSHA rules, to be certified by SAMSHA, OTPs must provide the following services:

- General services including medical, counseling, vocational, educational, and other assessment and treatment services;
- Initial medical examination services;
- Special services for pregnant patients including, for example, prenatal care and other gender specific services provided either by the OTP or by referral to appropriate providers;
- Initial and periodic assessment services to determine the most appropriate combination of services and treatment;
- Counseling services; and

- Drug abuse testing services, including at least eight random drug abuse tests per year, per patient in maintenance treatment. For patients in short-term detoxification treatment, at least one initial drug abuse test is required and for patients in long-term detoxification treatment, initial and monthly random tests are required.

Other SAMHSA requirements for OTPs include maintenance of a recordkeeping system; ensuring medications are administered by licensed, qualified practitioners; limiting the potential for diversion of take-home drugs; addressing administrative and organizational structure; establishing procedures for patient admission, quality assurance and staff credentialing; and those related to medication administration, dispensing and use. SAMHSA certification also requires that OTPs comply with all applicable state laws and regulations; allow for inspections and surveys by SAMHSA officials, accreditation bodies, the DEA, and other authorized state or federal authorities; comply with confidentiality requirements in 42 CFR Part 2 and with other Drug Enforcement Administration regulations; and operate in accordance with federal opioid treatment standards and accreditation elements.

CMS finalizes its proposals for OTP conditions of participation and provider agreements at §410.67(c), with one modification to the effective date of the provider agreement, as follows:

- OTPs must meet conditions of participation applicable to Medicare providers.
- OPTs must have in effect a Medicare provider agreement under 42 CFR part 489 of this title.

The effective date of the provider agreement is the date on which CMS accepts a signed agreement (finalized in §489.13(a)(2)). In cases where the conditions in §424.520(d) and §424.521(a) are met, retrospective billing dates are permitted. With respect to retroactive billing, in the final rule, CMS includes this rule in a new §489.13(a)(2)(iii) instead of in each of §424.520(d) and §424.521(a) as proposed.

Episode of Care. An episode of care is defined as one week or 7 continuous days of treatment.

Partial Episode of Care. CMS does not finalize its proposed definition of a partial episode of care. This decision is described more fully below.

3. Bundled Payments for OUD Treatment Services (§410.67(d))

The SUPPORT Act directed CMS to pay an OTP 100% of the bundled payment for Medicare OUD treatment services during an episode of care beginning January 1, 2020. In developing payments for those services, it permits the Secretary to consider TRICARE and Medicaid payments for those services. In the preambles to the proposed and final rules, CMS reviews TRICARE payments for OUD treatment services and describes some of the approaches that state Medicaid programs use for payment for OUD treatment services.

Duration of bundle. CMS finalizes its proposal that an episode of care for OUD treatment services is one week – or a contiguous 7-day period. Some commenters recommended a monthly episode of care but CMS believes a weekly episode of care will be less disruptive since most OTPs are generally familiar with, and are able to bill for, 7-day episodes. Commenters

supported CMS's policy to not include a maximum number of weeks for an overall course of treatment for OUD.

As a condition for billing an episode of care, CMS had proposed that an enrollee must receive at least 51% of the services identified in the patient's treatment plan over the course of a week. If they had not received 51% of those services, then the OTP would have been permitted to bill for a partial bundle. CMS declined to finalize the ability to bill for a partial bundle. Many commenters raised concerns and questions about how the 51% of services threshold would be calculated and how various services would count toward the threshold. In response to the complexities and concerns raised, CMS will finalize only the full bundle for which OTPs may bill if they provide at least one service to the patient during the week. CMS believes this lower threshold will minimize barriers to OTPs and notes that it will monitor for abuse.

As proposed, CMS finalizes two types of payment bundles: (i) A payment bundle with both a drug component and a non-drug component, and (ii) a non-drug episode of care payment bundle.

Non-Drug Episode of Care. CMS finalizes in §410.67(d)(1)(iii) without change, a non-drug episode of care to reimburse OTPs for non-drug services, including substance use counseling, individual and group therapy, and toxicology testing provided during weeks when a medication is not administered, for example, where a patient is being provided with drug treatment on a monthly basis or has a buprenorphine implant.

Drug component. CMS finalizes its proposal in §410.67(d)(1) to base bundled payment rates for OUD treatment services on the type of medication used for treatment. CMS will use the following categories of bundles as described in the preamble of the proposed rule:

- Methadone (oral)
- Buprenorphine (oral)
- Buprenorphine (injection)
- Buprenorphine (implant)
- Naltrexone (injection)
- A medication not otherwise specified. This category is intended to include new treatments that FDA may potentially approve in the future.

CMS clarifies that the buprenorphine (oral) drug category includes both the buprenorphine-only and the buprenorphine-naloxone products.

As proposed, payment for the drug component will be based on average sales price (ASP) when the ASP is reported. In §410.67(d)(2), CMS finalizes that the drug component of the bundled payment amount for implantable and injectable medications will be equal to 100 percent of the ASP. For oral medications for which the ASP is submitted, the payment amount will also be equal to 100 percent of ASP. If ASP data are not available, the payment amount must be based on an alternative methodology or invoice pricing until the necessary data become available. CMS plans to use invoice prices until another approach is identified.

Non-drug component. The non-drug component will include payment for the dispensing and administration of medications (if applicable), counseling, individual and group therapy (by those

authorized to provide such services under state law), and toxicology testing. CMS notes that SAMSHA certification standards require OTPs to provide adequate testing or analysis for abused drugs including at least 8 random drug tests per year for patients in maintenance treatment. CMS also notes that the cost of drug dispensing and administration are included in the non-drug component.

Add-on Code. CMS states that it recognizes that under certain circumstances, additional counseling or therapy services that substantially exceed the amount specified in the patient's treatment plan may be necessary. As a result, it proposed an add-on code to describe each additional 30 minutes of counseling or group or individual therapy provided during a week which exceeds the amount specified in the treatment plan and for which medical necessity is documented in the medical record.

In response to comments, CMS finalizes additional add-on codes that were not proposed: for intake activities, periodic assessments, take-home supplies of methadone, and take home supplies of oral buprenorphine. In response to a comments suggesting that CMS include case management or care management services as part of the bundle or as an add-on to the bundle, CMS says that it may consider doing so in future rulemaking. Likewise, CMS may consider additional coding or payment changes with respect to detoxification services in the future.

Site of Service (telecommunications). As noted above, CMS finalizes its proposal to permit OTPs to furnish substance use counseling, individual therapy, and group therapy via two-way interactive audio-video communication technology as clinically appropriate. CMS notes that this provision is parallel to requirements to make certain Medicare services available via telehealth under §410.78(a)(3). CMS received some comments supporting this provision and some comments requesting that it go further to allow other important OUD services to be provided via telecommunications. CMS notes that at this time, it is retaining its proposal to permit substance use counseling and individual and group therapy to be provided via telehealth but may revisit extending this flexibility further in future rulemaking.

Coding and Payment Rates. Table 18, duplicated below, provides the HCPCS G-codes and the corresponding payment rates that CMS finalizes for weekly bundles with drugs, without drugs, for a medication not otherwise specified, and add-on codes for additional counseling or therapy services, intake activities, periodic assessments, take-home supplies of methadone, and take home supplies of oral buprenorphine. CMS notes that the code describing the weekly bundle for a medication not otherwise specified should not be used when the drug is not a new opioid agonist or antagonist approved by the FDA for the treatment of OUD, in which case Medicare is not authorized to make payment.

Payment for Drug Component (§410.67(d)(2)(i)(B)). CMS proposed to calculate the payment for the drug component based on the typical or average maintenance dose for each of the drugs or: a 100 mg daily dose for methadone, a 10 mg daily dose for oral buprenorphine, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone. Commenters raised the concern that the 10 mg dosage for oral buprenorphine was too low, and CMS and some commenters noted that

SAMHSA's TIP 63 and the FDA labeling target a dosage of 16 mg of oral buprenorphine for maintenance treatment. As a result, CMS is finalizing all of the proposed dosages for payment purposes except for the 10mg of oral buprenorphine which will instead be finalized at 16 mg.

CMS proposed to pay for the drug component based on 100% of ASP for those drugs for which ASP is available. Some commenters were opposed to CMS not including the 6% add-on that is currently paid (in addition to 100% of ASP) for most Part B drugs. CMS disagreed with those commenters and finalizes as proposed. For those oral drugs for which ASP data are not available, the payment amount must be based on an alternative methodology or invoice pricing until the necessary data become available. In the proposed rule, CMS identified and requested comment on the following alternative approaches/data sources for setting the prices of drugs for which ASP is not reported:

Alternative Pricing Approaches

Pricing Alternative
Approach 1: The Methodology in Section 1847 of the Act Using WAC or invoice pricing.
Approach 2: Medicare's Part D Prescription Drug Plan Finder Data Set price based on data available in Medicare Prescription Drug Plan finder – for example national average of charged prices. Disadvantage of this approach is that the Plan Finder reflects prices negotiated by larger buying groups and may not adequately reflect the prices that smaller OTP facilities pay to acquire the drug. Does not include methadone since it is not considered a Part D drug.
Approach 3: Wholesale Acquisition Cost Currently used for certain Part B drugs when ASP is not available. May more closely reflect the price paid by an end user when compared with the AWP. Disadvantage is that WAC does not include prompt pay or other discounts, rebates, or reductions in price.
Approach 4: Medicaid's National Average Drug Acquisition Cost (NADAC) Data Data submitted by retail community pharmacies reflect their costs to acquire pharmaceuticals. May be metric closest to ASP; however, it is unclear how closely it reflects acquisition costs for OTPs.
Alternative approach for Methadone only: TRICARE payment

CMS reviews several comments on the alternative approaches and finalizes the following for drugs for which ASP is not reported: CMS will use the TRICARE rate to set the payment for the drug component of the methadone bundle and Medicaid NADAC data to set the payment for the drug component of the oral buprenorphine bundle. CMS notes that, for 2020, it was able to calculate an ASP for methadone using manufacturer reported data, but it did not receive ASP data from buprenorphine oral manufacturers. Therefore, CMS finalizes that the drug component of the oral buprenorphine weekly bundle for 2020 will be priced using NADAC survey data.

Payment for Non-Drug Component (§410.67(d)(2)). CMS proposed to use the TRICARE rates for the non-drug portion of its methadone treatment bundle as the basis for the Medicare payment rates as those amounts were established through notice and comment rulemaking among other reasons. In response to concerns that the TRICARE rates would be too low and access to services would be impacted, CMS finalizes a different approach to pricing the non-drug component. Instead of using TRICARE, CMS will set payment rates using the established rate for similar services under Medicare. CMS points out that this approach, which would rely on rates for similar services under the Medicare PFS, the Medicare CLFS, as well as state Medicaid programs, would be a better reflection of the cost of furnishing services to the

Medicare population. The detailed building blocks for those rates are described in the preamble and the final rates and their building blocks are duplicated below. (Table 18.)

Partial Episode of Care. CMS proposed a methodology for paying for partial episodes of care, but, as noted above, CMS is not finalizing payment for partial episodes of care.

Table 18: OTP Code Descriptors and Payment Amounts

HCPCS	Descriptor	Drug Cost*	Non-Drug Cost**	Total Cost
	Full weeks			
G2067	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$35.28	$172.21	$207.49
G2068	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$86.26	$172.21	$258.47
G2069	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program	$1,578.64	$178.65	$1,757.29
G2070	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,918.98	$407.86	$5,326.84
G2071	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$0	$427.32	$427.32
G2072	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,918.98	$626.97	$5,545.95
G2073	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,164.02	$178.65	$1,342.67
G2074	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare enrolled Opioid Treatment Program)	$0	$161.71	$161.71

HCPCS	Descriptor	Drug Cost*	Non-Drug Cost**	Total Cost
G2075	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	-	-	-
	Intensity Add-on codes			
G2076	Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho- social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$0	$179.46	$ 179.46
G2077	Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$0	$110.28	$ 110.28
G2078	Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$35.28	$0	$35.28
G2079	Take-home supply of buprenorphine (oral); up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$86.26	$0	$86.26
G2080	Each additional 30 minutes of counseling in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$0	$30.94	$30.94

*Methadone drug costs are calculated using ASP data, oral buprenorphine drug costs are calculated using NADAC data, and the other drug costs are calculated using data from the quarterly ASP Drug Pricing Files. The payment amounts in this table are based on data files posted at the time of the drafting of this final rule.

**The non-drug component for the non-drug bundle is based on the sum of the rates under Medicare for the following codes: CPT codes 90832, 90853, 80305, and HCPCS codes G0396 and G0480. For the codes that include oral medications (HCPCS codes G2067 and G2068), we added to that amount the rate for dispensing oral drugs using an approximation of the average dispensing fees under state Medicaid programs, which is $10.50. For the codes that include injectable drugs (HCPCS codes G2069 and G2073), we added to the non-drug bundle amount 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 the codes that include implantable buprenorphine (HCPCS codes G2070, G2071, and G2072), we added the rates under Medicare for the insertion, removal, and insertion/removal of buprenorphine implants (which is $$246.15, $265.61, and $465.26, respectively, based on the CY 2019 non-facility Medicare payment rates for HCPCS codes G0516, G0517 and G0518). The payment rate for HCPCS code G2076 is based on the CY 2019 non-facility Medicare payment rate for CPT code 99204 plus one presumptive toxicology test (CPT code 80305). The non-drug component for HCPCS code G2077 is based on the CY 2019 non-facility Medicare payment rate for CPT code 99214. The payment rate for HCPCS code G2080 is based on the CY 2019 non-facility Medicare payment rate for HCPCS code G2080 when furnished by an NPP. Additionally, the non-drug component of the bundled payment amounts will be geographically adjusted based on the PFS GAF, this adjustment will also be extended to the non-drug component add-on payments as discussed below.

Place of Service Codes for Services Furnished at OTPs. CMS finalizes a new place of service code 58 *(Non-residential Opioid Treatment Facility – a location that provides treatment for OUD on an ambulatory basis. Services include methadone and other forms of MAT).*

Duplicative Payments under Parts B and D (§410.67(d)(4)). CMS proposed to consider payment for medications delivered, administered or dispensed as part of an OTP bundle to be duplicative if it was also separately paid under Medicare Parts B or D. While CMS expects OTPs to take reasonable steps to ensure that items and services furnished under their care are not reported or billed under a Medicare benefit that is not the OTP benefit, CMS will monitor for program integrity and take appropriate action as necessary. CMS will also recoup the duplicative payments.

CMS received a number of comments indicating concern that it would be challenging for community pharmacies to know when a prescription that they are filling is a medication dispensed as part of an OTP bundle. As a result, the duplicative payments policy could create a barrier to beneficiaries receiving their prescriptions when the OTP is prescribing medications via a community pharmacy. CMS restates its mandate under statute that it take steps to ensure that no duplicative payments are being made and notes that it expects that OTPs will take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit. CMS finalizes this proposal with the clarification that the final policy on duplicative payments refers to payment for the same medication for the same beneficiary on the same date of service under a different Medicare benefit.

Cost Sharing (§410.67(e)). CMS finalizes its proposal that beneficiaries have zero copayment. CMS indicates that, as proposed, the zero copayment will be time-limited (for example, lasting through the duration of the national opioid crisis) but that it will address its continuation in future rulemaking. CMS also notes that the Part B deductible applies to OUD treatment services as for all Part B services.

4. Adjustments to Bundled Payment Rates for OUD treatment Services

a. Locality Adjustment (410.67(d)(4)(ii))

CMS notes that the SUPPORT Act gives it the discretion to implement bundled rates based on a number of specified factors (type of medication, frequency of services, scope of services furnished, and characteristics of individuals furnished with services) and to include any other factors that the Secretary determines to be appropriate. Because certain OTP treatment services will be subject to cost differences based on geographic locality, CMS finalizes its proposals to apply a geographic locality adjustment to the non-drug component of the bundled payment rate.

For the drug component, CMS believes that no geographic adjustment factor is necessary because payments for the drug component will be set based on national rates.

For the non-drug component of the bundled rates, CMS finalizes its proposal use the Geographic Adjustment Factor (GAF) described at 42 CFR §414.26 for a locality adjustment. CMS also considered using the Geographic Practice Cost Indices (GPCI) which measures the relative cost differences among localities compared to the national average for each of three fee schedule

components (work, PE, and malpractice) but because the OTP bundled payment is a flat rate, a single factor adjustment is preferred to the three components of the GPCI. CMS also considered using only a single component of the GPCI – the PE GPCI – value but concluded that the GAF is a better approach as it incorporates a composite of the factors that better reflect geographic cost differences. CMS did not propose to do so, but will also apply the GAF-based geographic adjustment to the add-on payment adjustments.

One commenter recommended a 17 percent rural add-on consistent with the existing 17 percent add-on for rural inpatient psychiatric facilities. CMS declines to do so at this time but may consider such an add-on in future rulemaking.

b. Annual update (§410.67(d)(2)(i) and §410.67(d)(4)(iii))
The SUPPORT Act requires the Secretary to update the OTP bundled rates annually. CMS will use a blended annual update reflecting different updates for the drug and non-drug components of the bundled payment rates. The updates will first apply for 2021.

For the drug component, CMS finalizes without change, its proposal to update the rates based on the reported changes in drug costs reflected in the most recently available data from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. CMS considered alternatives, for example a single uniform update factor across both drug and non-drug components of the rates, but rejected that approach because of the importance of recognizing the different rate of growth of drug costs compared to other services.

For the non-drug component, CMS finalizes as proposed, using the Medicare Economic Index (MEI) as it is used to update physicians' services. It considered alternative factors such as the consumer price index and the IPPS hospital market basket reduced by the multi-factor productivity adjustment. Those were rejected because a health-specific update factor was determined to be more appropriate for OTPs and because OTP services are likely to more closely resemble physician services than hospital services.

Although not proposed, CMS finalizes updating the add-on payment adjustments for non-drug services as well. They will be updated using the MEI as described above.

c. Other Comments
CMS responds to a number of other comments, noting in particular, those requesting clarification about how the new Medicare benefit would interact with Medicaid and with Medicare Advantage.

Commenters expressed concerns about the transition between paying for OUD treatment services under Medicaid to payment under Medicare for those individuals dually eligible for the two programs. In particular, some individuals anticipated delays in OTPs enrolling in Medicare in time for the transition on January 1. CMS clarifies that if an OTP is not yet enrolled in Medicare, then Medicaid must continue to pay for OTP services for dually eligible individuals if the service is covered by the state plan. CMS encourages states to reach out to OTP providers to encourage them to begin the Medicare enrollment process as quickly as possible.

With respect to Medicare Advantage plans, CMS clarifies that because the OTP benefit is a Part B benefit, plans must cover it either by establishing direct contracts with OTPs or arranging access on a non-contract basis. CMS also notes that if an enrollee is currently in treatment with an OTP provider, the plan should create a transition process to ensure continuity in care while the plan works with the individual to transition to a network provider. CMS also acknowledges that some state Medicaid programs may cover benefits or services for OUD that are not included in the Medicare OTP benefit. States may, under those circumstances, still provide those additional services to patients being treated for OUD under Medicare.

CMS explains how claims would "crossover" once Medicare starts covering the OTP services (in the case of Medicare fee-for-service claims) and describes the process for when a state is using different billing codes than Medicare. CMS also directs Medicare Advantage plans to the CY 2020 Call Letter released on April 1, 2019 which included guidance on incorporating the OTP services into coverage for 2020. CMS will furnish further guidance to plans on how the new benefit should be recorded in required data submission.

CMS is collaborating with SAMHSA to explore outreach or training on coordination of benefits issues. CMS rejected requests for implementation delays to give plans more time to finalize payment codes and develop operational systems for implementing the benefit, and requests for grace periods with respect to audits or other consequences that may be impacted by the new benefit.

5. Regulatory Impact

CMS increased its estimates of the net impact of coverage of OUD treatment by OTPs compared to the proposed rule to reflect changes in the final rule including the adoption of additional add-on codes. The impact, including FFS Medicare and Medicare Advantage, is estimated to total $1.48 billion over 10 years. CMS assumed that the average length of treatment will be 12 months with an average weekly rate of $220 (compared to $148 in the proposed rule) for 2020. That figure represents a weighted average of the final bundled payment rates for treatment with methadone, buprenorphine, and naltrexone. Those amounts were increased annually by the projected MEI.

H. Bundled Payment Under the PFS for Substance Use Disorder

In the 2019 PFS proposed rule, CMS sought feedback on creating a bundled episode of care to pay for management and counseling treatment of substance use disorder. That feedback informed the proposal finalized in this rule to establish a bundled payment for treatment of OUD that allows physicians and other professionals to bill for a bundle of services that is similar to the new bundled OUD treatment benefits provided by OTPs (described above).

The Part B bundle includes management, care coordination, psychotherapy, and counseling. It does not include medications – they will continue to be paid as either Part B or Part D drugs. It also excludes toxicology testing, which will continue to be separately billed under the Clinical Lab Fee Schedule. Payment for the bundle will not require that a consultation with a specialist be included.

CMS finalizes its proposal to create two HCPCS G-codes to describe monthly bundles of services. One code describes the initial month of treatment, including intake, the development of a treatment plan and other assessments necessary to begin treatment; a second code describes continuing treatment. An add-on code is also finalized for when circumstances require resources that substantially exceed the resources included in the base codes.

CMS seeks to balance the incentive for bundled payments to encourage efficient care with the concern, as expressed by some of the commenters, that the bundle should not inappropriately limit necessary care.

CMS finalizes the following codes as proposed, but includes several clarifications described below. The codes are:

- HCPCS code G2086: 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.
- HCPCS code G2087: 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.
- HCPCS code G2088: 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).

In the final rule, CMS establishes a requirement that in order to bill for HCPCS codes G2086 or G2087, at least one psychotherapy service must be furnished. It clarifies that practitioners can bill for additional psychotherapy using the add on code and, in cases where the psychotherapy is for co-occurring diagnoses, any of the Medicare psychotherapy codes may be used so long as the services are medically reasonable and necessary.

CMS finalizes the valuation of the codes as proposed, based on the work RVUs and direct PE inputs crosswalked from other services that they are most consistent with:

- The value for HCPCS code G2086 is:
    - Crosswalked to CPT code 99492 (initial psychiatric collaborative care management – 70 minutes) which has an RVU of 1.7 plus CPT code 90832 (psychotherapy, 30 minutes) with an RVU of 1.5 assumed to occur twice in a monthly period plus CPT code 90853 (group psychotherapy) with an RVU of .59 assumed 4 times in a month.
    - Together the total work RVU equals 7.06.
    - The required minimum number of minutes is based on a crosswalk to CPT code 99492.
    - The direct PE inputs are associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code G2087 is:
    - Crosswalked to CPT code 99493 (subsequent psychiatric collaborative care management, first 60 minutes) assigned a work RVU of 1.53 plus CPT code

90832, assigned a work RVU of 1.50 (assuming two per month) and CPT code 90853, with a work RVU of 0.59 (assuming four per month).
    - Together, the total work RVU equals 6.89.
    - The required minimum number of minutes is based on a crosswalk to CPT codes 99493.
    - The direct PE inputs are crosswalked to CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code G2088 is:
    - Crosswalked to CPT code 99494 (Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month) which has a work RVU of 0.82.
    - The required minimum number of minutes is based on a crosswalk to CPT codes 99493.
    - The direct PE inputs are crosswalked to CPT code 99494.

To avoid duplicative billing, CMS also finalizes as proposed its policy to prohibit the same practitioner from reporting the new OUD treatment codes as well CPT codes 90832, 90834, 90837, and 90853 for the same beneficiary in the same month. A separately reportable initial visit would commence the OUD treatment episode – this requirement is parallel to commencing chronic care management services. The same initiating visit for CCM and behavioral health integration (BHI) services will be permitted to serve as the initiating visit for the OUD bundles. For new patients or patients not seen by the practitioner within a year prior to the commencement of CCM services and BHI services, the billing practitioner must initiate the service during a "comprehensive" E/M visit (levels 2 through 5 E/M visits), annual wellness visit or initial preventive physical exam. The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) also qualifies as a "comprehensive" visit for CCM and BHI initiation.

The services in the bundle must be provided by providers qualified under state law and operating within their scope of practice; the billing clinician must manage the patient's overall care; and therapy and counseling services may be provided via telehealth if clinically appropriate. CMS recognizes that sometimes OUD can first become apparent in the emergency department but there are presently no specific codes for diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department. CMS requests that commenters describe the use of MAT in the emergency department. It is interested in descriptions of initiation of MAT, referral or follow-up care, and administration of long-acting MAT agents in the ER in order to better understand typical practice patterns to inform future rulemaking.

CMS received comments supporting the proposal; recommending additional payment amounts that recognize different levels of patient need and lowering the threshold for billing the add-on code; and expressing concern that the proposal would limit psychotherapy services or access to non-opioid paid management. CMS declines to lower the threshold for the add-on code and clarifies that practitioners can bill for additional psychotherapy using the add-on code or for co-occurring diagnoses as needed. CMS also notes that the bundled payment codes do not preclude practitioners from furnishing or billing for other non-opioid pain management treatments.

CMS also received a request from commenters that it create a new G-code for RHCs and FQHCs to bill for a bundle of OUD services. CMS declines to do so and points out that RHCs and FQHCs that provide OUD services can bill for individual psychotherapy services using a range of CPT codes that are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. They can also bill for care management services and receive a payment in addition to their AIR or PPS payment. CMS could consider this question again should it become aware that a separate code would be beneficial to RHCs and FQHCs.

I. Physician Supervision for Physician Assistant (PA) Services

Physician assistants (PAs) are allowed to furnish care to Medicare beneficiaries under the general supervision of a physician. General supervision, as defined at §410.32(b)(3)(i), means that PA services must be furnished under a physician's overall direction and control, but the physician presence is not required during the performance of PA services. Commenters have expressed concerns in the past about this general supervision requirement making the point that PAs are now practicing more autonomously, like nurse practitioners (NPs) and clinical nurse specialists (CNSs) as members of medical teams. In addition, they note that some states have already relaxed their requirements for PAs related to physician supervision. In particular, commenters have requested that CMS reconsider its interpretation of the statutory requirement regarding general supervision and instead PAs be allowed to operate similarly to NPs and CNSs, who furnish their services "in collaboration" with a physician.[20]

In light of the comments received in the past, as well as information CMS received regarding the scope of practice laws in some states regarding supervision requirements for PAs, CMS proposed to revise the regulation at §410.74 that established physician supervision requirements for PAs. In the final rule, CMS finalizes it proposal on PA physician supervision, with modifications, 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.

[20] §1861(s)(2)(K)(ii)

The majority of commenters supported the regulatory changes CMS proposed regarding physician supervision requirements. Commenters believed that deferring to state law and scope of practice rules for supervision of PA services will allow them to practice at the top of their education and expertise. They also note that state laws have increasingly redefined the PA-physician relationship moving away from "physician supervision" of PAs, to "physician collaboration." Based on their concerns about administrative burden, commenters did urge CMS to require that, in the absence of state law governing physician supervision of PA services, PAs should be required to document at the practice level, rather than in the medical record, the working relationship that they have with physicians. CMS notes in its comments that it was not its intent to create an overly burdensome and unnecessary documentation requirement, and thus modified its proposal, accordingly.

J. Review and Verification of Medical Record Documentation

1. Background

Medicare Part B makes payment under the PFS for teaching physician services when certain conditions are met. CMS amended its regulations in the 2019 PFS final rule to provide that a physician, resident, or nurse may document in the patient's medical record that the teaching physician presence and participation requirements were met.[21] For E/M visits furnished after January 1, 2019, the extent of the teaching physician's participation in services involving residents may be demonstrated by notes in the medical records made by a physician, resident or nurse. CMS made additional changes to its Medicare Claims Processing Manual that would allow a teaching physician to review and verify (sign/date) notes made by a student in a patient's medical record for E/M services, rather than have to redo the documentation.[22] Nonphysician practitioners have requested similar relief from E/M documentation requirements that have been granted to physicians.

2. Policy

CMS proposed to establish a general principle to allow the physician, the PA, or the advanced practice registered nurse (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. CMS states that this principle would apply across the spectrum of all Medicare-covered services paid under the PFS.

After consideration of comments received, CMS finalized its proposal, with a couple of modifications. CMS is explicitly naming PA and NP, clinical nurse specialist (CNS), certified nurse-midwife (CNM) and certified registered nurse anesthetist (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; and revising §§ 410.20, 410.69, 410.74, 410.75, 410.76, 410.77, 415.172 and 415.174 to reflect this change. Additionally, similar to the revisions CMS is making to the

[21] Sections 415.172(b) and 415.174(a)(6)
[22] Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B

regulations at §§ 410.20, 410.69, 410.74, 410.75, 410.76, 410.77, 415.172 and 415.174, CMS is amending its regulation at § 410.69 to add a new paragraph (5) under the definition of CRNA to include CRNAs as a category of APRNs for purposes of this policy, and to include CRNA students under the reference to APRN students.

Many commenters supported the premise for this documentation proposal which they stated almost unanimously would relieve burdensome documentation requirements. Another commenter urged CMS to improve its proposal by including CRNAs and their students because CRNAs are also included under the nursing industry's "APRN" umbrella. CMS agrees that it is appropriate to include CRNAs and their students, as well as other members of their health care team, for purposes of the medical record documentation.

K. Care Management Services

1. Background

CMS' review of claims data indicates that approximately 3 million unique beneficiaries (9 percent of the Medicare FFS population) receive care management services annually; chronic care management (CCM), transitional care management (TCM) and advanced care planning services (ACP) have the highest use. Table 19, reproduced below, provides a summary of the care management codes.

Table 19. Summary of Special Care Management Codes

Service	Codes	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision	G0181, G0182	Supervision of home health, hospice, per month
ESRD Monthly Service	90951 – 90970	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013)	99495, 99496	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019)	99487, 99489, 99490, 99491	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016)	99497, 99498	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017)	99484, 99492, 99493, 99494	Management of behavioral health condition(s), timed, per month
Assessment/Care Planning for Cognitive Impairment (adopted in 2017)	99483	Assessment and care planning of cognitive impairment, face-to-face visit

Table 19. Summary of Special Care Management Codes		
Service	**Codes**	**Summary**
Prolonged E/M Without Direct Patient Contact (adopted in 2017)	99358, 99359	Non-face-to-face E/M work related to a face-to-face visit, timed
Remote Patient Monitoring (adopted in 2019)	99091	Review and analysis of patient-generated health data, timed, per 30 days
Interprofessional Consultation (adopted in 2019)	99446 – 99449, 99451, 99452	Inter-practitioner consultation

2. Transitional Care Management (TCM) Services

CMS discussed findings by Bindman and Cox[23], reporting that utilization of TCM services is low when compared to the number of Medicare beneficiaries with eligible discharges and that beneficiaries receiving TCM services have reduced readmission rates, lower mortality, and decreased health care costs. Birdman and Cox identified two likely contributing factors for low utilization of TCM: the administrative burden associated with billing TCM services and the payment for TCM.

CMS discussed the billing restrictions that do not allow the same practitioner reporting TCM to bill 57 HCPCS codes during the 30-day period covered by TCM services. CMS noted this list mirrors reporting restrictions established by the CPT Editorial Panel for TCM codes. CMS reviewed these 57 codes and found that the majority of codes are either bundled, noncovered by Medicare, or invalid for Medicare payment purposes. Table 20 (reproduced below) lists the 14 codes that are separately payable under the PFS.

Table 20. HCPCS Codes that Currently Cannot be Billed Concurrently with TCM by the Same Practitioner and are Active Codes Payable by Medicare PFS		
Code Family	**Code**	**Descriptor**
Prolonged Service without Direct Patient Contact	88358	Prolonged E/M service before and/or after direct patient care; first hour, non-face-to-face time by a physician or other qualified health care professional
	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes
Home and Outpatient International Normalized Ration (INR) Services	93792	Patient/caregiver training for initiation of home INR monitoring
	93793	Anticoagulation management for a patient taking warfarin
End Stage Renal Disease Services	90960	ESRD related services monthly with 4 or more face-to-face visits per month; patients 20 years or older

[23] Bindman, AB, Cox DF. Changes in health care costs and mortality associated with transitional care management services after a discharge among Medicare beneficiaries (published online July 30, 2018). *JAMA Intern Med*, doi:10.1001/jamainternmed.2018.2572.

Table 20. HCPCS Codes that Currently Cannot be Billed Concurrently with TCM by the Same Practitioner and are Active Codes Payable by Medicare PFS		
Code Family	**Code**	**Descriptor**
(patients who are 20 years or older)	90961	ESRD related services monthly with 2-3 face-to-face visits per month; patients 20 years or older
	90962	ESRD related services monthly with 1 face-to-face visits per month; patients 20 years or older
	90966	ESRD related services for home dialysis per full month; patients 20 years or older
	90970	ESRD related services for home dialysis less than a full month; patients 20 years or older
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days
Complex Chronic Care Management Services	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month
	99489	Complex Chronic Care additional 30 minutes per month
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services (patient not present) requiring complex and multidisciplinary care within a calendar month; 30 or more minutes
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (patient not present) requiring complex and multidisciplinary care within a calendar month; 30 or more minutes

CMS believes there may not be substantial overlap between these 14 codes and TCM services and proposed to allow TCM codes to be billed concurrently with any of these codes. CMS also examined the current payment rates for TCM and based upon the results of the 2018 RUC survey of the TCM codes, CMS agrees with the RUC recommendation of a slight increase in work RVUs for these codes. Specifically, for 2020, CMS proposed the RUC-recommended work RVUs of 2.36 for CPT code 99495 and 3.10 for CPT code 99496. CMS does not propose any changes to the direct PE.

Most commenters supported removing the billing restriction associated with the 14 codes identified by CMS. Commenters recommended allowing CPT code 99491 (Chronic care management, provided personally by a physician or other qualified healthcare professional, 30 minutes per calendar month) to be separately payable in the same service period as TCM. In response, CMS notes that since the proposed rule, it has identified two additional chronic care management codes, CPT codes 99490 and 99491 that are not listed in the CPT manual as restricted from concurrent billing with TCM. CMS agrees that both codes should be added to the list of care management codes that can be billed concurrently with TCM.

After considering comments, CMS finalizes its proposal to allow concurrent billing of the care management codes currently restricted from being billed with TCM. Specifically, CMS will allow concurrent billing of TCM with the 14 codes specified in Table 20 and CPT codes 99490 and 99491. CMS hopes these changes will lead the CPT Editorial Panel to revise the current

prohibitions on billing TCMs with certain codes. CMS also finalizes for both TCM codes the proposed increases in work RVUs and the RUC-recommended direct PE inputs.

CMS notes that it received too few comments about factors affecting utilization of CCM and TCM services to know if payment affected the use of TCM.

3. Chronic Care Management (CCM) Services

CMS reports that utilization of CCM services is approximately 75 percent of the level it initially assumed but it believes that CCM services (especially complex CCM services) are underutilized. Stakeholder suggested that the time-increments for non-complex CCM performed by clinical staff need to recognize finer time increments and clarity is needed for some of the care planning requirements. To address these concerns, CMS proposed changes to the CCM codes.

a. Non-Complex CCM Services by Clinical Staff (CPT codes 99490, HCPCS codes GCCC1 and GCCC2)

The clinical staff code for non-complex CCM, CPT code 99490, describes 20 minutes or more minutes of clinical staff time spent doing CCM under the direction of a physician or qualified health care professional. Stakeholders believe that CMS undervalued this code because it assumed that the minimum time for this code, 20 minutes of clinical staff time, is typical. Stakeholders recommended that CMS should create an add-on code for non-complex CCM that would either define the service in 20-minute time increments or provide extra payment for 20 to 40 minutes. CMS agrees that coding changes to provide additional time increments would improve payment accuracy for non-complex CCM changes.

CMS proposed to adopt two new G codes – GCCC1 and GCCC2 – to be used for PFS payment instead of CPT code 99490. CMS notes that if the CPT Editorial Panel considered revisions to the current CPT code set it would consider adopting any related CPT code(s). CMS proposed the following:

- GCCC1: CCM, initial 20 minutes of clinical staff time directed by a physician or other qualified health care profession, per calendar month with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until death; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation or functional decline; and comprehensive care plan established, implemented, revised or monitored. (CCM of less than 20 minutes, in a calendar month, are not reported separately.)
    - CMS proposed a work RVU of 0.61 based on a crosswalk from CPT code 99490.

- GCCC2: CCM, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care profession, per calendar month (List separately in addition to code for primary procedure) (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4,99491.)
    - CMS proposed a work RVU of 0.54 based on a crosswalk from CPT code 11107[24]. CMS believed that CPT code 11107 has a similar work intensity as

[24] CPT code 11107 describes an incisional biopsy of skin (including simple closure, when performed); each separate/additional lesion; list in addition to code for primary procedure.

GCCC2. It noted that add-on codes often have lower intensity than the base code because they describe the continuation of an initiated service.

In addition to comments about this proposal, CMS sought comments on the following:

- Does the benefit of proposing G codes outweigh the burden of transition to their use before a decision is made by the CPT Editorial Panel?
- Should CMS limit the number of times the add-on code (GCCC2) can be reported in a given service period? CMS notes that complex CCM already describes, in part, 60 or more minutes of clinical staff time, and wonders if additional time beyond 40 minutes is necessary.
- How often beneficiaries who do not require complex CCM would need 60 minutes or more minutes of non-complex CCM clinical staff time and need more than one use of HCPCS code GCCC2 within a service period?

Several commenters supported the proposed add-on code GCCC2 and recommended that CMS establish a frequency limit to keep non-complex CCM distinct from complex CCM. Other commenters suggested limiting the frequency of reporting GCCC2 to twice during a service period. MedPAC also supported the proposed add-on code for non-complex CCM. A number of commenters were not supportive of using temporary G codes within the CCM set because they thought it produced administrative burden and confusion. In addition, commenters noted that in September 2019 the CPT Editorial Panel considered an application for similar changes and urged CMS to work with the CPT Editorial Panel on these codes.

In consideration of commenters' concerns about the administrative burden and confusion associated with temporary G codes and the CPT Editorial Panel's current ongoing work, CMS does not final its proposal to create HCPCS codes GCCC1 (or the HCPCPS codes proposed for complex CCM services, discussed below). CMS finalizes its proposal to create code GCCC2 (the add-on for non-complex CCM clinical staff time) as G2058 with a work RVU of 0.54 and a maximum frequency of two times within a given service period for a given beneficiary. CMS believes this code addresses an important gap in the current code set that needs to be immediately addressed.

b. Complex CCM Services (CPT codes 99487 and 99489, HCPCs codes GCCC3 and GCCC4)
CMS discusses the complex CCM requirements for establishment or substantial revision of the comprehensive care plan and the requirement for moderate to high complex medical decision-making. CMS believes that it is not necessary to explicitly include substantial care plan revision as a requirement because complex CCM because patients requiring moderate to high complex decision-making implicitly need and receive substantial care plan revision.

CMS proposed to adopt two new G codes – GCCC3 and GCCC4 – to be used for PFS payment instead of CPT codes 99487 and 99489, respectively. CMS noted that if the CPT Editorial Panel considered revisions to the current CPT code set it would consider adopting any related CPT code(s). CMS proposed the following:

- GCCC3: CCM services with the following required elements: multiple (two or more) chronic conditions chronic conditions expected to last at least 12 months, or until death;

chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation or functional decline; comprehensive care plan established, implemented, revised or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (CCM services of less than 60 minutes duration, in a calendar month, are not reported separately)).
    - CMS proposed a work RVU of 1.00, a crosswalk to CPT code 99487.

- GCCC4: each additional 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3) (Do not report GCCC4 for CCM of less than 30 minutes additional to the first 60 minutes of complex CCM during a calendar month).
    - CMS proposed a work RVU of 0.5, a crosswalk to CPT code 99489.

After consideration of comments, CMS does not finalize its proposal to create GCCC3 and GCCC4. Instead, for 2002, CMS will continue to recognize CPT codes 99487 and 99489, but with a different care planning element for purposes of Medicare billing. Specifically, for 2020, 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 monitored. CMS believes this is a relatively minor modification to the CPT code descriptor that does not require the use of G codes.

c. Typical Care Plan

In response to comments about the confusion of the care plan requirements, CMS proposed to simplifier the language related to describing the work of interacting and coordinating with resources external to the practice. CMS believes it is preferable, when feasible, to identify who is responsible for these interventions, but acknowledges it may be difficult to maintain a listing of responsible individuals when they are outside of the physician's practice.

CMS eliminates 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 inserts the phrase "interaction and coordination with outside resources and practitioners and providers". CMS finalizes the following new language for a comprehensive care plan:

The comprehensive care plan for all health issues typically includes, but it 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; and when applicable, revision of the care plan.

Commenters supported CMS' proposed definition of the typical care plan.

4. Principal Care Management (PCM) Services

CMS discusses stakeholders concerns, especially those in specialties that use office/outpatient E/M codes to report the majority of their services, that there are significant resources involved in care management for a single high disease or complex chronic condition. This issue was also raised in proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC).[25]

In response to these concerns, CMS proposed separate coding and payment for PCM services which describe care management services for one serious chronic condition. A qualifying condition would 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 proposed the following:

- GPP1: CCM for a single high-risk disease, e.g. PCM, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities.
    - CMS proposed a work RVU of 1.28 a crosswalk to CPT code 99217 (Observation care discharge day management).

- GPP2: CCM for a single high-risk disease, e.g. PCM, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities.
    - CMS proposed a work RVU of 0.61 a crosswalk to CPT code 99490 (clinical staff non-complex CCM)

CMS did not propose any restriction on the specialties that could bill for PCM, including the patient's primary care practitioner. CMS expects that most PCM services would be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that the overall care management can be returned to the patient's primary care practitioner. CMS also acknowledges that it is possible that the patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously.

[25] Submissions to PTAC are available at https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee.

CMS notes the similarity between both PCM and CCM services and proposed the following:

- requiring the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record (Table 18 in the proposed rule summarizes the CCM requirements);
- adding GPPP2 to the list of designated care management services allowing general supervision;
- PCM could not be billed by the same practitioner for the same patient concurrent with certain other care management services, such as CCM, BHI, and monthly capitated ESRD payments; and
- PCM could not be billed by the same practitioner for the same patient during a surgical global period.

Most commenters supported separate payment for PCM services; other commenters were concerned that the work described by PCM is duplicative of work furnished as part of CCM and encouraged CMS to work with the CPT Editorial Panel to develop codes for this service. Some commenters supported requiring the billing practitioner to document ongoing communication and care coordination, as applicable. A few commenters suggested that CMS not allow billing of PCM services by multiple practitioners for the same indication; other commenters thought it was not necessary to put any requirements on PCM and that requirements would be a barrier to use of the service.

CMS finalizes its proposal for two codes for PCM: G2064 (proposed GPP1) and G2064 (proposed GPP2). After consideration of comments, CMS finalizes work RVU for G2064 at 1.45 instead of the proposed RVU of 1.28. CMS finalizes its proposed work RVU of 0.61 for G2064. Table 23 in the final rule shows the required elements of CCM and Table 24 show the elements of CCM, as revised in response to comments, that will be required for PCM. CMS notes that it will add G2065 to the list of designated care management services for which it allows general supervision.

CMS finalizes 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. In addition, as with CCM, both the initiating visit and the patient's verbal consent are necessary and the beneficiary should be educated as to what PCM services are and any cost sharing that may apply.

CMS finalizes that PCM services should not be furnished with other care management services provided by the same practitioner for the same beneficiary. In addition, PCM services should not be furnished at the same time as interprofessional consultations for the same condition by the same practitioner for the same patient. CMS will consider remote patient monitoring services as distinct from PCM and therefore these services can be billed concurrently by the same practitioner for the same beneficiary provided that the time is not counted twice. CMS notes it will monitor billing of these services.

CMS notes that a commented requested that RHC and FQHCs be allowed to furnish and report PCM services. CMS will consider adding PCM to the RHC/FQHC-specific general care management code (G0511) in future rulemaking.

5. Chronic Care Remote Physiologic Monitoring Services

Chronic Care remote physiologic monitoring (RPM) involves the collection, analysis, and interpretation of digitally collected physiologic data, followed by a treatment plan, and the management of a patient under the treatment plan. The current CPT code 99457 is a treatment management code, billable after 20 minutes or more of clinical staff/physician/other qualified professional time with a patient in a calendar month.

For 2020, CPT revised these codes: CPT code 99457 describes the first 20 minutes of the treatment management service and CPT code 99458 is a new add-on code to describe subsequent 20 minutes interval of the services.

For CPT code 99458, CMS did not agree with the RUC-recommended work RVU of 0.61. Instead, CMS proposed a work RVU of 0.50, based on a crosswalk to CPT code 88381 (Microdissection) which has the same intraservice and total times of 20 minutes. CMS proposed the RUC-recommended direct PE inputs for 99458.

Numerous comments disagreed with the proposed work RVU of 0.50 for CPT code 99458 and provided additional information about the work associated with this service. In response, CMS finalizes a work RVU of 0.50 and the RUC-recommended direct PE inputs for 99458.

RMP services currently require direct supervision. For 2020, CMS finalizes its proposal that RPM services reported with codes 99457 and 994X0 may be furnished under general supervision. CMS believes that RPM services should be included as designated care management services. CMS notes that the physician or other qualified health care professional supervising the auxiliary personnel does not need to be the same individual treating the patient but only the supervising professional may bill Medicare for the incident to services.

Several commenters expressed concerns about the ambiguity of the code descriptors for the RPM codes and requested clarification about the definitions. Other commenters raised comments related to a broad range of issues related to RPM. Given the numerous questions raised by commenters, CMS plans to consider these issues related to RPM in future rulemaking.

In response to comments, CMS states that services such as RPM are not separately billable in RHCs and FQHCs because they are included in the RHC all-inclusive rate (AIR) or the FQHC PPS payment.

6. Comment Solicitation on Consent for Communication Technology-Based Services (CTBS)

CMS makes separate payment for services furnished via telecommunications technology : evaluation of recorded video and/or images (HCPCS code G2010), virtual check-in (HCPCS

code G2012, and interprofessional consultation services (CPT codes 99446 – 99449, 99451, and 99452).

CMS requires advance beneficiary consent for each of these services. CMS notes that stakeholders are concerned that requiring advance beneficiary consent for each of these services is burdensome. For the interprofessional consultation services, stakeholders find it difficult for the consulting practitioner to obtain consent from a patient they have never seen.

CMS requested comments on the following:

- Whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. The consent process will still make sure the beneficiary is aware of the cost sharing associated with these services.
- The appropriate interval of time or number of services for which consent could be obtained, for example, all services furnished within a 6 month or one-year period, or for a set number of services.
- Potential program integrity concerns associated with allowing advance consent and how to minimize these concerns.

Many commenters supported requiring a generalized consent for multiple communication technology-based services or interprofessional consultations. Most commenters suggested yearly consent and some suggested other intervals, such as every 6 months, quarterly, or none at all. A few commenters suggested that there should be a separate consent process for services that involve an interaction with a patient, such as G2010, and services that do not involve direct interaction with the patient, such as CPT code 99446. Commenters urged CMS to eliminate cost sharing for these services.

After consideration of comments, CMS finalized that a single consent, obtained annually, must be obtained for multiple CTBS or interprofessional consultation services.

In addition, CMS will continue to consider whether a separate consent should be obtained for services that involve direct interaction and those that do not involve interaction between the patient and the practitioner; CMS may address this issue in future rulemaking. CMS notes that it does not have the statutory authority to eliminate cost sharing for these services.

7. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

Current payment for general care management services (HCPCS code G0511) is set at the average of the national, non-facility payment rates for CPT codes 99490, 99487, and 99484. For 2020, CMS proposed 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 the proposals for GCCC1 and GCCC2 are finalized). The payment for HCPCS code G0511 would be the average of the national, non-facility payment rates for HCPCS codes GCCC1 and GCCC3 and CPT code 99484.

Since HCPCS codes GCCC1 and GCCC3 are not being finalized, CMS is not finalizing its proposal for RHCs and FQHCs. Therefore, payment for HCPCS G0511 will continue to be

based on the average of the national, non-facility payment rates for CPT codes 99490, 99487, 99491, and 99484.

L. Coinsurance for Colorectal Cancer Screening Tests

CMS discusses the numerous statutory provisions governing payment for colorectal cancer screening tests. CMS pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance.

CMS excludes from the definition of colorectal screening services colonoscopies and sigmoidoscopies that begin as a screening service but have a polyp or other growth removed as part of the procedure. CMS bases these exclusions on sections 1834(d)(2)(D) and 1834(d)(3)(D) of the Act. CMS also interprets sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(iii) of the Act to require payment for these tests as diagnostic tests, rather than as screening tests, and beneficiaries are responsible for the usual coinsurance that applies to the services (depending on the setting).

CMS acknowledges that beneficiaries are concerned about the coinsurance when they expected to receive a colorectal screening procedure without a coinsurance but instead received what Medicare considers to be a diagnostic procedure because polyps were discovered and removed. Physicians are also concerned about the need for beneficiaries to be responsible for a coinsurance. Other stakeholders and members of Congress have expressed concerns that CMS' policy is a misinterpretation of the law.

CMS discusses the many publicly available educational materials related to this issue. CMS is considering requiring physicians who plan to furnish a colorectal cancer screening to notify the patient in advance that the procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply.

CMS received over 1,600 comments on the requirements for coinsurance for colorectal cancer screening tests; many of the comments were on coverage and statutory issues. CMS notes that many commenters were confused about the policies for colorectal cancer screening tests. Based on these comments, CMS intends to take a comprehensive review of all outreach materials and clarify as appropriately.

M. Therapy Services

1. Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy

Section 50202 of the BBA of 2018 repealed the Medicare outpatient therapy caps and the therapy cap exceptions process. Nevertheless, the law continues to require the use of a modifier on claims above the prior therapy cap amounts. Further, the law requires targeted manual medical review of therapy services once a beneficiary has received $3,000 in therapy services for a year. While CMS explained and implemented these changes in its 2019 PFS rulemaking, it did

not codify those changes in regulation text. CMS finalizes its proposal, without modification, to codify these provisions at §§410.59 and 410.60 of the CFR.

In addition, the 2019 PFS final rule incorrectly stated that section 1833(g)(6)(B) of the Act continues to require that CMS accrue expenses for therapy services furnished by CAHs at the PFS rate towards the cap. The statutory provision was limited to 2013. CMS administratively continued the same policy and now requires CAHs to use a modifier on therapy services above the prior cap amounts based on PFS therapy rates.

2. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

Section 1834(v)(1) of the Act requires payment at 85 percent of the PFS amount for therapy services furnished in whole or in part by a therapy assistant effective January 1, 2022. Effective January 1, 2019, section 1834(v)(2) of the Act further requires CMS establish modifiers to be used on claims to identify therapy services furnished in whole or in part by a therapy assistant. Beginning January 1, 2022, use of these modifiers will trigger application of the reduced payment rate for outpatient therapy services furnished in whole or in part by a physical therapy assistant (PTA) or occupational therapy assistant (OTA).

CMS has defined "in whole or in part" as more than 10 percent of the service is furnished by the PTA or OTA. The modifiers apply to physical and occupational therapy services furnished by therapists in independent practice as well as those furnished by CORFs or otherwise paid under the PFS. The modifiers do not apply to therapy services billed by physicians or non-physician practitioners (NPP)[26] because therapy services furnished in physicians' or NPPs' offices must meet the qualifications and standards as if furnished by licensed therapists (although licensure itself is not required). This provision does not apply to therapy services furnished in a CAH.

The modifiers do not apply:

- To administrative or other non-therapeutic services that can be performed by others without the education and training of OTAs and PTAs.
- When PTAs/OTAs furnish services that can be done by a technician or aide who does not have the training and education of a PTA/OTA.
- When therapists exclusively furnish services without the involvement of PTAs/OTAs.

CMS proposed 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. For purposes of deciding whether the 10 percent standard is exceeded, CMS offered two different methods in the proposed rule:

1. Divide the PTA/OTA minutes by the total minutes for the service rounded to the nearest whole percentage. Eleven percent or above requires the modifier. For services furnished concurrently with the therapist, divide the PTA/OTA time by the total time for the service. For services furnished separately by the therapist and the PTA/OTA, divide PTA/OTA time by the PTA/OTA time plus the therapist's time; or

[26] Nurse practitioners, clinical nurse specialists or physician assistants.

2. Divide the total time for the service by 10 + 1 minute. If the minutes of service by the PTA/OTA equal or exceed the result, the modifier applies.

Many commenters objected to its proposal that the time for therapeutic service furnished "in part" by the PTA/OTA that counts toward the 10 percent standard include both the minutes spent concurrently with and separately from the therapist. In particular, many objected to the use of the word "concurrent" and suggested alternatives including "in tandem" or "team-based therapy." In response, CMS was persuaded by commenters' concerns and is revising its proposed policy so that the 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 finalizes 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 revises its regulation text at §§ § 410.59 (outpatient occupational therapy), 410.60 (physical therapy), and 410.105 (for PT and OT CORF services) accordingly. CMS states that it intends to provide further detail using examples of clinical scenarios and the applicability of the therapy assistant modifiers through information that it posts on the cms.gov website

Timed therapy services are defined by 15-minute increments per unit of service. CMS proposed that therapists or therapy assistants would apply the PTA/OTA modifiers to the timed codes by first following the usual process to identify all procedure codes for the 15-minute timed services furnished to a beneficiary on the date of service, add up all the minutes of the timed codes, decide how many total units of timed services are billable and assign billable units to each procedure code. The therapist or therapy assistant would then need to decide for each billed procedure code whether or not the therapy assistant modifiers apply using the methods described above.

Commenters opposed CMS' proposal to apply the 10 percent time standard, for billing purposes, to all the billed units of a service defined by a single procedure code, and urged CMS to not finalize the proposal. CMS found the commenters' concerns persuasive and, for purposes of billing, CMS finalizes 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. Accordingly, CMS revises its final policy to 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.

Beginning January 1, 2020, CMS proposed 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. The requirement would apply to both timed and untimed services. For example, when PTAs/OTAs assist PTs/OTs to furnish services, the treatment note could state one of the following, as applicable:

- "Code 97110: CQ/CO modifier applied – PTA/OTA wholly furnished"; or,
- "Code 97150: CQ/CO modifier applied – PTA/OTA minutes = 15%"; or,

- "Code 97530: CQ/CP modifier not applied – PTA/OTA minutes less than 10% standard"; or "CQ/CO modifier NA", or "CQ/CO modifier NA –PT/OT fully furnished all services."

Nearly all commenters were opposed to CMS' proposal to require that the treatment notes explain, in a short phrase or statement, the application of non-application of the therapy assistant modifier for each therapy service furnished. CMS was persuaded by the commenters and is not finalizing this provision, nor the requirement that the therapist and therapy assistant minutes be included in the documentation. 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. Further, CMS clarifies that it would expect the documentation in the medical record to be sufficient to know whether a specific service was furnished independently by a therapist or a therapist assistant, or was furnished "in part" by a therapist assistant, in sufficient detail to permit the determination of whether the 10 percent standard was exceeded.

3. Therapy KX Modifier Threshold Amounts

Section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) repealed the caps effective January 1, 2018. However, the law requires that a modifier be included on the Medicare claim once the prior therapy cap amounts have been reached. For 2020, therapy providers are required to use the KX modifier when annual per beneficiary expenditures exceed $2,080 for PT and SLP services combined, and $2,080 for OT services.[27] After the beneficiary's incurred expenditures for outpatient therapy services exceed these thresholds, claims for outpatient therapy services without the KX modifier are denied.

Along with the KX modifier thresholds, the law retains a medical review (MR) process. Under the prior process, all claims for therapy services above $3,700 were subject to manual medical review. Under the revised process, the law establishes a targeted MR process for therapy services above $3,000. The $3,000 threshold is retained until 2028 at which time it is indexed annually by the Medicare Economic Index. The MR threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. The law retains the provider liability procedures which first became effective January 1, 2013, extending limitation of liability protections to beneficiaries who receive outpatient therapy services, when services are denied for certain reasons, including failure to include a necessary KX modifier.

N. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2020 are available on the CMS website under downloads for the PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the proposed rule provide additional details about the proposed 2020 valuation of specific codes:

[27] These amounts are updated each year based on the Medicare Economic Index.

Table 26	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 27	Direct PE Refinements
Table 28	Direct PE Refinements -Equipment Refinements Due to Changes in Clinical Labor Time
Table 29	Invoices Received for Existing Direct PE Inputs
Table 30	New Invoices
Table 31	No PE Refinements

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

CMS provides an overview of the process for establishing RVUs for the PFS. CMS states that to establish RVUs it reviews available information including recommendations and supporting documentation from the RUC, the Health Care Professional Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparison with other codes, and input from CMS and other federal government health care professionals.

2. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.[28] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values. [29] CMS' concerns about RUC rationales and their underlying practitioner survey data have increased in recent years, most often centering on the incorporation of service times and time changes into specific work RVU proposals.

CMS discusses the methodology it uses for adjusting work RVU and/or time, including the methodology used when it believes there is overlap between a service typically furnished on the same day as an E/M service. The work RVU for a service is the product of the time involved with furnishing the service multiplied by the work intensity. CMS notes that the pre-service and post-service time have a long-established intensity of work per unit time (IWPUT) of 0.0224; thus, 1 minute of pre-service or post-service time equates to 0.0224 of a work RVU. Using this information, when CMS is concerned about overlap between a service and an E/M service, it generally removes 2 minutes of pre-service time and 2 minutes of post-service time from the procedure which results in removing a work RVU of 0.09 (4 minutes x 0.0224 IWPUT).

CMS discusses its concern that many codes reviewed by the RUC have recommended work RVUs that do not appear to account for significant changes in the reduction in time. In addition to using its standard methodologies such as survey data, crosswalk to key reference or similar codes, CMS uses the relationship between the old time values and the new time values to help identify alternative work RVUs based on changes in time components. CMS states that a

[28]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[29]Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each service. To assist in the development of pre-service time recommendations, the RUC created standardized pre-service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

decrease in time does not always equate to a one-to-one linear decrease in work RVUs but absent a rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs.

Several commenters disagreed with CMS' reference to older work time sources because these codes (codes with "CMS/Other" or "Harvard") were not surveyed and commenters believe the RVUs are based on flawed assumptions. Commenters thought it was invalid to use these codes as comparisons with newly surveyed work time and work RVUs recommended by the RUC. CMS disagrees and notes if it were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RUVs in the PFS and also undermine the validity of the allocation of indirect PE RVUs to physician specialties. It believes that it is critical to assume that the existing work times are accurate and that it is impossible to ignore changes in time based on the best available data. CMS also disagrees with comments that CMS should not use the time ratio methodology. CMS believes the use of time ratios is an appropriate method for identifying potential work RVUs when the values recommended by the RUC and other commenters do not account for survey information suggesting the service time for a code has significantly changed. CMS clarifies that it does not treat all components of physician time as having identical intensity and that it does not value services purely based on work time. CMS provides examples of codes reviewed in the final rule that have identical work times but have different work RVUs. CMS also disagrees with comments discouraging the use of work RVU increments and notes this is a valid methodology for setting values, especially for services within a family.

Table 26 list the codes and final work RVUs, work time and other payment information for all codes that CMS received recommendations from the RUC by February 10, 2019.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for developing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes.

Table 27 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

Common CMS refinements to RUC recommendations are related to or triggered by the following:

- Changes in work component times (e.g., intra-service time, postoperative visit levels);
- Changes in equipment time (e.g., pre-service clinical task is performed outside of highly technical equipment rooms and is excluded from equipment time);
- Clinical labor task times that are inconsistent with standard times in the CMS direct PE input database or overlap with associated E/M visit clinical labor time;

- Recommended items that are not direct PE inputs (e.g. items that are not clinical labor, disposable supplies or medical equipment or cannot be allocated to individual services or patients);
- New supply or equipment items (e.g., when invoices lack sufficient information)[30];
- Clinical labor time in the facility minutes (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap on imaging service

CMS received invoices for several new and existing supply and equipment items (see Tables 28 and 29). CMS encourages stakeholders to review these prices and if prices appear inaccurate it encourages stakeholders to submit invoices or other information to improve the pricing. CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations).

4. Proposed Valuation for Specific Codes

This section discusses finalized RVUs for 74 code groups (listed in the table below). Highlights of CMS' discussion are summarized; the numbering is consistent with the preamble format. The reader is referred to the final rule for more specific details.

Code Group Number and Name		Codes (CPT and HCPCS)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Finalizes Proposed Work RVUs
1	Tissue Grafting Procedures	15X00 - 15X04	Yes	Yes
2	Drug Delivery Implant Procedures	11981 - 11983, 20700 - 20705	No	No
3	Bone Biopsy	20220 and 20225	No	Yes
4	Trigger Point Dry Needling	20560 and 20561	No	Yes
5	Closed Treatment Vertebral Fracture	22310	No	Yes
6	Tendon Sheath Procedures	26020. 26055, and 26160	No	Yes
7	Closed Treatment Fracture- Hip	27220	No	Yes
8	Arthrodesis – SI Joint	27279	Yes	No
9	Pericardiocentesis & Pericardial Drainage	33016 - 33019	No	No
10	Pericardiotomy	33020 and 33025	No	No
11	Transcatheter Aortic Valve Replacement (TAVR)	33361 – 33366	Yes	Yes

[30] CMS may add an item to the direct PE input database as a zero price item to serve as a placeholder that is readily updated once accurate pricing information becomes available.

Code Group Number and Name		Codes (CPT and HCPCS)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Finalizes Proposed Work RVUs
12	Aortic Graft Procedures	33858, 33859, 33863, 33864, 33866 and 33871	No	Yes
13	Iliac Brach Endograft Placement	34717 and 34718	Yes	Yes
14	Exploration of Artery	35701 and 35703	Yes	Yes
15	Intravascular Ultrasound	37252 and 37253	No	No
16	Stab Phlebectomy of Varicose Veins	37765 and 37766	Yes	Yes
17	Biopsy of Mouth Lesion	40808	No	No
18	Transanal Hemorrhoidal Dearterialization	46945, 46946, and 46948	Yes	Yes
19	Preperitoneal Pelvic Packing	49013 and 49014	No	No
20	Cystourethroscopy Insertion Transprostatic Implant	52411 and 52442	No	Yes
21	Orchiopexy	54640	Yes	Yes
22	Radiofrequency Neurootomy SI Joint	62367-62370	Yes	Yes
23	Lumbar Puncture	66270, 62328, 62272, and 62329	No	Yes
24	Electronic Analysis of Implanted Pump	62367 - 62370	Only Reviewed for PE	
25	Somatic Nerve Injection	64400, 64408, 64115 – 64417, 64420, 66421, 66425, 66430, 66435, 66445 - 66450	No	Yes
26	Genicular Injection and RFA	64640, 64454, and 64624	No	Yes
27	Cyclophotocoagulation	66711, 66982 – 66984, 66987, and 66988	Yes	Yes
28	X-Ray: Sinuses	70210 and 70220	No	Yes
29	X-Ray: Skull	70250 and 70260	No	Yes
30	X-Ray: Neck	70360	No	Yes
31	X-Ray: Spine	72020, 72040, 72050,72052,72070, 72072, 72074, 72080, 72100, 72110,72114, and 72120	Yes	Yes
32	CT: Orbit-Ear-Fossa	70480 - 70482	No	Yes
33	CT: Spine	72125 - 72133	No	Yes
34	X-Ray: Pelvis	72170 and 72190	Yes	Yes
35	X-Ray: Sacrum	72200, 72202, and 72220	No	Yes
36	X-Ray: Clavicle-Shoulder	73000, 73010, 73020, 72030, and 73050	Yes	Yes
37	CT: Lower Extremity	73700 - 73702	Yes	Yes
38	X-Ray: Elbow-Forearm	73070, 73080, and 73090	Yes	Yes
39	X-Ray: Heel	73650	Yes	Yes
40	X-Ray: Toe	73660	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Finalizes Proposed Work RVUs
41	Upper GI Tract Imaging	74210, 74220, 74230, 74221, 74240, 74246, and 74248	Yes	Yes
42	Lower GI Tract Imaging	74250, 74251, 74270, and 74280	Yes	Yes
43	Urography	74425	Yes	Yes
44	Abdominal Aortography	75625 and 75630	No	Yes
45	Angiography	75726 and 75774	Yes	Yes
46	X-Ray Exam Specimen	76098	Yes	Yes
47	3D Rendering	76376	Yes	Yes
48	Ultrasound Exam	76604	Yes	Yes
49	X-Ray: Bone	77073 - 77077	Yes	Yes
50	SPECT-CT	78800 -77804, 78830 - 78832, and 78835	No	Yes
51	Myocardial PET	78459, 78429, 78491, 78431, 78492, 78432 - 78434	No	No
52	Cytopathology, Cervical Vaginal	88141, G0124, G0141, and P3001	No	Yes
53	Biofeedback Training	90912 and 90913	Yes	Yes
54	Corneal Hysteresis	92145	Yes	Yes
55	Computerized Dynamic Posturography	92548 and 92549	No	Yes
56	Auditory Function Evaluation	92626 and 92627	Yes	Yes
57	Septostomy	92992 and 92993	Yes*	Yes
58	Ophthalmoscopy	92201and 92202	Yes	Yes
59	Remote Interrogation Device Evaluation	93297 - 93299 and G2066	Yes*	Yes
60	Duplex Scan Arterial Inflow-Venous Outflow	93985 and 93986	Yes	Yes
61	Myocardial Strain Imaging	93356	Yes	Yes
62	Lung Function Test	94200	Yes	Yes
63	Long-Term EEG Monitoring	95700, 95705 - 95726	No	Yes
64	Health and Behavioral Assessment and Intervention	96156, 96158, 96519, 96164, 96165, 96167, 96518, 96170 and 96171	Yes	Yes
65	Cognitive Function Intervention	97129 and 97130	Yes	Yes
66	Open Wound Debridement	97597 and 97598	No	Yes
67	Negative Pressure Wound Therapy	97607 and 97608	Yes	Yes
68	Ultrasonic Wound Assessment	97610	Yes	Yes
69	Online Digital Evaluation Service (e-Visit)	98970- 98972 , G2061-G6063	No	Yes

Code Group Number and Name		Codes (CPT and HCPCS)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Finalizes Proposed Work RVUs
70	Emergency Department Visits	99281 - 99285	Yes	Yes
71	Self-Measured Blood Pressure Monitoring	99473, 99474, 93784, 94786, 93788, and 93790	Yes	Yes
72	Online Digital Evaluation Service	99421-99423	Yes	Yes
73	Radiation Therapy	G6001-G6017	NA**	Yes
74	Immunization Administration	G0008 -G0010	NA	No
*Contractor Priced Codes: 66983, 66X01, 66X02, 92992, 92993, and GTTT1 **CMS proposed to continue to use the current work RVUs for these codes				

(4) Trigger Point Dry Needling (CPT codes 20560 and 20561)
Commenters disagreed with CMS' proposal to designate these codes as "always therapy" procedures since they are done by a wide range of professionals and are provided as either a therapy or non-therapy service. After considering comments, CMS does not finalize these codes as "always" or "sometimes" therapy services and notes that dry needling services are non-covered unless otherwise specified through a national coverage determination (NCD).[31]

(8) Arthrodesis – Sacroiliac Joint (CPT code 27279)
CMS identified this code as identified as a potentially misvalued code. Based on results from a 2018 survey, the RUC recommended maintaining the current work RVU of 9.03. CMS notes that a stakeholder requested that CMS protect patient access and implement payment parity between this code and CPT code 27280, which has a work RVU of 20.00. CMS proposed the RUC-recommended work RVU but solicited comment on whether the alternative valuation of 20.00 is more appropriate.

In response to a commenter questioning the appropriateness of a non-RUC stakeholder comment, CMS states that it may take into account information provided by many stakeholders, including specialty societies that did not agree with the RUC recommendation. The RUC restated that it not does believe there is compelling evidence to revalue this procedure as the intensity required to perform the service has not changed. Most commenters stated that the work for the service is undervalued because it is based on a crosswalk from 2014 rather than updated survey data. Commenters provided numerous codes for CMS to consider as crosswalks. CMS agrees with the RUC that CPT code 27279 is not analogous to the open procedure CPT code 27280 because it is a more complex service and requires twice the amount of intraservice time to perform than CPT code 27279. After consideration of comments, CMS believes the code is undervalued and finalizes a work RVU of 12.13 with a direct crosswalk to CPT code 75288 (Sling operation for stress incontinence).

[31] NCD information is available in the NCD Manual, Section 30.3 available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf

(11) Transcatheter Aortic Valve Replacement (TAVR) (CPT codes 33361 – 33366)
CMS finalizes the proposed RUC-recommended work RVUs for all codes in this family. CMS acknowledges that TAVR procedure are being adopted by more physicians and there is greater intensity for a physician when this new technology is being adopted. CMS disagrees with comments that the proposed values were too low. CMS intends to continue to examine whether TAVR services are appropriately valued as their use increases.

(15) Intravascular Ultrasound (CPT codes 37252 and 27253)
A few commenters disagreed with CMS' proposed values and urged CMS to accept the RUC-recommended values. A commenter stated that the increased utilization of these codes may be for a variety of reasons, including the increased complexity of interventions being performed in the arterial, venous and aortic spaces and that reducing the RVUs to maintain work neutrality may result in reducing access to Medicare beneficiaries. The commenter noted that CMS has many different ways to determine inappropriate billing by some providers. After considering comments, CMS is persuaded to address concerns about increased utilization by claims analysis. Instead of the proposed work RVUs, CMS finalizes the RUC-recommended work RVUs.

(17) Biopsy of Mouth Lesion (CPT code 40808)
Commenters disagreed with CMS' methodology for determining work RVUs stating it ignored the original valuation in 1995 that resulted in a negative IWPUT. After considering comments CMS finalizes the RUC-recommended work RVUs.

(24) Electronic Analysis of Implanted Pumps (CPT codes 62367 – 62370)
Several commenters disagreed with the proposed reduction in the nonfacility PE RVUs for this family of codes and were concerned that the proposed payment reductions would limit access to this important alternative therapy for treatment of chronic intractable pain. Commenters stated that CMS provided no rational in the proposed rule for removing the minimum multi-specialty visit pack (SA048) from the entire family of codes. Commenters also did not believe that a reduction in clinical labor time was appropriate. A commenter also stated that although the service is typically furnished to a beneficiary on the same day as an E/M service, they did not believe the time spent by clinical staff is duplicative. CMS agrees that there are important tasks provided by clinical staff but without specific examples of the clinical tasks that are specific to these codes, it believes that those clinical labor tasks are included in the typically billed same day E/M code for CPT code 62370. CMS finalizes its proposal for the direct PE inputs for these codes.

(50) SPECT-CT (CPT codes 78800 - 78804, 78830- 78832, and 78835)
Commenters provided additional information about the clinical labor minutes allocated for the CA016 activity. Specifically, comments stated that the additional minutes accounted for the additional handling of the radiotracers or setting up the patient in the camera. CMS appreciates these comments and does not finalize its proposed refinements to the minutes allocated to the CA016 activity. In addition, a commenter sent invoices to update the price for the "gamma camera system, single-dual head SPECT CT" (ER097) equipment. Based on the submission of five invoices, CMS finalizes an increase in the price of this equipment from the proposed $464,428.95 to $703,443.37.

(51) Myocardial PET (CPT codes 78459, 78429, 78491, 78431, 78492, 78432 -78434)
CMS disagrees with a comment urging CMS to phase in the payment reduction from contractor-priced to active status as required by section 1847(c)(7) of the Act. Section 1847(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs will be phased-in over a 2 year period. CMS finalizes its proposal to exempt CPT codes 78459, 78491, and 78492 from the phase-in of significant reductions. As previously finalized in the 2016 PFS final rule (80 FR 70927 – 70929), CMS believes that either the shift from contractor-priced status to active status or inclusion as part of a code family undergoing major revisions constitutes a "revised" code for purposes of section 1848(c)(7) of the Act.

(63) Long-Term EEG Monitoring (CPT codes 95700, 95705- 95726)
CMS acknowledges the concerns about the usefulness of these codes in establishing appropriate values for these services and continues to seek updated information, especially empirical data, about the resources involved in providing these services. In response to concerns about the applicability of these new codes in various clinical settings furnished to patients with various needs, CMS finalizes the direct PE inputs as proposed for the PC-only codes in the family (CPT codes 95717 – 95726) and finalizes the assignment of contractor pricing for the TC-only codes in the family (CPT codes 95700 – 95716). CMS seeks information about these services and how the finalized changes in the codes and payment affects appropriate access to care for beneficiaries. If access concerns become apparent, CMS notes it will consider establishing G-codes for services in particular settings of care in future rulemaking.

(67) Negative Pressure Wound Therapy (CPT codes 97607 and 97608)
CMS appreciates the submission of additional invoices for supply SA131 ranging from $208 to $494. CMS continues to final disposal negative pressure wound kits available for purchase online for approximately $100. CMS compared the kits submitted on the invoices to the kits available for purchase online and thinks they are comparable. CMS finalizes a price of $208 for the SA131 supply based on the lower end of the average supply costs provided by commenters.

(73) Radiation Therapy (GCPCS codes G6001-G6016)
The Patient Access and Medicare Protection Act (Pub. L. 114-114, December 28, 2015) required that the code definitions, the work RVUs and the direct input for the PE RUVs for radiation treatment delivery and related imaged services (identified by 2016 HCPCS G codes) for the 2017 and 2018 PFS remain the same as those established for the 2016 PFS. The BBA of 2018 extended this provision through 2019. For 2020, CMS finalizes its proposal to continue to use the G codes for radiation therapy services, as well as their current work RVUs and direct PE inputs.

(74) Immunization Administration Services (HCPCS codes G0008-G0010)
CMS did not make any specific proposals to change payment for these administrative services, but it did receive comments noting a decrease in payment for these services. The commenters noted the linked crosswalk between CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection) and a number of immunization services, and the impact that a proposed reduction to code 96372 would have on payment for immunization services. Given it is in the public interest

to ensure appropriate payment for immunization administration services, for 2020, CMS finalizes it is maintaining the 2019 national payment amount for these codes. CMS plans to review the valuations for these services in future rulemaking to ensure appropriate payment.

O. Response to Comment Solicitation on Opportunities for Bundled Payments

CMS was interested in exploring new options for establishing PFS payment rates or adjustments for services that are furnished together (bundled payment). CMS believes that the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing a service, allows considerable flexibility for developing payments under the PFS. CMS sought comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS.

CMS received many comments; some commenters expressed general support for bundled payments, while others urged caution and suggested working with specialty societies and the CPT Editorial Panel to identify opportunities for bundled payments. Some commenters stated that bundled payments are not within the statutory authority of the PFS and that CMS should continue to use the Innovation Center to test these concepts. CMS will review the comments and consider this issue further for potential future rulemaking.

P. Payment for Evaluation and Management (E/M) Visits

1. Background and Prior Proposals

Clinicians of nearly every specialty and practitioner type furnish E/M services to Medicare beneficiaries, and E/M services comprise roughly 40 percent of PFS allowed charges. In multiple prior PFS rules, CMS expressed increasing concerns about the E/M services CPT code set and its associated Documentation Guidelines (DGs), questioning their relevance to current clinical practice and payment accuracy, particularly for primary care services. During 2019 rulemaking, CMS proposed and finalized – for 2021 implementation – a set of major changes to the coding, payment, and documentation for the Office/Outpatient subset of E/M services (CPT codes 99201-99215). This subset of E/M services represents about 20 percent of PFS allowed charges. CMS indicated that the 2019 changes, outlined below, were intended to reduce administrative burden, improve payment accuracy, and better reflect current medical practice:[32]

- Permitting practitioners to choose to document office/outpatient E/M level 2 through 5 visits using medical decision-making (MDM) or time, or the existing framework based on the 1995 or 1997 Documentation Guidelines;
    - For documentation of level 2-4 visits based on MDM or the DGs, setting a minimum documentation audit standard to that of a level 2 visit; documentation for level 5 visits need to meet the relevant MDM or DG requirements.

[32] To enhance primary care delivery and to address perceived gaps in Office/Outpatient E/M coding and reimbursement for advanced primary care services, CMS has sequentially expanded coverage and payment to include new E/M services (e.g., transitional care management (2013), chronic care management (2015), advance care planning (2016), and cognitive assessment and care planning (2017).

    - Documentation of any level visit based on time requires stating the medical necessity for the visit and the time spent by the billing practitioner personally with the beneficiary; the face-to-face time required at each level is the CPT code's "typical time".
- Creating add-on G codes (HCPCS codes GPC1X and GCG0X) to reflect the differential resource costs of performing primary care and particular kinds of non-procedural specialized medical care during levels 2-4 visits;
- Adopting a new "extended visit" add-on G code (HCPCS code GPRO1) for use only with office/outpatient E/M level 2 through 4 visits;
- Paying a single "blended rate" for office/outpatient E/M visit levels 2 through 4 (one rate for established patients and another rate for new patients); and
- Retaining the existing payment rate for office/outpatient E/M visit level 5.

2. 2020 Final Rule Changes for 2021 Implementation

No new office visit E/M service proposals were made by CMS to take effect for 2020. In response to the above proposals for 2021 implementation, a joint CPT/RUC Workgroup on E/M was convened by the AMA. The workgroup recommended major revisions to the descriptors for the Office/Outpatient E/M codes and their associated prefatory language and instructional guidance. The workgroup recommendations were finalized by the CPT Editorial Panel in February 2019 for inclusion in the CPT 2021 Edition. Under the auspices of the AMA's RUC, the revised codes were revalued using the RUC's survey process, and recommendations for new values were forwarded to CMS in April 2019 for consideration during 2020 PFS rulemaking.

Having considered the CPT Editorial Panel and RUC actions along with further stakeholder input obtained at listening sessions and other forums, CMS proposed to replace the 2019 proposals previously finalized for 2021 implementation, with a new set of proposals for 2021 implementation:

- Adopting revised code descriptors for 99202-99215 as they appear in the CPT 2021 Edition, and their associated prefatory language and instructional guidance, as well accepting the deletion of 99201;
- Allowing practitioner choice of time or MDM as the basis for visit level selection, (using the revised CPT interpretive guidelines for MDM)
    - Eliminating the option for visit level selection based on history and/or physical examination (as described in the extant DGs);
    - Eliminating the level 2 minimum documentation audit standard;
- Deleting HCPCS code GPRO1 and adopting new CPT code 99XXX for prolonged office/outpatient E/M visits;
    - No longer recognizing CPT codes 99358-99359 for separate payment in association with office/outpatient E/M visits;[33]

[33] CPT add-on codes 99358-99359 describe prolonged non-face-to-face service before and/or after direct patient care.

- Revising the descriptor for the resource cost, add-on code, HCPCS code GPC1X for use with all qualifying office visit services, and deleting HCPCS code GCG0X;[34]
- Increasing the value for HCPCS code GPC1X and allowing it to be reported with all office/outpatient E/M visit levels;
- Deleting the level 2-4 blended payment rate and restoring separate payment for each visit level of the office/outpatient E/M codes as revised for the CPT 2021 Edition;
- Adopting the RUC recommendations for revaluation of the CPT 2021 Edition revised codes, with minor refinement;
- Adopting the RUC recommendations for the direct PE inputs for the revised codes as recommended by the RUC with one exception: CMS proposes: to remove equipment item ED021 (computer, desktop, with monitor) as a direct PE input, considering it instead an indirect PE cost; and
- Accepting the RUC recommended times (based on survey data) for time values for the revised office/outpatient E/M visit codes without refinement for CY 2021.

CMS states a belief that the most recent set of proposals as just described would accomplish greater burden reduction than the policies previously finalized for CY 2021, as well as be more intuitive and consistent with the current practice of medicine.

3. Office/Outpatient E/M Services for 2021: Comments, Responses, and Final Actions

CMS notes having received "many thousands of comments" on the Office/Outpatient E/M services changes for 2021 implementation, most of which are not separately acknowledged in the final rule and, therefore, are not reviewed in this summary.

a. Revised code descriptors, prefatory language, instructional guidelines (CPT codes 99202-99215, CPT 2021 Edition)

Commenters were generally supportive of the revised coding (including the deletion of CPT code 99201). Some commenters were concerned that the revised MDM guidelines needed further refinement before adoption (e.g., to reflect the importance of key physical exam findings and to discourage upcoding,). CMS states an intention to monitor claims data to identify shifts in levels billed in general and by specialty that could identify a need to further refine the codes, prefatory language, or instructional guidance.

CMS finalizes adoption of the code descriptors, prefatory language, and instructional guidelines as proposed.

b. Visit level selection based only on time or MDM (and not the 1995 or 1997 DGs)

One commenter expressed concern that MDM alone does not adequately represent the complexity of neurologic patients, though supported level selection based on time. Several commenters asked that urgent care practitioners be allowed to continue level selection based on the DGs as their work is not captured by the revised MDM guidelines. CMS declines this request related to the need to balance flexibility with administrative burden. Questions were

[34] The code descriptor for GPC1X specifies for use "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". (See Table 36 of the final rule).

raised by a few commenters about defining the time limits of the visit when accounting for non-face-to-face work before and after the visit and when assessing the MDM if relevant test results remain pending after the day of the visit. CMS notes a commitment from the AMA to undertake educational efforts about using the revised guidelines which may address some of the concerns raised about time delineation.

CMS finalizes the proposal to allow visit level selection based only on time or MDM.

c. *Coding for prolonged office/outpatient E/M visits* (deleting HCPCS code GPRO1, adopting new CPT code 99XXX, and no longer recognizing CPT codes 99358-99359 for separate payment)

Commenters generally supported the proposals from CMS for reporting prolonged visits, such that CPT code 99XXX would be used to report all prolonged time spent on the day or date of the visit. Some requested clarification of "day or date of the visit", which CMS describes as the 24-hour period for the date of service reported for the primary office/outpatient E/M visit code.

Some commenters asked about potential overlap between CPT code 99XXX and codes 99358-99359. CMS notes some potential ambiguity in the instructions for codes 99XXX and 99358-99359 and restates its proposed interpretation that CPT codes 99358-99359 should not be reported with 99XXX. CMS notes that having a single code for prolonged visit reporting (99XXX) would be easier to understand, less burdensome, and simpler to administer. Further, CMS notes that multiple methods for reporting prolonged service time when time is chosen for office/outpatient visit level selection could lead to Medicare program integrity issues and to inappropriately-increased beneficiary cost-sharing. Finally, CMS states that codes 99358-99359 might be considered misvalued when viewed in the context of the entire package of office/outpatient service reporting revisions.

Commenters supported the adoption of CPT prefatory language about activities that qualify for inclusion when calculating prolonged time spent with a beneficiary during a visit. Support also was received for the proposed deletion of HCPCS code GPRO1. Some commenters were concerned about proper coding and documentation when visit level is selected based on time for "split visits" (i.e., when a beneficiary sees both a physician and a nonphysician practitioner at one visit). CMS states that no proposals about split visits were made for 2020 and will consider the concerns raised in future rulemaking.

CMS finalizes adopting new CPT code 99XXX; no longer recognizing codes 99358-99359 for separate payment if used along with code 99XXX; adopting CPT prefatory language about activities to be counted toward prolonged time calculations; and deleting HCPCS code GPRO1.

d. *Revising the descriptor for HCPCS add-on G code GPC1X, deleting add-on code GCG0X, and revaluing code GPC1X*

Commenters who bill primarily levels 4-5 office/outpatient visits and few procedural services were very supportive of the proposed changes, the net result of which is a single code that may be applied to any office visit at any level that satisfies the revised GPC1X code descriptor (i.e., "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"). The commenters also were very supportive of the revised, higher valuation proposed for code GPC1X (25 percent increase from 0.25 to 0.33 RVUs).

Other commenters disagreed not only with the proposed changes but also with the rationale for adding code GPC1X to the Medicare PFS at all. They noted that the revised office visit code set already specifies care of seriously ill or complex patients as part of level 4-5 visits, and not at levels 1-3. Some stated that the added reimbursement for GPC1X was unnecessary given the revaluation of the entire office/outpatient visit code set (addressed further below), and represented added payment for "outlier" patients who have not been clearly defined as such. Some commenters also noted that projected expenditures for GPC1X would exacerbate the significant, redistributive payment effects already projected to result from the statutory budget neutrality adjustment to the PFS that will be required to offset the proposed increased values for the revised office/outpatient code set (discussed further below). These commenters suggested strategies for mitigating the redistribution (e.g., phasing in the changes over several years).

CMS responds that the patients to whom code GPC1X would apply are not "outliers" but are receiving ongoing care related to their single, serious, or complex chronic condition(s), and that such care is qualitatively different from the care of the typical patient as described by the revised office/outpatient code set. CMS states an intention to consider strategies to mitigate the redistributive payment effects as part of future rulemaking.

CMS concludes by finalizing the revised HCPCS add-on code descriptor and its assigned work value of 0.33 RVUs, along with deletion of the previously finalized code GCG0X.

e. *Deleting the level 2-4 blended payment rates; restoring separate payment for each visit level of the office/outpatient E/M codes as revised for the CPT 2021 Edition; adopting the RUC-recommended revaluations for the revised office/outpatient visit code set; and deleting the minimum level 2 visit documentation audit standard*

The majority of commenters indicated support of all of the changes, while others voiced methodologic reservations about adoption of the RUC-recommended code revaluations. Concerns were expressed about insufficient compelling evidence to support changed values, flawed RUC survey instruments, and lack of familiarity with the revised coding structure by survey respondents. CMS responds that the RUC survey and code revaluation processes were robust and their outcomes represent a significant improvement over current coding and values. CMS notes that additional pertinent information about the values submitted prior to February 10, 2020 (in time for 2021 rulemaking) will be considered. CMS also states that the values may require updating as experience with their use accumulates. CMS considers deletion of the minimum documentation standard as necessary and appropriate since the standard was linked to the blended payment rates, and no objections from commenters were described by CMS.

CMS finalizes deleting the level 2-4 blended payment rates; restoring separate payment for each visit level of the office/outpatient E/M codes as revised for the CPT 2021 Edition; adopting the RUC-recommended revaluations; and deleting the minimum level 2 visit documentation audit standard, as proposed.

CMS notes that many commenters voiced concerns about the redistributive impact of revaluing the entire office/outpatient E/M visit code set, particularly on practitioners who do not routinely bill office/outpatient E/M visits (e.g., radiologists, pathologists). CMS acknowledges the potential for major payment redistributions but goes on to state "Given that these revised codes and values do not take effect until CY 2021, and we do not know the magnitude of redistribution resulting from other policies we may adopt through rulemaking before then, we believe it would be premature to finalize a strategy in this final rule as these values would not be effective until CY 2021".

.

f. Direct Practice Expense (PE) Inputs (Removal of ED021)

Most commenters opposed the classification of equipment item ED021 (computer, desktop, with monitor) as an indirect practice expense rather than as a direct PE input for the revised office/outpatient visit code set. They emphasized the several uses of the computer during each visit (e.g., documentation, checking test results). CMS states its view that ED021 and its use cannot be specifically and directly attributed to a given beneficiary but is used for both administrative and clinical tasks performed by clinicians and their clinical staff members throughout each day. CMS cites similar services that require computer use and for which ED021 is not considered a direct PE input (e.g., CPT code 99483 (Cognitive Assessment and Care Planning). CMS states that RUC-recommended direct PE inputs are accurate other than the inclusion of ED021.

CMS finalizes adoption of all of the RUC-recommended direct PE inputs other than ED021.

g. Adoption of the RUC-recommended service times for use by CMS in PFS ratesetting

For purposes of ratesetting and updating the CMS time file, many commenters recommended that CMS should consider total time to be the median total time for each of the revised office/outpatient E/M services as recommended by the RUC. CMS reviews the time estimates collected in the RUC survey process (pre-, intra-, and post-service times, termed "component times", along with total service time) and goes on to discuss details of the time data collection that may have contributed to discrepancies between averaged total times (as estimated directly by survey respondents) and total times derived by summing the averaged component times. CMS views the discrepancies as problematic for code valuations and for PFS ratesetting for several reasons: 1) the component and total times for E/M services are regularly used as reference values when assigning new or revised valuations to individual codes, and 2) the programming used for PFS ratesetting in general requires that the component times sum to the total time. Using the median total times would not resolve either of the identified problems that would arise because of the time discrepancies. An example of a service with a time discrepancy is shown below.

CMS does not modify its proposal to accept the RUC-recommended times but indicates that this topic will be considered further in future rulemaking.

Example of Time Discrepancy[a]					
HCPCS Code	**Preservice Time (min)**	**Intraservice Time (min)**	**Postservice Time (min)**	**Actual Total Time (min)**	**RUC rec Total Time (min)**
99203	**5**	**25**	**5**	**35**	**40**

[a] Excerpted from Table 27A of the proposed rule; values have not changed between the proposed and final rules
Actual Total Time = sum of separately-averaged component time responses
RUC rec Total Time = average of respondent answers for total time

h. Burden and Impact Considerations of E/M Office Visit Changes for 2021

CMS describes the office visit E/M changes developed by the AMA, now finalized for adoption in 2021 by CMS, as more intuitive and consistent with the current practice of medicine than CMS' previously finalized proposals. CMS also states its belief that the AMA framework achieves greater burden reduction than the previously finalized policies, but does not update the detailed burden analysis that was provided during rulemaking for 2019.

Because the revised office visit codes and values would not become effective until 2021, CMS does not include their estimated impacts in Table 119, the CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty. CMS does, however, provide for illustrative purposes an impact analysis of the E/M value changes finalized for 2021 PFS inclusion, as if those changes were finalized for 2020 implementation (Table 120, reproduced at the end of this summary). This analysis does not reflect the impacts calculated for all changes to the PFS for 2020 implementation other than the E/M changes (as shown in Table 119). CMS emphasizes that 1) further changes could occur to the E/M code set prior to implementation of the office/outpatient service revisions finalized for 2021 implementation; 2) changes not related to E/M services will be finalized for 2021 PFS implementation (e.g., updates of PE inputs, changes to codes identified to be misvalued, new codes unrelated to E/M services); and 3) CMS cannot estimate with any degree of certainty the impact of changes that are not yet known (but will occur through rulemaking). For these reasons, CMS does not now provide an estimate of the combined impact of the 2021 E/M service revisions with other policy changes adopted for the 2021 PFS.

CMS concludes by adding the following information about the simulated E/M impact analysis (Table 120):

- The simulation required an estimate of utilization of the newly finalized HCPCS G code GPC1X that will be available for use as an add-on to office visits 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" (excerpted from Table 36 of the rule).
    - CMS assumed that the following specialties would add code GPC1X to their claims for 100 percent of their office/outpatient visits: 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.

- The overall specialty-level impacts of the office/outpatient E/M changes reflect the typical billing patterns of each specialty, positive impacts for specialties providing a preponderance of higher-level visits and negative impacts for those whose practitioners seldom bill for office visits.

4. Office visits in global surgical packages

a. Background

The RUC also recommended that values for codes with global periods in which office visits are included in the service should be adjusted to reflect the new RUC-recommended values for freestanding office visit. CMS proposed not to accept this recommendation because of 1) longstanding concerns about accurately valuing global surgical packages (e.g., insufficient validated data about the number and type of postoperative visits furnished by surgeons during the global period for each surgical service); and 2) the process that was then in progress to collect data to facilitate accurate valuation of global surgical services. The data collection process was mandated by section 523(a) of MACRA and halted a plan finalized by CMS for transitioning all global periods to 0 days; the transition was to be completed in time for the 2019 PFS.

CMS contracted with RAND for assistance with information collection and analysis. CMS released three reports from RAND contemporaneously with issuing the 2020 PFS proposed rule. CMS describes the RAND report findings as follows:[35]

- Report 1 covers data collected by requiring certain practitioners to submit claims for CPT code 99024 (postoperative visit within a global period) after performing procedures with 10- or 90-day global periods. Response rates were low, especially for 10-day global period procedures. The percentage of expected post-operative visits that were reported were 4 percent and 39 percent within 10- and 90-day global periods, respectively.
- Report 2 covers a targeting 2018 survey about visits after three common major surgical procedures. Response rates were under 20 percent. Results for visit work and time were slightly below expected for cataract and hip procedures and greater than expected for both work and time after complex wound repairs.
- Report 3 discusses potential global package policy options using the data collected, including modeling work and total RVUs allocating PE RVU allocations.

b. Revaluing E/M services within global surgical packages: Comments, responses, and final actions

Most commenters opposed the decision by CMS not to use the revised office/outpatient E/M service valuations to revise the values of global surgical packages. Objections included:

- Historically, CMS has aligned changes in valuation of stand-alone office visits with valuation of the office visits in the surgical global period.

[35] Report 1 is a compressed (zip) file, available for download using a link provided at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html. Report 2 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RAND-Survey-Based-Report.pdf. Report 3 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RAND-Revaluation-Report.pdf.

- Not revising the global service values will disrupt relativity within the PFS.
- Applying new values to standalone E/M but not global service E/M codes would pay physicians unequally for providing the same services, which is forbidden by law.
- By failing to adopt all of the RUC-recommended work and time values for the revised office visit E/M codes, including the recommended adjustments to the 10- and 90-day global codes, CMS is implementing the revised values in an arbitrary fashion.

CMS responds that historical adjustments to global package E/M services were aligned with standalone E/M visit changes in the absence of data to suggest the alignment was inaccurate. CMS states that the RAND reports raise questions about proper valuation of surgical package E/M services compared to standalone E/M services. CMS questions the propriety of using the historical building block approach to global package revaluation when that approach may conflict with potentially more accurate valuations made through magnitude estimation. CMS suggests that the RAND reports reinforce ongoing CMS concerns about the accuracy of the postoperative E/M visit numbers assumed within current global package valuations. Increasing values based on inaccurate visit numbers actually could worsen PFS relativity and accuracy.

CMS ends this discussion thread by declining to apply the revised office/outpatient visit E/M valuations to postoperative global surgical package office visits. CMS states that the information reported by RAND thus far supports that the valuations for E/M services embedded in current surgical global packages are already overstated. Raising global surgical E/M visit values to align with those for standalone office visits would amplify that PFS inaccuracy, and would be inconsistent with the directions in MACRA section 523(a) to use the information collected to improve the accuracy of surgical service values. CMS closes by stating an intent to continue assessing the RAND report results and use them to develop an approach for global surgical package revaluations.

Lastly, CMS notes that commenters also voiced concerns about RAND's methodology and, thereby, of the information gathered by RAND, including the following:

- Disproportionate sampling of large physician practices;
- Failure to capture postoperative visits that were furnished but for which claims for code 99024 were not submitted;
- RAND data collection preceded the RUC revaluations, so the RAND findings are outdated and no longer applicable;
- Flawed matching of procedures with associated claims for code 99024 visits;
- Distortions introduced by RAND's overreliance on sensitivity analyses;
- Bias introduced through the use of "half-visits" from the CMS time file; and
- Information gathered about 10-day global procedure visits was disproportionately generated for a very limited subset of 10-day global package codes.

CMS responds that RAND will be issuing a report, to be posted on the CMS website, which will respond to all of the methodological questions raised. Further, CMS cites support from MedPAC for the decision not to follow the RUC's recommendation to adjust global surgical packages using the revised values for office/outpatient E/M visits.

5. Comment Solicitation on Revaluing the Office/Outpatient E/M Visit within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services

In the proposed rule, CMS discussed other PFS services whose values may be linked to those of office visits and whether consideration should be given to updating those linked services using the proposed, mostly increased, office visit revaluations. Services identified as potentially linked and appropriate for revaluation included transitional care management (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); some ESRD monthly services (selected CPT codes from 90951 through 90961); Initial Preventive Physical Exam (G0438) and Annual Wellness Visit (G0439). Services similar to office visits but provided in other settings were also identified as potentially linked, such as ophthalmological evaluation services, home visits, and psychotherapy visits. Finally, CMS invited comment on the necessity and/or benefit of systematically adjusting other related PFS services to maintain their relativity to office visits, without specifying criteria for "related PFS services".

Many supportive comments were received for potential revaluations of all of the potentially linked services described above as well as for their PFS related services. Some commenters proposed new values for specific services (e.g., ophthalmological evaluations and psychotherapy services). Some commenters also recommended code descriptor and/or documentation requirement changes. CMS states an intention to consider all comments in future rulemaking.

III. Other Provisions

A. Changes to the Ambulance Physician Certification Statement Requirement

As summarized below, CMS finalizes its proposal, with technical modifications, to revise §§410.40 and 410.41 to clarify that there is no CMS-prescribed form for physician certification statements (PCSs) for ambulance transplants. Ambulance suppliers and providers can choose the format by which the requirements for ambulance transport are documented. CMS also finalizes its proposal to allow ambulance suppliers and providers greater flexibility for obtaining a non-physician certification statement.

1. Exceptions to Certification Statement Requirements

Section 1861(s)(7) of the Act provides coverage of ambulance services when the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. The medical necessity requirements for both nonemergency, scheduled repetitive ambulance services and nonemergency ambulance services that are either unscheduled or scheduled on a nonrepetitive basis are specified in §410.40(d). A PCS must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that transportation is medically necessary. If the attending physician is unavailable, a non-physician certification statement can be obtained from other authorized staff.

CMS finalizes its proposal to revise §410.40 to add a new paragraph (a) which will define both PSCs and non-physician certification statements; redesignate existing paragraph (a) "Basic rules"

as paragraph (b); redesignate existing paragraph; and redesignate the remaining paragraphs, respectively. "Medical necessity requirements" will be redesignated as paragraph (e).

Physician Certification Statement. CMS finalizes its proposal that paragraph (a) would clarify that the PCS is a statement signed and dated by the beneficiary's attending physician and certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement does not need to be a stand-alone document and no specific format or title is required. CMS finalizes its proposal for a conforming change to newly designated paragraph (e)(2) to remove language requiring that an order certifying medical necessity must be obtained.

CMS believes its regulations never prescribed the precise format of this required documentation. This finalized policy provides ambulance providers and suppliers flexibility in using a form which conveys the requirements of proposed §410.40(e), so long as it clearly expressed the threshold determination requirement. CMS notes this might include Emergency Medical Treatment & Labor Act (EMTALA) forms and other medical transport forms required by other federal, state, or local laws.

Non-physician Certification Statement. CMS finalizes its proposal that the definition of a non-physician certification statement in paragraph (a) incorporates the existing requirements that apply when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and obtained a non-physician certification statement. This includes requirements that the staff have personal knowledge of the beneficiary's condition at the time the transport is ordered or the service is furnished; the employment requirement; and the specific type of staff that can sign instead of the attending physician. The statement does not need to be a stand-alone document and no specific format or title is required.

CMS also finalizes its proposal for a corresponding change to §410.40(c)(1) to add that ambulance providers or suppliers must indicate on the claim form "when applicable, a PCS or no-physician certification statement is on file."

The determination of whether a service is medically necessary is determined by the Secretary (77 FR 691610). CMS finalizes its proposal to allow contractors to establish the medical necessity of transports by focusing more on the medical necessity determination threshold instead of the form or format of the documentation. CMS does not anticipate this will alter the frequency of claims denials.

2. Addition of Staff Authorized to Sign Non-Physician Certification Statements

When an ambulance provider and supplier is unable to obtain the attending physician's signature within 48 hours of the transport, CMS finalized §410.40(d)(3)(iii) that providers and suppliers could obtain a signed certification (not a PCS) from staff members. Specifically, a physician assistant (PA), nurse practitioner (NP), certified nurse specialist (CNS), and discharge planners can sign a non-physician certification statement. In addition, the staff must be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and the staff have personal knowledge of

the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

CMS finalizes its proposal to add licensed practical nurses (LPNs), social workers, and case managers to the list of staff that can sign a certification statement. The additional requirements for staff would remain.

Several commenters supported the changes to the ambulance certification requirements. In response to a comment, CMS clarifies that it did not propose the elimination of the PCS as a requirement for hospital-to-hospital transport. Instead, it is clarifying that the precise form or format of the certification statement is not prescribed, thereby increasing the flexibility of ambulance suppliers' and providers' compliance with the certification statement requirements. CMS also notes that the clarifications do not obviate a provider's or supplier's responsibility to submit required documentation upon request to Medicare contractors. In response to questions about specific scenarios, CMS states that specific fact-based scenarios should be discussed with the appropriate Medicare Administrative Contractor (MAC). CMS will consider suggestions about additional staff who could sign the non-physician certification in future rulemaking.

One commenter recommended several modifications to promote consistency and readability within the regulations. In response to these recommendations, CMS deletes superfluous language in §410.40(e)(3)(1) and adds references to both suppliers and providers in §410.41(c) and (c)(2). CMS also makes additional technical changes to §§§410.40(e)(3)(iv), 410.41(c)(1) and 410.40(e)(3)(iii).

CMS finalizes its proposed revisions to §§410.40 and 410.41 with the modifications discussed above. In addition, it is making conforming technical changes to update cross-references in §§409.27 and 414.605.

B. Establishment of a Medicare Ground Ambulance Services Data Collection System

Section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically,

- The Secretary is required to develop a data collection system (which may include a cost survey) to collect cost, revenues, utilization, and other information necessary from ground ambulance providers and suppliers. The collection system must be designed to collect information (1) needed to evaluate the extent reported costs relate to payment rates under the ambulance fee schedule (AFS); (2) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a) of the Act; and (3) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas (super rural areas) (section 1834(l)(17)(A)).
- The Secretary is required to specify the data collection system by December 31, 2019, and to identify the providers and suppliers that would be required to submit information, including the representative sample (section 1834(l)(17)(B)(i) and (ii)).

- No later than December 31, 2019, for the data collection for the first year and each subsequent year through 2024, the Secretary must determine a representative sample to submit information. The sample must be representative of different types of providers and suppliers (such as emergency service or government organizations) and geographic location (such as urban, rural, and low population density areas) and not include an individual provider or supplier in the sample for 2 consecutive years, to the extent practicable (section 1834(l)(17)(B) (ii)).
- A ground ambulance provider or supplier identified in the representative sample must submit the information specified in a form and manner specified by the Secretary ((section 1834(l)(17)(C)).
- Beginning January 1, 2022, the Secretary is required to apply a 10 percent payment reduction that would otherwise be made to a ground ambulance organization that is identified for reporting but fails to sufficiently submit data. A hardship exemption to the payment reduction is authorized. The Secretary is required to establish an informal review process of the payment reduction determination (section 1834(l)(17)(D)).
- The Secretary is allowed to revise the data collection system as appropriate, taking into consideration reports submitted to Congress by MedPAC. As determined appropriate by the Secretary, the Secretary can require submission of information after 2024, but no more frequent than once every 3 years ((section 1834(l)(17)(E)).
- MedPAC must assess and submit a report to Congress on the information submitted by March 15, 2023, and as determined necessary by MedPAC. The report must include an analysis of the information, the burden associated with submission, and a recommendation as to whether information should continue to be submitted or if the system should be revised (section 1834(l)(17)(F)).
- The Secretary is required to post information on the results of the data collection system on the CMS website ((section 1834(l)(17)(G)) and implement the data collection system through notice and comment rulemaking ((section 1834(l)(17)(H)).
- The Paperwork Reduction Act does not apply to the required collection of information ((section 1834(l)(17)(I)) and there is no administrative or judicial review of the data collection system or identification of respondents.

CMS discusses interest from many stakeholders in providing similar information for other ambulance service organizations, such as air ambulance organization. Commenters discussed the limitations in the current payment for air medical services and noted that except for the annual ambulance inflation factor, CMS has not adjusted the air AFS since it was established in 2002. Several commenters urged CMS to exercise its existing authority to develop, with stakeholder input, a data collection provide current cost data that could be used to rebase the air AFS. CMS agrees that it is essential that Medicare beneficiaries have adequate access to air ambulance and appreciates the suggestions for updating those rates. It notes that the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organization and does not have the statutory authority to implement a data collection system for air ambulance services.

1. Research to Inform the Development of a Ground Ambulance Data Collection System

CMS discusses the resources its contractor used for developing recommendations for the collection and reporting of data with the least amount of burden possible to ground ambulance organizations. This included an environmental scan of peer-reviewed literature, government and association reports, and targeted web searches; interview with ambulance providers and suppliers, billing companies and other stakeholders; and analysis of Medicare claims and enrollment data for all FFS Medicare claims with dates of service in 2016 (the most recent complete year of claims data for ground ambulance services). In addition the contractor also analyzed data from data collection tools that collect data from ground ambulance organizations: The Moran Company Statistical and Financial Data Survey (the "Moran survey")[36] commissioned by the American Ambulance Association (AAA); Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California's Medicaid program[37]; The Emergency Medical Services Cost Analysis Project (EMSCAP) framework[38] funded by the National Highway Traffic Safety Administration; a GAO ambulance survey[39]; and the Rural Ambulance Service Budget Model[40] developed by a task force of the Rural EMS and Trauma Technical Assistance Center.

The contractor's analysis of this information revealed there was overlap of the broad cost categories (e.g. labor, vehicles, and facilities cost) and there were significant differences in the specific data collected within these categories. The tools had different instructions, format and design in how organizations' total costs were allocated to ground ambulance costs, the time frame for reporting, and the flexibility of reporting. The contractor's report, "Medicare Ground Ambulance Data Collection System – Sampling and Data Collection Instrument Considerations and Recommendations (referred to as the CMS Alliance to Modernize Healthcare or "the CAMH" report) provides more details on the research, findings and recommendations for the data collection instrument and sampling.[41]

CMS disagrees with commenter's concerns that CMS did not test the data collection instrument and sampling methodology prior to making its proposals. CMS notes it conducted an extensive environmental scan and consulted with many stakeholders during the tight timeframe between when the law was enacted and the statutory deadline (December 31, 2019) for specifying the data collection system. CMS plans to conduct extensive stakeholder outreach and develop

[36] The Moran Company (2014). Detailing "Hybrid Data Collection Method" for the Ambulance Industry: Beta Test Results of the Statistical & Financial Data Survey & Recommendations. Available at https://s3amazonaws.com/americanambulance-advocay/AAA+Final+Report+Detailing+Hybrid+Data+Collection+MEthod.pdf.
[37] State of California – Health and Human Services Agency Department of Health Care Services Ground Emergency Medical Transportation (2013). Ground Emergency Medical Transportation Services Cost Report General Instructions for Completing Cost Report Forms. Available at https://www.dhcs.ca.gov/provgovpart/Documents/GEMT/CostRptInst.pdf
[38] Lerner, EB, Nichol, G, Spaite DW et.al. (2007) A comprehensive framework for determining the cost of an emergency medical services system. Available at https://www.mew.edu/departments/emergency-medicine/research/emergency-medical-services-cost-analysis-project
[39] US GAO (2012) Survey of Ambulance Services. Available at https://www.gao.gov/assets/650/649018.pdf
[40] Health Resources and Services Administration. The Rural Ambulance Service Budget Model. Available at https://www.ruralcenter.org/resouce-library/rural-ambulance-service-budget-model.
[41] The report is available at https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html

educational materials. CMS also plans to make revisions to the data collection instrument and sampling plan as expeditiously as possible to address any issues identified.

2. Final Policies for the Data Collection Instrument

As discussed below, CMS finalizes its proposals for the format, scope, costs, and revenues with several modifications or clarifications.

a. Format

Based on its analysis of data collection instruments, CMS finalizes its proposal to collect ground ambulance organization data using a survey developed specifically for this purpose (referred to as the data collection instrument), which will be available via a secure web-based system. CMS believes this instrument will be used by all ground ambulance organizations, regardless of their size, scope of operations, services offered, and structure. The survey will be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS. CMS codifies these policies, with a few technical changes, at §414.626.

Many commenters supported CMS' proposal and several offered suggestions to facilitate data entry. Some commenters were concerned that a complex data collection instrument will result in a low response rate and inaccurate data, particularly for small ground ambulance organizations. CMS appreciates the overwhelming support for the proposed format of the data collection instrument and will implement many of the suggestions to ensure the system is user friendly. In response to concerns about the complexity of the system, CMS expects that the use of screening questions and skip patterns will make the collection instrument specific to an organization and will make it easier and less time consuming to complete than a cost report spreadsheet. It believes that all ground ambulance organizations that participate in the data collection, will work with CMS and their ambulance associations to obtain any assistance they need to report the required data.

Some commenters preferred a two-stage approach to data collection which would include a first stage to collect key organizational information to use to obtain a representative sample for data collection. In response, CMS states it believes the Medicare claims and enrollment data provides enough data to appropriately stratify the sample and that multiple data collections would increase respondent burden. In addition, it believes that collecting data on organizational characteristics as part of one data collection effort will enable skip patterns within the survey to limit the number of questions specific types of organizations will need to answer.

b. Scope of Cost, Revenue, and Utilization Data

CMS discussed several options for defining the scope of data collected. One option would require ground ambulance organizations to report on the following related to ground ambulance services: (1) total costs; (2) total revenue; and (3) total utilization. The second option considered would collect only those costs relevant to ground ambulance services furnished to Medicare beneficiaries. The third option would consider only those costs that are related to the specific ground ambulance transport services that are paid under the AFS.

CMS finalizes its proposal to use the first option which requires ground ambulance organizations to report on the following related to ground ambulance services: (1) total costs; (2) total revenue; and (3) total utilization. Total data will be collected regardless of whether the services was billable to Medicare or related to a Medicare beneficiary.

CMS acknowledges that many ground ambulance organizations share operational costs and staff with other entities, including fire departments; other public service organizations; and hospitals. To more accurately define costs and total revenues related to ground ambulance services that provide other services, CMS finalizes its proposal that the instructions for the data collection instrument will separately address three further refined categories of total ground ambulance costs and revenues:

- Costs and revenue components completely unrelated to ground ambulance services. This information is unrelated to the data collection and not reported. Examples include administrative staff without ground ambulance responsibilities, health care delivery outside of ground ambulance, and fire and police public safety response.

- Cost and revenue components partially related to ground ambulance services. This information will be reported in full but respondents will report additional information that can be used to allocate a portion of the costs to ground ambulance services. Examples include EMTs who are also firefighters and facilities with both ground ambulance and fire department functions.

- Cost and revenue components entirely related to ground ambulance services. These costs are reported in full. Examples include EMTs with only ground ambulance responsibilities.

CMS believes the collected data will be available to estimate total costs and revenues relevant to ground ambulance services. The data could be analyzed to calculate an average per-transport cost for each organization and calculate Medicare margins with and without add-on payments or could provide the basis for other analyses to link reported costs to AFS rates.

Many commenters supported CMS' proposal. One commenter expressed concerns that several categories of "hidden" or "opportunity costs", such as volunteers using their own cars to respond to calls, were not captured in the data collection instrument. CMS does not agree with the suggestion to collect "hidden" costs and notes the statute requires collection on actual costs and not costs that would occur under certain circumstances.

c. Data Collection Elements

Table 37, reproduced below, provides an overview of the elements of the data collection instrument. CMS organized costs by category, which is the approach used in the GEMT and the AAA/Moran survey.

Table 37: Components for the Data Collection Instrument		
Data Collection Instrument		**Broad Description of the Component**
Component	**Section**	
Ground ambulance organization characteristics	2 -4	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions
Utilization: Ground ambulance service volume and service mix	5 and 6	Number of responses and transports, level of services reported by HCPCS code.
Costs	7-12	Information on all costs partially or entirely related to ground ambulance services
• Staffing and Labor	7	Number and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities	8	Number of facilities; rent and mortgage payments, insurance, maintenance, and utility costs.
• Vehicles	9	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual depreciation; total fuel, maintenance, and insurance.
• Equipment & Supply	10	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other	11	All other costs not reported elsewhere
• Total Costs	12	Total costs for the ground organization included as a way to cross-check costs reported in the instrument.
Revenue	13	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

Highlights of each category are discussed below; the interested reader is referred to the final rule for more details.[42]

(1) Ground Ambulance Provider and Supplier Characteristics

In addition to collection on services furnished in different geographic locations, CMS recognizes that there are additional differences among ground ambulance organizations based on ownership (for-profit or non-profit, government or non-government, etc.); service volume; organization type (including whether costs are shared with fire or police response or health care delivery operations); EMS responsibilities; and staffing models. CMS included questions related to these differences because it believes this information impacts costs and revenues and can be collected with minimal burden. CMS considered obtaining this information from the Medicare enrollment form (CMS 855A) but believes the data accuracy will be improved if reported directly by respondents during this data collection. CMS explains that some proposed questions about organization characteristics are necessary to tailor later parts of the data collection instrument to the respondent.

CMS discusses the need to collect information about ground ambulance organizations primary service area in which they are responsible for a certain type of service (e.g. ALS-1 emergency response within a municipality) and any secondary service areas they may have for providing

[42] The draft data collection instrument is available at the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Ambulance-Instrument-072419.pdf.

mutual or auto-aid[43], or providing a different service in a secondary area (e.g. non-emergency transports state-wide). CMS considered several options for obtaining this information including, Medicare claims data, narrative description, and ZIP codes for primary and other service areas. CMS finalizes its proposal to require ground ambulance organizations to identify their primary service area by either: (1) providing a list of ZIP codes that constitute their primary service are; or (2) selecting a primary service area using pre-populated drop-down menus at the county and municipality level. CMS also finalizes its proposal to require respondents to specify whether they have a "secondary" service area and to identify the secondary service area using the options provided for reporting the primary service area information. CMS notes it will not collect information on areas served only in exceptional circumstances, such as areas rarely served under mutual or auto-aid agreements or deployments in response to natural disasters or mass casualty.

CMS also finalizes its proposal to collect information about average trip time and response times in primary and secondary service areas. CMS notes that ground ambulance organizations recommended the collection of average trip time in addition to average mileage because some rural and remote areas may have long average trip times even with modest mileage due to terrain, the quality of the roads and other factors. CMS believes that collecting this information will allow analysis of whether different communities with different response time expectations have systematically different costs.

Many commenters supported CMS' proposal for collection information about organizational characteristics. As discussed in the final rule, commenters made several specific recommendations for changes to the data collection instrument and CMS makes detailed responses to recommendations, including clarifications and changes to some of the questions.

Commenters were also supporting of collecting information about service area using ZIP code level data. In response to a comment, CMS clarifies that each ambulance organization will determine what it considers to be its primary service area, usually based on whether it has primary EMS or responsibilities within a specific jurisdiction or if it has contractual or other arrangements to provide a certain level of service within a particular region. CMS contrasts this to an area when the ambulance organization renders aid to other organizations. CMS expects that in most cases, over 50 percent of an organization's transports will occur in the primary service area. After consideration of comments, CMS clarifies in the data collection instrument that responses to questions related to the primary and secondary service area should be based on the respondents' best judgement. It also clarifies the primary and secondary area definitions through new examples in the data collection instrument instructions.

(2) Ground Ambulance Utilization

CMS finalizes its proposal to collect utilization data related to all services, not just transports, because other services that contribute to the total volume of responses have direct implications for costs. CMS finalizes a two-pronged approach to collect data on both the volume and mix of services. First, CMS will collect the total volume for the following categories: total responses (including those where a ground ambulance was not deployed); responses when a ground ambulance was deployed; ground ambulance responses that did not result in a transport; ground

[43] CMS defines mutual aid agreements as joint agreements with neighboring areas in which they can ask each other for assistance. Auto-aid agreements allow a central dispatch to send the closest ambulance to the scene.

ambulance transports; paid ground transports; standby events; paramedic intercept services (as defined by Medicare); and other situations where paramedic staff contributes to a response where another organization provides the ground ambulance transport.

Second, to account for this variation in the mix of ground ambulance services, CMS will collect the following: the share of responses that were emergency versus non-emergency; share of transports that were land versus water (water ambulances); share of transports by service level; and the share of transports that were inter-facility transports.

CMS finalizes its proposal for reporting the share of total ground ambulance responses that were in a secondary rather than the primary service area in a single question. Respondents will not report on their mix of services in primary and secondary service areas. CMS also did not propose to collect detailed information regarding the mix of services for total transports and paid transports because of the associated reporting burden. CMS notes that stakeholders believe it is reasonable to assume that the distribution of transports across categories would be the same.

Many commenters supported CMS' proposal for collection utilization data on all services, not just transports. After consideration of comments, CMS will use the Medicare manual definitions of Medicare ground ambulance services, clarify the definitions of other response and transport categories, and remove the Medicare medical necessity requirement from the definition of "ground ambulance transport". CMS will also redefine the definition of 'interfacility transport' in the data collection instrument to include transports where the origin and destination are one of the following: a hospital or skilled nursing facility that participated in the Medicare program or a hospital-based facility that meets Medicare's requirements for provider-based status. CMS also adds an additional question to the data collection instrument that specifically asks for interfacility transports that are covered under Medicare Part A.

(3) Collecting Data on Costs

CMS finalizes two proposals that impact the reporting of all the cost sections. First, when a sampled organization is part of a broader organization (a single parent company operates different ground ambulance providers), CMS finalizes that respondents will report an allocated portion of the relevant ground ambulance labor, facilities, vehicle, supply/equipment, and other costs from the broader parent organization level using the allocation approach they regularly use.

Second, CMS finalizes including a general instruction stating that when costs are paid by another entity which the respondent has an ongoing business relationship, the respondent must collect and report these costs. Examples include when a municipality pays rent or when hospitals provide supplies and medications to ground ambulance operations at no cost. CMS acknowledges this will be an additional response for some organizations but is concerned that the lack of reported cost data in one of the major categories will significantly affect calculated total cost.

CMS considered asking respondents to report fair market values for donated vehicles and buildings. To avoid the burden associated with providing this information, CMS finalizes that respondents only report the ambulances, other vehicles and buildings that have been donated

without the fair market estimate. CMS believes fair market values can be imputed using publicly available data.

Commenters were supportive of the categories of costs proposed for the data collection system. Some commenters noted that the lack of a standard approach to the allocation of costs between ambulance organizations and their parent organization could potential lead to differences in how costs are reported. CMS does not believe a specific, standardized allocation method is necessary as it expects only a small share or reporting ground ambulance organizations to allocate patent organization costs in this way. CMS agrees with commenters that certain items such as depreciation will be difficult for some agencies to estimate and it will provide additional information in the survey instructions. CMS also adds a question to the 'other costs' section for funds paid to other organizations for services (such as non-transporting organizations providing medical personnel).

(i) Collecting Data on Staffing and Labor Costs

CMS agrees with ambulance providers and suppliers that labor, specifically medical staff such as EMTs and paramedics, is one of the largest contributors to total ground ambulance costs. CMS finalizes its proposal to collect information on the number of staff and labor costs for several detailed categories of response staff (for example, EMT-basic, EMT-intermediate, and EMT-paramedic), a single category for paid administrative and facilities staff, and a category for medical directors. To collect additional detailed information on specific administration and facilities labor categories, CMS finalizes its proposal to ask additional questions about the functions staff perform.

Reporting Staffing Levels. CMS considered several options for reporting staffing levels, including the burden associated with each option. CMS proposed collecting information on the number of staff in terms of hours worked over a typical week. The instructions ask respondents to "select a week for reporting that is typical, in terms of seasonality, in the volume of services that you offer (if any) and staffing levels during the reporting year."

After consideration of comments, CMS removes the instruction to report staffing levels during a typical week and instead, it finalizes reporting staff levels in terms of hours over the entire annual reporting period. CMS notes this will result in reporting instructions that are more similar for staffing levels and labor costs. CMS is not changing the instructions that ask respondents to categorize each staff member in only one category.

Scope of Reported Labor Costs. CMS finalizes its proposal to define labor costs to include compensation, benefits, stipends, overtime pay, and all other compensation to staff (fully-burdened costs). After consideration of comments, CMS adds new items to the labor section. CMS also clarifies that organizations should only report the costs they pay for a medical director, not an estimated true cost for the value of that medical director's labor.

Volunteer Labor. Ground ambulance organizations reported that a significant share of ambulance providers and suppliers rely in part or entirely on volunteer labor and the systems used to collect this information varies among organizations. CMS finalizes its proposal to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same

EMT/response staff and administrative and facilities staff categories used for paid labor. The data collection will collect information only on the amount of volunteer labor and not a market value for that labor which can be determined using readily available information. CMS also finalizes collecting the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs are collected.

CMS agrees with commenters that the definition of "stipends and/or benefits" should be broadened to include all forms of compensation from the ground ambulance organization such as insurance, stipends, or other forms of compensation.

Allocation and Reporting Staff with Other Non-Ground Ambulance Responsibilities. Since firefighters/EMTs are common in many ambulance suppliers, CMS finalizes its proposal to ask respondents that share costs with a fire or police department to report total hours in a typical week unrelated to ground ambulance or fire/police response duties.

As further discussed in the final rule, commenters made several specific recommendations for changes to the data collection instrument for staff and labor costs and CMS makes detailed responses to recommendations, including clarifications and changes to some of the questions.

(ii) Collecting Data on Facility Costs

Facility costs may include rent, mortgage payments, depreciation, property taxes, utilities, insurance and maintenance. CMS considered several options for reporting this information and finalizes a hybrid approach involving both per-facility and aggregate reporting of information. CMS finalizes its proposal that respondents report the total number of facilities and then report relevant rent, mortgage, and annual depreciation for each facility. Facilities-related insurance, maintenance, utilities, and property taxes will be aggregated across all facilities. CMS notes this requires respondents to provide both the square footage of each facility and the share of square footage for the facility that is related to ground ambulance operations.

In response to a comment, CMS states it is not specifying a particular methodology for calculating the percent of square footage attributable to ground ambulance services because it does not want to burden organizations who might already have a particular methodology. CMS will also provide additional examples for clarification on how a ground ambulance organization should report the percentage of the facility attributed to ground ambulance services in the data collection instrument.

(iii) Collecting Data on Vehicle Costs

CMS finalizes its proposal to collect data on ground ambulances and all other related vehicles. This would include information on the number of vehicles, total miles traveled and per-vehicle information of annual depreciated value for owned vehicles, and annual lease payments for rented vehicles. CMS also finalizes collecting aggregate costs associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined (ambulance and non-ambulance).

CMS discusses the need for ground ambulance organizations that share operational costs with fire and police responses or other non-ground ambulance activities to report the allocated vehicle

costs related to ground ambulance services. CMS finalizes its proposal to list the percent of total maintenance and fuel costs attributable to each type of vehicle.

Many commenters generally supported the approach to collect vehicle cost data. In response to comments, CMS notes it intent is to collect data on the costs of vehicles only associated with the reporting organization. For example, the costs reported may include fire trucks if the fire trucks are sent to the scene with EMS personnel. If there are no firefighters co-trained as EMS personnel, then these fire trucks are not related to ground service and should not be included. CMS will add more general examples of non-ambulance vehicles used to support ground ambulance services, which should be included in reporting.

(iv) Collecting Data on Equipment and Supply Costs

Ground ambulance organizations informed CMS that not all organizations would be able to report detailed item-by-item equipment and supply information. CMS finalizes its proposal to request total costs for a small number of equipment and supply categories instead of obtaining itemized information for all equipment and supply categories. CMS finalizes requesting total costs for capital medical equipment; medications; all other equipment, supplies and consumables; capital non-medical equipment; uniforms; and all other non-medical equipment and supplies.

Reporting of Capitol Versus Non-Capital Equipment. CMS finalizes its proposal to obtain information separately for capital costs (including annual depreciated cost) and non-capital costs. Based on feedback from ground ambulance organizations, CMS finalizes its proposal to allow respondents to report annual maintenance and service costs for capital equipment. CMS will allow respondents to use their own standard accounting practice to categorize equipment as capital or non-capital.

Allocation of Shared Costs. For organizations that indicate the use of shared services, CMS finalizes its proposal to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services.

Many commenters expressed a desire to work with CMS to develop additional categories for equipment and supply costs. CMS appreciates that there are many other potential equipment and supply categories but in order to balance the level of detail collected with the burden of data reporting, it decided to limit this section to only a small number of specific types of supplies and equipment. It believes that there might be a need for additional refinements in future years. For example, rather than collecting information on all drugs in aggregate, in the future in might collect information by category of drug or even for individual drugs.

(v) Collecting Data on Other Costs

For contracted services, CMS finalizes its proposal that respondents indicate whether their organization utilize contracted services to support a variety of tasks, the associated annual cost for these services, and the percentage of costs attributable to ground ambulance services. For other miscellaneous costs not otherwise captured, CMS finalizes that respondents report additional cost using an extensive list of other potential cost categories and use write-in fields if

necessary. To account for miscellaneous shared costs, CMS finalizes that respondents report an allocation factor for each contracted service and miscellaneous expenses.

As further discussed in the final rule, commenters made several specific recommendations for changes to the data collection instrument and CMS makes detailed responses to recommendations, including clarifications and additional examples in the data collection instrument instructions.

d. Data Collection on Revenue

CMS believes that collecting information on total revenue is essential to understanding the variations in financing ground ambulance services. CMS finalizes its proposal to ask for total revenue in aggregate, total revenue from paid ground ambulance transports for Medicare, and if possible, total revenue by payer category for other payers. CMS finalizes its proposal to ask whether revenue by payer includes corresponding patient cost sharing or whether cost sharing amounts are included in a self-pay category. For shared revenue, respondents will report the share of revenue for each category that is attributable to ground ambulance services. To collect information on uncompensated care, including charity care and bad debt, CMS will collect information on both total and paid transports.

After consideration of the comments regarding the data collection instrument, CMS will add an option to separately report Medicaid Managed care revenues, and an option to separately report contract revenues from local governments, including tax revenue from local governments.

3. Final Policies for Sampling

CMS is required to identify a representative sample of ground ambulance providers and suppliers that would be required to submit information under the data collection system. This sample must be representative of different types of providers and suppliers and account for geographic locations. In addition, to the extent practicable, no individual ambulance provider and supplier can be included in 2 consecutive years.

Eligible Organizations. CMS is not aware of any existing data source that lists all ground ambulance organizations or one that encompasses all the characteristics that impact costs and revenues. Medicare claims and enrollment data are the only source that has all the providers and suppliers that bill Medicare in a given year. Medicare data can provide information about several important organizational characteristics including provider versus supplier status, ownership, service area population density, Medicare billed transport volume, and type of services provided. CMS notes that other data such as the use of volunteer labor, staffing model, and response times are not available in Medicare data.

CMS finalizes its proposal to sample ground ambulance organizations that are enrolled in Medicare and billed for at least one Medicare ambulance transport in the most recent year of an available full year of claims data prior to sampling. Since ground ambulance organizations have a full year to submit claims after the date of service, claims data for a calendar year are generally not considered complete until the end of the following calendar year. Thus, CMS will use 2017 Medicare claims and enrollment data to determine the sample for the 2020 data collection period.

Sampling at the NPI level. CMS considered sampling at a broad parent organization but based on all the difficulties associated with all the complexities of a business relationship and identification of all NPI that may be affiliated with the same parent organization, finalizes its proposal to select the sample at the NPI level.

Organizations using volunteer labor. CMS considered the opposing opinions from stakeholders about volunteer labor. Some stakeholders suggested that ground ambulance organizations relying on volunteer labor above a certain threshold (10 percent) should be exempt from sampling while other stakeholders thought organizations using volunteer labor should not be excluded because this would eliminate smaller suppliers in rural and super rural areas. CMS believes that the data collection information will provide important information about volunteer labor and that reported hours can be converted to market rates. CMS finalizes its proposal that ambulance providers and suppliers that use any amount of volunteer labor should be included in the sample.

Sampling file. CMS finalizes its proposal to develop sampling files using the most recent full year of claims data. For the first sample of ground ambulances notified in 2019 and reporting in 2020, CMS will use 2017 claims and enrollment data.

Implications of historical sampling files. CMS acknowledges that there may be some organizations in the sample that may no longer be operating and new organizations that started operating between when the time the sample was pulled and when reporting begins. Since CMS will collect a full, continuous 12-months of data, it finalizes that ground ambulance providers and suppliers organizations selected for the sample that were not in business for the full 12 continuous months of the data collection period would be exempt from reporting for the applicable data collection period. Newer ground ambulance organizations will be eligible for sampling and reporting in future years.

Sampling rate. CMS finalizes its proposal that 25 percent of ground ambulance organizations will be sampled from all strata in each of the first 4 years of reporting without replacement. CMS notes if an organization is sampled in Year 1, it will not be eligible for sampling in the subsequent 3 years of data collection. CMS states that a lower sample rate would be of inadequate precision and a higher sample rate provides only marginal gains.

CMS will notify selected ground ambulances by listing them on the CMS website and provide written notification to each organization by email or mail. Notification on the CMS website will be at least 30 days prior to the start date for collecting data. For 2020, the list of the selected ground ambulances is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule.

Approach for Sampling. CMS finalizes its proposal to use a stratified random sample approach. A stratified random sample first stratifies all ground ambulance organizations based on selected characteristics and then a sample is selected randomly from the strata. CMS will sample from each strata at the same 25 percent rate. CMS believes that data collected from this type of sample can be adjusted via statistical weighting to be representative of all ground ambulance

organizations billing Medicare even if response rates vary across the characteristics used for stratification. CMS assumes that all ground ambulance providers and suppliers organizations sampled will report because reporting is required, there is a 10 percent payment reduction for failure to sufficiently report, and it believes organizations want to participate in this evaluation.

Variables for Stratification. CMS finalizes its proposal to stratify the sample based on four characteristics:

(1) provider versus supplier status,
(2) ownership (for-profit, non-profit, and government),
(3) service area population density (transports originating in primary urban, rural, and super rural zip codes), and
(4) Medicare billed transport volume categories.

Based on its analysis of ground ambulance organizations' transports in 2016, CMS finalizes its proposal to use four volume categories: 1 to 200, 201 to 800, 801 to 2500, and 2501 or more paid Medicare transports. CMS notes that the volume categories aim to divide ground ambulance organizations into roughly similar-sized groups and separate organizations with very high volume (greater than 2500 Medicare transports per year) into a separate category. CMS expects that due to economies of scale, the highest-volume organizations may have different costs than lower-volume organizations.

CMS believes these four characteristics are the key defining characteristics of ground ambulance organizations and that Medicare claims and enrollment data provides enough information to stratify ground ambulance on these four characteristics. This stratification approach results in 36 groupings of ground ambulance suppliers and 36 groupings of ground ambulance providers (defined by combinations of the three ownership categories, three service area population density categories, and four Medicare billed volume categories).

CMS noted that sampling could be impacted because some of the groupings could contain a small number of ground ambulance organizations with the four characteristics. To minimize sampling from strata that contain only a few ambulance providers and suppliers in the entire population, CMS will stratify ground ambulance providers based only on service area population density. Using this characteristic satisfies the requirement to collect information on services furnished in different geographic locations, including rural and low population density. In addition, due to the small number of for-profit ground ambulance suppliers that primarily service super-rural areas in the two highest volume categories, CMS finalizes its proposal to collapse the two highest Medicare ground ambulance transport volume categories (801 – 2500 and 2501 or more transports) into a single category (801 and more transports) for the for-profit ground ambulance suppliers.

CMS states that the 25 percent sampling rate is expected to result in more than 200 responses in each subgroup except for ground ambulance providers. For ground ambulance providers, CMS expects a 25 percent sample rate will result in 153 responses. CMS also expects a 25 percent sampling rate will also result in more than 200 responses for other organizations not represented in the strata, including organizations providing primarily non-emergency transports and transports to and from dialysis centers, and will result in more than 200 responses for

organizations that rely primarily on volunteer labor. This number of expected responses will ensure that small to medium differences in means between groups can be detected.

Commenters were generally supportive of CMS' proposals and agreed that data collection must cover all types of ground ambulance organizations regardless of size and service area. Commenters noted that it may be more difficult for some smaller or rural/super-rural ground ambulance organizations to provide data. A few commenters suggested CMS exempt ground ambulance organizations with low volumes of Medicare-billed transports and organizations with workforces consisting of 50 percent or more volunteer labor. CMS recognizes that there may be some ground ambulance organization that have limited resources that affect their ability to report the required information, however it believes that it is critical that all types of organizations submit data.

4. Collecting and Reporting of Information

CMS finalizes its proposal to define the data collection period as a continuous 12-month period of time, as either the calendar year aligning with the data collection year or the 12-month period that is the fiscal year that begins during the data collection year. CMS clarifies s that the first data collection period will be January 1, 2020 through December 31, 2020 for an organization reporting on a calendar year basis. Organizations reporting on a fiscal year basis would collect data over a continuous 12-month period of time from the start of the fiscal year beginning in 2020. Ground ambulance organizations selected as part of the sample must notify CMS of their annual accounting period within 30 days according to the instructions in the notification letter.

CMS also finalizes its proposal that ground organizations would have up to 5 months to report (the data reporting period) to CMS the data following the end of its 12-month data collection period. CMS believes this allows providers and suppliers time to validate the information and certify the accuracy of their data required under the data collection before reporting to CMS. CMS provides examples of the data collection and reporting period for a ground ambulance organization with a calendar year accounting period (Table 38) and an accounting period not based on a calendar year (Table 39).

5. Payment Reduction for Failure to Report

CMS notes that the timeline for the determination of the 10 percent reduction of payments depends on:

- The 12-month data collection period based on the organization's accounting period;
- The end of the 5-month data reporting period that corresponds with the selected data collection period; and
- The time it takes CMS to review the data to determine whether it has been sufficiently submitted.

CMS finalizes its proposal that an ambulance organization will be subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ambulance organization's data reporting period ends. CMS provides examples of the time frame in the final rule.

CMS finalizes its proposal that if the data reported is not sufficient, it will notify the ground ambulance organization that it will be subject to the 10 percent payment reduction for ambulance services provided during the next calendar year. The payment reduction will be applied to the final AFS payment, after all other adjustments have been applied under §414.60. CMS interprets "sufficient" to mean the data reported by the ground ambulance organization is accurate and includes all required data requested on the data collection instrument.

Hardship Exemption The Secretary can exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy , or other similar situations that the Secretary determines interfered with the ability of the provider or supplier to submit information in a timely manner for the specified period.

CMS finalizes its proposal that to request a hardship exemption, a ground ambulance organization will submit a completed request form and includes the following information: ambulance provider or supplier name; NPI number; location address; CEO or any other designated personnel contact information; reason for requesting a hardship exemption; evidence of the impact of the hardship; and date when the organization would be able to begin submitting information under the data collection system.

The completed exemption request form must be signed and dated by the CEO or designee of the ambulance company and be submitted as soon as possible, and not later than 90 calendar days from the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction. The request form should be submitted to the Ambulance ODF mailbox at AMBULANCEODF@cms.hhs.gov. After receipt of the form, CMS will provide: (1) a written acknowledgement that the request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days of the date CMS received the request.

Informal Review. To request an informal review of a determination that is subject to the 10 percent reduction, CMS finalizes its proposal that a ground ambulance organization must submit the following information: ground ambulance organization name; NPI number; CEO or any other designated personnel contact information; ground ambulance organization's selected data collection and data reporting period; and a statement of the reasons why the organization does not agree with CMS' determination, including any supporting documentation.

Similar to the process for a hardship exemption, the informal review request must be signed and dated by the CEO or designee of the ambulance company and be submitted within 90 calendar days of the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction. CMS believes 90 calendar days provides sufficient time for organizations to gather the information needed to support the request for an informal review. The request should be submitted to the Ambulance ODF mailbox at AMBULANCEODF@cms.hhs.gov. After receipt of the request, CMS will provide: (1) a written acknowledgement that the request has been received; and (2) a written response to the CEO and

any designated personnel using the contact information provided in the request within 30 days of the date CMS received the request.

Questions on the ground ambulance data collection system should be sent to AmbulanceDataCollection@cms.hhs.gov.

Commenters supported CMS' proposal for hardship exemption and informal review. CMS notes that the hardship exemption form is available on its website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule.

6. Public Availability

CMS finalizes its proposal to post a report that includes summary statistics, respondent characteristics and other relevant results in the aggregate on the CMS web site. CMS will not post information that identifies individual ground ambulance organizations. CMS plans to make the data available to the public at least every 2 years. This time frame would allow CMS time to analyze the data that is being reported and factor in the various accounting periods of the first group of sampled ground ambulance organizations. CMS plans to post summary results by the last quarter of 2022.

CMS appreciates commenters supporting its proposal to make the data collected publicly available. CMS is exploring several mechanisms for posting the report to its website, including the use of the standard Healthcare Cost Report Information System (HCRIS) and other Public Use Files (PUF) as an additional subsystem to the ground ambulance data collection system.

7. Limitations on Review

CMS codifies at §414,62(g) that there is no administrative or judicial review of these regulations under sections 1869 or 1878 of the Act.

8. Regulatory Impact

CMS assumes that ground ambulance providers and suppliers will incur costs for data collection and data reporting. In the first year, based on a sampling rate of 25 percent, 2,690 respondents are expected. CMS estimates a total data collection cost of approximately $3.1 million (2,690 respondents * $1,156 per respondents). Assuming it will require 3 hours to enter, review, and submit information into the web-based data collection system and the cost of the associated staff wage is $57.82/hour, CMS estimates a total cost for data reporting of $466,603 (2,6900 respondents * 3 hours * $57.82/hour). The total annual impact for ground ambulance organizations is approximately $3.577 million. Based on discussions with ambulance organizations, CMS does not anticipate that larger or smaller ambulance organizations will face significant differences in the costs incurred for data collection and data reporting.

CMS expects only a few ground ambulance organizations will request either a hardship exemption or an informal review. Because CMS does not have any experience in collecting data from ground ambulance organizations, it assumes that the total 25 percent sample, 2,690

respondents, will request a hardship exemption and an informal review. CMS estimates the total cost associated with the completion and submission of the hardship exemption request form will be approximately $38,884 and the costs associated with the completion and submission to submit the informal review request will be $38,884.

C. Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR)

1. Background

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new section 1861(eee) of the Act to provide coverage of cardiac rehabilitation (CR) and intensive cardiac rehabilitation under Medicare part B.[44] The statute specified certain conditions for these services and an effective date of January 1, 2010. CR and ICR were covered services for beneficiaries who had experienced one or more of the following: (1) an acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty or coronary stenting; or (6) heart or heart-lung transplant (§420.49(b)). For CR only, other cardiac conditions may be added as specified through a national coverage determination (NCD). Effective February 2014, CMS expanded coverage of CR to beneficiaries with stable, chronic heart failure (CHF), defined as 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. (NCD 20.10.1).

2. Statutory Authority

Effective February 9, 2018, section 51004 of the BBA of 2018 amended section 1861(eee)(4)(B) of the Act to expand coverage in ICR program to additional conditions:

- Stable, CHF defined as patients with left ventricular ejection fraction of 35% or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks; or
- Any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered unless the Secretary determines, using the same process used to determine the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

CMS noted that the statute explicitly states cardiac rehabilitation. Therefore, the proposal was specific to CR and ICR for cardiac conditions and did not include applying CR and ICR to other conditions (for example, cancer, diabetes, peripheral artery disease, etc.).

---

[44] Cardiac rehabilitation (CR) services are physician-supervised programs that furnish physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, outcomes assessment and other items/services as determined by the Secretary under certain conditions. Intensive cardiac rehabilitation (ICR) services are physician-supervised programs that furnish the same items/services under the same conditions as a CR program but must also demonstrate, based on peer-reviewed published research, that the program improves patients' cardiovascular disease through specific outcome measurements as described in 42 CFR 410.49(c). (Medicare Benefit Policy Manual, Chapter 15, 232.)

3. Proposal for Implementation

CMS proposed modifications to existing requirements under (§420.49(b)) to implement the coverage changes to ICR. The proposal involved: (1) expanding coverage of ICR to beneficiaries with CHF with left ventricular ejection fraction of 35% or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, with an effective date of February 9, 2018 and (2) providing for modifications to covered cardiac conditions for ICR, in addition to CR, as specified through an NCD.

Commenters supported this proposal. CMS finalizes this proposal.

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

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid EPs and eligible hospitals can receive incentive payments for the adoption, implementation, upgrade, and meaningful use of Certified Electronic Health Record Technology (CEHRT). To demonstrate meaningful use of electronic health records (EHR) technology, the EHR user is required to report clinical quality measures selected by CMS or a state and submit them in the form and manner specified by CMS or the state. In selecting electronic clinical quality measures (eCQMs) for EPs to report, Section 1848(o)(2)(B)(iii) of the Act requires the Secretary to avoid redundant or duplicative reporting.

For 2019, Medicaid EPs were required to report on any six eCQMs relevant to the EPs' scope of practice, regardless of whether they report via attestation or electronically. CMS also adopted the MIPS requirement that EPs report on at least one outcome measure or, if an applicable outcome measure is not available or relevant, one other high priority measure.

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

Measures. For 2020, CMS finalizes its proposal to continue to require that Medicaid EPs report on any six eCQMs relevant to the EPs' scope of practice, regardless of whether they report via attestation or electronically. EPs will be required to report on at least one outcome measure or, if an applicable outcome measure is not available or relevant, one other high priority measure.

In the CY 2019 PFS final rule (83 FR 59702) CMS established three methods to identify which of the available measures are high priority measures for EPs. For 2020, CMS proposes to use the same methods to identify high priority measures.

Commenters supported CMS proposals. The eCQMs available for Medicaid EPs in 2020 will consist of the list of quality measures available under the cecum collection type on the final list of quality measures established under MIPS for the 2020 performance period.

Reporting Period. CMS proposed that the 2020 reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year would be a minimum of any continuous 274-day period within 2020. This 274-day eCQM reporting period corresponds to the 9-month period from January 1, 2020 to September 30, 2020. Medicaid EPs would not be required to use that exact reporting period, they could use any continuous 274-day period within 2020.

In addition, CMS proposed that states would be required to allow sufficient time for EPs to attest for program year 2020 beyond January 1, 2021 so that EPs may select EHR and eCQM reporting periods that take place at any time within 2020 through December 31, 2020. CMS noted this proposal would allow states to accept attestations for program year 2020 as early as October 1, 2020 and could give states additional time to prepare for 2021. CMS considered whether to propose a reporting period for 2020 from January 1, 2020 through September 30, 2020 and not allow flexibility for EPs to select an alternative 274-day reporting period. CMS also considered whether to propose a date prior to December 31, 2020. CMS decided to propose a reporting period that will allow as much flexibility as possible for Medicaid EPs and to facilitate an orderly end of the Medicaid Promoting Interoperability Program in 2021.

For 2020, CMS proposed that EPs demonstrating meaningful use for the first time, the eCQM reporting period will continue to be any continuous 90-day period consistent with existing rules.

All commenters supported CMS' proposal to shorten the cecum reporting period for 2020 but most commenters, including provider organizations, health IT vendors, and state Medicaid agencies, opposed a 274-day reporting period and recommended a 90-day reporting period for 2020. CMS agrees with commenters and finalizes a continuous 90-day cecum reporting period for all Medicaid EPs in 2020. EPs may select any continuous 90-day period within the calendar year.

CMS notes that under the finalized policy, EPs may be able to attest to meaningful use as early as April 1, 2020. CMS encourages states to begin taking attestations as early as possible in 2020, as that would allow states as much time as possible to process and make 2020 payments before preparing for the 2021 program year. CMS expects states to provide EPS the opportunity to use any 90-day period in 202, up to and including a period that ends December 31, 2020. CMS notes that states must submit their attestation deadlines to CMS for approval each year

3. Objective 1: Protect Patient Health Information in 2021

In the Stage 3 final rule (80 FR 62762, 62832), CMS established Meaningful Use Objective 1: "Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards". CMS also finalized that this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period; if it occurs after the EHR reporting period it must occur before the provider attests to meaning use of CEHRT or before the end of the calendar year, whichever comes first. CMS notes this means that EPs do not attest to meaningful use of CEHRT before completing this measure.

All state Medicaid Promoting Interoperability Program incentive payments must be issued by the statutory deadline of December 31, 2021. Although states can establish state-specific deadlines for Medicaid EPs to attest to the state meaningful use of CEHRT in 2021, because of changes CMS previously finalized for the Medicaid Promoting Interoperability Program EHR and eCQM reporting periods for 2021, all states must set attestation deadlines on or before October 31, 2021. CMS is concerned that if an EP or practice typically conducts the security risk analysis at the end of each year, the 2021 timeline for attesting to meaningful use of CEHRT may create burden for all Medicaid EPs and for non-EP health care providers within the same organization as Medicaid EPs. In addition, CMS is concerned that disruption of the interval between security risk analyses is not optimal for protecting information security.

To reduce burden for EPs and non-EPS related to changes required to meet the 2021 Medicaid Promoting Interoperability Program attestation timelines, CMS finalizes its proposal to allow Medicaid EPs to conduct a security risk analysis at any time during 2021, even if the EP conducts the analysis after the EP attest to meaningful use of CEHRT to the state. A Medicaid EP who has not completed a security risk analysis for 2021 by the time they attest to meaningful use of CEHRT for 2021 will be required to attest that they will complete the required analysis by December 31, 2021.

CMS notes that states could require Medicaid EPs to submit evidence that the security risk analysis has been competed, even after the incentive payment has been issued. In addition, states could require EPs to attest that if a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. CMS plans to work with states to develop post-payment verification and audit processes.

The majority of commenters supported this proposal and appreciated the increased flexibility provided to EPs. A few commenters, including state Medicaid agencies, opposed the proposal to allow EPs to conduct their security analysis risk after the EP attests to meaningful use of CEHRT to the state. Commenters were concerned about program integrity risk and state burden. In response, CMS states that there are safeguards available to mitigate program integrity risk, including requiring Medicaid EPs to submit evidence of the security analysis risk once it is completed. CMS acknowledges there is some additional state burden but they believe that is outweighed by the reduced burden on Medicaid EPs. CMS finalizes this policy as proposed.

E. Medicare Shared Savings Program (MSSP)

1. Quality Measures

For performance year 2020, for the MSSP, CMS finalizes 23 quality measures to determine ACO quality performance. This information is based on information submitted by the ACO through the CMS Web Interface, calculated from administrative claims data, and collected by the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

a. Changes to Web Interface and Claims-based Measures

CMS tries to align the MSSP measure set with changes to the CMS Web Interface measures under the Quality Payment Program (QPP). In the 2017 PFS final rule, CMS adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through QPP rulemaking, and that any changes would be applicable to ACO quality reporting (81 FR 80499). Thus, CMS is not making any specific proposals related to changes in CMS Web Interface measures reported under the MSSP.

CMS finalizes not making any changes to the CMS Web Interface measure set for performance year 2020. (See discussion in section III.I.3.B.1 of the final rule.) For performance year 2020, ACOs will continue to be responsible for reporting the following measure:

- ACO -14: Preventive Care and Screening Influenza Immunization

CMS finalizes its proposal to maintain the measure with the "substantive" change described in the measure. CMS does not believe this change is significant and it retains the measure as pay-for-performance for the 2020 performance year.

CMS does not finalize its proposal to add the following measure for ACO reporting[45]:

- ACO-47: Adult Immunization Status

For performance year 2020, ACOs will not be responsible for reporting this measure.

CMS proposed the following substantive changes to previously finalized quality measures:

- ACO-17: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- ACO-43: Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment

ACO-17. CMS agrees with extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Tobacco Use measure (ACO-17) is inconsistent with the intent of this measure as modified in the 2018 QPP final rule (82 FR 54) and is unduly burdensome on clinicians. For the 2018 performance year, CMS designated the measure pay-for-reporting. For 2020, CMS proposed modification to this measure. If this modification was finalized as proposed, CMS expected it could to use historical data reported on this measure to establish an appropriate 2019 benchmark and proposed the measure would be pay-for-performance for performance year 2019 and subsequent years.

Commenters supported the proposed update to the numerator and unanimously opposed CMS designating the measure as pay-for-performance for performance years starting in 2019 and suggested it remain pay-for-reporting for 2019. Commenters were concerned that there would not be sufficient time for vendors and/or ACOs to update workflows and reports before the start of the reporting period and this could have a negative impact on performance. Many commenters suggested that CMS keep the measure for pay-for-reporting for 2018 and 2019 consistent with its policy that newly introduced measures will be pay-for-reporting for 2 years.

[45] See Appendix 1, Table A.3 of this final rule for a discussion of comments received on this proposal

After consideration of comments, CMS finalizes that ACO-17 will be pay-for-reporting for performance year 2019, but will revert to pay-for-performance for performance year 2020. CMS is exercising their discretion to redesignate a measure as pay-for-reporting when there is a determination that the measure has undergone a substantive change (§425.502(a)(5)

ACO-43. AHRQ, the measure steward for ACO-43 (Ambulatory Sensitive Condition Acute Composite), made an update that will require a change to the measure specifications for performance year 2020[46]. The measure currently assesses the risk adjusted rate of hospital discharges for acute Prevention Quality Indicator (PQI) conditions with a principal diagnosis of dehydration, bacterial pneumonia and urinary tract infection (UTI). The updated measure will include only two conditions: bacterial pneumonia and UTI. The measure is a composite measure and the rate of hospital discharges is approximately equal to the sum of the rates of discharges for each of its components. Because the removal of dehydration is a substantive change, CMS finalizes its proposal to redesignateACO-43 as pay-for-reporting for 2020 and 2021.

Table 40, reproduced below, shows the entire quality measure set for the MSSP for performance years beginning with 2020. Table 41, also reproduced below, provides a summary of the number of measures by domain and the total domain weights that will be used for scoring quality performance standards for performance year 2020 and subsequent performance years.

TABLE 40: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2020

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff		NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination		NQF #N/A AHRQ	Survey	R	R	P
	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P

[46] https://www.qualityindicators.ahrq.gov/Modules/PQI_TechSpec.aspx

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
Care Coordination/ Patient Safety	ACO - 38	Risk-Standardized Acute Admission Rates or Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)	X	AHRQ	Claims	R	R	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Depression	ACO - 40	Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes	ACO - 27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension: Controlling High Blood Pressure		NQF #0059 NCQA	CMS Web Interface	R	P	P

Table 41: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years 2020

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

b. Comments on Aligning the MSSP quality score with the MIPS quality score
To reduce burden and allow ACOs to more effectively target their resources for improving care, CMS solicited comments on how to potentially align the MSSP quality performance scoring methodology more closely with the MIPS quality performance scoring. CMS also solicited comments on the alternatives discussed below and any other recommendations for alignment of quality performance. Highlights of comments and CMS' responses are summarized; the reader is referred to the final rule for more specific details.

Aligning the Shared Savings Program quality reporting program with the MIPS quality reporting program. Several commenters supported the concept of aligning the Shared Savings Program quality score with the MIPS quality performance score. Some commenters stated that given all the other changes required by ACOs this was not the appropriate time to overhaul quality requirements. The majority of comments opposed aligning the two programs, noting that ACOs are focused on the total population they service and accountable for total costs of that population. Commenters stated that ACOs should have a separate quality measure set and a separate methodology for scoring quality. A commenter thought the measures used in the Shared Savings Program should lead and not follow MIPS measures. Several commenters thought a significant restructuring of the Shared Savings Program quality performance requirements would introduce more confusion for ACOs transitioning into new pathway tracks and uncertainty as CMS makes changes to the MIPS program.

Replace the Shared Savings Program quality score with the MIPS quality performance category score. CMS notes it received very few comments on this topic. Some commenters supported this approach because it could reduce the complexity and burden of reporting. One commenter did not support this concept because they prefer the current Shared Savings Program quality program that focuses on the total care delivered and not just the physician component.

Include MIPS quality measures in the Shared Savings Program. The majority of commenters opposed this concept and cited many difficulties that the measures would introduce for the Shared Savings Program.

Determining the threshold for minimum attainment. The majority of commenters opposed the approach of determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category score. Commenters did not support the option of using a MIPS quality scoring approach that would hold ACOs to a higher standard to be eligible to share in savings and were concerned the MIPS quality scoring methodologies could result in narrow bands for measures with clustered performance that could result in inequitable scores for very small differences in performance, especially for a small sample size. Commenters also expressed concerns about the concept of removing the pay-for-reporting year currently provided to ACOs in their first year of their first agreement.

CMS will consider all the comments it received in the development of future proposals.

2. Technical Change to Correct Reference in SNF-3 Day Rule Waiver Provision

CMS finalizes its proposed technical change to cross-reference within a provision of the Shared Savings Program's regulations on the SNF 3-day rule waiver, to conform with amendments to §425.612 that were adopted in the December 2018 final rule.

F. Open Payments

1. Background

In 2013, CMS published the "Transparency Reports and Reporting of Physician Ownership or Investment Interest" final rule (Open Payments Final Rule) (78 FR 9458) which implemented section 1128G of the Act, as added by section 6002 of the ACA. Under the Open Payments law and regulations, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) must submit information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Applicable manufacturers and applicable group purchasing organizations (GPOs) must also disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors.

CMS issued final regulations in the 2015 PFS final rule (79 FR 67758) that revised the Open Payment regulations. In the 2017 PFS final rule (81 FR 46395), CMS identified areas in those regulations that it believed might benefit from revision and asked for comments to inform future rulemaking. CMS was also interested in suggestions on ways to streamline or make the process more efficient.

Section 6111 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-270) amended the definition of covered recipient to include physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse midwives (CNMs).

CMS proposed to revise the Open Payments regulations by (1) expanding the definition of a covered recipient to codify the SUPPORT Act changes; (2) expanding the nature of payment categories; and (3) standardizing data on reported covered drugs, devices, biologicals, or medical supplies. CMS finalizes all its proposals without modification. The changes will apply to data collected in 2021 and reported in 2022.

CMS also finalizes its proposal to make a correction to the national drug code (NDC) reporting requirements for drugs and biologicals. The effective date for this change is 60 days after the final rule is published in the Federal Register.

2. Expanding the Definition of Covered Recipient

CMS makes a number of technical changes to its regulations to include NPs, PAs, CNSs, CRNAs, and CNMs in the definition of covered recipient. Additionally, CMS notes that the existing exception from reporting requirements for physicians who are employed by the reporting manufacturer also applies to NPs, PAs, CNSs, CRNAs, and CNMs employed by the reporting manufacturer. It makes a number of technical changes to the regulation text, including referring to physicians and the non-physician practitioners above as non-teaching hospital covered recipients.

CMS will update the submissions template before the start of the 2021 data collection period; it says technical support will be provided through direct outreach, guidance, webinar sessions and direct assistance through the program help desk. It acknowledges difficulties in identifying mid-level practitioners and will work with stakeholders to develop practical solutions to ensure the accuracy and availability of data.

CMS estimates there will be approximately $10 million per year in increased burden to reporting entities and the new covered recipient groups for submitting, collecting, retaining, and reviewing data; this estimate is unchanged from the proposed rule.

3. Modification of the "Nature of Payment" Categories

Applicable manufacturers and GPOs characterize payments made to covered recipients by selecting the "Nature of Payment" category that most closely describes the payment. CMS finalizes changes to its Nature of Payment categories to (i) consolidate two existing categories which it finds duplicative and (ii) add three new categories.

CMS consolidates two separate categories for continuing medical education payments. Current regulations distinguish between accredited/certified and unaccredited/non-certified continuing education programs. CMS abandons that distinction and will refer more generally to medical education programs; the category name will be "Compensation for serving as faculty or as a speaker for a medical education program."

CMS adds three new categories: debt forgiveness, long-term medical supply or device loans, and acquisitions. The new categories will operate prospectively, meaning there is no requirement to update previously reported payments/transfers of value.

Debt Forgiveness (§403.904(e)(2)(xi)). This category characterizes transfers of value that forgive the debt of a covered recipient, a physician owner, or the immediate family member of a physician who holds an ownership or investment interest.

Long-Term Medical Supply or Device Loan (§403.904(e)(2)(xiv)). There is currently 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 90 days or a quantity for 90 days' average use). The new category characterizes loans of covered devices or medical supplies for

longer than 90 days. CMS makes a conforming change to its regulations to more precisely describe the existing category as a "short-term medical supply or device loan" in §403.904(h)(5).

Acquisitions (§403.904(e)(2)(xviii)). This category will characterize buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest.

CMS anticipates minor additional costs for system updates associated with modifying the nature of payment categories and estimates a minimal impact.

4. Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

Devices. CMS will require applicable manufacturers and GPOs to provide device identifiers (if any) to identify reported devices in a comprehensive fashion. It does not require a full unique device identifier (UDI). The HHS OIG had recommended that the Open Payments program require more specific information about devices. Commenters raised concerns with the policy, including scenarios where multiple device identifiers could be associated with one transaction or where a device may be associated with multiple identifiers. CMS responds that it will discuss solutions with stakeholders and that it believes there is sufficient time before the 2021 collection period for issues to be resolved and for stakeholders to be prepared.

CMS states that it is unable to estimate the total cost of the addition of the new data element because the cost depends on whether the covered entity already tracks this data element and the extent to which the entity must update their systems to be able to report it.
Drugs and Biologicals. In the 2015 PFS final rule, CMS says it inadvertently struck a reference in its regulation text requiring NDCs to be reported for non-research payments. It states that its policy has always been to require NDCs for drugs and biologicals for both research and non-research payments in Open Payments reports. CMS changes the regulation text to clarify that NDCs are required for both research and non-research payments for drugs and biologicals.

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

The 21st Century Cures Act established a new Medicare home infusion therapy benefit effective January 1, 2021. CMS discussed several options for meeting the statutory requirement that prior to furnishing home infusion therapy, the physician establishing the plan provide notification of the available options for furnishing infusion therapy. This included verbal discussion with annotation in the medical record or written options with a written patient attestation.

CMS solicited comments on the statutory requirement that prior to furnishing home infusion therapy, the physician who establishes the plan of care for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) to their patient.

Several commenters supported the proposed examples of the physician verbally discussing the infusion therapy options and annotating the resulting decision in the medical record and initial plan of care. Commenters thought that written material may be a helpful supplement to a verbal discussion. Commenters also recommended CMS minimize the paperwork burden imposed on physicians and patients. Some commenters recommended that the policy should allow for other professionals, such as social works and home health nurses, to assist in this notification. CMS appreciates the comments and will take them into consideration for developing future policy through rulemaking.

H. Bundled Payment Under the PFS for Substance Use Disorder

In the 2019 PFS proposed rule, CMS sought feedback on creating a bundled episode of care to pay for management and counseling treatment of substance use disorder. That feedback informed the proposal finalized in this rule to establish a bundled payment for treatment of OUD that allows physicians and other professionals to bill for a bundle of services that is similar to the new bundled OUD treatment benefits provided by OTPs (described above).

The Part B bundle includes management, care coordination, psychotherapy, and counseling. It does not include medications – they will continue to be paid as either Part B or Part D drugs. It also excludes toxicology testing, which will continue to be separately billed under the Clinical Lab Fee Schedule. Payment for the bundle will not require that a consultation with a specialist be included.

CMS finalizes its proposal to create two HCPCS G-codes to describe monthly bundles of services. One code describes the initial month of treatment, including intake, the development of a treatment plan and other assessments necessary to begin treatment; a second code describes continuing treatment. An add-on code is also finalized for when circumstances require resources that substantially exceed the resources included in the base codes.

CMS seeks to balance the incentive for bundled payments to encourage efficient care with the concern, as expressed by some of the commenters, that the bundle should not inappropriately limit necessary care.

CMS finalizes the following codes as proposed, but includes several clarifications described below. The codes are:

- HCPCS code G2086: 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.
- HCPCS code G2087: 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.
- HCPCS code G2088: 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).

In the final rule, CMS establishes a requirement that in order to bill for HCPCS codes G2086 or G2087, at least one psychotherapy service must be furnished. It clarifies that practitioners can bill for additional psychotherapy using the add on code and, in cases where the psychotherapy is for co-occurring diagnoses, any of the Medicare psychotherapy codes may be used so long as the services are medically reasonable and necessary.

CMS finalizes the valuation of the codes as proposed, based on the work RVUs and direct PE inputs crosswalked from other services that they are most consistent with:

- The value for HCPCS code G2086 is:
    - Crosswalked to CPT code 99492 (initial psychiatric collaborative care management – 70 minutes) which has an RVU of 1.7 plus CPT code 90832 (psychotherapy, 30 minutes) with an RVU of 1.5 assumed to occur twice in a monthly period plus CPT code 90853 (group psychotherapy) with an RVU of .59 assumed 4 times in a month.
    - Together the total work RVU equals 7.06.
    - The required minimum number of minutes is based on a crosswalk to CPT code 99492.
    - The direct PE inputs are associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code G2087 is:
    - Crosswalked to CPT code 99493 (subsequent psychiatric collaborative care management, first 60 minutes) assigned a work RVU of 1.53 plus CPT code 90832, assigned a work RVU of 1.50 (assuming two per month) and CPT code 90853, with a work RVU of 0.59 (assuming four per month).
    - Together, the total work RVU equals 6.89.
    - The required minimum number of minutes is based on a crosswalk to CPT codes 99493.
    - The direct PE inputs are crosswalked to CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code G2088 is:
    - Crosswalked to CPT code 99494 (Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month) which has a work RVU of 0.82.
    - The required minimum number of minutes is based on a crosswalk to CPT codes 99493.
    - The direct PE inputs are crosswalked to CPT code 99494.

To avoid duplicative billing, CMS also finalizes as proposed its policy to prohibit the same practitioner from reporting the new OUD treatment codes as well CPT codes 90832, 90834, 90837, and 90853 for the same beneficiary in the same month. A separately reportable initial visit would commence the OUD treatment episode – this requirement is parallel to commencing chronic care management services. The same initiating visit for CCM and behavioral health integration (BHI) services will be permitted to serve as the initiating visit for the OUD bundles. For new patients or patients not seen by the practitioner within a year prior to the commencement

of CCM services and BHI services, the billing practitioner must initiate the service during a "comprehensive" E/M visit (levels 2 through 5 E/M visits), annual wellness visit or initial preventive physical exam. The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) also qualifies as a "comprehensive" visit for CCM and BHI initiation.

The services in the bundle must be provided by providers qualified under state law and operating within their scope of practice; the billing clinician must manage the patient's overall care; and therapy and counseling services may be provided via telehealth if clinically appropriate.
CMS recognizes that sometimes OUD can first become apparent in the emergency department but there are presently no specific codes for diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department. CMS requests that commenters describe the use of MAT in the emergency department. It is interested in descriptions of initiation of MAT, referral or follow-up care, and administration of long-acting MAT agents in the ER in order to better understand typical practice patterns to inform future rulemaking.

CMS received comments supporting the proposal; recommending additional payment amounts that recognize different levels of patient need and lowering the threshold for billing the add-on code; and expressing concern that the proposal would limit psychotherapy services or access to non-opioid paid management. CMS declines to lower the threshold for the add-on code and clarifies that practitioners can bill for additional psychotherapy using the add-on code or for co-occurring diagnoses as needed. CMS also notes that the bundled payment codes do not preclude practitioners from furnishing or billing for other non-opioid pain management treatments.

CMS also received a request from commenters that it create a new G-code for RHCs and FQHCs to bill for a bundle of OUD services. CMS declines to do so and points out that RHCs and FQHCs that provide OUD services can bill for individual psychotherapy services using a range of CPT codes that are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. They can also bill for care management services and receive a payment in addition to their AIR or PPS payment. CMS could consider this question again should it become aware that a separate code would be beneficial to RHCs and FQHCs.

I. Deferring to State Scope of Practice Requirements

Citing the growth in the use of non-physician practitioners (e.g., NPs, PAs, CRNAs, etc.) in medical practice, CMS notes that it has updated its policies and regulations over the years to permit non-physician practitioners (NPPs) to furnish services within their state scope of practice in Medicare-certified facilities. CMS proposed changes to its regulations for ambulatory surgical centers (ASCs) and hospice programs to expand the ability of NPPs to provide services in these settings. CMS received about 4,000 comments, and it finalizes the proposals with one clarification described below.

1. Ambulatory Surgical Centers (§416.42(a))

CMS had proposed revisions to the ASC conditions for coverage at §416.42(a) to permit either a physician or an anesthetist to examine a patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed. The intent behind the proposal was to make ASC patient evaluations more consistent by allowing the option for the same clinician to complete both the pre- and post-procedure anesthesia evaluations. The revision would also permit CRNAs to perform the anesthesia risk and evaluation on the patient in ASCs that use these NPPs.

In response to concerns raised by commenters that anesthetists are not trained to perform the clinical assessment for the overall procedure, CMS clarifies in regulation text two separate evaluations and who may perform them:

- Only a physician may perform the clinical assessment for the overall procedure to evaluate the risk of the procedure to be performed.
- A physician or an anesthetist may conduct the pre-surgical anesthesia risk assessment and the post-surgical anesthesia evaluation.

CMS estimates annual savings of approximately $17.3 million for this policy change. CMS assumes that 30 percent of all procedures would utilize the services of a nurse anesthetist instead of a physician for this requirement, which reduces the cost of the examination.

2. Hospice (§418.106(b))

Section 51006 of the Bipartisan Budget Act of 2018 amended the definition of attending physician for purposes of hospice to include PAs. CMS in its FY 2019 Hospice final rule modified the definitions at §418.3 to codify this change. After that codification, stakeholders observed that requirements at §418.106(b) would not permit a hospice to accept an order for drugs from an attending physician who is a PA because those requirements only permit drug orders from physicians and NPs.

CMS finalizes its proposal to revise §418.106(b) to permit a hospice to accept drug orders from PAs acting within their state scope of practice and hospice policy. The PA must be the patient's attending physician, and the PA may not have an employment or contractual arrangement with the hospice. Commenters supported the policy change; some asked CMS to permit the policy to also apply to PAs employed by the hospice whether directly or under contract with the parent organization of the hospice. CMS declines to do so, citing concerns with patient safety and program vulnerabilities. It also clarifies that a PA employed by a parent company that operates the hospice is considered an employee of the hospice under these regulations. CMS also notes that the need for an attending physician outside the hospice to write orders related to implementing the hospice plan of care should be rare.

CMS does not believe there are any associated financial impacts for hospices from this policy change.

Noting in the proposed rule that there are no provisions in the hospice conditions of participation regulations that address PA issues, such as personnel requirements, descriptions of whether PA services would be considered core or non-core, or provisions to address co-signatures, CMS sought comment on a number of issues related to PAs and to NPPs generally. It says it will take into account the responses it received in developing future hospice condition of participation policies.

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

In response to a 2018 Request for Information on the Physician Self-Referral Law, several commenters raised concerns about aspects of the CMS advisory opinion process for guidance on whether certain referrals would violate that law. Commenters complained that the process is too restrictive, that advisory opinions apply only to specific circumstances of the party requesting the opinion, and that the process was arduous and inefficient.

Noting that CMS has only issued 30 advisory opinions in the 20 years that the process has been in place, the agency reviewed its policies and regulations to address limitations or restrictions that may be unnecessarily impeding a more robust opinion process.

CMS reminds readers that there are other avenues to find answers to questions about the application of the physician self-referral law, including its Physician Self-Referral Call Center and responses provided in FAQs. CMS is also considering other means by which it may provide general guidance and compliance advice outside the advisory opinion process.

1. Matters Subject to Advisory Opinions (§411.370)

Under regulations, CMS does not consider requests for advisory opinions that present a general question of interpretation, that pose a hypothetical situation, or that involve the activities of third parties. CMS interprets the statute (section 1877(g) of the Act) as permitting opinions on specific referrals involving physicians in specific situations. Commenters suggested revising these limitations to permit opinions on general questions of interpretation or for hypothetical situations. In the final rule, CMS rejects continued stakeholder requests to provide advisory opinions on general questions of interpretation or for hypothetical situations, arguing that those topics are not appropriate given the restrictions of the statute. To provide clarity, CMS strikes language in §411.370(b)(1) that refers to general questions of interpretation or for hypothetical situations and instead simply indicates that it will not consider requests that involve the activities of third parties.

CMS does finalize modifications to clarify matters that qualify for advisory opinions and the parties that may request them. Specifically, the regulation text in §411.370(b)(1) will now specify that a request for an advisory opinion must "relate to" (as opposed to "involve") an existing arrangement or an arrangement that a requester specifically plans to enter into.

CMS also specifies in the regulation language that a requester must provide a sufficiently detailed description of the arrangement; additionally, the requester must respond in a timely

manner to CMS' requests for additional information about the arrangement at issue. Commenters generally supported these requirements.

CMS notes that there are some matters that are inappropriate for advisory opinions, such as where a financial arrangement is illegal or impermissible under other provisions of federal or state law. Thus it clarifies in new §411.370(e)(1)(v) that it will not accept an advisory opinion request for an arrangement that is not legally permissible for reasons other than under the physician self-referral law.

CMS finalizes its proposal to ease the restriction at §411.370(e)(2) which states the agency will not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities. CMS strikes the language "or substantially the same" from the regulation text. As modified, the agency will not accept an opinion request or issue an opinion if, after consulting the OIG and DoJ, it determines the 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. Commenters supported the less restrictive nature of the regulation as modified.

2. Timeline for Issuing Advisory Opinions (§411.380)

CMS previously established a 90-day deadline to respond to an advisory opinion request; that deadline may be extended in the case of complex legal issues or highly complicated fact patterns. In the final rule, CMS changes this to 60 working days (or 30 working days in the case of an expedited request); the period begins when CMS formally accepts the request. The deadline can be tolled for a number of reasons, including during periods when the request is being revised or additional information is being prepared for submission to CMS. CMS clarifies that a working day is any day other than a Saturday, Sunday, or legal holiday.

Under the new timeframe, CMS will maintain its current 15-day review period to make a preliminary determination whether the submission sufficiently describes the arrangement for the agency to provide an opinion; it will also determine whether grounds exist to reject the request. If the submission lacks the relevant detail, CMS will notify the requestor(s) and seek additional information.

CMS sought comment on whether it should provide a process for expedited request for certain advisory opinion requests; commenters supported the proposal. As finalized, a party may request expedited review of an arrangement is "indistinguishable in all material aspects" from another arrangement that has been reviewed and found compliant with the physician self-referral law. Only these types of requests may use the expedited request process. CMS says it will promptly make determinations on eligibility for an expedited request, and the 30-day period for completion of the opinion begins when the agency formally accepts the submission for review.

3. Certification Requirement (§411.373)

A requestor must certify that its submission is truthful and complete. In the case of a proposed arrangement, the requestor certifies that it intends (in good faith) to enter into that arrangement (which may be made contingent on receipt of a successful advisory opinion). The regulations list with great specificity the relevant officers of corporations, partnerships, limited liability companies etc., who must sign the certification. CMS finalizes a less restrictive requirement that in the case of a corporation the certification must be signed by an officer that is authorized to act on behalf of the requester.

CMS had considered eliminating the certification requirement in light of another federal law (section 1001 of Title 18, United State Code) that prohibits material false statements in matters within the jurisdiction of a federal agency and imposes criminal sanctions for violations. After consideration of comments, it does not make that change.

4. Fees for the Cost of Advisory Opinions (§411.375)

The regulations provide that CMS imposes an initial charge of $250 for an advisory opinion. CMS states that it charges parties a consolidated fee based on the cost of preparing an opinion. CMS had proposed instead to use an hourly rate of $220; for expedited requests, it had considered charging $440 per hour. It had also considered establishing a cap on the total amount it may charge for an advisory opinion.

Most commenters believed that a $220 hourly rate was reasonable. CMS agrees and makes the following changes to its policies:

- It eliminates the requirement for an initial fee of $250.
- It uses the $220 hourly rate for both regular and expedited advisory opinions; this is due to the relatively narrow scope of requests that may qualify for the expedited review.

CMS does not establish a cap on the amount that may be charged for an advisory opinion. Commenters asked the agency whether it could provide cost estimates before incurring any costs; others noted that the rates may be prohibitive for solo practitioners or small, rural providers. CMS says it will see if it is feasible to provide cost estimates, and it may consider case-by-case discounts of its fees for certain parties.

5. Reliance on an Advisory Opinion (§411.387)

CMS' previous position is that an advisory opinion could only be legally relied upon by the parties who made the request; thus, a favorable advisory opinion on a particular arrangement could not be relied upon by all parties to the arrangement—only by those who made the advisory opinion request. CMS did not find that policy to be helpful to stakeholders and proposed to extend protection to any party to an arrangement that receives a favorable advisory opinion. It finalizes that proposal; thus, a favorable advisory opinion precludes imposition of sanctions on the parties requesting the opinion as well as on parties to the specific arrangement that is the subject of the favorable opinion.

CMS finalizes its proposal not to pursue sanctions under the physician self-referral law against any individual or entity that is a party to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion. However, CMS cautions that all facts relied on and influencing a legal conclusion in a favorable advisory opinion are material; any deviation from those facts would render the advisory opinion inapplicable and would not provide for protection against sanctions.

CMS also finalizes its proposal to specifically state that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to specific facts and circumstances.

Commenters supported these proposals saying that they would eliminate confusion. CMS says it will continue to publish advisory opinions on its website with redactions to protect the identities of the parties involved. Some commenters noted that ACO arrangements can take on a variety of forms, so any single ACO arrangement may be substantially similar but not identical to another ACO arrangement that received a favorable advisory opinion; they sought additional flexibility. CMS believes that the changes it finalizes would permit ACO participants to rely on an advisory opinion as non-binding guidance; if the ACO wanted to reassure itself as to compliance, it could request an expedited advisory opinion.

6. Rescission (§411.382)

CMS may rescind or revoke an advisory opinion though it has not done so to date. CMS had asked for comment on whether it should limit its ability to rescind or revoke an advisory opinion to circumstances where there is a material regulatory change that impacts the conclusions of the opinion or when a party who received a negative advisory opinion asks the agency to reconsider its decision based on new facts or law.

Commenters supported imposing restrictions on when the agency could rescind an advisory opinion. CMS finalizes changes to its rescission policy to provide that it may only rescind or revoke an advisory opinion for good cause. Good cause exists (i) when there is a material change in the law that affects the conclusions reached in an opinion; or (ii) when a party that has received a negative advisory opinion seeks reconsideration based on new facts or law. CMS will provide notice to the affected parties and to the public of any rescission or revocation.

In response to comments, CMS notes that it currently permits a "wind down" period for parties to bring existing arrangements to a halt after an advisory opinion has been rescinded or revoked; it rejects a request to establish a set period of time by which the arrangement must be terminated.

7. Other Procedural Requirements

CMS makes a number of minor modifications to §411.372 to improve readability and clarity and to strike references to stock certificates as part of a request submission.

IV. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

CMS specifies that the entire scope of designated health services (DHS) for purposes of the physician self-referral prohibition is defined in a list of CPT/HCPCS codes (the Code List) which is updated annually to account for both changes in the most recent CPT and HCPCS publications and changes in Medicare coverage policy and payment status. The Code List was last updated in the 2019 PFS final rule (83 FR 59718). CMS did not receive any comments related to the 2019 Code List.

The updated comprehensive Code List effective January 1, 2020 is available on the CMS website: http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html. Additions and deletions to the Code List conform to the most recent publications of CPT and HCPCS Level II codes and to changes in Medicare coverage policy and payment status. Tables 67 and 68 in the rule identify additions and deletions to the Physician Self-Referral List. These tables also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in §411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in §411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

V. Interim Final Rule with Comment Period (CMS-1715-IFC)

A. Coding and Payment for E/M, Observation and Provision of Self-Administered Esketaminine

Spravato™ (esketamine) nasal spray, was approved by the FDA on March 5, 2019[47], for use in conjunction with an oral antidepressant, for treatment of depression in adults with treatment-resistant depression (TRD). Because of the risks resulting from sedation and dissociation caused by Spravato administration and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a FDA required Risk Evaluation and Mitigation Strategy (REMS).

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by post-administration observation of the patient for at least 2 hours under direct supervision of a health care professional. Each nasal spray device contains a total of 28 mg of esketamine; each treatment requires either two devices (for a total does of 56 mg) or three devices (for a total dose of 84 mg). In addition, the prescriber and the patient must sign a Patient Enrollment Form and the product can only be administered in a certified medical office where the health care provider can monitor the patient.

Because this new treatment regimen addresses an urgent need for people with TRD, including Medicare beneficiaries, CMS believes it is in the public interest to ensure appropriate patients have access to this treatment. CMS believes that beneficiaries access would be limited without specific Medicare coding and payment. To facilitate prompt beneficiary access, CMS is creating two new HCPCS G codes, G2082 and G2083 (see table below), effective January 1, 2020 on an

[47] The final rule incorrectly states the approval date of Spravato as March 5, 2009.

interim final basis. For 2020, CMS establishes RVUs for these G codes based on the relative resource costs associated with the E/M, observation, and provision of the self-administered esketamine. For 2020, CMS expects the impact on other PFS services is negligible as it expects the diffusion of this treatment into the market will occur over several years. CMS will consider the public comments on this interim final policy as it finalizes coding or payment rules for this treatment in 2021.

HCPCPS G Codes for Treatment Session of Esketamine	
G2082	Office or other outpatient visit for the E/M 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
G2083	Office or other outpatient visit for the E/M of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation

Interim final value for these codes was developed using the building block methodology. For the overall E/M and observation elements of the services, CMS incorporated the work RVUs, work time and direct PE inputs associated with CPT code 99212, a level two office/outpatient visit for an established patient.[48] CPT code 99212 has a total work time of 16 minutes, based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a postservice time of 4 minutes. CMS also incorporates the CPT codes (CPT codes 99415 and 99416[49]) for prolonged clinical staff services beyond the typical service time during an E/M. CPT codes 99415 and 99416 do not have work RVUs but include direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner.

CMS accounts for the cost of the provision of esketamine as a direct PE input by incorporating the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, CMS uses $590.02 for the supply describing 56 mg esketamine (supply code SH109) and for HCPCS code G2083, CMS uses $885.02 for the supply input describing 84 mg of esketamine (supply code SH110). CMS anticipates using ASP or WAC in future years and expects to address this issue in future rulemaking.

When the health care professional supervising the self-administration and observation does not also provide the esketamine product, the provider cannot report HCPCS codes G2082 or G2083. The visit and the extended observation could be reported using the appropriate E/M codes that describe the prolonged service of the professional or the clinical staff. CMS notes it will monitor claims data to safeguard against duplicative billing for these services.

[48] CPT code 99212 is an office or outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key component: problem focused history; problem focused examination; straightforward medical decision making. Typically, 10 minutes are spent face-to-face with the patient and/or family
[49] CPT code 99415 is for the first hour of prolonged clinical staff service beyond the typical service time during an E/M office or outpatient visit, with direct patient contact with physician supervision CPT code 99416, is billed in addition to 99415 and is for each additional 30 minutes (beyond the first hour) of prolonged clinical staff service beyond the typical service time during an E/M office or outpatient visit, with direct patient contact with physician supervision.

CMS seeks comments on the following:

- The interim final values established for these codes, including the assigned work RVUs, work times, and direct PE inputs.
- How to best establish input process for the esketamine product.
- How to best establish input prices for other potential self-administered drugs that necessitate concurrent medical services.

B. Waiver of Proposed Rulemaking for Provisions

The Administrative Procedure Act (APA, section 553(b)) requires the agency to publish a notice of the proposed rule in the Federal Register before the provisions of a rule take effect. Section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements and section 1871(b)(2)(C) of the ACT provides for exceptions from the notice and 60-day comment period requirements: an agency is authorized to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

CMS finds good cause to waive the required notice and comment requirements due to the urgent need of some Medicare beneficiaries for effective treatment for TRD. CMS believes it is in the public interest to adopt these interim final policies to ensure access by making available appropriate payment to health care providers providing these services. It finds that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2020 is negligible and there is no other practical payment under Medicare Part B for this treatment.

IV. Regulatory Impact Analysis

A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2019 with payment rates for 2020 using 2018 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83

percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 and beyond. Section 53106 of the BBA of 2018 requires an update of 0.0 percent, before applying any other adjustments. In addition to the update factor, the CF calculation for 2020 takes into account an RVU budget neutrality adjustment.

The CF for 2020 is $36.0896, which reflects the 0.00 percent update adjustment factor specified under the BBA of 2018 and a budget neutrality adjustment of 0.14 percent (2019 conversion factor of $36.0391*1.00*1.0014). The 2020 anesthesia conversion factor is $22.2016, which reflect the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for anesthesia specialty. See Tables 117 and 118 from the final rule, which are reproduced below.

Table 117: Calculation of the 2020 PFS Conversion Factor

Conversion Factor in effect in 2019		**$36.0391**
Statutory Update Factor	0.00 percent (1.0000)	
2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
2020 Conversion Factor		**$36.0896**

Table 118: Calculation of the 2020 Anesthesia Conversion Factor

2019 National Average Anesthesia Conversion Factor		**$22.2730**
Update Factor	0.00 percent (1.000)	
2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
2020 Practice Expense and Malpractice Adjustment	-0.46 percent (0.9954)	
2020 Conversion Factor		**$22.2016**

Table 119 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

2020 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. CMS attributes specialty impact changes to increases/decreases in value for particular services based on recommendations from the AMA RUC Committee and CMS review, updates to supply and equipment pricing for certain codes, and the continued

implementation of the adjustment to indirect PE allocation for some office-based services (primarily behavioral health specialties).

Column F of Table 119 shows the estimated 2020 combined impact on total allowed charges by specialty of all the RVU changes. These specialty impacts range from an increase of 4 percent for clinical social worker, increase of 3 percent for clinical psychologist, increase of 2 percent for podiatry, to a decrease of 4 percent for ophthalmology, a decrease of 3 percent for diagnostic testing facility, and a decrease of 2 percent for cardiac surgery, neurology, optometry, and vascular surgery.

TABLE 119: 2020 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$237	0%	0%	0%	0%
Anesthesiology	$2,002	0%	0%	0%	0%
Audiologist	$71	0%	1%	0%	1%
Cardiac Surgery	$281	-1%	-1%	0%	-2%
Cardiology	$6,618	0%	0%	0%	0%
Chiropractor	$756	0%	0%	-1%	-1%
Clinical Psychologist	$793	1%	2%	0%	3%
Clinical Social Worker	$787	0%	3%	0%	4%
Colon And Rectal Surgery	$163	0%	1%	0%	1%
Critical Care	$349	0%	0%	0%	0%
Dermatology	$3,550	0%	1%	-1%	0%
Diagnostic Testing Facility	$703	0%	-3%	0%	-3%
Emergency Medicine	$3,035	1%	0%	1%	1%
Endocrinology	$490	0%	0%	0%	0%
Family Practice	$6,056	0%	0%	0%	0%
Gastroenterology	$1,721	0%	0%	-1%	0%
General Practice	$410	0%	0%	0%	0%
General Surgery	$2,047	0%	0%	0%	0%
Geriatrics	$188	0%	0%	0%	0%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,678	0%	0%	0%	0%
Independent Laboratory	$597	0%	1%	0%	1%
Infectious Disease	$643	0%	0%	0%	0%
Internal Medicine	$10,581	0%	0%	0%	0%
Interventional Pain Mgmt	$890	0%	1%	0%	1%
Interventional Radiology	$434	0%	-2%	0%	-1%
Multispecialty Clinic/Other Phys	$149	0%	0%	0%	0%
Nephrology	$2,176	0%	0%	0%	0%
Neurology	$1,512	-1%	-1%	0%	-2%
Neurosurgery	$807	0%	0%	-1%	0%
Nuclear Medicine	$50	0%	1%	0%	1%
Nurse Anes / Anes Asst	$1,297	0%	0%	0%	0%
Nurse Practitioner	$4,532	0%	0%	0%	0%
Obstetrics/Gynecology	$624	0%	1%	0%	1%
Ophthalmology	$5,413	-2%	-2%	0%	-4%
Optometry	$1,335	0%	-1%	0%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Oral/Maxillofacial Surgery	$72	0%	0%	-1%	-1%
Orthopedic Surgery	$3,750	0%	1%	0%	1%
Other	$35	0%	0%	0%	0%
Otolaryngology	$1,230	0%	0%	0%	0%
Pathology	$1,212	0%	0%	0%	0%
Pediatrics	$64	0%	0%	0%	0%
Physical Medicine	$1,117	0%	0%	0%	1%
Physical/Occupational Therapy	$4,273	0%	0%	0%	0%
Physician Assistant	$2,650	0%	0%	0%	0%
Plastic Surgery	$373	0%	0%	0%	0%
Podiatry	$2,017	0%	1%	0%	2%
Portable X-Ray Supplier	$96	0%	0%	0%	0%
Psychiatry	$1,134	0%	1%	0%	1%
Pulmonary Disease	$1,665	0%	0%	0%	0%
Radiation Oncology And Radiation	$1,762	0%	0%	0%	0%
Radiology	$4,995	0%	0%	0%	0%
Rheumatology	$536	0%	0%	0%	0%
Thoracic Surgery	$355	-1%	0%	0%	-1%
Urology	$1,745	0%	1%	0%	1%
Vascular Surgery	$1,211	0%	-2%	0%	-2%
TOTAL	**$93,487**	**0%**	**0%**	**0%**	**0%**

** Column F may not equal the sum of columns C, D, and E due to rounding.

The following is an explanation of the information for Table 119:

- Column A (Specialty): Identifies the specialty for which data is shown.

- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2018 utilization and 2019 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.

- Column C (Impact of Work RVU Changes): This column shows the estimated 2020 impact on total allowed charges in the work RVUs, including the impact of changes due to potentially misvalued codes.

- Column D (Impact of PE RVU Changes): This column shows the estimated 2020 impact on total allowed charges in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2020 impact on total allowed charges in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2020 combined impact on total allowed charges of all the changes in the previous columns

B. Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for 2021

Although CMS is not proposing changes to E/M coding and payment for 2020, CMS provides an illustrative impact analysis given that it is proposing certain changes for 2021. Table 111 in the final rule and reproduced above in section II.P of this summary, illustrates the estimate specialty level impacts associated with implementing the RUC-recommended work values for the office/outpatient E/M codes, as well as the revalued HCPCS add-on G codes for primary care and certain types of specialty visits in 2020, rather than delaying until 2021.

The specialty-level impacts shown are large and affect almost every specialty. For example, twenty-one specialties would be expected to experience a decrease in Medicare payments of 5 percent or more and fifteen specialties would be expected to experience an increase in Medicare payments of 5 percent or more. Under this scenario, ophthalmology would experience the largest decrease in Medicare payment of 10 percent, and endocrinology would experience the largest increase of 16 percent.

C. Impacts of Other Proposals

The expected impacts of other changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary to the extent the impact is material. This includes the effect of changes to Medicare coverage for opioid use disorder treatment services, coverage expansion of Intensive Cardiac Rehabilitation, among other policies.

D. Changes Due to the Quality Payment Program

CMS estimates that approximately 59 percent of the nearly 1.5 million clinicians billing to Part B (879,966) will be assigned a MIPS score for 2022 because others will be ineligible for or excluded from MIPS. Table 122, reproduced below, provides the details of clinicians' MIPS eligibility status for 2022 MIPS payment year (2020 MIPS performance year). CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policies; CMS assumes 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to 2018 MIPS performance period would elect to opt-in to the MIPS program.

TABLE 122: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the 2020 PFS Assumptions***

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians	PFS allowed charges ($ in mil)***
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	201,708	$48,349
	Do not participate in MIPS	18,610	$4,147
Group eligibility	Submit data as a group	639,004	$15,426

(only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria and submit as a group)			
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low- volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	20,644	$1,019
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**879,966***	68,941
Not MIPS Eligible			
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	380,352	$9,069
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	81,982	$444
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	265,982	$10,980
Total Number of Clinicians Not MIPS Eligible		728,316	20,493
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,608,282	89,434

*Estimated MIPS Eligible Population

** This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 20,000 clinicians and $1,672 million in PFS allowed charges).

*** Allowed charges estimated using 2017 and 2018 dollars. Low volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

In the aggregate, CMS estimates that for the 2022 payment year, it would redistribute about $433 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 6.2 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 92.5 percent of eligible clinicians are expected to have a positive or neutral payment adjustment and 7.5 percent will have a negative payment adjustment.

Table 123, reproduced below, shows the impact of payments by practice size and based on whether clinicians are expected to submit data to MIPS. CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would not perform as well as larger sized practices. For example, almost 19 percent of clinicians in small practices (1-15 clinicians) are expected to receive a negative payment adjustment compared with about 3.5 percent for clinicians in very large practices (100+). CMS notes that it is using 2018 MIPS performance data and that it is likely there will be changes that it cannot account for at this time, because the performance thresholds increased for the 2020 MIPS performance period to avoid a negative payment adjustment.

Table 123: MIPS Estimated Payment Year 2022 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*					
Practice Size*	**Number of MIPS eligible clinicians**	**Percent Eligible Clinicians with Positive or Neutral Payment Adjustment**	**Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**	**Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount****
Among those submitting data***					
1) 1-15	140,825	81.1%	36.2%	18.9%	1.0%
2) 16-24	43,304	87.4%	40.0%	12.6%	1.3%
3) 25-99	199,829	92.0%	40.7%	8.0%	1.4%
4) 100+	477,991	96.5%	50.3%	3.5%	1.8%
Overall	**861,949**	**92.5%**	**45.3%**	**7.5%**	**1.4%**
Among those not submitting data					
1) 1-15	15,993	0.0%	0.0%	100.0%	-8.6%
2) 16-24	663	0.0%	0.0%	100.0%	-8.6%
3) 25-99	904	0.0%	0.0%	100.0%	-8.8%
4) 100+	457	0.0%	0.0%	100.0%	-8.7%
Overall	**18,017**	**0.0%**	**0.0%**	**100.0%**	**-8.6%**

*Practice size is the total number of TIN/NPIs in a TIN.

** 2018 data used to estimate 2020 performance period payment adjustments. Payment estimated using 2018 dollars trended to 2022.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

CMS estimates that approximately 210,000 to 270,000 eligible clinicians will become QPs for the 2022 payment year and a total of $535 to $685 million in APM incentive payments will be made.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. CMS bases its analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility, participant lists using the 2019 predictive APM Participation List, 2018 QPP Year 2 data and CAHPS for ACOs. The scoring model results assume that 2018 QPP Year 2 data submissions and performance are representative of 2020 QPP data submissions and performance. In particular, CMS anticipates that clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. In addition, because CMS used historic data, it assumes that participation in the three performance categories in MIPS Year 2 would be similar to MIPS Year 4 performance.

CMS states that given these limitations and others, there is considerable uncertainty around its estimates.

E. Impact on Beneficiaries

CMS notes that there are a number of changes in this final rule that will have an effect on beneficiaries. In general, CMS believes that many of these changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the policy changes could result in a change in beneficiary liability as relates to coinsurance. For example, the 2019 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $109.92 which means in 2019 a beneficiary would be responsible for 20 percent of this amount, or $21.98. Based on this final rule, using the estimated 2020 CF, the 2020 national payment amount in the nonfacility setting for CPT code 99203 is $110.43 which means that in 2020, the beneficiary coinsurance would be $22.09.

F. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the final rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on this year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $874.88 (8.0 hours x $109.36) and the total cost of reviewing this regulation is about $38 million ($874.88 x 43,432 reviewers).