Physician Fee Schedule Proposed Rule for 2020
Summary Part I

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

[CMS-1715-P]

On July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2020[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the August 14, 2019 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2019. **The 60-day comment period ends at close of business on September 27, 2019.**

HPA is providing a summary in two parts. Part I covers sections I through III.J of the proposed rule, including 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. Part II will cover the updates to the Quality Payment Program (QPP).

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

I. Introduction

The proposed rule would update 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 proposed rule includes a proposal to adopt, for implementation in 2021, the AMA RUC-recommended values for the office/outpatient E/M codes and proposals related to care management services, including a proposal to create a Principal Care Management (PCM) service.

The proposed rule includes proposals 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 proposed rule also includes proposals 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 proposed conversion factor 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*1.000*1.0014. The 2020 proposed anesthesia conversion factor is $22.2774, which reflects the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for the anesthesia specialty.

The most widespread specialty impacts of the RVU changes are generally related to proposed changes to RVUs for specific services resulting from the Misvalued Code Initiatives, including the establishment of proposed 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 estimates that the combined impact of the proposed policies range from an increase of 3 percent for clinical psychologist and clinical social worker, increase of 2 percent for neurology, to a decrease of 4 percent for ophthalmology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, optometry, oral/maxillofacial surgery, and vascular surgery.

II. Provisions of the Proposed 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 proposes 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 would use PE/HR data from emergency medicine, and hematopoietic cell transplantation and cellular

[2] These became recognized Medicare specialties in 2018.

therapy would use PE/HR data from hematology/oncology. This relevant PE/HR data can be found in the 2020 PFS Proposed Rule PE/HR file published on CMS' website.[3]

CMS proposes to clarify the expected specialty assignment for a series of cardiothoracic services that had been incorrectly assigned a crosswalk to the cardiac surgery specialty instead of thoracic surgery. The 91 affected codes for which CMS proposes to change its expected specialty to thoracic surgery are show in Table 1 in the proposed rule (page 26 of the display copy). The complete list of expected specialties assignments (2,083 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 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 propose 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

[3] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-NPRM-PEHR.zip

[4] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-NPRM-Specialty-Assignment.zip

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 proposes to establish 23 new scope equipment codes (Table 5 in the proposed rule reproduced below)

Table 5: CY 2020 Proposed New Scope Equipment Codes

CMS Code	Proposed Scope Equipment Description	Proposed Price	Number of Invoices
ES070	rigid scope, cystoscopy		0
ES071	rigid scope, hysteroscopy		0
ES072	rigid scope, otoscopy		0
ES073	rigid scope, nasal/sinus endoscopy		0
ES074	rigid scope, proctosigmoidoscopy		0
ES075	rigid scope, laryngoscopy	$3,966.08	5
ES076	rigid scope, colposcopy	$14,500.00	1
ES077	non-channeled flexible digital scope, hysteroscopy		0
ES078	non-channeled flexible digital scope, nasopharyngoscopy		0
ES079	non-channeled flexible digital scope, bronchoscopy		0
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51	7
ES081	channeled flexible digital scope, cystoscopy		0
ES082	channeled flexible digital scope, hysteroscopy		0
ES083	channeled flexible digital scope, bronchoscopy		0
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39	5
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00	1
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81	6
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		

ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35	5
ES089	multi-channeled flexible digital scope, ileoscopy		0
ES090	multi-channeled flexible digital scope, pouchoscopy		0
ES091	ultrasound digital scope, endoscopic ultrasound		0
ES092	non-video flexible scope, laryngoscopy	$5,078.04	4

For the eight new scope items where invoices were submitted for pricing, CMS proposes to replace the existing scopes with the new scope equipment. Based on recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, CMS proposes to make this scope replacement for about 100 codes in total (see Table 6 in the proposed rule). It proposes the same equipment time for the new scope equipment that replaces the existing scope in all but three cases. For these three CPT codes – 92612, 92614, and 92616 – CMS adds the ES080 equipment (non-channeled flexible digital scope with a scope video system) rather than replacing the FEES video system (ES027) and the FEESST video system (ES028). CMS also found some inconsistencies with three of the workgroup recommendations and is not proposing to add one of the new scope equipment items to these procedures (CPT codes – 45350, 31595, and 43232).

CMS did not receive pricing information for the other 15 new scope equipment items. CMS proposes to establish new equipment codes, but given the lack of pricing information, it is not proposing to replace the existing scope equipment with the new equipment items. **CMS welcomes feedback from stakeholders regarding the pricing of these scope equipment items, particularly the submission of detailed invoices with pricing data.**

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

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

- CMS proposes 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 proposes 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 7 in the proposed 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 proposes 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.[5]

[5] CMS refers reader to the 1992 PFS final rule where this policy was established (56 FR 59515) and to Chapter 23 of the Medicare Claims Processing Manual for additional information.

d. Updates to Prices for Existing Direct PE Inputs

For 2020, CMS proposes 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). See Table 22 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.

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.[6] 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 8 in this rule (reproduced below).

Table 8: 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	

[6]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 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

CMS highlights two other instances where it proposes to phase-in any new or updated pricing over the remaining years of the proposed 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 proposes to update the prices of the supply and equipment items listed in Table 9. 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.

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-NPRM-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 proposes to continue with the third year of the transition of this adjustment to the standard process for allocating indirect PE. There are 47 codes affected by this policy, and the list is available on CMS' website.[7]

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.[8] 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. CMS proposes to review, and if necessary, update the MP RVUs at least every 3 years, similar to its review and update of the GPCIs. If these were to be aligned, CMS would conduct the next statutorily-mandated review and update of both the GPCI and MP RVU for implementation in 2023.

For 2020, CMS proposes to implement the fourth comprehensive review and update of MP RVUs. The methodology for the proposed revision is discussed below.

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

[8] 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.

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

a. General Discussion

CMS calculated the proposed MP RVUs using updated malpractice premium data obtained from state insurance filings. The methodology CMS proposes to use 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 proposed 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 states, 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 (NPP) specialties, and all risk classifications that were available in the rate filings.

b. Proposed Methodological Refinements

CMS proposes certain methodological improvements that will expand the specialties and the amount of filings data used to develop the proposed 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 proposes the following methodological improvements:

(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.
(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.
(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 proposed improvements would allow it to utilize as much of the information from the filings as possible instead of discarding that information. Additional technical details are available in its interim report, "Interim Report for the 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule," on its website.[9]

[9] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-NPRM-GPCI-Interim-Report.pdf

CMS seeks comment on these proposed methodological improvements.

c. Proposed Methodological Refinements

CMS calculation of the proposed MP RVUs follows the same conceptual specialty-weighted approach used in the 2015 update, along with the proposed 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 proposed 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 15 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 10 in the proposed rule (reproduced below).

Table 10: Proposed Specialties Subdivided into Service Risk

Service Risk Groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), 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)

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 proposes to assign 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. **CMS seeks information on the most comparable and appropriate proxy for the broader set of TC-only services that would support assignment of an alternative risk factor.**

Table 11 in the proposed rule shows the proposed 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 proposed list of codes and expected specialties is available on its website.[11]

CMS seeks comment on the list of expected specialties.

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 proposed 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-P.html.

Estimates of the impact on payment can be found in the Regulatory Impact Section (section VI of this proposed 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-NPRM-Malpractice-Risk-Factors.zip

[11] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-NPRM-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 proposes to phase in 1/2 of the latest GPCI adjustment in 2020. For 2020, CMS proposes updated GPCI values based on calculations done by a contractor. More details can be found in the contractor's report "Draft Report on the CY 2020 Update of the Geographic Practice Cost Index 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 proposes 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 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.

[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-NPRM-GPCI-Interim-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 proposed work GPCIs do not reflect this 1.0 floor since this provision has not been extended for 2020.

- 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 proposed 2020 MP GPCI update reflects premium data presumed in effect as of December 30, 2017.

CMS proposes to continue using the current cost share weights for determining the PE GPCI values and locality GAFs (last revised in 2014). The proposed GPCI cost share weights for 2020 are displayed in Table 12 in the proposed rule (reproduced below).

Table 12: Proposed Cost Share Weights for 2020 GPCI Update

Expense Category	Current Cost Share Weight	Proposed 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 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-

[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.

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 this proposed rule, CMS identified two technical refinements to the methodology that it states yield improvement over the current method.

- CMS proposes 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 proposes to use a weighted average when calculating the final county-level wage index—remove the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data.

4. Proposed GPCI Update Summary

The proposed 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 proposed 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-P.html

[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.

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.

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).

- 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.

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.

[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 proposes the three public and CMS nominated codes as potentially misvalued and seeks comment on these codes.

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 proposed changes.

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 proposes to add three HCPCS G-codes related to treatment for opioid use disorder - new services being proposed in this year's rule – that 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 proposes to add the face-to-face portions of these three services to the list:

- HCPCS code GYYY1: Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.
- HCPCS code GYYY2: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.

- HCPCS code GYYY3: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).

CMS believes that adding these codes will complement the existing policies related to flexibilities in treating SUDs under Medicare telehealth.

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

1. Background

CMS proposes to implement section 2005 of the SUPPORT Act which authorizes a new Medicare benefit for OUD treatment services furnished by OTPs. The new statutory provision defines opioid use disorder treatment services and opioid treatment programs and establishes a bundled payment for opioid use disorder treatment services. Finally, it includes OTPs as Medicare providers for the purposes of furnishing opioid use disorder treatment services. Payment for these services begins January 1, 2020.

CMS proposes to create new section 410.67 to establish definitions of OUD treatment services and OTP and to propose a methodology for determining Medicare payment for the services provided by OTPs.

2. Proposed Definitions

Opioid use disorder treatment services. The statute defines opioid use disorder treatment services as:

A. Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal, Food, Drug, and Cosmetic Act 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.
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; and
F. Other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation.

In addition to the first 5 items, CMS proposes to include counseling services and individual and group therapy services furnished via a two-way interactive audio-video communication technology in the definition of opioid disorder treatment services consistent with Medicare's telehealth benefit. CMS states that OTPs in rural communities or in health professional shortage areas could use the telehealth services to improve access. **Comments are requested on other**

components of the bundle that may be clinically appropriate to be furnished via communication technology.

CMS explains that the FDA has so far approved three drugs for the treatment of opioid dependence: buprenorphine, methadone, and naltrexone**. It seeks 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 addition, CMS asks whether there are any drug development efforts in the pipeline that could result in medications intended for use in the treatment of OUD with a novel mechanism of action.**

CMS seek comments on any other items and services currently covered under Medicare Part B that should be added to this definition, including any supporting evidence for their use. CMS states that it is particularly interested in whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD treatment services.

Opioid Treatment Program (§410.67(b). CMS proposed to adopt the definition for an Opioid treatment program that is in in existing SAMSHA regulations at 42 CFR 8.2 and to meet the following requirements 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.

To be certified by SAMSHA, OTPs are required to 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 patient 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 DEA regulations; and operate in accordance with federal opioid treatment standards and accreditation elements.

CMS further proposes that:

- OTPs meet conditions of participation applicable to Medicare providers.
- The effective date of the provider agreement is the date on which CMS accepts a signed agreement (proposed amendment to § 489.13(a)(2)).
- To create a basis for termination of the provider agreement if the OTP no longer meets the requirements in part 489 or elsewhere in that chapter (including if it no longer has a SAMHSA certification or accreditation by a SAMHSA approved accrediting body).
- To ensure that OTPs have access to the appeals process in case of an adverse determination concerning continued participation in the Medicare program.

CMS is not proposing any additional conditions for participation at this time but welcomes input on whether there are additional conditions that should be considered.

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

Partial Episode of Care. CMS proposes to define a partial episode of care to mean an episode of care in which there is at least one opioid use disorder treatment service, but less than a majority of opioid use disorder treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) is furnished.

3. Proposed Bundled Payments for OUD Treatment Services

The SUPPORT Act directed CMS to pay an OTP a bundled payment for Medicare OUD treatment services during an episode of care. In developing those rates it established that the Secretary can consider TRICARE and Medicaid payments for those services. In the proposed rule, 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.

CMS proposes to specify the following aspects of the bundled payment in §410.67(b) for Medicare OTP services:

Duration of bundle. As noted above, CMS proposes that an episode of care for OUD treatment services would be one week – or a contiguous 7-day period.

- Where an enrollee has received 51% of the services identified in the patient's treatment plan over the course of a week, CMS proposes that the OTP may bill for the full weekly bundle.
- Where an enrollee has received at least one item but less than 51% of their items or services in the treatment plan, and is unable to finish the services, the OTP could bill for a partial weekly bundle. **CMS seeks comment on the threshold for a full or partial-episode bundled payment.**

Each payment bundle would be comprised of a drug component and a non-drug component.

Non-Drug Episode of Care. CMS proposes in §410.67(d), 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 proposes to base bundled payment rates for OUD treatment services on the type of medication used for treatment. The categories of bundles would be codified in §410.67(d)(1) and would be for (1) each type of opioid agonist and antagonist described in the preamble as

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

And (2) for a medication not otherwise specified. This category is intended to include new treatments that FDA may potentially approve in the future. Finally, as noted above, CMS would provide for each bundle to also have a parallel non-drug episode of care bundled payment.

Payment for the drug component would be based on ASP when the ASP is reported. In §410(d)(2), CMS proposes that the drug component of the bundled payment amount for implantable and injectable medications would be equal to 100 percent of the average sales price (ASP). For oral medications for which the ASP is submitted, the payment amount would 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 and **requests comment on approaches (enumerated below) for estimating the acquisition cost and payment amounts for these drugs. CMS also welcomes comments on how new medications that may be approved by the FDA in the future with a novel mechanism of action should be priced.**

Non-drug component. The non-drug component would 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 requests comment on any other items and services that it should use its discretion to include as OUD treatment services – for example periodic assessments or intake activities.**

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 proposes an add-on code (HCPCS code GXX19) to describe each additional 30 minutes of counseling or group or individual therapy provided during a week which exceed the amount specified in the treatment plan and for which medical

necessity is documented in the medical record. CMS plans to monitor the use of this code to ensure that OTPs do not document minimal counseling and therapy services in order to increase their opportunities to bill using the add-on code.

Coding and Payment Rates. Table 15, duplicated below, provides the HCPCS G-codes and the corresponding payment rates that CMS proposes for weekly bundles with drugs, without drugs, for a medication not otherwise specified, and an add-on code for additional counseling or therapy services. 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. **CMS welcomes comments as to whether this code is needed or not considering the potential for its misuse.**

Payment for Drug Component. As noted above, CMS is proposing to pay for the drug component based on ASP for those drugs for which ASP is available. 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. CMS plans to use invoice prices until another approach is identified and requests comment on the following alternative approaches or other potential data sources for setting the prices of drugs for which ASP is not reported:

Alternative Pricing Approaches and Estimated* Initial Drug Payment Rates Examples

Pricing Alternative	Estimated Initial Weekly Drug Payment for Methadone	Estimated Initial Weekly Drug Payment for Oral Buprenorphine
Approach 1: The methodology in section 1847 of the Act Using WAC or invoice pricing.	$29.61	$117.68
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.	$22.47	$97.65
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 reduction in price.	$27.93	$111.02
Approach 4: Medicaid's National Average Drug Acquisition Cost (NADAC) data Data submitted by retail community pharmacies reflects their costs to acquire pharmaceuticals. May be metric closest to ASP however, it is unclear how closely it reflects acquisition costs for OTPs.	$11.76	$97.02
Alternative approach for Methadone only: TRICARE payment	$22.19	N/A

*The estimated payment amounts in this table are based on data files posted at the time of the drafting of the proposed rule. CMS would develop final CY 2020 pricing using the most recent data available at the drafting of the final rule.

Payment for Non-Drug Component. CMS proposes to use the TRICARE rates for the non-drug portion of its methadone treatment bundle as the basis for the Medicare payment rates. CMS notes that those amounts were established through notice and comment rulemaking. Under the proposal, those amounts would be adjusted to reflect the actual drug used, for example, by subtracting the dispensing fees for methadone and instead adding amounts for the administration of an injection when an injectable drug is used. Likewise, the payment rates for the non-drug component of the codes for the weekly bundled payments for buprenorphine implants would be adjusted to add an amount for insertion and/or removal based on a direct crosswalk to the non-facility payment rates under the Medicare PFS for the insertion, removal, or insertion and removal of these implants, which describe the physician work, practice expense (PE), and malpractice costs associated with these procedures, and to remove the costs of daily drug dispensing. (See Table 15, duplicated below, for complete list of cross-walked rates.)

CMS notes that it plans to monitor the use of non-drug services by the Medicare population and potentially consider in future rulemaking whether the TRICARE payment rate for these services should be modified for the Medicare population.

Partial Episode of Care. For payments for partial episodes of care, CMS is proposing that the non-drug portion of the bundle is halved to reflect the median cost of furnishing those services (after adjusting for the administration costs of the drug involved.) The drug costs are halved except in the case of drugs that are administered at the start of the episode, for example those injected or implanted at the start of the treatment episode.

Table 15, duplicated below, describes the proposed codes and their associated payment amounts.

Table 15: OTP Code Descriptors and Proposed Approximate Payment Amounts

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
	Full weeks			
GXXX1	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)	$22.19	$110.96	$133.15
GXXX2	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)	$97.02	$110.96	$207.98
GXXX3	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)	$1,580.00	$117.40	$1,697.40
GXXX4	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)	$4,792.10	$211.46	$5,003.56

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
GXXX5	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) 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	$227.32	$227.32
GXXX6	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)	$4,792.10	$305.16	$5,097.26
GXXX7	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)	$1,164.38	$117.40	$1,281.78
GXXX8	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)	N/A	$100.46	$100.46
GXXX9	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)	-	-	-
	Partial episodes			
GXX10	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); partial episode. *Do not report with GXXX1.*	$11.10	$55.48	$66.58
GXX11	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); partial episode. *Do not report with GXXX2.*	$48.51	$55.48	$103.99
GXX12	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); partial episode. *Do not report with GXXX3.*	$1,580.00	$67.17	$1,647.17*
GXX13	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); partial episode (only to be billed once every 6 months). *Do not report with GXXX4.*	$4,792.10	$161.23	$4,953.33*

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
GXX14	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); partial episode. *Do not report with GXXX5.*	$0	$177.09	$177.09*
GXX15	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); partial episode. *Do not report with GXXX6.*	$4,792.10	$254.93	$5,047.03*
GXX16	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); partial episode. *Do not report with GXXX7.*	$1,164.38	$67.17	$1,231.55*
GXX17	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); partial episode. *Do not report with GXXX8.*	N/A	$50.23	$50.23
GXX18	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); partial episode. Do not report with GXXX9.	-	-	-
Intensity Add-on code				
GXX19	Each additional 30 minutes of counseling or therapy 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.	N/A	$26.60	$26.60

* Full drug cost and administration/dispensing fee included.

** Drug pricing subject to change pending additional data. Methadone drug costs are calculated here using TRICARE rates, oral buprenorphine drug costs are calculated here using NADAC data, and the other drug costs are calculated using the ASP data. The estimated payment amounts in this table are based on data files posted at the time of the drafting of this proposed rule. We would develop the final pricing for CY 2020 using the most recent data files available at the drafting of the CY 2020 PFS final rule.

*** The non-drug component of the methadone bundled payment rate (HCPCS code GXXX1) is $110.96 crosswalked from the TRICARE CY 2019 rate for non-drug services, which is the weekly rate of $133.15 minus the drug cost of $22.19); the non-drug component of the oral buprenorphine bundled payment rate (HCPCS code GXXX2) is also $110.96 (crosswalked from the non-drug component of the methadone bundled payment rate). The non-drug component of both the injectable buprenorphine bundled payment rate (HCPCS code GXXX3) and the injectable naltrexone bundled rate (HCPCS code GXXX7) is $117.40 ($110.96 minus a $10.50 dispensing fee plus a $16.94 administration fee). The non-drug components of the buprenorphine implant bundled payment rates (HCPCS codes GXXX4, GXXX5, and GXXX6 for implant insertion, removal, and insertion and removal, respectively) are $211.46, $227.32, and $305.16, respectively ($110.96 minus a $10.50 dispensing fee plus the corresponding PFS non-facility rate for implant insertion, removal, and insertion and removal, HCPCS codes G0516, G0517, and G0518, which are $111.00, $126.86, and $204.70, respectively). The rate for the no medication bundled payment (HCPCS code GXXX8) is $100.46 ($110.96 minus a $10.50 dispensing fee). As described in further detail above, we are proposing that the codes describing a medication not otherwise specified

(HCPCS codes GXXX9 and GXX18) would be priced according to the methodology described above based on whether the medication is oral, injectable or implantable (based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees). The non-drug component of the codes describing partial episodes (HCPCS codes GXX10, GXX11, GXX12, GXX13, GXX14, GXX15, and GXX16) are calculated as described in further detail above, based on a crosswalk to half of the rate for non-drug services included in the TRICARE weekly bundled payment (adjusted to account for administration and dispensing of that drug. Finally, the non-drug component for HCPCS code GXX19 is calculated based on rates set by state Medicaid programs for similar services. All non-drug components of the valuations would be geographically adjusted as discussed in the locality adjustment section of this proposed rule.

Place of Service Codes for Services Furnished at OTPs. A new place of service code will be provided for OTPs in future guidance.

Duplicative Payments under Parts B and D. CMS proposes 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 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 payment.

Cost Sharing. CMS proposes that beneficiaries would have no copayment amount (at §410.67(e)) for a limited period of time, for example, through the duration of the national opioid crisis. Conflicting provisions of the SUPPORT Act authorize usual cost-sharing for OUD services as for all other Part B services (Sec. 2005 amendments to section 1833(a)(1)) and require cost sharing to be set to zero (Sec. 2005 amendments to Sec. 2005). CMS interprets these apparently conflicting provisions as giving it permission to determine whether or not cost sharing will be established for the benefit. It welcomes feedback on its conclusion, and on possible metrics to use to determine when to begin requiring a copayment. Also noted is that the Part B deductible would apply for OUD treatment services as for all Part B services.

4. Adjustments to Bundled Payment Rates for OUD treatment Services

a. Locality Adjustment

CMS notes that the SUPPORT Act gives it the discretion to implement bundled rates based on a number of specified factors (type of medications, 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 proposes a geographic locality adjustment to the bundled payment rate for those services.

For the drug component, CMS believes that no geographic adjustment factor is necessary because payments for the drug component are proposed to be set at national rates.

For the non-drug component of the bundled rates, CMS proposes 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 welcomes comments on other factors besides the GAF that could be used to adjust rates for locality. In addition, it is interested in information on whether rural areas have appropriate access to treatment for OUD and whether additional adjustments should be made to account for the costs of OUD treatment in those areas.**

b. Annual update

The SUPPORT Act requires the Secretary to update the OTP bundled rates annually. CMS proposes to use a blended annual update reflecting different updates for the drug and non-drug components of the bundled payment rates.

For the drug component, CMS proposes updates based on the reported changes in drug costs reflected in the most recently available data at the time of ratesetting for the applicable calendar year. This would be codified at §410.67(d)(3)(i). 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. CMS welcomes comments on alternative approaches.

For the non-drug component, CMS proposes to use 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.

5. Regulatory Impact

CMS estimates the net impact of coverage of OUD treatment by OTPs, including Medicare and FFS and Medicare Advantage over 10 years to be just over $1 billion. It assumed that the average length of treatment would be 12 months with average weekly rate of $148 for CY 2020. That figure represents a weighted average of the proposed 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 included in this proposed 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 would include management, care coordination, psychotherapy, and counseling. It would not include medications – they would continue to be paid as other Part B or Part D drugs. It would also exclude toxicology testing, which would continue to be separately billed under the Clinical Lab Fee Schedule. Payment for the bundle would not require that a consultation with a specialist be included.

CMS is proposing two HCPCS G-codes to describe monthly bundles of services. CMS considered weekly-reported codes (as under the OTP benefit proposed above) but determined that monthly-reported codes would be less burdensome and would align with the kinds of care management offered for treatment of OUD in office settings. One code would describe the initial month of treatment including intake, the development of a treatment plan and other assessments necessary to begin treatment; a second code would describe continuing treatment; and an add-on code would be made available 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 invites comment on whether it should create an additional separately billable code or codes for additional resources needed after the first month and the resource inputs that it should consider for such codes.

The proposed codes would be:

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

CMS proposes to value the codes based on the work RVUs and direct PE inputs crosswalked from other services that they are most consistent with:

- The value for HCPCS code GYYY1 would be:
    - 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 would be = 7.06.
    - The required minimum number of minutes would be based on a crosswalk to CPT code 99492.
    - The direct PE inputs would be associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code GYYY2 would be:
    - 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 would be = 6.89.
    - The required minimum number of minutes would be based on a crosswalk to CPT codes 99493.
    - The direct PE inputs would be crosswalked to CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four).

- The value for HCPCS code GYYY3 would be:
    - 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 would be based on a crosswalk to CPT codes 99493.
    - The direct PE inputs would be crosswalked to CPT code 99494.

Table 22 provides additional detail on the proposed PE inputs for the three codes.

To avoid duplicative billing, CMS also proposes 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 BHI services would 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.

Under the proposal, the services in the bundle must be provided by providers qualified under state law and operating within their scope of practice; the billing clinician would manage the patient's overall care; and therapy and counseling services would be permitted to be provided via telehealth if clinically appropriate.

CMS notes that it would consider using other available CPT codes for the OUD treatment services in future rulemaking, potentially as early as 2021. CMS also 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.

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 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, as well as information CMS received regarding the scope of practice laws in some states regarding supervision requirements for PAs, CMS proposes to revise the regulation at §410.74 that established physician supervision requirements for PAs. Specifically, CMS proposes to revise §410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would need to be documented in the medical record indicating the PA's approach to working with physicians in furnishing their services. Documentation would need to be available to CMS, upon request. CMS notes that this has the benefit of substantially aligning its regulation on physician supervision for PA services with its current regulations on physician collaboration for NP and CNS services.

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

[20] §1861(s)(2)(K)(ii)
[21] Sections 415.172(b) and 415.174(a)(6)

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. Proposal

CMS proposes 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.

To reflect CMS' approach to medical record documentation it proposes to amend the following sections of its regulations §410.20 (Physician's services), §410.74 (PA services), §410.75 (CNS services), and 410.77 (CNM services) to add a new paragraph entitled "Medical record documentation". This paragraph would specify that, when furnishing their professional services, the clinician may review and verify (sign/date) notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team, including notes documenting the practitioner's presence and participation in the services, rather than fully re-documenting the information.

CMS also proposes conforming amendments to §§415.172(b) and 415.174(a)(6) to also allow physicians, residents, nurses, students, or other members of the medical team to enter information in the medical record that can then be reviewed and verified by a teaching physician without the need for re-documentation.

CMS invites comments on these proposed amendments to its regulations.

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 16, reproduced below, provides a summary of the care management codes. CMS proposes refinements to TCM and CCM services, proposes new coding for principal care management (PCM) services, and addresses chronic care remote physiologic monitoring (RPM) services.

[22] Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B

Table 16. 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
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 discusses 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 discusses 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 notes 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 17 (reproduced below) lists the 14 codes that are separately payable under the PFS.

[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 17. 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 (patients who are 20 years or older)	90960	ESRD related services monthly with 4 or more face-to-face visits per month; patients 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 proposes to allow TCM codes to be billed concurrently with any of these codes. **CMS seeks comments on the following:**

- Whether there is overlap of these services with TCM and if so, which services should be restricted from being billed concurrently with TCM by the same practitioner.
- Whether CPT code 99491 for CCM by a physician or other qualified health care professional overlaps with TCM or should be separately payable in the same service period when billed by the same practitioner.

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 proposes 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.

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. As discussed below, to address these concerns, CMS proposes 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 proposes 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 proposes 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 proposes 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 proposes a work RVU of 0.54 based on a crosswalk from CPT code 11107[24]. CMS believes that CPT code 11107 has a similar work intensity as GCCC2. It notes that add-on codes often have lower intensity than the base code because they describe the continuation of an initiated service.

[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.

In addition to comments about this proposal, **CMS seeks 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?

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 proposes to adopt two new G codes – GCCC3 and GCCC4 – to be used for PFS payment instead of CPT codes 99487 and 99489, respectively. 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 proposes 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 proposes 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 proposes a work RVU of 0.5, a crosswalk to CPT code 99489.

In addition to comments about this proposal, **CMS seeks comments on whether the benefit of proposing G codes outweigh the burden of transition to their use before a decision is made by the CPT Editorial Panel**?

c. Typical Care Plan

In response to comments about the confusion of the care plan requirements, CMS proposes 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 proposes 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.

In addition to comments about this proposal, **CMS seeks additional language that would guide practitioners as they decide what to include in their comprehensive care plan for CCM recipients**.

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 proposes 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 proposes 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 proposes a work RVU of 1.28 a crosswalk to CPT code 99217 (Observation care discharge day management).

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

- 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 proposes a work RVU of 0.61 a crosswalk to CPT code 99490 (clinical staff non-complex CCM)

CMS is not proposing 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.

CMS notes the similarity between both PCM and CCM services and proposes 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.

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

- Are separate codes for physician and clinical staff necessary?
- Is an add-on code for additional time spent each month (similar to GCCC2) necessary when PCM services are furnished by clinical staff under the direction of the billing practitioner?
- Are requirements necessary to document ongoing communication with the patient's primary care practitioner to demonstrate continuity of care? Are there requirements necessary to prevent potential care fragmentation or service duplication?
- How best to educate practitioners on the benefits of PCM services and the cost sharing that may apply?
- Potential for duplicative payment between PCP and other services such as interprofessional consultation services (CPT codes 99446 – 99449, 999451, 99452) and remote patient monitoring services (CPT code 99091, 99453, and 99457).

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 994X0 is a new add-on code to describe subsequent 20 minutes interval of the services.

For CPT code 994X0, CMS does not agree with the RUC-recommended work RVU of 0.61. Instead, CMS proposes 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 proposes the RUC-recommended direct PE inputs for 994X0.

RMP services currently require direct supervision. For 2020, CMS proposes 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.

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

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 seeks 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.

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 proposes 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.

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 requests comments on whether it should require the physician or their staff, to provide a verbal notice with a notation in the medical record, or whether it should consider a different approach, such as a written notice with standard language that a physician, or their staff, would be required to provide to patients prior to a colorectal cancer screening. CMS also invites comments on how to monitor compliance with a notification requirement.

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 is rectifying that oversight with revisions to §§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.

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

CMS proposes that the CQ/CO modifiers would apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes – the sum of the minutes spent by the therapist and therapy assistant – for that service. For purposes of deciding whether the 10 percent standard is exceeded, CMS offers two different methods:

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
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.

CMS provides examples for how to apply the 10 percent standard to services that are billed based on timed units and other services:

- Untimed Services:

Evaluations and re-evaluations: PTAs/OTAs cannot furnish evaluative or assessment services, but to the extent that they furnish a portion of these services, the 10 percent standard applies. For example, if a PTA/OTA assists a therapist for 5 minutes of a service that requires 30 minutes of face-to-face time with a therapist, the 10 percent standard is met (e.g. 10/30=33% which is equal to or greater than 11% or 5 minutes is greater than 30/10=3+1=4 minutes).

Group Therapy: If PTA/OTA participates concurrently with the therapist for 5 minutes of a total group therapy service time of 40-minutes (based on the time of the therapist); or separately furnishes 5 minutes of a total group time of 40 minutes (5 minutes of the PTA/OTA time and 35 minutes of therapist time), the modifier applies because: 1) 5/40=12% and is equal to or greater than 11% or 2) 5 minutes is equal to or greater than 40/10=4+1=5.

Supervised Modalities: Supervised modalities (for example, electrical stimulation), do not require the constant attendance of the therapist or a supervised therapy assistant. For supervised modalities, only the attended time is considered when determining whether the 10 percent standard is met.

For example, if attended time is 8 minutes furnished by the PTA/OTA and therapist concurrently, the modifier applies when the PTA/OTA furnishes 2 minutes of the service because 1) 2/8=25% and is equal to or greater than 11% or 2) 2 minutes is equal to or greater than 8/10=0.8 rounded to 1 minute + 1 minute=2 minutes.

Alternatively, the PTA/OTA furnishes 3 minutes of the service separately from the therapist who furnishes 5 minutes of treatment for a total time of 8 minutes. The modifier applies because 1) 3/8=37.5% which is equal to or greater than 11% or 2) 3 minutes is equal to or greater than 8/10=0.8 round 1 minute + 1 minute=2 minutes.

- Timed Services:

Timed therapy services are defined by 15-minute increments per unit of service. 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.

Beginning January 1, 2020, CMS is proposing 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."

CMS is seeking comment on documentation standards that will minimize burden of medical review. It is also interested in hearing from therapists and therapy providers about current burden associated with the medical review process based on current policy that does not require the times for individual services to be documented. Based on comments received, if CMS were to adopt a policy to include documentation of the PTA/OTA minutes and total time (TT) minutes, the CQ/CO modifier explanation could read similar to the following: "Code 97162 (TT = 30 minutes): CQ/CO modifier not applied – PTA/OTA minutes (3) did not exceed the 10 percent standard."

CMS provides a number of additional examples of various complexities for time services which illustrate how the billing rules apply for timed services and how the modifiers would apply as well.

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:

Table 20	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 21	Direct PE Refinements

Table 22	Existing Invoices
Table 23	New Invoices
Table 24	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.[27] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[28] 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 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.

[27]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.

[28]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.

Table 20 list the codes and proposed work RVUs, including 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 proposing 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 21 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 $0.30 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the $0.30 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)[29];
- 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 services.

CMS received invoices for several new sand existing supply and equipment items (see Tables 22 and 23). 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 proposed 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 proposed rule for more specific details. **CMS seeks comments on the work values, direct PE inputs, or both, for all these code groups.**

[29] 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 Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations
1	Tissue Grafting Procedures	15X00 - 15X04	Yes
2	Drug Delivery Implant Procedures	11981 - 11983, 206X0 - 20685	No
3	Bone Biopsy	20220 and 20225	No
4	Trigger Point Dry Needling	205X1 and 205X2	No
5	Closed Treatment Vertebral Fracture	22310	No
6	Tendon Sheath Procedures	26020. 26055, and 26160	No
7	Closed Treatment Fracture- Hip	27220	No
8	Arthrodesis – SI Joint	27279	Yes
9	Pericardiocentesis & Pericardial Drainage	3X000 - 3X003	No
10	Pericardiotomy	33020 and 33025	No
11	Transcatheter Aortic Valve Replacement (TAVR)	33361 - 33366	Yes
12	Aortic Graft Procedures	338XX – 338X2, 33863, 33864, and 33866	No
13	Iliac Brach Endograft Placement	34X00 and 34X01	Yes
14	Exploration of Artery	35701, 35X00, and 35X01	Yes
15	Intravascular Ultrasound	37252 and 37253	No
16	Stab Phlebectomy of Varicose Veins	37765 and 37766	Yes
17	Biopsy of Mouth Lesion	40808	No
18	Transanal Hemorrhoidal Dearterialization	46945, 46946, and 46X48	Yes
19	Preperitoneal Pelvic Packing	490X1 and 490X2	No
20	Cystourethroscopy Insertion Transprostatic Implant	52411 and 52442	No
21	Orchiopexy	54640	Yes
22	Radiofrequency Neurootomy SI Joint	6XX00 and 6XX01	Yes
23	Lumbar Puncture	66270, 622X0, 62272, and 622X1	No
24	Electronic Analysis of Implanted Pump	62367 - 62370	Yes
25	Somatic Nerve Injection	64400, 64408, 64115 – 64417, 64420, 66421, 66425, 66430, 66435, 66445 - 66450	No
26	Genicular Injection and RFA	64640, 64XX0 and 64XX1	No
27	Cyclophotocoagulation	66711, 66982 – 66984, 66X01, and 66X02	Yes*
28	X-Ray: Sinuses	70210 and 70220	No
29	X-Ray: Skull	70250 and 70260	No
30	X-Ray: Neck	70360	No
31	X-Ray: Spine	72020, 72040, 72050,72052,72070, 72072,	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations
		72074, 72080, 72100, 72110,72114, and 72120	
32	CT: Orbit-Ear-Fossa	70480 - 70482	No
33	CT: Spine	72125 - 72133	No
34	X-Ray: Pelvis	72170 and 72190	Yes
35	X-Ray: Sacrum	72200, 72202, and 72220	No
36	X-Ray: Clavicle-Shoulder	73000, 73010, 73020, 72030, and 73050	Yes
37	CT: Lower Extremity	73700 - 73702	Yes
38	X-Ray: Elbow-Forearm	73070, 73080, and 73090	Yes
39	X-Ray: Heel	73650	Yes
40	X-Ray: Toe	73660	Yes
41	Upper GI Tract Imaging	74210, 74220, 74230, 74X00, 74240, 74246, and 74X01	Yes
42	Lower GI Tract Imaging	74250, 74251, 74270, and 74280	Yes
43	Urography	74425	Yes
44	Abdominal Aortography	75625 and 75630	No
45	Angiography	75726 and 75774	Yes
46	X-Ray: Specimen	76098	Yes
47	3D Rendering	76376	Yes
48	Ultrasound Exam	76604	Yes
49	X-Ray: Bone	77073 - 77077	Yes
50	SPECT-CT	78800 – 77804, 788X0 – 788X3	No
51	Myocardial PET	78459, 78X29, 78491, 78X31, 78492, 78X32 – 78X35	No
52	Cytopathology, Cervical Vaginal	88141, G0124, G0141, and P3001	No
53	Biofeedback Training	908XX and 909XX	Yes
54	Corneal Hysteresis	92145	Yes
55	Computerized Dynamic Posturography	92548 and 92XX0	No
56	Auditory Function Evaluation	92626 and 92627	Yes
57	Septostomy	92992 and 92993	Yes*
58	Opthalmoscopy	92X18 and 92X19	Yes
59	Remote Interrogation Device Evaluation	93297 – 93299 and GTTT1	Yes*
60	Duplex Scan Arterial Inflow-Venous Outflow	93X00 and 93X01	Yes
61	Myocardial Strain Imaging	933X0	Yes
62	Lung Function Test	94200	Yes
63	Long-Term EEG Monitoring	95X01 – 95X23	No
64	Health and Behavioral Assessment and Intervention	961X0 – 961X8	Yes
65	Number Skipped in Rule	NA	NA
66	Cognitive Function Intervention	971XX and 9XXX0	Yes
67	Open Wound Debridement	97597 and 97598	No
68	Negative Pressure Wound Therapy	97607 and 97608	Yes
69	Ultrasonic Wound Assessment	97610	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations
70	Online Digital Evaluation Service (e-Visit)	98X00 – 98X02 and GNPPA – GNPP3	No
71	Emergency Department Visits	99281 - 99285	Yes
72	Self-Measured Blood Pressure Monitoring	99X01, 99X02, 93784, 94786, 93788, and 93790	Yes
73	Online Digital Evaluation Service	9X0X1 – 9X0X3	Yes
74	Radiation Therapy	G6001 – G6017	NA
*Contractor Priced Codes: 66983, 66X01, 66X02, 92992, 92993, and GTTT1			

(3) Bone Biopsy (CPT Codes 20220 and 20225)
For CPT code 20225 CMS proposes to replace the bone biopsy device (SF055) supply with the bone biopsy needle (SC077). CMS also proposes to adopt a 90 percent utilization rate for the use of the CT room (EL007) equipment. CMS notes this is consistent with the increased equipment utilization rate of 90 percent for expensive diagnosis equipment priced at more than $1 million, which included CT and MRI equipment (74 FR 61754).

(4) Closed Treatment Vertebral Fracture (CPT code 22310)
(7) Closed Treatment Hip Fracture (CPT code 27220)
These services were identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 22310, CMS disagrees with the RUC recommended work RVUs because it did not believe the RUC work reduction is consistent with the RUC-recommended 33-minute reduction in intraservice time and a 105-minute reduction in total time. For CPT code 27220, CMS does not believe the RUC-recommended work reduction is consistent with the RUC-recommended 19 minute reduction in intraservice time and an 80-minute reduction in total time.

(8) Arthrodesis – Sacroiliac Joint (CPT code 27279)
CMS identified this code as identified as a potentially misvalued code. Based on results form 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 proposes the RUC-recommended work RVU but solicits comment on whether the alternative valuation of 20.00 is more appropriate**.

(9) Transcatheter Aortic Valve Replacement (TAVR) (CPT codes 3361 – 33366)
CMS proposes the RUC-recommended work RVUs for all codes in this family and discusses concerns that the recommended work RVUs do not match the decreases in surveyed work time. CMS acknowledges that TAVR procedure is being adopted by more physicians and there will be greater intensity for a physician when this new technology is being adopted. CMS intends to continue to examine whether TAVR services are appropriately valued as their use increases.

(46) X-Ray Exam Specimen (CPT Code 76098)
The American College of Radiology (ACR) requested review of this code. ACR believed this code was undervalued because of the assumption that the service is typically furnished concurrently with another service and expressed concerns about the appropriateness of reducing

physician time and intensity for a code to account for overlap with other services that are furnished to a patient on the same day. CMS proposes the RUC-recommended work RVUs for this code of 0.31 (an increase over the current value of 0.16). In response to the ACR's concerns, **CMS seeks stakeholder feedback and suggestions about what parameters should be used to evaluate services furnished concurrently by the same provider to the same patient on the same day to account for the overlap in physician work time and intensity, and PE, and how these parameters affect code values**.

(59) Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS code GTTT1)
CMS remains concerned about the direct practice expense allocated for these codes: CPT codes 93297 and 93298 are work-only codes and CPT code 93299 is direct PE. CMS has not established national pricing for 93299 and it is contractor priced.

The RUC re-examined theses codes for PE and recommended PE for 93297 and 93298 and deleted 93299. CMS does not accept the RUC recommendations noting several concerns including the lack of a detailed description of the clinical labor tasks and the typical supplies and equipment used when furnishing these services. CMS proposes not to allocate direct PE input for 93297 and 93298 and seeks additional information about the clinical labor tasks, supplies and equipment. Because 93299 is being deleted for 2020, CMS proposes to create a G-code, GTTT1, to describe the services previously furnished under 93299.

(68) Negative Pressure Wound Therapy (CPT codes 97607 and 97608)
In response to stakeholder feedback, CMS evaluated these codes and determined there was adequate volume to assign them an active status and they would no longer be contractor prices.

(70) Online Digital Evaluation Service (e-Visit) (CPT codes 98X00 - 98X02)
(73) Online Digital Evaluation Service (e-Visit) (CPT codes 9X0X1 - 9X0X3)
The CPT Editorial Panel created six non-face-to-face codes to describe patient initiated digital communications that require a clinical decision that otherwise typically occurs in the office. CPT codes 9X0X1- 9X0X3 are for practitioners who can independently bill E/M services and CPT codes 98X00 – 98X02 are for practitioners who cannot independently bill E/M services.

CMS notes that for E/M services that are outside the Medicare benefit category of the practitioners who may bill for the service, it typically creates parallel HCPCS G-codes. For 2020, CMS proposes separate payment for online digital assessments by three HCPCS G codes that mirror the RUC recommendations: HCPCS code GNPP1 – GNPP3.

(74) 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 proposes to continue to use the G codes for radiation therapy services, as well as their current work RVUs and direct PE inputs. CMS also proposes to continue to use a utilization rate assumption of 60 percent for the equipment item: ER089, "IMRT Accelerator."

O. Comment Solicitation on Opportunities for Bundled Payments under the PFS

CMS is 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 seeks comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS.

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

1. Background

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 previous PFS rules, CMS has 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. To enhance primary care delivery, CMS has progressively expanded coverage and payment to include new E/M services such as chronic care management.[30]

For 2019, CMS focused its attention on existing E/M services provided in outpatient settings, most commonly in physicians' offices; these services constitute about 20 percent of allowed charges. Parallel CPT code families for new (99201-99205) and established (99211-99215) patients each contain 5 visit levels that vary in complexity, required documentation, and payment. CMS proposed extensive office E/M service changes (83 FR 35832-35848) intended to reduce administrative burden, improve payment accuracy, and better reflect current medical practice, such as code addition for primary care visit complexity and application of a single, "blended" payment rate to level 2-5 visits.

CMS received several thousand comments about its E/M-related proposals, ranging from widespread support for decreasing redundancy to broad-based opposition to blended payments. Numerous commenters recommended delaying implementation to await the outcome of a joint CPT/RUC Workgroup on E/M sponsored by the AMA. For 2019, CMS finalized only two proposals: 1) eliminating added documentation of medical necessity for home visits, and 2) allowing clinicians to review and update previously recorded history and physical exam information at subsequent visits, rather than requiring complete reentry. However, CMS also finalized several proposals for 2021 implementation, including addition of inherent complexity

[30] Chronic Care Management services (CPT codes 99487-99490) are based upon a comprehensive care plan and are furnished on a per month basis to patients with two or more ongoing, long-term conditions to reduce the risk of acute exacerbation, decompensation, functional decline and death.

codes and adoption of a single, blended payment structure for level 2-4 visits. Finally, CMS indicated plans to continue discussions with stakeholders and to follow the AMA workgroup's progress (83 FR 59625-59653).

Following publication of the 2019 PFS final rule, CMS has held public listening sessions and met with numerous stakeholder groups, and the AMA workgroup has finished its deliberations. The workgroup revised the CPT code descriptors and prefatory language for Office/Outpatient E/M Services and approved a grid to guide use of medical decision-making (MDM) complexity for selecting among office visit levels. The workgroup's recommendations were finalized by the CPT Editorial Panel in February 2019 for use beginning in 2021, and the revised codes were sent to the RUC for revaluation.[31] During the RUC's April 2019 meeting, survey results from over 50 specialty societies were reviewed, after which the RUC sent recommendations to CMS for work values, service times, and direct PE inputs for the revised office visit codes.

2. Office Visit Reporting in 2020

No new office visit E/M service proposals are made by CMS to take effect for 2020. Clinicians will continue to report existing CPT codes for new and established patient visits (99201-99215) and for prolonged face-to-face office visit time (99354-99355). Prefatory and other instructional language to facilitate correct coding has not changed. Visit level selection remains based upon three key components (history, physical exam, and MDM complexity) and is guided by either the 1995 or 1997 DG edition; DG edition choice is left to the clinician. Time may be used for level selection only when over 50 percent of the visit's face-to-face time consists of counseling and/or care coordination, in which case level selection is guided by the "typical times" that accompany the code descriptors.[32]

3. E/M Office Visit Proposals for 2021

a. Overview

Changes finalized during 2019 rulemaking and implemented in 2019 are not being reconsidered, but modifications are being proposed to several policies previously finalized for 2021. CMS also makes proposals that are new for 2021 implementation, mostly related to the CPT revisions that will become effective for 2021.

b. Code descriptors, prefatory language, MDM grid, and time ranges (new)

CMS proposes to adopt for 2021 the office visit codes as revised by the AMA Workgroup and finalized by the CPT Editorial Panel (CPT codes 99202-99215; 99201 will be deleted), as well adopting the associated prefatory language and MDM complexity grid. The revised code descriptors require history and physical exam performance only to the extent medically necessary and clinically appropriate; history and exam are no longer considered key components

[31] Changes to the office visit codes are available at https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf. The MDM guideline grid is available at https://www.ama-assn.org/system/files/2019-06/cpt-revised-mdm-grid.pdf.

[32] The same provision for time-based coding appears in Medicare's Claims Processing Manual as well as in CPT.

for level selection. Ranges for total time (face-to-face and non-face-to-face) expended by the billing clinician in caring for a patient on the date of the patient's office visit are given for each code, replacing the typical face-to-face times previously provided, and CMS proposes to adopt the new time ranges. For example, the level 4 new patient visit in 2021 would read as follows:

99024 Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making.

When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter.

c. Visit level selection and documentation (audit) standard (previously finalized, modified)

CMS had finalized for 2021 that visit level selection (for levels 2-5) could be based upon 1) face-to-face time, using the typical times of the codes; 2) MDM complexity, using MDM grids from the 1995 or 1997 DGs; or 3) the extent of history, physical exam, and MDM performed, using the key component level selection framework of the DGs. If CMS' new proposal to adopt the office visit codes and instructions for their use as revised by CPT for 2021 is finalized, CMS' previously finalized visit level selection policies for 2021 would no longer be applicable. Instead, level selection would be chosen by 1) total clinician time expended for a patient on the date of the office visit, using the time ranges provided with the revised code descriptors; or 2) MDM complexity using CPT's MDM grid. Level selection using the DG's key components framework would cease to be an option.

Concomitantly, CMS had finalized that the minimum documentation required to support level 2-4 visits (e.g., during a post-payment audit) when selected by extant MDM complexity or DG guidelines, would be that of a level 2 visit, even when a level 3 or 4 visit had been billed. CMS adopted this standard because level 2-4 visits would be paid at the same blended rate beginning in 2021. Documentation required for level 2-4 visits selected by time was finalized to include medical necessity and the billing clinician's face-to-face time; the typical time specified with the code descriptor for each level would serve as the audit standard. Since separate level 5 payment was to be maintained, documentation for those visits would require description of the MDM complexity, typical time, or key components associated specifically with a level 5 visit as described in CPT and/or the DGs.

As discussed further below, CMS is proposing to set separate payments for each visit level of the revised codes. As a result, CMS' minimum documentation standard policies for 2021 are no longer applicable. Instead, when visit level is selected by MDM complexity, documentation guided by the MDM grid elements for that level would be expected. When visit level is chosen based upon time, documentation of the clinician's total time expended for that patient on the date of the visit and the medical necessity for the visit would be expected. CMS emphasizes that for all visit levels, no matter how selected, the overarching requirement that the medical necessity of the visit be documented remains unchanged.

d. Complexity add-on codes (previously finalized, modified)

CMS previously finalized codes GPC1X and GCG0X for 2021 to account for inherent complexity of primary care and nonprocedural specialist office visits, respectively, that CMS believes is not captured by existing office visit CPT codes (99201-99215). The two G-codes were structured as add-on codes to be reported alongside current new and established patient office visit codes, and the two G-codes were valued equally by CMS (0.25 work RVUs). Stakeholders voiced continued concerns about ambiguity of the code language as finalized and lack of guidance from CMS for correct use of the codes.

CMS believes that the revised office visit code set and their (mostly increased) values (CPT codes 99202-99215) are more accurate than their predecessors but still fail to completely account for the added resources expended during visits with inherent complexity. For 2021 CMS now proposes to delete GCG0X but to retain and revise GPC1X; the latter code would be available for add-on to all office visits with inherent complexity. The revised code descriptor is reproduced below from Table 28 of the rule. CMS states that the newly revised code would better describe the kind of care that should be reported with revised GPC1X and should be more easily understood. CMS does not propose guidelines for appropriate use of revised GPC1X.

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

e. Prolonged office visit E/M codes (previously finalized, modified)

CMS previously finalized code GPRO1 for 2021, to be added to level 2-4 office visits that extended beyond the time ranges established by CMS for the blended level 2-4 code payments. Existing CPT prolonged service codes with face-to-face contact (99354-99355) would remain applicable to level 5 visits that exceeded the associated typical times by at least 30 minutes. Alternatively, when revising the office visit base code set (99202-99215), CPT added new code 99XXX to capture practitioner total time on the date of an office visit when total time exceeds that for a level 5 visit and the visit level is being selected based on time. (Shorter visits can be coded based upon their total time using level 2-4 codes, and time would not be relevant when visit level selection is based upon MDM complexity.) As a CPT "add-on" code, 99XXX must be appended to a base code; for 99XXX, the available base codes are the revised office visit codes (99202-99215).

Having proposed to adopt CPT's revised office visit codes for 2021, CMS also proposes to delete GPRO1 and adopt CPT code 99XXX for use starting in 2021. However, CMS identifies some potential ambiguity in the prefatory language for 99XXX, particularly about the interactions among office visit base codes (99202-99215), 99XXX, and existing codes 99358-99359 (prolonged services without face-to-face contact). CMS provides examples of correct use of 99XXX with base codes 99205 and 99215 in Table 26 of the rule. For further clarity, CMS adopts the interpretation that codes 99358-99359 are not to be reported on any date in

conjunction with any base office visit code, since the revised base codes were valued to include clinician work within 3 days prior to and 7 days after the office visit. Finally, CMS states that allowing only a single prolonged service add-on code (99XXX) to be used when base code visit level selection is time-based, offers administrative simplicity and minimizes practitioner burden.

CMS invites comment upon the interactions that would be appropriate between the office visit base codes, 99XXX, and 99359-99359; CMS' interpretation that prohibits use of 99358-99359 with base office visit codes; and whether codes 99358-99359 need to be redefined, resurveyed, or revalued for proper use with the revised office visit base codes.

f. *Code revaluations (new)*

Codes 99202-99215 and 99XXX

For 2021, CMS proposes to adopt the RUC-recommended work values (expressed in relative value units) for each level of the revised office visit CPT codes and for 99XXX. These values represent increases from the current values for most of the revised codes, other than for 99202 and 99211; the latter codes often primarily involve clinical office staff or require only straightforward decision-making. CMS also proposes to accept the direct PE inputs for these codes as recommended by the RUC with one exception: removal of equipment item ED021 (computer, desktop, with monitor). CMS believes that this item is better characterized as an indirect cost applicable to many services and patients rather than as a cost to be allocated directly to an individual service provided to an individual patient. Finally, CMS also proposes to accept the service times recommended for these codes by the RUC, although raises a question related to the RUC's survey methodology for time collection (discussed further below). In adopting the revised CPT codes and RUC recommendations, CMS would drop its blended payment rates for new and established patient level 2-4 visits, as previously finalized for 2021. Instead, CMS proposes to return to distinct payment rates for each office visit level for 2021; as noted above, this proposal also would render the related, previously finalized, level 2 visit minimum documentation (audit) standard no longer applicable.

Table 27B, reproduced below from the rule, lists the total times and work values for codes 99201-99215 and 99XXX currently, as finalized in 2019 for use in 2021 ("CY 2021"), and as proposed in this rule for use in 2021 ("RUC rec").

TABLE 27B: Side by Side Comparison of Work RVUs and Physician Time for the Office/Outpatient E/M Services Code Set, and the New Prolonged Services Code (Current Versus Revised)

HCPCS Code	Current Total Time (min)	Current Work RVU	CY 2021 Total Time (min)	CY 2021 Work RVU	RUC rec Total Time (min)	RUC rec Work RVU
99201	**17**	**0.48**	**17**	**0.48**	**N/A**	**N/A**
99202	**22**	**0.93**	**22**	**1.76**	**22**	**0.93**
99203	**29**	**1.42**	**29**	**1.76**	**40**	**1.6**
99204	**45**	**2.43**	**45**	**1.76**	**60**	**2.6**
99205	**67**	**3.17**	**67**	**3.17**	**85**	**3.5**

HCPCS Code	Current Total Time (min)	Current Work RVU	CY 2021 Total Time (min)	CY 2021 Work RVU	RUC rec Total Time (min)	RUC rec Work RVU
99211	**7**	**0.18**	**7**	**0.18**	**7**	**0.18**
99212	**16**	**0.48**	**16**	**1.18**	**18**	**0.7**
99213	**23**	**0.97**	**23**	**1.18**	**30**	**1.3**
99214	**40**	**1.5**	**40**	**1.18**	**49**	**1.92**
99215	**55**	**2.11**	**55**	**2.11**	**70**	**2.8**
99XXX	**N/A**	**N/A**	**N/A**	**N/A**	**15**	**0.61**

Methodology question. For codes 99202-99215, the RUC survey required that respondents report pre-, intra-, and post-service times (termed "component times") along with total service time, basing their answers on considerations of total time spent on the visit day as well as within 3 days prior to and 7 days after the visit.[33] The RUC then calculated averages separately for each component time and for the total time. CMS notes that prior RUC surveys have collected pre-, intra-, and post-service times without specifying an overall service time frame. CMS further notes that the separately-averaged component and total times introduce time discrepancies for some codes; that is, the sum of the component times does not always equal the total time (as shown in Table 27A of the rule; a discrepant line example is shown below). CMS is concerned about the time discrepancies for two reasons: 1) intra-service and total times of office visits are used regularly by CMS, the RUC, and others as references when developing valuations for other E/M and non-E/M services; and 2) the programming used by CMS for setting PFS rates requires that component service times sum to the total time. **CMS, therefore, seeks comment about how to resolve differences between the component and total times when they conflict.**

Example of Time Discrepancy taken from TABLE 27A

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**

Actual Total Time = sum of separately-averaged component time responses
RUC rec Total Time = average of respondent answers for total time

Code GPC1X

While CMS proposes to accept the RUC-recommended work values for the revised office visit codes and notes increases from current values, CMS continues to believe that higher per-visit resource costs are associated with ongoing care that is most often furnished by primary care and non-procedural specialists. After reviewing the revised (increased) office visit values and relevant reference codes, CMS proposes that the previously finalized value for code GPC1X (0.25 work RVUs) should be increased to 0.33 work RVUs for the revised GPC1X code. **CMS**

[33] Because 99XXX is an "add-on" code, it considered to have only intra-service time and therefore does not create any methodologic concerns.

invites comment as to whether the single code GPC1X as revised will be sufficient or whether an additional code(s) is necessary or would be beneficial.

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

CMS describes the office visit E/M changes developed by the AMA, and proposed 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 provide specifics and refers readers to https://www.ama-assn.org/cpt-evaluation-and-management for more details.

Because the revised office visit codes and values would not become effective until 2020, CMS does not include their estimated impacts the CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty (Table 110 of the rule). CMS does, however, provide for illustrative purposes an impact analysis of the E/M value changes as if those changes were proposed for 2020 implementation. The estimated combined effect of the changes actually proposed for 2020 implementation and the office E/M value changes are shown in Column F ("combined impact") of Table 111 (reproduced below from the rule with the addition of the 2020 combined impact without the office E/M value changes as Column G). CMS states that the combined impact estimate of Table 111 allows insights into potential payment shifts across specialties that would result from implementing the updated values for the office E/M codes and the revised, revalued visit complexity add-on code (GPC1X) as recommended by the RUC.

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021 (modified from proposed rule)

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact Work RVU Changes 2021	(D) Impact PE RVU Changes 2021	(E) Impact MP RVU Changes 2021	(F) Combined Impact 2021 (w/E/M)	(G)* Combined Impact 2020 (w/o E/M)
Allergy/Immunology	$236	4%	3%	0%	***7%***	***0%***
Anesthesiology	$1,993	-5%	-1%	0%	***-7%***	***0%***
Audiologist	$70	-4%	-2%	0%	***-6%***	***1%***
Cardiac Surgery	$279	-5%	-2%	-1%	***-8%***	***-1%***
Cardiology	$6,595	2%	1%	0%	3%	0%
Chiropractor	$750	-5%	-3%	-1%	***-9%***	***-1%***
Clinical Psychologist	$787	-7%	0%	0%	***-7%***	***3%***
Clinical Social Worker	$781	-7%	0%	0%	***-6%***	***3%***
Colon And Rectal Surgery	$162	-3%	-1%	-1%	-4%	1%
Critical Care	$346	-5%	-1%	0%	***-6%***	***1%***
Dermatology	$3,541	0%	1%	-1%	-1%	0%
Diagnostic Testing Facility	$697	-1%	-4%	0%	-4%	-2%
Emergency Medicine	$3,021	-6%	-2%	1%	***-7%***	***1%***
Endocrinology	$488	11%	5%	1%	***16%***	***0%***
Family Practice	$6,019	8%	4%	1%	***12%***	***0%***
Gastroenterology	$1,713	-2%	-1%	-1%	-4%	-1%
General Practice	$405	5%	2%	0%	***8%***	***0%***

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact Work RVU Changes 2021	(D) Impact PE RVU Changes 2021	(E) Impact MP RVU Changes 2021	(F) Combined Impact 2021 (w/E/M)	(G)* Combined Impact 2020 (w/o E/M)
General Surgery	$2,031	-3%	-1%	0%	-4%	0%
Geriatrics	$187	2%	1%	0%	3%	0%
Hand Surgery	$226	-1%	0%	0%	-1%	1%
Hematology/Oncology	$1,673	8%	4%	1%	***12%***	***0%***
Independent Laboratory	$592	-3%	-1%	0%	-4%	1%
Infectious Disease	$640	-3%	-1%	0%	-3%	0%
Internal Medicine	$10,507	2%	2%	0%	4%	0%
Interventional Pain Mgmt	$885	4%	3%	1%	***8%***	***1%***
Interventional Radiology	$432	-3%	-3%	0%	-6%	-2%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%	0%
Nephrology	$2,164	-2%	0%	0%	-2%	1%
Neurology	$1,503	2%	5%	0%	***8%***	***2%***
Neurosurgery	$802	-3%	-1%	-2%	-6%	-1%
Nuclear Medicine	$50	-4%	0%	0%	***-5%***	***1%***
Nurse Anes / Anes Asst	$1,291	-7%	-2%	0%	***-9%***	***0%***
Nurse Practitioner	$4,503	5%	3%	0%	***8%***	***0%***
Obstetrics/Gynecology	$620	4%	3%	0%	***7%***	***1%***
Ophthalmology	$5,398	-4%	-5%	0%	***-10%***	***-4%***
Optometry	$1,325	-2%	-3%	0%	-5%	-2%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-4%	-2%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%	1%
Other	$34	-3%	-2%	0%	***-5%***	***1%***
Otolaryngology	$1,225	3%	2%	0%	5%	0%
Pathology	$1,203	-5%	-3%	-1%	***-8%***	***0%***
Pediatrics	$62	3%	2%	0%	***6%***	***0%***
Physical Medicine	$1,110	-2%	0%	0%	-2%	0%
Physical/Occupational Therapy	$4,248	-4%	-3%	0%	***-8%***	***0%***
Physician Assistant	$2,637	4%	2%	0%	***7%***	***0%***
Plastic Surgery	$369	-3%	-1%	-1%	-5%	0%
Podiatry	$1,998	0%	1%	0%	1%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%	0%
Psychiatry	$1,120	4%	3%	0%	***7%***	***1%***
Pulmonary Disease	$1,658	0%	1%	0%	1%	0%
Radiation Oncology/Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%	0%
Radiology	$4,971	-5%	-3%	0%	***-8%***	***-1%***
Rheumatology	$534	9%	5%	1%	***15%***	***0%***
Thoracic Surgery	$352	-5%	-2%	-1%	***-7%***	***-1%***
Urology	$1,739	4%	4%	0%	***8%***	***1%***
Vascular Surgery	$1,203	-2%	-3%	0%	-5%	-2%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**	**0%**

*Source data for Column G taken from Column F of Table 110 in the rule. Specialties that would experience changes of allowed charges greater than 5 percentage points as a result of the office visit E/M changes are shown in bold italic font (30 of 56 specialties).

CMS states that the direction and magnitude of the impact of the office visit E/M changes are driven by each specialty's pattern of claims for office visits: the largest positive effects would accrue to those who regularly bill higher level established office visits (e.g., family practice, endocrinology, rheumatology), while specialties that less often bill office visits would experience

the largest negative effects (e.g., emergency medicine, pathology, radiology). Among nonphysician practitioners, larger positive effects would be seen by nurse practitioners and physicians' assistants with larger negative effects experienced by clinical psychologists, clinical social workers, nurse anesthetists and anesthesia assistants, and physical/occupational therapy. CMS concludes by noting that further coding and relative value changes may occur prior to the 2021 final rule that could alter the office visit-related impacts, and by stating its inability to estimate with certainty the impact of such changes. CMS emphasizes that any further changes in office visit coding and payment would be subject to notice and comment rulemaking.

4. Office visits in global surgical packages

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 values recommended for freestanding office visits by the RUC to CMS. CMS notes that every procedure with a 10-day or 90-day global period includes at least one-half of an E/M visit in the period. CMS adds that global package valuations are generally made using the magnitude estimation method – in which the work value of the total package is assessed as a unit – rather than by summing the resources used for the procedure itself with those for each other component (e.g., office visit) included in the package to construct a total package value. (While not used when discussing the global surgical package in section II.P.3.f. of the rule, CMS refers to the latter valuation approach as the "building block methodology" earlier in the preamble during a review of methods employed by CMS when establishing RVUs, section II.N.2.) CMS does not further consider adjusting global surgical package values by incorporating the proposed updated office visit values.

CMS does go on to reprise its concerns about accurately valuing global surgical packages and notes the following related events: 1) in the 2015 PFS, CMS finalized transitioning all global periods to 0 days, allowing separate payments for postoperative follow-up E/M visits, to be completed for the 2019 PFS (79 FR 67548, 67585; published November 13, 2014); and 2) section 523(a) of MACRA prohibited the finalized transition from being implemented (Pub. L. 114-10 enacted April 15, 2015, signed into law on April 16, 2015). MACRA further provided that CMS:

- Develop a process to collect information needed to value surgical services from a representative sample of physicians;
- Collect information about the number and level of medical visits, and other items and services, furnished within global periods;
- Begin data collection no later than January 1, 2017;
- Have the Office of the Inspector General (OIG) audit a data sample for accuracy;
- Use the collected information and other available data, as appropriate, to improve the accuracy of surgical service valuations, beginning in 2019; and
- Could implement a payment withhold of up to 5% for practitioner failure to report data.

CMS contracted with RAND for assistance with information collection and analysis. Data collection based upon requiring a wide range of practitioners to report post-operative outpatient visits using code 99024 was completed for multiple procedures in 10 states from July 1, 2017 through June 30, 2018. RAND also surveyed practitioners performing cataract surgery, hip arthroplasty, and complex wound repair about details of their postoperative visits from

September through December 2018. CMS released three reports from RAND contemporaneously with the proposed rule.

CMS describes the RAND report findings as follows:[34]

- Report 1 covers the 99024-based data collection. Response rates were low, especially for 10-day global period procedures. The percentage of expected post-operative visits that were reported for procedures with 10- and 90-day global periods was 4 percent and 39 percent respectively.
- Report 2 covers the 2018 survey about three 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.

CMS notes that the OIG has previously reported on global surgical package visits but does not comment as to whether or when the OIG would conduct a specific audit of a sample of data collected by RAND for accuracy, as required by MACRA. CMS states plans to allow time for stakeholders and the public to study the RAND reports and consider revaluation approaches, but no timeline or specifics are provided. CMS concludes by stating that it will continue to study and consider alternative ways to value global surgical package services.

5. Revaluing services with values linked to office visits

CMS discusses 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 valuations. Services identified by CMS as linked services for potential revaluation include 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). CMS initially states that these services may be appropriate for revaluation since each always includes an office visit, but subsequently states that some do not involve an E/M visit but should be considered because their values were established through crosswalking to office visit values. **CMS seeks comment about revaluing these services in future rulemaking using the proposed 2021 office visit values if finalized.**

CMS also invites comment on the necessity and/or benefit of systematically adjusting other related PFS services to maintain their relativity to office visits. CMS does not offer criteria for "related PFS services" but notes particular interest in values for E/M visits performed in other settings (e.g., home) or specific code subsets used in place of or in association with office visits

[34] 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.

(e.g., ophthalmological examination and evaluation, stand-alone psychotherapy codes). CMS offers some examples of how these other codes might be adjusted to reflect the proposed office visit values.

III. Other Provisions of the Proposed Regulations

A. Changes to the Ambulance Physician Certification Statement Requirement

CMS proposes 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 proposes 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 proposes 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 proposes 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 proposes 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 have never prescribed the precise format of this required documentation. This proposal 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 proposes that the definition of a non-physician certification statement in proposed paragraph (a) would incorporate the existing requirements

that apply when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and obtain 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 proposes 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 proposes 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 proposes 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.

In addition to comments about this proposal, **CMS requests commenters identify other staff** that should be included to be authorized to sign certification statements, including such staff's licensure and position and the reason it would be appropriate for them to sign a certification statement.

B. Proposal to Establish 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. CMS notes that the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organization and welcomes **comments about how CMS can work within its statutory authority to ensure appropriate payments are made to air ambulance organizations**.

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")[35] commissioned by the American Ambulance Association (AAA); Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California's Medicaid program[36]; The Emergency Medical Services Cost Analysis Project (EMSCAP) framework[37] funded by the National Highway Traffic Safety Administration; a GAO ambulance survey[38]; and the Rural Ambulance Service Budget Model[39] 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.[40]

[35] 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.

[36] 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

[37] 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

[38] US GAO (2012) Survey of Ambulance Services. Available at https://www.gao.gov/assets/650/649018.pdf

[39] Health Resources and Services Administration. The Rural Ambulance Service Budget Model. Available at https://www.ruralcenter.org/resouce-library/rural-ambulance-service-budget-model.

[40] The report is available at https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html

2. Proposals for the Data Collection Instrument

a. *Proposed Format*

CMS discusses the limitations of the data collection tools reviewed by the contractor. Some stakeholders preferred data collection through a cost report spreadsheet, such as the GEMT and other similar tools used by state Medicaid programs. CMS notes that only a small number of states use these tools that cannot be used by all ground ambulance organizations without significant revisions because they are generally designed to collect information from government run entities. Other stakeholders preferred survey-based reporting, such as the Moran survey, because they believe survey reporting is less burdensome. CMS agrees that survey reporting can provide greater flexibility and reduce reporting burden but is concerned the Moran survey recommended excluding small ground ambulance organizations, which are a large percentage of total ground ambulances. The Moran survey would also need significant revisions to take into account the unique differences of government run ground ambulances. Some stakeholders recommended using cost reporting guidelines similar to the Medicare Cost Report (MCR); CMS notes that many smaller ground ambulance organizations said they would have difficulty complying with complex cost reporting guidelines.

Based on its analysis of data collection instruments, CMS proposes 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 proposed survey would 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 proposes to codify these policies at §414.626.

b. Proposed Scope of Cost, Revenue, and Utilization Data

CMS discusses 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. This approach is similar to the information ground ambulance organizations collect for their own internal budgeting. This method was also used in the 2012 GAO study and an HHS report[41] that used data from the MCS as its data source. The second option considered would collect only those costs relevant to ground ambulance services furnished to Medicare beneficiaries. CMS believes that excluding other services, such as Medicaid transports, would be burdensome and complex for organizations. 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 believes requiring reporting related for specific levels of services reported with HCPCS codes would also be overly

[41] The HHS study, "Report to Congress Evaluation of Hospitals' Ambulance Data on MCRs and Feasibility of Obtaining Cost Data from All Ambulance Providers and Suppliers" is available at https://www.cms.gov/Medicare/MEdicare-Fee-for-Service-PAyment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.

burdensome and complex. CMS notes that stakeholders would find it difficult to report services furnished exclusively to Medicare beneficiaries or Medicare services covered under the AFS.

CMS proposes 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 would 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 proposes that the instructions for the data collection instrument would separately address three further refined proposed categories of total ground ambulance costs and revenues:

- Costs and revenue components completely unrelated to ground ambulance services. This information would be unrelated to the data collection and not reported. Examples including 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 would be reported in full but respondents would 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 would 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 (similar to the analysis in the GAO report) 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.

c. Proposed Data Collection Elements

Table 29, reproduced below, provides an overview of the proposed 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 29: Proposed 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

Table 29: Proposed Components for the Data Collection Instrument		
Data Collection Instrument		**Broad Description of the Component**
Component	**Section**	
		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.

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. Highlights of each category are discussed below; the interested reader is referred to the proposed rule and the draft collection instrument for more details.

(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 includes 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

mutual or auto-aid[42], 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 proposes 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 is also proposing 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 is not proposing to 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 proposes 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.

(2) Ground Ambulance Utilization

CMS proposes 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 proposes a two-pronged approach to collect data on both the volume and mix of services. First, CMS proposes to 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 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 proposes to 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 does not propose respondents report on their mix of services in primary and secondary service areas. Instead, CMS proposes reporting the share of total ground ambulance responses that were in a secondary rather than the primary service area in a single question. CMS is also not proposing 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.

[42] 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.

(3) Collecting Data on Costs

CMS makes 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 proposes to have respondents 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 proposes to include 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 would be an additional response for some organizations but is concerned that the lack of reported cost data in one of the major categories would 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 proposes respondents only report the ambulances, other vehicles and buildings that have been donated without the fair market estimate. CMS believes fair market values could be imputed using publicly available data.

(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 proposes 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 proposes 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 proposes to collect 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."

Scope of Reported Labor Costs. CMS proposes to define labor costs to include compensation, benefits, stipends, overtime pay, and all other compensation to staff (fully-burdened costs).

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 proposes 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 proposed data collection collects 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 proposes to collect the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs are collected.

Allocation and Reporting Staff with Other Non-Ground Ambulance Responsibilities. Since firefighters/EMTs are common in many ambulance suppliers, CMS proposes 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.

(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 proposes a hybrid approach involving both per-facility and aggregate reporting of information. CMS proposes 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 would be aggregated across all facilities. CMS notes this proposal 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,

(iii) *Collecting Data on Vehicle Costs*

CMS proposes 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 proposes to collect 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 proposes to list the percent of total maintenance and fuel costs attributable to each type of vehicle.

(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 proposes 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 proposes to request 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 proposes to obtain information separately for capital costs (including annual depreciated cost) and non-capital costs. Based on feedback from ground ambulance organizations, CMS also proposes to allow respondents to report annual maintenance and service costs for capital equipment. CMS proposes to 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 proposes to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services.

(v) *Collecting Data on Other Costs*

For contracted services, CMS proposes 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 proposes 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 proposes that respondents report an allocation factor for each contracted service and miscellaneous expenses.

d. Proposed Data Collection on Revenue

CMS believes that collecting information on total revenue is essential to understanding the variations in financing ground ambulance services. CMS proposes 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 also proposes 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, CMS proposes to have respondents 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 proposes to collect information on both total and paid transports.

3. Proposals 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 proposes 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, proposes to select the sample at the NPI level.

Organizations using volunteer labor. CMS discusses 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 proposes that ambulance providers and suppliers that use any amount of volunteer labor should be included in the sample.

Sampling file. CMS proposes 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 proposes to use 2017 claims and enrollment data. CMS does not propose 2018 data because it is concerned that the data may not be complete when the sample is selected.

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 proposes to collect a full, continuous 12-months of data, it proposes 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 would be eligible for sampling and reporting in future years.

Sampling rate. CMS proposes that 25 percent of ground ambulance organizations would 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 would 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 proposes to notify selected ground ambulances by listing them on the CMS website (https://www.cms.goc/Center/PRovider-Type/Ambulances-SErvices-CEnter.html and provide written notification to each organization by email or mail. Notification on the CMS website would be at least 30 days prior to the start date for collecting data. For 2020, CMS plans to post information on the website when the 2020 PFS final rule is issued.

Approach for Sampling. CMS discusses several possible sampling options and proposes 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 specifically proposes to 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 discusses several characteristics that vary among ground ambulance organizations and are important contributors to cost and revenue.

CMS proposes 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 proposes four volume categories: 1 to 200, 201 to 800, 801 to 2500, and 2501 or more paid Medicare transports. CMS notes that the proposed 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 focuses on these four characteristics because of data availability and analysis which showed these are the key defining characteristics of ground ambulance organizations. CMS believes that Medicare claims and enrollment data provides enough information to stratify ground ambulance on the 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 notes 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 proposes to stratify ground ambulance providers based only on service area population density. CMS proposes this characteristic to satisfy 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 proposes 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 proposed 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.

4. Proposals for Collecting and Reporting of Information

CMS proposes 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. This proposal is based on feedback from ground ambulance organizations that stated they prefer to collect data based on the annual accounting period used by the organization. CMS proposes that the first data collection period would be January 1, 2020 through December 31, 2021 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. CMS proposes that 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 proposes 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 30) and an accounting period not based on a calendar year (Table 31).

5. Proposed 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 proposes that an ambulance organization is 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 proposed rule.

CMS proposes that if the data reported is not sufficient, it would 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 would 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 proposes that to request a hardship exemption, a ground ambulance organization submits a completed request form[43] 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.

CMS proposes that the completed exemption request form 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 proposes to 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 proposes 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 proposal for a hardship exemption, CMS proposes that 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 proposes to provide: (1) a written acknowledgement that the request has been received; and (2) a written response to the

[43] The hardship exemption form can be found on the Ambulance Services Center Website at https://www.cms.gov/Center/PRovider-Type/Ambulances-Services-Center.html.

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

6. Public Availability

CMS proposes 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 also proposes that the data will be made 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 proposes to post summary results by the last quarter of 2022.

7. Limitations on Review

CMS proposes to codify 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 proposed 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 proposed 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, would 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 notes that the statute explicitly states cardiac rehabilitation. Therefore, this proposed rule is specific to CR and ICR for cardiac conditions and does not include applying CR and ICR to other conditions (for example, cancer, diabetes, peripheral artery disease, etc.).

3. Proposals for Implementation

CMS proposes modifications to existing requirements under (§420.49(b)) to implement the coverage changes to ICR. The proposal involves: (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.

[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.)

D. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid Eligible Professionals (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 Medicare-based Incentive Payment System (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

For 2020, CMS proposes to again 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 would 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:

- Use the high priority measures identified for eligible clinicians under the MIPS program;

- Include as high priority measures those available eCQMs in the previous year's "Core Sets" that are also on the MIPS list of eCQMs. CMS is required to develop and annually update two sets of quality measures that states may voluntarily report. The measures specifically focus on populations served by the Medicaid and CHIP programs. These Core Sets are comprised of quality measures for children (the Child Core Set) and for adults (Adult Core Set). CMS notes that because the child and adult Core Sets are released at the beginning of each year, it is not be possible to update the list of high-priority eCQMs with those added to the current year's Core Sets. CMS proposes the following eCQMs that are available for EPs to report in 2020 and are both part of the Core Sets and on the MIPs list of eCQMs:
    - CMS2, "Preventive Care and Screening: Screening for Depression and Follow-Up Plan"
    - CMS122, "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)"

- CMS125, "Breast Cancer Screening"
- CMS128, "Anti-depressant Medication Management"
- CMS136, "Follow-Up Care for Children Prescribed ADHD Medication (ADD)"
- CMS137[45], "Initiation and Engagement of Alcohol and Other Drug Dependence Treatment"
- CMS153, "Chlamydia Screening for Women"
- CMS155, "Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents"
- CMS165, "Controlling High Blood Pressure"

- Give each state the flexibility to identify which of the available eCQMs selected by CMS are high priority measures for EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans; this is similar to the flexibility granted states to modify the definition of Meaningful Use at §495.332(f).

CMS also proposes that the 2020 reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year 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 proposes 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 notes 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 states it 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 proposes 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.

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.

[45] CMS clarifies that this measure was inadvertently listed as "CMS4" in the 2019 PFS final rule.

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 proposes 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 would 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 a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. If this program is finalized, CMS will work with states to develop post-payment verification and audit processes.

E. Medicare Shared Savings Program (MSSP) Quality Measures

CMS reviews the regulatory history of the MSSP program and notes that it has historically used the annual PFS rules to address quality reporting for the program. In this proposed rule, CMS discusses the follow:

- Aligning the MSSP quality measure set with proposed changes to the Web Interface measure set under MIPS per previously-finalized policy;
- A proposed change to the claims-based measures;
- Soliciting comment on aligning the MSSP quality score with the MIPS quality performance score; and
- A proposed technical change to the MSSP's regulations on the skilled nursing facility (SNF) 3-day rule waiver.

1. Quality Measures

For performance year 2019, the MSSP uses 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. Proposed 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.

For 2020, the proposed changes to the CMS Web Interface measures for performance year 2020 (MIPS Payment Year) are discussed in Appendix 1:

- Table Group A (New Quality Measures Proposed for Addition Beginning with the 2022 MIPS Payment Year),
- Table C (Existing Quality Measures Proposed for Removal Beginning with the 2022 MIPS Payment Year),[46]
- Table DD (Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year).

Based on the proposed changes, ACOs will no longer be responsible for reporting the following measures for performance year 2020:

- ACO -14: Preventive Care and Screening Influenza Immunization

If this measure is not finalized for removal, CMS plans to maintain the measure with the "substantive" change described in the measure. CMS does not believe this change is significant and it would retain the measure as pay-for-performance for the 2020 performance year.

CMS proposes to add the following measure for ACO reporting:

- ACO-47: Adult Immunization Status

Consistent with the existing policy regarding the scoring of newly introduced quality measures, this measure would be pay-for-reporting for all ACOs for 2 years (performance years 2020 and 2021). This measure would phase into pay-for-performance in performance year 2022 (see Table 32 reproduced below).

CMS proposes 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. CMS notes that due to the current guidance, it is unable to rely on historical data to benchmark the measure and for the 2018 performance year, CMS designates

[46] In Appendix 1, Table C, CMS proposes to remove 55 quality measures from the MIPS Program.

the measure pay-for-reporting. For 2021, proposed modification to this measure are discussed in Appendix 1, Table DD. If this modification is finalized as proposed, CMS expects it will be able to use historical data reported on this measure to establish an appropriate 2019 benchmark and the measure would be pay-for-performance for performance year 2019 and subsequent years.

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[47]. 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 proposes to redesignate ACO-43 as pay-for-reporting for 2020 and 2021.

Table 32, reproduced below, shows the entire quality measure set for the MSSP for performance years beginning with 2019. Table 33, 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 32: 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

[47] 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)		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 - 47	Adult Influenza Status	X	NQF #N/A NCQA	CMS Web Interface	R	R	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		Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes		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 33: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 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%

Table 33: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2020				
Domain	**Number of Individual Measures**	**Total Measures for Scoring Purposes**	**Total Possible Points**	**Domain Weight**
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

b. Seeking Comment 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 solicits comments on how to potentially align the MSSP quality performance scoring methodology more closely with the MIPS quality performance scoring. CMS reviews both the quality performance standards for ACO's, including the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO, and MIPS. CMS solicits comments on how to potentially align the MSSP quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology. **CMS solicits comments on the alternatives discussed below and any other recommendations for alignment of quality performance**.

(1) Replace the MSSP quality score with the MIPS quality performance category score

Currently, for ACOs in track (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. For Shared Savings Program quality scoring purposes, CMS discusses utilizing the MIPS quality performance category score, converted to a percentage of points earned out of the total points available, as the ACO's quality score for purposes of financial reconciliation. For performance year 2017 (the only year with complete data), the weighted mean MIPS quality performance category score for ACOs in the Shared Savings Program tracks (or payment models within a tract) that are not an Advanced APM was 45.01 and the weighted median MIPS quality performance score for these ACOs was 46.8, out of a possible 50 points assigned for the quality performance category.

Advanced APMs (currently, Track1 and BASIC Track Levels A, B, C, and D) whose eligible clinicians are QPs for the year and are excluded from the MIPS reporting requirements, do not receive a quality performance category score under MIPS. The quality data reported by the ACO to the CMS Web Interface combined with the ACO's CAHPS data and the administrative claims-based measures calculated by CMS are used for scoring the quality performance. CMS discusses an alternative that utilizes a MIPS quality performance score for these ACOs and use this score to assess the quality performance of the ACO.

Under this approach, CMS would utilize the same scoring methodology to determine the quality performance for purposes for Shared Shaving Programs that are participating in Advanced APMS and ACOS in Shared Savings Program tracks that do not meet the definition of an Advanced APM. CMS notes this would not change whether eligible clinicians participating in

the ACO obtain QP status and are excluded form MIPS and would not change the ACO participant TINs' eligibility to receive Advanced APM incentive payments.

CMS solicits comments on this approach of using the MIPS quality performance category score to assess quality performance for purposes of the MSSP quality performance standard. CMS also solicits potential alternative approaches for aligning quality performance between the MSSP and MIPS.[48]

(2) Include all of the MIPS claims-based measures for ACOs

For the 2021 MIPS performance year, CMS proposes to add the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category (section III.I.3.b.(1)(ii) of this proposed rule). If this proposal is finalized, CMS is considering both including the MIPS claims-based measures (MCC) and MIPS All-Cause Readmission measure) in the MIPS APM scoring standard for ACOs that are not Advanced APMS and in the MIPS quality performance category equivalent score for ACOs in Advanced APMs. CMS discusses how the proposed MIPS MCC and ACO MCC are similar because they both target patients with multiple chronic conditions but the cohort, outcome, and risk model for the proposed MIPS MCC measure would vary from the ACO MCC measure. The cohort for the MIPS MCC measure includes nine condition (diabetes is included) and adjusts for two area-level social risk factors.[49]

CMS believes the MIPS and Shared Savings Program versions of the All Cause Readmission measure are essentially re-specifications of the same hospital measure and are updated annually to maintain alignment. The primary difference among the measures is only the entity that is accountable, either an ACO or a MIPS-eligible clinician.

Instead of the 3 claims-based measures in the Shared Savings Program quality score, CMS is considering including all the MIPS claims-based measures for all ACOs. CMS would continue to assess ACOs on the CAHPS for ACO survey but quality performance would be calculated by the methodology used for scoring the CAHPS for MIPS survey. The scoring and benchmarking approach for the CAHPS for MIPS assigns points based on each summary survey measure (SSM) and then average the points for all the scored SSMs to calculate the overall CAHPS score. For ACOs, the current methodology provides up to 2 points for each of the 10 SSMs for a total of 20 points.

CMS solicits comments on potentially including all of the MIPS claims-based measure in the MIPS quality performance category score for ACOs and using this score in place of the current Shared Savings Program for all ACOs.

(3) Determining the threshold for minimum attainment

In the first performance year of their agreement period, ACOs are considered to have met the quality performance standard. ACOs in all other performance years are required to completely

[48] In section III.I.3.a.(3) of this proposed rule, CMS solicits comments on simplifying MIPS by implementing a core measure set using administrative claims-based measures.

[49] More details about the MIPS MCC measure are in Appendix 1 Table AA (New Quality Measures Proposed for Addition for the 2023 Payment Year and Future Years) of this proposed rule.

and accurately report and meet the minimum attainment level on at least one measure in each domain to be determined to have met the quality performance standard and to be eligible to share in savings. For these ACOs, minimum attainment is defined as a score that is at or above 30 percent or the 30th percentile of the performance benchmark. The 30th percentile for the Shared Savings Program is the equivalent of the 4th decile performance benchmark under the MIPS APM quality performance category scoring.

To more closely align with MIPS, CMS is considering how to determine whether ACOs have met the minimum attainment level. One alternative discussed continues to not change the definition for complete and accurate reporting for ACOs in their first performance year but a MIPS quality performance category score above the 4th decile would be required for ACOs in all other performance years. ACOs with quality scores below the 4th decile of all MIPS quality performance scores would not meet the quality performance standard for the Shared Savings Program and not be eligible to share in savings or would owe the maximum shared losses, if applicable. These ACOs would also be subject to compliance actions and possible termination.

CMS acknowledges that a requirement that ACOs achieve an overall MIPS quality performance score (or equivalent score) that meets or exceeds the 4th decile across all MIPS performance quality scores is a higher standard than the current requirement to meet the 30th percentile on one measure per Shared Savings Program quality domain. CMS notes that section 1899(b)(3)(C) of the Act not only provides CMS discretion to establish quality performance standards for the Shared Savings Program but also indicates CMS should seek to improve the quality of care over time by specifying higher standards and consistent with section 1899(b)(3)(C) of the Act, it is consistent to require a higher standard of care for ACOs to continue to share in any savings they achieve.

CMS is also considering setting a higher threshold, such as the median or mean quality performance category score across all MIPS quality category scores, for determining eligibility to share in savings under the Shared Savings Program. This alternative would include all ACOs except those in the first year of their agreement period.

CMS solicits comments on potential approaches for determining Shared Savings Program quality minimum attainment using MIPS data.

(4) Utilize the MIPS quality performance score to adjust shared savings and losses

CMS discusses the current methodology for using the ACO's quality score for determining the amount of shared savings and shared losses owned, if applicable. As an alternative, CMS is considering establishing a minimum attainment threshold, such as a score at or above the 4th decile of all MIPS quality performance scores or the median or the mean quality performance score, that would allow ACOs to share in savings based on the full sharing rate of their track.

CMS solicits comments on potential approaches for utilizing MIPS quality performance category score or an alternative score in determining shared savings or shared losses under the Shared Savings Program.

(5) Use the methodology for non-ACO group reporters using the CMS Web Interface for MIPS quality reporting

ACOs must report all Web Interface measures to compete quality reporting. For ACOs in the first year of their first agreement period, minimum attainment is set at the level of complete and accurate reporting of all measures.

Using the methodology used for calculating non-ACO group reporters using the CMS Web Interface would result in an ACOs receiving a score for each measure they report and zero points for those measures they do not report. If CMS adopted this approach, it would no longer impose a different quality standard for ACOs in the first year of their participation agreement and no longer transition from pay-for-reporting to pay-for-performance. CMS believes this would be an appropriate policy since nearly 100 percent of ACOs consistently satisfactorily report all quality measures. **CMS solicits comments on this alternative**.

(6) Use the MIPS quality improvement scoring methodology

ACOs can earn a Quality Improvement Reward in each of the four quality domains; ACO's in their first performance year are excluded. MIPS improvement points are generally awarded as part of the MIPS quality performance category score if a MIPS eligible clinician meets the following requirements: (1) has a quality performance category achievement percent score for the previous and the current performance period; (2) fully participates in the quality performance category for the current performance year; and (3) submits data under the same identifier for the 2 consecutive periods.

If CMS adopted the MIPS quality performance category score for the Shared Savings Program quality score, quality improvement points earned under MIPS would be included in the MIPS score and CMS would not need to add additional points to the quality score.

CMS solicits comments to determine quality improvement under the Shared Savings Program.

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

CMS proposes a 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. 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 (PA), nurse practitioners (NP), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM).

CMS proposes 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. The changes would apply to data collected in 2021 and reported in 2022.

CMS also proposes to make a correction to the national drug codes (NDCs) reporting requirements for drugs and biologicals. The effective date for this change (if finalized) would be 60 days after the final rule is published.

2. Expanding the Definition of Covered Recipient

CMS proposes 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.

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.

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 proposes to make changes to its Nature of Payment categories by (i) consolidating two existing categories which it finds duplicative and (ii) adding three new categories.
CMS proposes to consolidate two separate categories for continuing medical education payments. Current regulations distinguish between accredited/certified and unaccredited/non-

certified continuing education programs. CMS proposes to abandon that distinction and to refer more generally to medical education programs; the category name would be "Compensation for serving as faculty or as a speaker for a medical education program".
CMS proposes to add three new categories: debt forgiveness, long-term medical supply or device loans, and acquisitions. The new categories would operate prospectively, meaning there would be no requirement to update previously reported payments/transfers of value.
Debt Forgiveness (§403.904(e)(2)(xi)). This category would be used to characterize 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 of 90-days average use). The new category would be used to characterize loans of covered devices or medical supplies for longer than 90 days.

Acquisitions (§403.904(e)(2)(xviii)). This category would be used to 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 proposes to require applicable manufacturers and GPOs to provide device identifiers (if any) to identify reported devices in a comprehensive fashion. It does not propose to require a full unique device identifier (UDI). The HHS OIG had recommended that the Open Payments program require more specific information about devices.
CMS states that it is unable to estimate the total cost of the proposed addition of the new data element because it would depend on whether the entity already tracks this data element and the extent to which the entity would need to update their system to be able to report it.
Drugs and Biologicals. CMS reports that in the 2015 PFS final rule it inadvertently removed 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 proposes to change 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 discusses 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 includes verbal discussion with annotation in the medical record or written options with a written patient attestation.

CMS is soliciting 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.

H. Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

1. Background

CMS reviews section 2005 of the SUPPORT Act and the proposed rules for OTP providers described above and the requirement that an OTP be enrolled in the Medicare program to qualify as an OTP under Medicare. In addition, it reviews the current process for providers to become Medicare participating providers.

2. Proposed OTP Enrollment Provisions

CMS proposes a new 42 CFR 424.67 to require that an OTP provider qualify as a Medicare provider and enroll in the program in order to receive payment for OUD treatment services.

a. Enrollment

Enrollment requirements would include the completion and submission of the Medicare Enrollment application for Clinics/Group Practices and Certain Other Suppliers (OMB Control No. 0938-0865) and any necessary supplements or attachments. The OTP would be required to:

- Maintain and provide a list to CMS of all physicians and eligible professionals who are authorized by the OTP to prescribe, order or dispense controlled substances;
- Have a current, valid SAMSHA certification (CMS will not accept a provisional SAMSHA certification);
- Certify via Form CMS855B and any applicable supplements or attachments that the OTP meets and will continue to meet the specific requirements and standards for enrollment; and
- Pay an application fee.

With respect to screening and review of OTPs, CMS is assigning OTPs at the high level of risk and therefore would propose screening requirements at the highest level of scrutiny. As such, the MAC would, in addition to routine screening (which includes verifying that the provider or supplier meets all federal regulations and state requirements, is licensed by the state, and undergoes database check to ensure that they continue to meet enrollment criteria) they are subject to a site visit, fingerprint and background checks for those individuals with more than 5 percent ownership interest. Those re-validating their Medicare enrollment would be screened at the moderate risk level – which requires a site visit but not fingerprinting.

CMS proposes that all OTP staff that meet the definition of managing employees -- which includes the medical director and program sponsor (described in SAMSHA regulations at 42 CFR 8.2) -- must be reported on Form CMS-855 and on any applicable supplement. A managing employee, defined in section 424.502 includes a general manager, business manager, administrator, director or other individual exercising operational or managerial control of the provider.

b. Other Requirements for Participating OTPs

In addition to the enrollment requirements, CMS proposes that:

- An OTP would be prohibited from employing or contracting with a prescribing or ordering physician or other professional authorized to dispense narcotics who has been convicted of a detrimental felony within the preceding 10 years. Detrimental felonies include those found at 42 CFR 424.535(a)(3) and may include others on a case by case basis. This standard would apply to pharmacists, registered nurses and licensed practical nurses.
- The OTP would not be permitted to employ or contract with any person who is revoked from participating in Medicare, is on the preclusion list, or has a current or prior adverse action imposed by a state oversight board.
- An OTP would be required to sign and adhere to the terms of a provider agreement.
- An OTP would have the ability to appeal a revocation of their provider agreement and jointly appeal revocation of their enrollment as a Medicare provider.
- CMS would be permitted to deny an OTP's enrollment application if the provider does not have in effect a current valid SAMHSA certification; if the OTP fails to meet any other applicable requirements of proposed §424.67; or for any of the reasons for a denial of a provider's enrollment application enumerated in §424.530 (Denial of Enrollment in the Medicare Program).
- Providers and suppliers of OTP services would be required to maintain a valid SAMSHA certification and remain in full compliance with all of the requirements set out in proposed §424.67, revalidation provisions in §424.515 and deactivation and reactivation provisions in §424.540.
- CMS would be permitted to revoke an OTP's enrolment for those same reasons or for any of the revocation reasons in §424.535 (Revocation of Enrollment in the Medicare Program).
- Prescribing individuals' NPIs would be required to be listed on health insurance claims forms.
- Consistent with other Medicare providers, the effective date of billing privileges would be the later of (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location. They would be permitted to retrospectively bill for services for up to 30 days prior to their effective date, however, if circumstances precluded enrollment or up to 90 days prior in the event of a Presidentially-declared disaster.

c. Other Revisions Related to Patient Harm

Revisions to §§424.530 and 424.535 to Incorporate all Part B and Part D Drugs. Under these existing sections, CMS is permitted to revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or fails to meet other Medicare requirements. CMS proposes to revise this provision to apply more broadly to all Part B and Part D drugs.

Prior Actions. In addition, CMS proposes to add new provisions to §424.535 to allow it to revoke or deny a physician's or other eligible professional's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body that has ascertained that their conduct led to patient harm. In doing so, CMS would consider the nature of the harm, the nature of the provider's conduct, the number and type of disciplinary actions that have been imposed, the nature of IRO determination (if any), the number of patients impacted, and any other information deemed relevant.

Definitions. Finally, CMS proposes to add a definition of "state oversight board" to §424.502 (Definitions) specifically for the purpose described above. CMS would define it to mean "any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the state." CMS requests comment on the proposed definition of "state oversight board," proposed revocation and denial authorities as well as any additional means of preventing fraud, waste, and abuse in OTP settings.

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. In this proposed rule, CMS would make changes to its regulations for ambulatory surgical centers (ASCs) and hospice programs to expand the ability of NPPs to provide services in these settings.

1. Ambulatory Surgical Centers

CMS proposes 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. CMS believes this would make ASC patient evaluations more consistent by allowing the option for the same clinician to complete both the pre- and post-procedure anesthesia evaluations. CMS notes that the revision would permit CRNAs to perform the anesthetic risk and evaluation on the patient in ASCs that use these NPPs. **CMS seeks comments and suggestions for revisions to other ASC requirements to permit greater flexibility in the use of NPPs**.

CMS estimates annual savings of approximately $17.3 million for this proposal. CMS assumes that 30 percent of all procedures would utilize the services of a nurse anesthetist instead of a physician for this requirement, which would reduce the cost of the examination. CMS invites comment on its assumptions.

2. Hospice

Section 51006 of the BBA of 2018 amended the definition of attending physician for purposes of hospice to include PAs. CMS in its FY 2019 Hospice final rule added the modified 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 proposes 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. CMS would further require that the PA be the patient's attending physician and that the PA not have an employment or contractual arrangement with the hospice.

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

CMS notes 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 seeks comment on the following issues related to PAs and NPPs generally**:

- The role of NPPs in delivering safe and effective hospice care to patients, including duties they should perform, their role within the hospice interdisciplinary group and how that role is distinct from the role of physicians, nurses, social workers, and counseling members.
- Because nursing services are required core services within hospice there is a defined role for NPs in the hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?
- How should NPP services be supervised in light of different state supervision requirements, and who should be responsible for this supervision—the hospice medical director or other physicians employed by or under contract with the hospice? What would adequate supervision be, especially when NPPs and the supervising physician are located in different offices?
- What requirements and time frames currently exist at the state level for physician co-signatures of NPP orders? Are these requirements appropriate for the hospice clinical record and, if not, what requirements would be appropriate?
- What are the essential personnel requirements for PAs and other NPPs?

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, that using the OIG advisory opinion process for the antikickback statute was an inappropriate model for a payment rule, 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 impede a more robust 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. CMS does not propose to do so in this rulemaking though it **seeks comment on whether it should in future rulemaking**.

CMS does propose some modifications to clarify matters that qualify for advisory opinions and the parties that may request them. Specifically, CMS would 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 notes there are other avenues for stakeholders 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 proposes to enumerate in regulation another reason for rejecting a request for an advisory opinion: requesters who do not provide a sufficiently detailed description of the arrangement or who fail to timely respond to CMS requests for additional information about the arrangement at issue.

CMS proposes to ease the restriction at §411.370(e)(2) which currently states that 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 proposes to modify the language to indicate that it "may elect not to" 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, and issuing an advisory opinion could interfere with the investigation or proceeding. **CMS seeks comment on this approach**.

The agency notes that a favorable advisory opinion on the Physician Self-Referral Law would not insulate parties from potential liability under the antikickback statute or other federal laws or regulations.

2. Timeline for Issuing Advisory Opinions (§411.380)

The current deadline for CMS to respond to an advisory opinion request is 90 days (which may be extended in the case of complex legal issues or highly complicated fact patterns). CMS proposes to reduce this to 60 days which would begin when CMS formally accepts the request; **it seeks comment on the shortened deadline**. The 60-day deadline would be tolled during periods when the request is being revised or additional information is being prepared for submission to CMS.

CMS is also considering whether to permit an expedited review option; under this option, the agency would complete the opinion within 30 days. **CMS seeks comment on whether it should establish this expedited process**.

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 proposes to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requester.

CMS is also considering whether to eliminate 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. **CMS seeks comment on this issue**.

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 proposes to use an hourly rate of $220. As noted above, CMS is also considering whether to prepare advisory opinions on an expedited basis; if it finalizes such a policy, CMS proposes to charge an hourly rate of $440 to process those expedited requests. CMS is also considering establishing a cap on the total amount it may charge for an advisory opinion. **It seeks comment on an appropriate cap amount as well as whether it should eliminate the initial fee of $250**.

5. Reliance on an Advisory Opinion (§411.387)

CMS' position is that an advisory opinion may 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 does not find that to be helpful to stakeholders and proposes to extend protection to any party to an arrangement that receives a favorable advisory opinion. Thus, a favorable advisory opinion would preclude 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.

Additionally, CMS proposes that it will not 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. CMS notes 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 proposes to amend its regulations to recognize 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.

CMS seeks comment on all these proposals.

6. Rescission (§411.382)

CMS may rescind or revoke an advisory opinion though it has not done so to date. **CMS seeks comment on whether that right to rescission should be limited**. Specifically, should the right to rescission only apply when 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?

7. Other Procedural Requirements

CMS proposes to make what it describes as minor modifications to §411.372 to improve readability and clarity and to strike references to stock certificates as part of a request submission.

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 proposed 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 proposed 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 proposed anesthesia conversion factor is $22.2774, 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 108 and 109 from the proposed rule, which are reproduced below.

Table 108: Calculation of the Proposed 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 109: Calculation of the Proposed 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	-0.12 percent (0.9988)	
2020 Conversion Factor		**$22.2774**

Table 110 (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 proposed changes to RVUs for specific services resulting from the Misvalued Code Initiatives, including the establishment of proposed 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 110 shows the estimated 2020 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. These specialty impacts range from an increase of 3 percent for clinical psychologist and clinical social worker, increase of 2 percent for neurology, to a decrease of 4 percent for ophthalmology, and a decrease of 2 percent for diagnostic testing facility, interventional radiology, optometry, oral/maxillofacial surgery, and vascular surgery.

TABLE 110: 2020 PFS Proposed Rule 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	$236	0%	0%	0%	0%
Anesthesiology	$1,993	0%	0%	0%	0%
Audiologist	$70	0%	0%	0%	1%
Cardiac Surgery	$279	-1%	-1%	0%	-1%
Cardiology	$6,595	0%	0%	0%	0%
Chiropractor	$750	0%	0%	-1%	-1%
Clinical Psychologist	$787	1%	2%	0%	3%
Clinical Social Worker	$781	0%	3%	0%	3%
Colon and Rectal Surgery	$162	0%	1%	0%	1%
Critical Care	$346	0%	0%	0%	1%
Dermatology	$3,541	0%	1%	-1%	0%
Diagnostic Testing Facility	$697	0%	-2%	0%	-2%
Emergency Medicine	$3,021	1%	0%	1%	1%
Endocrinology	$488	0%	0%	0%	0%
Family Practice	$6,019	0%	0%	0%	0%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	0%	0%	0%	0%
General Surgery	$2,031	0%	0%	0%	0%
Geriatrics	$187	0%	0%	0%	0%
Hand Surgery	$226	0%	0%	0%	1%
Independent Laboratory	$592	0%	1%	0%	1%
Infectious Disease	$640	0%	0%	0%	0%
Internal Medicine	$10,507	0%	0%	0%	0%
Interventional Pain Mgmt	$885	0%	0%	0%	1%
Interventional Radiology	$432	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	0%	0%	0%	1%
Neurology	$1,503	-1%	3%	0%	2%
Neurosurgery	$802	0%	0%	-1%	-1%
Nuclear Medicine	$50	0%	1%	0%	1%
Nurse Anes / Anes Asst	$1,291	0%	0%	0%	0%
Nurse Practitioner	$4,503	0%	0%	0%	0%
Obstetrics/Gynecology	$620	0%	1%	0%	1%
Ophthalmology	$5,398	-2%	-3%	0%	-4%
Optometry	$1,325	0%	-1%	0%	-2%

Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-2%
Orthopedic Surgery	$3,734	0%	0%	0%	1%
Other	$34	0%	0%	0%	1%
Otolarngology	$1,225	0%	0%	0%	0%
Pathology	$1,203	0%	0%	0%	0%
Pediatrics	$62	0%	0%	0%	0%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	0%	0%	0%	0%
Physician Assistant	$2,637	0%	0%	0%	0%
Plastic Surgery	$369	0%	0%	0%	0%
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	0%	0%	0%	0%
Psychiatry	$1,120	0%	0%	0%	1%
Pulmonary Disease	$1,658	0%	0%	0%	0%
Radiation Oncology And Radiation	$1,756	0%	0%	0%	0%
Radiology	$4,971	0%	0%	0%	-1%
Rheumatology	$534	0%	0%	0%	0%
Thoracic Surgery	$352	-1%	0%	0%	-1%
Urology	$1,739	0%	1%	0%	1%
Vascular Surgery	$1,203	0%	-2%	0%	-2%
TOTAL	**$92,979**	**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 110:

- 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 of the proposed changes 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 of the proposed changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2020 impact on total allowed charges of the proposed changes 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 proposed 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 some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes to Medicare coverage for opioid use disorder treatment services, coverage expansion of Intensive Cardiac Rehabilitation, among other proposals.

D. Changes Due to the Quality Payment Program

CMS estimates that approximately 55 percent of the nearly 1.5 million clinicians billing to Part B (818,391) will be assigned a MIPS score for 2022 because others will be ineligible for or excluded from MIPS. Table 113, 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 proposed policy; CMS assumes 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to 2017 MIPS performance period would elect to opt-in to the MIPS program.

TABLE 113: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the 2020 PFS Proposed 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	203,027	$48,306
	Do not participate in MIPS	17,954	$4,054
Group eligibility	Submit data as a group	566,164	$14,145

(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	31,246	$1,497
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**818,391***	68,002
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	385,635	$9,277
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	77,450	$403
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	202,684	$9,322
Total Number of Clinicians Not MIPS Eligible		665,769	19,002
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,484,160	87,004

*Estimated MIPS Eligible Population

** This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 13,000 clinicians and $2,763 million in PFS allowed charges).

*** Allowed charges estimated using 2016 and 2017 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 $586 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 5.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 87.3 percent of eligible clinicians are expected to have a positive or neutral payment adjustment and 12.7 percent will have a negative payment adjustment. Table 114, 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 one-quarter of clinicians in small practices (1-15 clinicians) are expected to receive a negative payment adjustment compared with about 8 percent for clinicians in very large practices (100+). CMS notes that it is using 2017 performance period submission data for these calculations as 2018 data were not available in time to incorporate. CMS plans to use data from the 2018 MIPS performance period for the final rule.

Table 114: 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	145,457	76.5%	41.2%	23.5%	0.9%
2) 16-24	42,691	81.9%	40.8%	18.1%	1.1%
3) 25-99	189,603	85.3%	44.4%	14.7%	1.3%
4) 100+	422,686	92.5%	62.4%	7.5%	2.1%
Overall	**800,437**	**87.3%**	**53.2%**	**12.7%**	**1.4%**
Among those not submitting data					
1) 1-15	16,116	0.0%	0.0%	100.0%	-8.1%
2) 16-24	674	0.0%	0.0%	100.0%	-8.2%
3) 25-99	953	0.0%	0.0%	100.0%	-8.3%
4) 100+	211	0.0%	0.0%	100.0%	-8.5%
Overall	**17,954**	**0.0%**	**0.0%**	**100.0%**	**-8.2%**

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

** 2016 and 2017 data used to estimate 2020 performance period adjustments. Payments are trended to 2022.

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

CMS estimates that approximately 175,000 to 225,000 eligible clinicians will become QPs for the 2022 and a total of $500 to $600 million in 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, 2017 QPP Year 1 data and CAHPS for ACOs. The scoring model results assume that 2017 QPP Year 1 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 1 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 proposed rule that would have an effect on beneficiaries. In general, CMS believes that many of the proposed changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the proposed 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 proposed 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 proposed 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 proposed 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 last 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 proposed 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 $13.4 million ($874.88 x 15,316 reviewers).