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Physician Fee Schedule Proposed Rule for 2022
Summary Part I

Medicare Program: 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider and Supplier Prepayment and Post-payment Medical Review Requirements
[CMS-1751-P]

On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2022[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 23, 2021, issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2022. **The 60-day comment period ends at close of business on September 13, 2021.**

This summary is provided in two parts. Part I covers sections I through III.R and the Regulatory Impact Analysis. This includes payment policies under the PFS; Medicare Shared Savings Program requirements; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and postpayment medical review activities; requirements for electronic prescribing for controlled substances for a covered Part D drug; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; and amendments to the physician self-referral law regulations. Part II will cover the updates to the Quality Payment Program.

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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 (IDTFs). The proposed rule includes proposals to modify current policies for split (or shared) E/M visits, critical care services, and services furnished by teaching physicians involving residents. CMS is also proposing policies for services added to the Medicare telehealth list during the COVID-19 PHE and proposal for telehealth services used for the diagnosis, evaluation, or treatment of a mental health disorder.[2]

The proposed conversion factor for 2022 is $33.5848, which reflects the expiration of the 3.75 percent increase for services furnished in 2021[3], the 0.00 percent update adjustment factor

[2] These proposals implement certain provisions of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), December 27, 2020.
[3] The Consolidated Appropriations Act provided an increase to PFS payments for 2021 of 3.75 percent.

specified under section 1848(d)(19) of the Act, and a budget neutrality adjustment of -0.14 percent.

Special-specific payments impact in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. CMS's proposed update to clinical labor pricing appears to be the primary cause of redistributive effects for certain specialties. Specialties that rely primarily on clinical labor rather than supply or equipment, such as portable x-ray (+10%), endocrinology (+2%), family practice (+2%), general practice (+2%), geriatrics (+2%) and hand surgery (+2%) would receive the largest increases relative to other specialties.[4] In contrast, specialties that rely primarily on supply or equipment items, such as interventional radiology (-9%), vascular surgery (-8%), radiation oncology and radiation therapy centers (-5%), and oral/maxillofacial surgery (-4%), would receive the largest decreases relative to other specialties. These payment impacts, however, **do not** show the impact of the expiration of the 3.75 percent increase to PFS payments for 2021 from the Consolidated Appropriations Act.[5] Thus, the combined effect of RVU changes and the conversion factor is much larger than these impacts.

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.

[4] Since the PE component maintains budget neutrality, increased pricing for clinical labor holds a corresponding relative decrease for other components of PE such as supplies and equipment. The portable x-ray specialty may have seen a large increase because the code with the highest allowed charges (Q0092, set-up portable x-ray equipment) for the specialty relies primarily on clinical labor.

[5] The Consolidated Appropriations Act (CAA) (Pub.L. 116-260) was enacted December 27, 2020.

For 2022, CMS makes note of several issues in this section.

CMS has incorporated the available utilization data for two new specialties: Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD).[6] 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. MDS would use PE/HR data from dermatology, and ACHD would use PE/HR data from cardiology. The relevant PE/HR data can be found in the 2022 PFS Proposed Rule PE/HR file published on CMS' website.[7]

With respect to the formula for calculating equipment cost per minute, CMS notes in the 2021 Medicare PFS final rule it finalized its proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of its equipment price per minute formula. It notes that it continues to update the useful life of equipment items based on the American Hospital Associations' "Estimated Useful Lives of Depreciable Hospital Assets" guidelines (last updated in 2019).

CMS also recognizes that 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 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 2022: 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.

[6] These became recognized Medicare specialties in 2020.
[7] See https://www.cms.gov/files/zip/cy-2022-pfs-proposed-rule-pehr.zip

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

For 2022, CMS proposes to correct several issues brought to its attention after publication of the 2021 Medicare PFS final rule.

In that rule, CMS made a technical change to ensure that the indirect PE allocation was the same for all three levels of occupational therapy evaluations codes (CPT codes 97165 through 97167) to ensure consistent reimbursement. Stakeholders, however, expressed concern because the finalized PE RVU values were less for 2021 than proposed values after the technical fix CMS adopted. CMS notes that it did not make a technical error in applying the indirect PE methodology, but that by forcing these three CPT codes to have the same indirect PE allocation, CMS no longer relied on the claims data which had an impact in the indirect practice cost index (IPCI) for the wider occupational therapy specialty. Given that these codes are high volume, this resulted in a lower IPCI and a smaller allocation of indirect PE than it had initially proposed.

To address this issue, CMS proposes to assign all claims data associated with CPT codes 97165 through 97167 to the occupational therapy specialty. This will ensure that each of these codes receive the same indirect PE allocation and prevent any fluctuations to the IPCI for the wider occupation therapy specialty. This also avoids a potential rank order anomaly in which the simple case for a service is valued higher than the complex case. **CMS seeks comments on this proposal and specifically on what commenters suggest as the most appropriate method of assigning indirect PE allocation for these services.**

For the provision of self-administered esketamine, CMS created two new HCPCS G codes, G2082 and G2083 in the 2020 PFS final rule. In the 2021 PFS final rule, CMS finalized a proposal to refine the value for these codes using a building block methodology (85 FR 84641 through 84642). Following publication of the 2021 PFS final rule, stakeholders expressed their concern that the finalized PE RVU values had decreased compared to the proposed valuation and compared to the prior year valuation. They suggested that an error had been made in the PE RVU allocation since CMS had finalized increases in the direct PE inputs for the services.

After review of the indirect PE allocation for HCPCS G2082 and G2083, CMS discovered a technical change that was applied in error. CMS change the assigned physician specialty for these codes to "General Practice" in the 2021 PFS final rule from "All Physicians", but did not discuss this change during the PFS rulemaking for 2021. CMS notes in its explanation that it had always intended for the assigned physician specialty to be "General Practice" rather than "All Physicians". Because CMS applied this technical change in the 2021 PFS final rule without providing an explanation, CMS issued a correction notice (86 FR 14690) to remove this change and maintain the "All Physicians" specialty assignment through 2021.

For CY 2022, CMS proposes to maintain the currently assigned physician specialty of "All Physicians" for indirect PE allocation for HCPCS codes G2082 and G2083. CMS states this will help maintain payment stability for these codes and preserve access to this care for beneficiaries. **CMS seeks comment to help it discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083.** CMS

notes it does not believe, however, that it would be appropriate to assign the Psychiatry specialty for these services given that HCPCS codes G2082 and G2083 include the high direct costs associated with esketamine supplies. It also notes that this specialty is an outlier compared to most other specialties, allocating indirect costs at a 15:1 ratio based on direct costs because psychiatry services typically have very low direct costs (other specialties have roughly a 3:1 ratio). Assignment of most other specialties would result in allocation of direct costs at roughly a 3:1 ratio. CMS requests that commenters explain how the indirect PE allocation would affect the payment for these services.

Note: The proposed 2022 PE RVU values for G2082 and G2083 are significantly lower than the corrected 2021 values for these codes even with CMS proposing to maintain the currently assigned physician specialty of All Physicians; G2082 would decrease by 18 percent from 24.06 RVUs to 19.62 RVUs and G2083 would decrease by 20 percent from 34.72 RVUs to 27.78 RVUs. This change may be related to other proposed policies including the redistributive effects of the proposed clinical labor pricing updates (discussed in more detail below), which impacts specialties and services that rely primarily on supply and equipment items.

For CPT code 35860 (Exploration of for postoperative hemorrhage, thrombosis or infection; extremity), CMS proposes to update the intraservice work time to 90 minutes (from 60 minutes) to match the RUC survey results. The RUC had inadvertently recommended a time of 60 minutes for the code and CMS had finalizes this time in the 2012 PFS, but the survey results support 90 minutes of intraservice time.

c. Updates to Prices for Existing Direct PE Inputs

For 2022, CMS proposes to update the prices of six supplies and two equipment items in response to the public submission of invoices. The proposed prices for these items were generally calculated following its standard methodology of averaging together the prices on the submitted invoices. Since this is the final year of the supply and equipment pricing update,[8] the new pricing for these items would take effect for 2022 as there are no remaining years of the transition. See Table 16 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.

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/files/zip/cy-2022-pfs-proposed-rule-market-based-supply-and-equipment-pricing-update.zip

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 2022). 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.

[8] 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.

For 2022, CMS also discusses in this section autologous platelet-rich plasma supply inputs. Stakeholders have requested that CMS revalue the autologous platelet-rich plasma supply items used in HCPCS code G0460 given the creation of a new 3C patch system that will represent the typical case and will be substantially more expensive than the cost inputs currently assumed for this code. CMS shares the concern that patient access to the 3C patch could be materially impacted if the current PE RVUs for this code were maintained. Based on submission of invoices, CMS plans to add this 3C patch system to its database at a price of $625. CMS proposes, however, to maintain contractor pricing for 2022 for HCPCS code G0460 as it does not currently have sufficient information to establish national pricing and believes this approach would allow for more flexibility in pricing. **CMS seeks comment on any additional information commenters can supply that CMS should consider to establish national payment for this code.**

d. Clinical Labor Pricing Update

CMS proposes to update the clinical labor pricing for 2022 in conjunction with the final year of the supply and equipment pricing update. Clinical labor rates were last updated in 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources when BLS data were not available (66 FR 55257 through 55262). Given the long delay since clinical labor pricing was last updated has created a significant disparity between CMS' clinical wage data and the market average for clinical labor. CMS notes that since the pool of aggregated direct PE inputs is budget neutral, if the rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies.

CMS proposes to use the same methodology outlined in the 2002 PFS final rule, which primarily uses BLS wage data to update clinical labor pricing. It continues to believe that BLS data is the most accurate source to use as a basis for clinical labor pricing and it used the most recent BLS survey data available for its calculations of wage data (2019). For certain labor categories where BLS data were not available, CMS had to crosswalk or extrapolate the wages using supplementary data sources for verification. This included using national salary data from the Salary Expert, an online project of the Economic Research Institute, which CMS also used as the primary backup source of wage data during its last update of clinical labor pricing. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type. Using the Salary Expert data as a reference, CMS identified BLS wage data for Respiratory Therapists as the best proxy category.

The proposed cost per minutes for each clinical labor staff type was simply derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost.[9] To account for the employers' cost of providing fringe benefits, such as sick leave, CMS used the same benefits multiplier of 1.366 as used in 2002. For "blend" clinical labor categories, CMS combined the rates for each labor type inf the blend and then divided by the total number of labor types in the blend.

[9] In cases where only an annual salary was available, CMS divided by 2080 (number of hours in a typical work year) to arrive at an hourly rate and then divided by 60 to calculate a per minute cost.

Table 5 lists the proposed updates to its clinical labor prices for the 50 clinical labor types (excerpt of this table is reproduced below). In most cases, the updated proposed rates are 50 percent more than their current value. CMS notes that it proposes to use the 75th percentile of the average wage data for the Medical Physicist (L152A), as the available BLS wage data describes the more general category of physicist which is paid at a lower rate. CMS also proposes to maintain the Behavioral Health Care Manager (L057B) clinical labor type rather than update it (the updated data showed a decrease in wages, which CMS acknowledges could have been a mistake).

Excerpt of Selected Labor Categories from Table 5: Proposed Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	% Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.32	39%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.39	50%
L032B	EEG Technician	BLS 29-2098	0.32	0.51	59%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.59	59%
L038B	Cardiovascular Technician*	BLS 31-2011	0.38	0.68	79%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.69	64%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.70	67%
L043A	Mammography Technologist*	BLS 29-1126	0.43	0.70	63%
L045A	Cytotechnologist*	BLS 29-2035	0.45	0.81	80%
L046A	CT Technologist*	BLS 29-2035	0.46	0.81	76%
L047A	MRI Technologist	BLS 29-2035	0.47	0.81	72%
L050C	Radiation Therapist	BLS 29-1124	0.50	1.00	100%
L051A	RN	BLS 29-1141	0.51	0.85	67%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.84	65%

* A proxy BLS wage rate is used as the clinical labor type does not have a direct BLS labor category.

CMS seeks comments on the proposed updated clinical labor pricing. It is particularly interested in additional wage data for the clinical labor types for which it lacked direct BLS wage data and made use of proxy labor categories for pricing.

To examine the anticipated effects of the clinical labor pricing update on specialty payments, CMS compared the proposed 2022 rates with and without the clinical labor pricing updates in place. These detailed results are shown in Table 6 of the proposed rule (excerpt of this table is

reproduced below). The impacts on particular specialties are largely driven by the share that labor costs represent of the direct PE inputs for a given specialty. Specialties like radiology, vascular surgery, and oral/maxillofacial surgery which have much higher supply and equipment costs, showed decreases based on updating the clinical labor prices. For example, the family practice specialty has a higher share of direct costs associated with clinical labor compared to Diagnostic Testing Facilities and would receive a 2% increase compared with a 6 percent decline for Diagnostic Testing Facilities. These impacts do not reflect the impacts of other policies CMS proposes in this rule.

Excerpt of Anticipated Clinical Labor Pricing Effect on Specialty Impacts from Table 6†

Specialty*	Allowed Charges (mil)	New CL Pricing Change
Portable X-Ray Supplier	$95	10%
Family Practice	$6,020	2%
Endocrinology	$508	2%
General Practice	$412	1%
Hand Surgery	$246	1%
Nurse Practitioner	$5,100	1%
Pediatrics	$67	1%
Geriatrics	$192	1%
Orthopedic Surgery	$3,812	1%
Internal Medicine	$10,730	1%
Psychiatry	$1,112	1%
Pulmonary Disease	$1,654	1%
Physician Assistant	$2,901	1%
Neurology	$1,522	1%
Neurosurgery	$811	1%
Cardiology	$6,871	-1%
Infectious Disease	$656	-1%
Other	$48	-1%
Audiologist	$75	-1%
Urology	$1,810	-1%
Nuclear Medicine	$56	-1%
Pathology	$1,265	-1%
Interventional Pain Mgmt	$936	-1%
Radiology	$5,275	-1%
Otolarngology	$1,271	-1%
Dermatology	$3,767	-1%
Hematology/Oncology	$1,707	-2%
Allergy/Immunology	$247	-2%
Independent Laboratory	$645	-3%
Vascular Surgery	$1,293	-4%
Oral/Maxillofacial Surgery	$79	-4%
Radiation Oncology And Radiation Therapy Centers	$1,809	-4%
Interventional Radiology	$499	-5%
Diagnostic Testing Facility	$748	-6%
*Specialties with 0% anticipated clinical labor pricing effect are not listed in this excerpt		

†Note: This table is intended to show only the anticipated effect of the isolated clinical labor pricing update and not all of the policies proposed in this rule.

Given these potential significant shifts in payment, CMS stated that it is considering the use of a 4-year transition to implement the clinical labor pricing update (similar to the market-based supply and equipment pricing update). This could smooth out the increases and decreases in payment caused by the pricing update for affected stakeholders. On the other hand, CMS notes such a transition would delay implementation of the update pricing and thus continue to rely, in part, on outdated data. **CMS seeks comment on this transition and discusses a potential 4-year phase-in as an alternative in the Regulatory Impact Section.** Table 135 in this section illustrates specialty-specific impacts using the first year of a potential 4-year phase-in for clinical labor pricing.

e. Proposal to Establish Values for Remote Retinal Imaging (CPT code 92229), Comment Solicitation for Fractional Flow Reserve Derived from Computed Tomography (CPT Code 0503T) and Comment Solicitation for Evolving Innovative Technology

CMS discusses in this section how to better account for innovative technology, such as software algorithms and Artificial Intelligence (AI) within its PE methodology. It has traditionally considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated medical equipment. It believes that an underlying problem is that the source of the specialty specific indirect percentage is the Physician Practice Information Survey (PPIS), that was last administered in 2007 and 2008 when emerging technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical. As described in the 2021 PFS final rule, the RAND corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it.[10] This section discusses two specific innovative technologies and how CMS proposes to approach accounting for their resource costs as well as solicits general comments about accounting for innovative technology in its PE methodology.

(1) Proposal to Establish Values for Remote Retinal Imaging.

CMS proposes to establish values for remote retinal imaging (CPT code 92229) using its crosswalk approach, and thus this service would no longer be contractor-priced. CMS proposes a crosswalk to a code with similar resource costs in the physician office setting while it continues to consider potentially refining the PE methodology and updating the data it uses to establish PE RVUs under the PFS. Specifically, CMS proposes a crosswalk to CPT code 92325 (Modification of contact lens (separate procedure), with medical supervision of adaptation), a PE-only code used for the eye. CMS believes this code is an appropriate crosswalk because the total resource costs are similar even if the services provided are very different. **CMS solicits comments on its proposal to crosswalk CPT code 92229 to CPT code 92325, and whether other codes would provide a more appropriate crosswalk in terms of resource costs.**

[10] CMS held a Town Hall meeting conducted by the RAND Corporation on June 16, 2021 titled "Improving Practice Expense Data & Methods." Among other issues, CMS sought feedback on how best to update information from the PPIS survey. Materials can be found at https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods.

(2) Fractional Flow Reserve Derived from Computed Tomography

CMS seeks comment on a similar crosswalk approach for the technical component only code (CPT code 0503T) for fractional flow reserve derived from computed tomography (FFRCT). FFRCT is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through coronary CT scans. It uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing or treatment (typically, a coronary angiogram).

In 2018, CMS began payment for this code in the hospital outpatient department setting under OPPS. For the PFS, CMS notes that it typically assigns contractor pricing for Category III code since they are temporary codes assigned to emerging technology and services. In the 2021 PFS final rule, CMS noted that it found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology. Based on its recent reviews of this code, it believes that the overall cost of CPT code 0503T in the physician office setting to be similar to the costs reflected in payment under the OPPS (85 FR 84630). It believes that the geometric mean cost reported by hospital outpatient departments of $804.35 is instructive as this reflects actual costs that hospitals incurred and believes that these costs would be similar in the physician office setting.

CMS identifies two cardiac catherization codes (CPT codes 93455 and 93458) paid under the PFS that have similar resources costs (based on the geometric mean costs under the OPPS) and are technical component-only service codes that could be used as crosswalks for FFRCT. **It seeks comment on whether CPT code 93455 and CPT code 93458 would be appropriate crosswalks for FFRCT. CMS also seeks comment on whether other codes would provide a more appropriate crosswalk in terms of resource costs.**

(3) *Comment Solicitation for Evolving Innovative Technology*

CMS is also more broadly soliciting comments to help it better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. Specifically, it is seeking feedback on the following questions:

- To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work? CMS gives CPT codes 92229, 77X01, and 0503T as examples.
- How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?
- How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting?
    - Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs?
    - How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service?

        - As technology adoption grows, do these costs decrease over time?
- How is innovative technology affecting beneficiary access to Medicare-covered services?
    - How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI?
    - To what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care?
- Are PFS services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse?
    - To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?
- Are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? CMS provides the example of CPT code 92229 that could increase access to services to detect diabetic retinopathy.
    - Are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI? The concern is that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged.
- How might CMS consider updating the underlying data used in its PE methodology to reflect ongoing advances in technology so that it could establish appropriate relative values without resorting to crosswalks? CMS refer readers to the RAND Corporation's two reports that discusses some of these issues.[11]

C. Potentially Misvalued Services under the PFS

1. Background

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.

[11] Reports can be found at https://www.rand.org/pubs/research_reports/RR2166.html and https://www.rand.org/pubs/research_reports/RR3248.html.

In the 2012 PFS final rule (76 FR 73058), CMS finalized a process for the public to nominate potentially misvalued codes. 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.

2. CY 2022 Identification and Review of Potentially Misvalued Services

CMS received ten submissions nominating codes for review under the potentially misvalued code initiative.

Table 7: Stakeholder's Nominations of CPT Codes as Potentially Misvalued for 2022	
CPT Code	**CPT Descriptor**
22551	Neck spine fuse&remov bel c2
49436	Embedded ip cath exit-site
55880	Abtlj mal prst8 tiss hifu
59200	Insert cervical dilator (PE supply)
66982 to 66986	Cataract codes

CPT code 22551 (Neck spine, fusion with removal of disc, anterior approach, complex) and "common related services"
A stakeholder raised concerns that there is a discrepancy between the total RVUs for codes billed for vertebral fusion procedures using three synthetic cage devices with plate and vertebral fusion procedures performed using three allografts with plate. Both methods of vertebral fusion are described by CPT code 22551. The stakeholder is concerned that the associated services are misvalued; the stakeholder asserts that vertebral fusion employing three synthetic cage devices with plate should be 63.15 work RVUs and vertebral fusion employing three allografts with plate should be 52.21.[12]

CMS notes that the stakeholder's determination that the code and common related services are potentially misvalued is based on the billing patterns for the two methods of a procedure. CMS does not propose CPT code 22551 as potentially misvalued. CMS does not believe that the stakeholder provided support that the CPT code is misvalued, or that any of the codes identified as common related services are misvalued.

CPT code 49436 (Delayed creation of exit site of intraperitoneal cannula or catheter)
A stakeholder nominated CPT code 49436 as misvalued because it is not valued for payment in the non-facility-setting. CMS notes the submission did not include detailed recommendations for the associated costs in the facility setting (e.g., items, quantity, clinical labor) that might be incurred in the non-facility setting. CMS' review of Medicare claims data for 2018 and 2019 showed that this code is solely performed in the facility ambulatory surgical center (ASC) setting. CMS does not propose CPT code 49436 as potentially misvalued.

[12] According to the stakeholder, both procedures are billed with CPT code 22551, 2 units of CPT code 22552, and 1 unit of CPT code 22846. The spinal fusion using three synthetic cage devices with a plate also involves CPT code 22853 and CPT code 20930. The spinal fusion using three allografts with plate includes CPT codes 20931.

CPT code 55880 (Ablation of malignant prostate tissue with high intensity-focused ultrasound (HIFU)
A stakeholder nominated CPT code 55880 as misvalued because it is not valued for payment in the non-facility-setting. CMS notes the submission did not include detailed recommendations for the associated costs in the facility setting (e.g., items, quantity, clinical labor) that might be incurred in the non-facility setting. The stakeholder stated this procedure is equally effective and as safe as the cryoablation procedure (CPT code 55873) which is valued in the non-facility setting. CMS notes that CPT code 55880 was reviewed and valued in the 2021 PFS final rule and was only valued for the facility setting.[13] CMS states it does not have enough claims to make an accurate comparison to similar codes furnished in the non-facility setting. CMS does not propose CPT code 55880 as potentially misvalued.

CPT code 59200 (Insertion cervical dilator)
A stakeholder nominated CPT code 59200 as misvalued because the direct PE inputs do not include the supply item, Dilapan-S. CMS notes that the stakeholder had requested a Level II HCPCS code for Dilapan-S but that request was not approved. The stakeholder recommended adding 4 rods of Dilapan-S at $80.00 per unit, as a replacement item for the current PE supply item, laminaria tent (listed as 3 units at $4.0683 per unit). CMS does not make any determination about this nomination.

CPT codes 66982 through 66986 (Cataract codes)
A stakeholder nominated these codes as misvalued because they have not been valued in the non-facility setting. The stakeholder did not submit any support for this nomination. CMS notes that some cataract-related procedures were initially reviewed and valued in the 2020 PFS final rule and that additional codes in this family are discussed in this proposed rule (Section II.E. Valuation of Specific Codes). Based on CMS' review of claims data in 2018 and 2019 these services were almost always performed in the ASC facility setting and in 2020 they were performed in the hospital impatient or hospital outpatient facility setting. CMS does not propose these codes as potentially misvalued.

D. Telehealth and Other Services Involving Communications Technology and Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services—Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

1. 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.[14]

[13] 85 FR 84614-84615
[14] CMS provides the following examples of clinical benefit: ability to diagnose a medical condition in a patient population without access to in-person diagnostic services; treatment option for a patient population without access

In the 2021 PFS final rule (85 FR 84507), CMS created a third category for the Medicare telehealth list, Category 3. This new category describes services that were added to the Medicare telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not sufficient evidence available to consider adding the services under the Category 1 or Category 2 criteria. Services added as a Category 3 telehealth service would ultimately need to meet the Category 1 or Category 2 criteria to be permanently added to the telehealth service list.

CMS considered the following criteria when assessing whether there was a potential likelihood of a clinical benefit for a service and if the service should be added to the telehealth list on a Category 3 basis:

- Whether, outside of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether outside the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize the quality of care.
- Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

The Medicare telehealth services list is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html. Information about submitting a request to add services to the Medicare telehealth services list is also available on this website. For 2022, requests must have been received by February 10, 2021.

a. Requests to Add Services to the Medicare Telehealth Services List for 2022

CMS received several requests to permanently add services to the Medicare telehealth services list for 2022 (Table 8 in the proposed rule, reproduced with modifications below). CMS does not approve the addition of any of these requests.

Requests for Permanent Addition – CMS Does Not Propose for Addition	
Service Type	**CPT codes**
Urodynamics	51741
Biofeedback	90901, 90912, 99013
Neuropsychological and Psychological Testing	96130-96133, 96136-96139
Therapy Procedures	97110, 97112, 97116, 97150
Physical Therapy Evaluations	97161-97164
Therapeutic Activities	97530
Therapy Personal Care	97535, 97537, 97542
Therapy Tests and Measurements	97750, 97755, 97763
Personal Care	98960-98962
Evaluation and Therapeutic Services	92607-92609

to in-person treatment options; reduced rate of complications; decreased rate of subsequent diagnostic or therapeutic interventions; decreased number of hospitalizations or physician visits; more rapid beneficial resolution of the disease process treatment; decreased pain, bleeding or other quantifiable symptom; and reduced recovery time.

Urodynamics (CPT code 51741)
This code describes the acquisition of uroflowmetric information and analysis of the information; the code includes a technical and professional component. CMS does not believe that the technical component, which would include acquisition of the uroflowmetric information, meets the criterion to be added either as a Category 1 or Category 2 service. In addition, CMS does not consider remote interpretation of diagnostic tests to be a telehealth service under section 1834(m) of the Act or the regulation at §410.78.[15]

Biofeedback Services (90901, 90912, 99013)
CMS does not believe these services are similar to Category 1 services. CMS thinks that proper application of electrodes and monitoring of the patient's response requires the furnishing practitioner to be in the same location as the beneficiary. CMS notes that the information provided with the request to add these services as Category 2 services, was insufficient to determine if the objective outcomes, including Activities of Daily Living (ADLs), were similar to outcomes when patients are treated in person.

Neuropsychological and Psychological Testing (96130-96133, 96136-96139)
CMS continues to believe these services are not Category 1 services because they require close observation to monitor how a patient responds and progresses through the testing. CMS notes that the information provided with the new request did not address CMS concerns over patient safety, the ability to be accurately and thoroughly performed these tests via telehealth, and the clinical benefit for Medicare beneficiaries to perform these tests via telehealth.

Therapy Procedures (97110, 97112, 97116, 97150); Physical Therapy Evaluations (97161-97164); Therapeutic Activities (97530); Therapy Personal Care Services (97535, 97537, 97542); and Therapy Tests and Measurements (97750, 97755, 97763)
CMS reiterates it prior comments that because these services are furnished predominately by physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs), who cannot furnish and bill for Medicare telehealth services, it does not believe these services should be added to the Medicare telehealth service list.[16] In response to a 2018 request, CMS stated that since the majority of the codes are furnished over 90 percent of the time by therapy professions, it thought that added these services to the Medicare telehealth list would be confusing. CMS continues to believe this.

CMS reviewed the request to add these services separately and determined that they do not meet the Category 1 criteria. CMS notes that the information provided with the request to add these services as Category 2 services, was insufficient to determine if the objective outcomes, including Activities of Daily Living (ADLs), were similar to outcomes when patients are treated in person.

[15] See discussion in previous rulemaking, 83 FR 59483.
[16] See discussion in the 2017 PFS final rule (81 FR 80198), which noted that section 1834(m)(4)(E) of the Act specifies the types of physicians who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C). PTs, OTs, and SLPs are not among the allowed practitioners.

Personal Care (98960-98962)
CMS notes that these services are not separately payable when furnished in-person and thus would not be separately payable when furnished as telehealth services. These services are always bundled into the payment of other services.

Psychotherapy (90849)
CMS notes that this service is not separately payable when furnished in-person and thus would not be separately payable when furnished as telehealth services. This service has a restricted payment status, indicating that claims must be adjudicated on a case-by-case basis when furnished in-person.

CMS received requests to temporarily add Neurostimulators (CPT codes 95970-95972) and Neurostimulators, Analysis-Programming services (CPT codes 95983 and 95984) to the Medicare telehealth services list using the Category 3 criteria (see Table 10). These services are on the expanded telehealth service list for the public health emergency (PHE) but were not added by CMS on a category 3 basis to the Medicare telehealth list in the 2021 PFS final rule. The requestor stated they would conduct a future study and submit the data to CMS at a later date. CMS concludes they do not have sufficient information to decide if additional time on the Medicare telehealth list as a Category 3 services would result in these services meeting the category 1 or category 2 criteria. CMS proposes not to add these services as a Category 3 and encourages the commenters to submit all available information, when available, for future consideration.

b. Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

In the 2021 PFS final rule[17], CMS stated that associated waivers and interim policies related to the PHE would expire at the conclusion of the PHE and payment for Medicare telehealth services would again be limited by the requirements of section 1834(m) of the Act. Services that were temporarily added on an interim basis during the PHE would not be continued on the Medicare telehealth services list after the end of the PHE.

In response to stakeholders concerns about the uncertainty about when the PHE may end, CMS proposes to revise the timeframe for inclusion of the services added to the Medicare telehealth list on a Category 3 basis until the end of 2023. CMS believes this will allow additional time for stakeholders to collect, analyze and submit data to support their consideration for permanent addition to the list on a Category 1 or Category 2 basis.

Table 11 in the proposed rule, reproduced with modifications below, lists the services that were added to the Medicare telehealth services list on an interim basis during the PHE but were not added to the telehealth services list on a temporary Category 3 basis. As of the date the PHE ends, these services will be removed from the telehealth services list. **CMS requests comments on whether any of these services should now be added to the Medicare telehealth list on a**

[17] 85 FR 84507

Category 3 basis to allow for additional data collection for submission for CMS to consider as part of the rulemaking process.

Services Added to the Medicare Telehealth Service List Only for the Duration of the PHE (Not added to the Medicare Telehealth List on a Category 3 Basis)	
Code Family	**HCPCS Code**
Radiation Oncology	77427
Ophthalmological Services	92002, 92004, 92012, 92014
Speech, Language, and Auditory Services	92508, 92526, 92570, 92587, 92588, 92601-92604, 92550, 92552, 92553, 92555-92557, 92563, 92565-92568, 92607-92610, 92625-92627,S9512
Cardiological Services	93750,93797, 93798
Ventilation Assistance Management	94002-94005, 94664
Neurological Services	95970-95972, 95983, 95984, 96105
Behavioral and Health Services	90875, 96110, 96112, 96112, 96125, 96127, 96158, 96170, 96171, 97129, 97130, 97151-97158, 0373T, 0362T, G0410
PT, OT, and SPL	97150, 97530, 97542
Hospital In-patient Services	99221-99223
Observation Services	99218-99220, 99234-99236
Nursing Facility Services	99304-99306, 99324-99328, G9685
Home Services	99341-99345
Office/Outpatient Services*	99441-99443
Critical Care Services	99468, 99481, 99473, 99475, 99477
Cardiac and Pulmonary Rehabilitation	G0422-G0424
*In the 2021 PFS final rule, CMS stated that no payment would be made for these services when furnished using interactive telecommunication systems after the end of the PHE.	

c. Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

CMS discusses the provisions of the CAA[18] pertaining to Medicare telehealth services provided to diagnosis, evaluation, or treatment of a mental health disorder.

- Section 123(a) of Division CC of the CAA amended section 1834(m)(7)(A) of the Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and allows the patient's home as an originating site for telehealth services for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE.
- Section 123 (a) of the CAA added subparagraph (B) to section 1834(m)(7)(A) of the Act to prohibit payment for a telehealth service furnished in the patient's home unless the physician or practitioner furnished an item or service in-person, without the use of telehealth, within 6 months prior to the first telehealth service provided to the beneficiary by the physician or practitioner, and thereafter, at such times as the Secretary determines appropriate.

[18] The CAA (Pub.L. 116-260) was enacted December 27, 2020.

CMS notes that section 123(a) of the CAA clarified that the periodic requirement for an in-person item or service does not apply if the telehealth service would have been allowed. Thus, this requirement would not apply to the provision of the SUPPORT Act which specified that the telehealth geographic restriction did not apply and included the patient's home as an originating site for telehealth services furnished to a patient with a diagnosed substance use disorder (SUD) for treatment of that disorder or a co-occurring mental health disorder.[19]

CMS requests comments on the following related issues:

- Whether it should adopt a claims-based mechanism to distinguish between the mental health services that are within the scope of the CAA and for those for which payment was authorized before the CAA. If CMS uses a claims-based mechanism, what should that be?
- Should it add the following clarification to the regulation at §410.78: The requirement that the physician or practitioner must furnish an item or service in person, without the use of telehealth, within a specified time frame shall not apply to telehealth services furnished for treatment of a diagnosed SUD or co-occurring mental health disorder, or to services furnished in an originating site described in paragraphs (b)(3)(I0 through (viii) or (xiii) that meets the geographic requirements specified in paragraph (b)(4) other than (b)(4)(iv)(D).

To implement the statutory requirement for an in-person service, CMS proposes that as a condition of payment for mental health telehealth services authorized under the CAA, the physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service. CMS notes that the language in the CAA states that the physician or practitioner furnishing the in-person service must be the same person as the practitioner furnishing the telehealth service. CMS discusses several circumstances under which it considered the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual, including the definition of a new or established patient.[20]

CMS requests comments on the following:

- Whether this required service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service.
- The extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition.
- Alternative policies to allow the prerequisite in-person, non-telehealth service for certain mental health telehealth services to be furnished by a practitioner in the same

[19] Section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, October 24, 2018) amended section 1837(m)(7) of the Act.

[20] The Medicare Claims Processing Manual (Chapter 12, section 30.6.7) defines "new patient" as a patient who has not received any professional services from the physician of physician group (same physician specialty) within the previous 3 years.

specialty/subspecialty in the same group when the physician or practitioner who furnishes the telehealth service is unavailable or the two professionals are practicing as a team.

To implement the statutory requirement for subsequent in-person services, CMS proposes that an in-person, non-telehealth service must be furnished by the physician or practitioner at least once within 6 months after the first telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders by the same practitioner, other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and that the distinction between telehealth and non-telehealth services must be documented in the patient's medical record. CMS will distinguish between mental health services furnished for a diagnosed SUD or co-occurring mental health disorder and those furnished to beneficiaries without a SUD diagnosis based on ICD-10 diagnosis codes on claims. **CMS seeks comments on whether a different interval, shorter or longer, may be appropriate for the subsequent in-person service.**

As discussed below in this section, CMS proposes to revise its regulatory definition of "interactive telecommunications system" to permit the use of audio-only communications technology for mental health services under certain conditions when provided to beneficiaries located in their home. CMS proposes there would need to be an in-person visit within 6 months of any telehealth services, including audio-only communication, for mental health services (excluding SUD or co-occurring mental health disorder) documented in the patient's medical record. **CMS seeks comments on whether it would be appropriate to establish a different interval for these telehealth services for mental health disorders (excluding SUD or co-occurring mental health disorder) when furnished as permitted through audio-only communications technology.**

In addition, section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add a rural emergency hospital to the list of permissible telehealth originating sites. The CAA added a rural emergency hospital as a new provider type, beginning in 2023.

d. Payment for Medicare Telehealth Services Furnished Using Audio-Only Communications Technology

CMS discusses the requirements for Medicare payment for telehealth services that are furnished via a "telecommunications system". CMS defines "telecommunications system" to mean an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner (§410.78(a)(3)). During the PHE, CMS used waiver authority to waive the requirement for certain behavioral health services and for audio-only E/M visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology and it makes payment for certain telehealth services furnished using audio-only communications technology. CMS notes that when the PHE ends, telehealth services will again be subject to all statutory and regulatory requirements.

CMS discusses the reasons it has not proposed any permanent modifications to the definition of 'interactive telecommunications system" to allow for use of audio-only communications including its concern for inappropriate overutilization. Based on its review of claims data during

the PHE, audio-only E/M visits have been one of the most commonly performed telehealth services and most of these services were for the treatment of a mental health condition. Given the generalized shortage of mental health care professionals and the existence of areas and populations with limited access to broadband, CMS believes beneficiaries rely on audio-only communication to receive mental health services. CMS also discusses stakeholders suggestions that telehealth services provided by audio-only communications would increase access for mental health services.

Based on all the above considerations, CMS proposes to amend its regulations at §410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. Consistent with the CAA requirement (discussed above), CMS also proposes an ongoing requirement that an in-person item or service must be furnished within 6 months of an audio-only communications. CMS limits this proposal to the home as the originating site because other enumerated telehealth originating sites are medical settings that have access to reliable broadband internet services.

CMS also proposes to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing mental health services via audio-only because the beneficiary is unable to use, does not want to use, or does not have access to two-way, audio/video technology. CMS believes this proposal would limit audio-only to situations facilitating access to care.

CMS proposes using a service-level modifier that would identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology.

CMS seeks comments on these proposals as well and the following specific issues:

- What, if any, additional documentation should be required in the patient's medical record to support the clinical appropriateness for providing audio-only telehealth services for mental health? CMS suggests additional documentation could include information about the patient's level of risk and any other guardrails that demonstrate clinical appropriateness and minimize program integrity and patient safety concerns.
- For purposes of the proposed audio-only mental health telehealth services exception, should CMS exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis?
- Should the full scope of service elements for these codes be performed via audio-only communications? CMS notes that audio-only technology might give patients access to care needed to address their higher level or acute mental health needs when they are unable to access two-way, audio/video communication technology.

e. Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Expiration of PHE Flexibilities for Direct Supervision Requirements. Prior to the PHE, direct supervision of diagnostic tests, services incident to physician services, and other specified services required the immediate availability of the supervising physician or other practitioner. CMS interpreted this "immediate availability" to mean in-person, physical availability and not virtual availability. During the PHE, CMS changed the definition of "direct supervision" to allow the supervising professional to be immediately available through a virtual presence using real-time audio/video technology for the direct supervision of diagnostic tests, physicians' services and some hospital outpatient services. CMS finalized continuation of this policy through the end of the year in which the PHE ends or December 31, 2021.[21]

CMS notes this temporary exception to allow immediate availability for direct supervision through a virtual presence also facilitates the provision of telehealth services by clinical staff of physicians and practitioners incident to their own professional services. This allowed PT, OT, and SLP services provided incident to a physician to be provided and reimbursed.

CMS is interested in comments about whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology should be continued for an additional time after the PHE ends or should it be made permanent. CMS seeks comments on the following:

- Should the timeframe for the flexibility of direct supervision be extended beyond the PHE to facilitate obtaining additional information about the implications of a permanent policy change?
- If the policy was made permanent, should this be allowed only for a subset of services as there may be potential patient safety concerns if the physician is not immediately available in-person?
- If the policy was made permanent, should a service level modifier be required to identify when the requirement for direct supervision were met using two-way, audio/video communications technology?

Interim Final Provisions in the 2021 PFS Final Rule. In the 2021 PFS final rule, on an interim basis, CMS established HCPCS code G2252 for a virtual check-in service that consisted of 11-20 minutes of medical discussion.[22]HCPCS code G2252 was valued through a direct crosswalk to CPT code 99442.

Based on support with comments, CMS is proposing to permanent adopt HCPCS code G2252 and continue to crosswalk payment to CPT code 99442.

Regulatory Impact
CMS discusses the increase in telehealth utilization during the PHE. Before the PHE, approximately 15,000 FFS Medicare beneficiaries received a telemedicine visit each week.

[21] 85 FR 19245-19245 and 85 FR 84538-84540.
[22] 85 FR 84533-84536

According to a report prepared by the Assistant Secretary for Planning and Evaluation (ASPE),[23] in the last week of April, nearly 1.7 million beneficiaries received telehealth services and half of all Medicare primary care visits were for telehealth. There are approximately 270 services on the list of Medicare telehealth services, including more than 160 added on a temporary basis during the PHE. Preliminary data indicates that the largest increase in telehealth services were for services that were on the Medicare telehealth service list before the PHE.

CMS does not anticipate any significant increase in Medicare telehealth services listed on a Category 3 basis until the end of 2023 as these represent less than 0.1 percent of the telehealth services currently reported during the PHE. In addition, outside of the PHE, all of the statutory restrictions under section 1834(n) of the Act will apply limiting any significant increase in utilization.

E. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2022 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 2022 valuation of specific codes:

Table 13	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 14	Direct PE Refinements
Table 15	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 16	Invoices Received for Existing Direct PE Inputs
Table 17	New Invoices
Table 18	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.[24] CMS notes the importance of not only the RUC-

[23] Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic (hhs.gov)
[24]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.

recommended work and time values but also the accompanying rationales for setting those values.[25]

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 ongoing 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.

Table 13 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2020.

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 14 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 15 details proposed refinements in direct PE due to changes in the equipment time and the conforming changes in clinical labor time.

CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

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

[25]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.

- 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);
- Clinical labor time in the facility setting (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap.

CMS received invoices for several existing and new supply and equipment items (see Tables 16 and 17). 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). CMS notes that in some cases it does not use the price listed on the invoice because it identifies publicly available alternative prices or information that suggests a different price is more accurate.

CMS reminds stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. CMS includes the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment in Tables 16 and 17.

For 2022, CMS identified the following new and revised codes as services which meet the definition of "imaging services" for purposes of the OPPS cap. This includes breast computed tomography (CPT codes 0633T-0638T); quantitative magnetic resonance for analysis of tissue (0648T, 0649T); trabecular bone score (77X01-77X04); capsule endoscopy (9111X); and 3D echocardiographic imaging (933X0).

4. Proposed Valuation for Specific Codes

This section discusses proposal for 43 code groups (listed in the table below). Highlights of CMS' discussions 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. As discussed below, CMS also seeks comments about:**

- The impact of infectious disease on codes and ratesetting and
- Separate PFS coding and payment for chronic pain management.

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
1	Anesthesia for Cardiac Electrophysiologic Procedures	00537	No	Yes
2	Anesthesia Services for Image-Guided Spinal Procedures	01XX2-01XX7	No	Yes
3	Closed Treatment of Nasal Bone Fracture†	21315 & 21320	No	Yes
4	Insertion of Intralaminar/Interspinous Device	22867	PE	NA
5	Treatment of Foot Infection	28001-28003	No	Yes
6	Percutaneous Cerebral Embolic Protection	33XXX	Yes	NA
7	Exclusion of Left Atrial Appendage	33XX3-33XX5	Yes	Yes
8	Endovascular Repair of Aortic Coarctation	338X1, 338X2, & 338X0	No	NA
9	Harvest of Upper Extremity Artery†	35XX0 & 35600	No	NA
10	Needle Biopsy of Lymph Node	38505	Yes	Yes
11	Drug Induced Sleep Endoscopy	42XXX	Yes	Yes
12	Per-Oral Endoscopic Myotomy	434XX	No	Yes
13	Placement-Removal of Seton†	46020 & 46030	No	No
14	Periurethral Balloon Continence Device Procedures	53XX1-53XX4	NA*	NA*
15	Intracranial Laser Interstitial Thermal Therapy†	617X1 & 617X2	No	No
16	Arthrodesis Decompression	630XX & 630X1	No	NA
17	Hypoglossal Nerve Stimulator	645X1-645X3	No	Yes
18	Destruction by Neurolytic Agent	64633-64636	No	Yes
19	Destruction of Intraosseous Basivertebral Nerve	646X0 & 646X1	No	Yes
20	Dilation of Aqueous Outflow Canal	66174 & 66175	No	Yes
21	Cataract Removal with Drainage Device Insertion	669X1, 669X2, 66982, 66984,66987, 66988, & 0X12T	No	Yes
22	Retinal Detachment Prophylaxis	67141 & 67145	Yes	Yes
23	Strabismus Surgery	67311-67320, 67321-67335, & 67340	Yes	Yes
24	Lacrimal Canaliculus Drug Eluding Implant Insertion	68XXX	Yes	No
25	Transcutaneous Passive Implant-Temporal Bone	69714, 69717, 69X50-69X53	Yes	No
26	X-Rays at Surgery Add-on	74301	Yes	NA
27	Trabecular Bone Score†	77X01-77X04	Yes	No
28	Pathology Clinical Consult†	80XX0-80XX3	No	No
29	ESRD MCP†	90954	NA	NA

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
30	Colon Capsule Endoscopy	91110, 91111 & 9111X	No	No
31	External Cardiovascular Device Monitoring†	93228 & 93229	No	No
32	Electrophysiologic Evaluation	93621	No	NA
33	Cardiac Ablation Services†	93653-93657	No	NA
34	3D Imaging of Cardiac Structures†	933X0	Yes	NA
35	Cardiac Catheterization for Congenital Defects	93X1X-93X6X	No	NA
36	Outpatient Pulmonary Rehabilitation Services	946X1 & 946X2	No	No
37	Remote Therapeutic Monitoring†	989X1-989X5	Yes	No
38	Principal Care Management & Chronic Care Management†	99490, 99439, 99491, 99X21, 99487, 99489, 99X22-99X25	Yes	Yes
39	Moderate Sedation†	G0500	NA	NA
40	Payment for Synthetic Skin Substitutes†	GXXAB-GXXAI	NA*	NA*
41	External Extended ECG Monitoring	93241-93248	NA*	NA*
42	Comment Solicitation for Impact of Infectious Diseases on Codes†	NA	NA	NA
43	Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management†	NA	NA	NA
†Discussed in HPA summary *Contractor Priced Codes				

(3) Closed Treatment of Nasal Bone Fracture (CPT codes 21315 and 21320)
This code family is an example of codes with a change in the global period from 10- to 00-day global period codes. CMS supports the change in the global period but is concerned that the RUC recommendations do not adequately account for the loss of the bundled E/M visits associated with the 10-day global period.

(9) Harvest of Upper Extremity Artery (CPT codes 35XX0 and 35600)
CMS discusses its concerns about the global period designation for these codes. The RUC acknowledged these codes are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures. CMS notes that such codes are designated as add-on procedures and are assigned a ZZZ-day global period (code related to another service and is always included in the global period of the other code). The RUC requested a XXX-day global period (global concept does not apply) to allow the individual that performs the harvest of the artery procedure to report it under their own provider number. The RUC noted that it is often a NP or PA doing the harvesting procedure and not the surgeon performing the CABG. Because the RUC survey used the ZZZ-day global period, CMS proposes to assign the ZZZ-day global period to these codes. **CMS seeks comments and requests information about why these codes**

should have an XXX-day global period instead of the ZZZ-day global period that is customary for add-on codes.

(13) Placement-Removal of Seton (CPT codes 46020 and 46030)
This code family is another example of codes with a change in the global period from 10- to 00-day global period codes. CMS supports the change but again raises concerns that the RUC recommendations do not adequately account for the loss of the bundled E/M visits associated with the 10-day global period. For this code family, CMS also raises concerns that the RUC proposal includes the standard 090-day preservice times associated with clinical labor activities and post-procedure services.

(15) Intracranial Laser Interstitial Thermal Therapy (LITT) CPT codes 617X1 and 617X2)
This code family is an example of the application of CMS' 23-Hour Stay Outpatient Surgical Services Policy which includes 60 minutes of immediate postservice time.[26] CMS does not believe the RUC correctly applied this policy and discusses the valuation methodology in the proposed rule. CMS is also concerned that the RUC recommended 90-day preservice times despite surveying the service as a 00-day service.

(27) Trabecular Bone Score (TBS) (CPT codes 77X01-77X04)
CPT codes 77X01 and 77X03 include a new supply input "TBS iNight Software". The submitted invoice for this supply indicates it is a licensing fee associated with the use of the software. CMS discusses that it has historically considered most computer software and associated licensing fees to be indirect costs linked to associated costs for hardware considered to be medical equipment. CMS reiterates stakeholders concerns with this policy especially for new technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware (discussed above in section II.B). CMS acknowledges that the RUC recommended resource costs for these codes are not well accommodated by the PE methodology which is based on data collected in 2007 through 2008.

For these codes, CMS proposes to value the PE through the use of a crosswalk to a comparable service, CPT code 71101 (Radiologic examination of ribs). CPT recognizes that the services being performed in this crosswalk code are not the same services but it believes that the direct resource cost would be analogous. CMS thinks this is the most accurate way to incorporate the cost of the software which would not be considered direct PE under its current methodology.

(28) *Pathology Clinical Consult (CPT codes 80XX0-80XX3)*
CMS discusses its concerns with the levels of decision making included in these code descriptors and is concerned that there is not sufficient information presented to support these levels of medical decision making. **CMS seeks comments on how these codes would most typically be billed relative to use of existing pathology codes.**

[26] 75 FR 73226

(29) End-stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) (CPT code 90954)
In response to stakeholders request to update the value of CPT code 90954, CMS proposes to increase the work RVU of 15.98 to a work RVU of 20.86. As recommended by a stakeholder, CMS crosswalked this code to CPT code 33977 (Removal of a ventricular assist device).

(31) External Cardiovascular Device Monitoring (CPT code 93228 & 93229)
CMS proposes to reduce the RUC recommended work RVUs to account for efficiencies gained by technologic advances. CMS acknowledges that the number of ECG tracings and daily reports have increased as the average time wearing these devices has increased from 14 to 20 days. Given the comments by the specialty societies and the RUC that the increase in the duration is offset by technologic advancements making it easier to review the data more efficiently, CMS proposes a lower work RVU (0.43) than recommended by the RUC (0.52).

CMS also proposes a reduction in the RUC recommended PE. CMS discusses the RUC recommendation for quality assurance "overread" done by a second, senior technician, Clinical Activity Code CA 021, Line 67 on RUC PE Spreadsheet for these codes. CMS proposes 0 minutes for this Clinical Activity Code. **CMS seeks additional information from IDTFs about (1) their current quality assurance measures and parameters within the ECG recording program that should act as some degree of quality assurance and (2) the current error rate for improperly transmitted tracings to physicians that would support that it is typical for a second, senior technician to perform "overread".**

CMS also requests additional information about the acquisition costs for equipment item EQ340 Patient Worn Telemetry System. CMS notes that due to the proprietary nature of this equipment, invoices were unattainable to update this equipment item and substantial technological improvements have been made since the last update in 2008. CMS notes that according to the RUC, EQ340 is the only equipment item with a useful life of 3 years or less and CPT code 93228 is the only code with an equipment item of more than 500 minutes of equipment time and a useful life of 3 years or less. **CMS seeks comments on the manufacturing costs and other information to help update this equipment item and information on the useful lifetime of this item.**

(33) Cardiac Ablation Services Bundling (CPT codes 93653-03657)
In October 2020, the CPT Editorial Panel revised the cardiac ablation codes to be bundled with 3D mapping and other services. Based on the survey results, the RUC advisory committee believes that many of the respondents may not have realized that the code descriptors had been substantially revised and that services were now bundled into the existing codes. The RUC recommended that these services be valued as interim to allow for re-survey and subsequent review at the April 2021 RUC meeting. CMS reviewed the initial survey information and it agrees that for some of the codes in this family, survey respondents might not have considered all the work time in the new bundled codes. CMS proposes the following:

- CPT code 9653 - Maintain the current work RVUs of 14.75 instead of the RUC recommendation of 18.49;
- CPT code 93654 - Accept the RUC recommendation to maintain the current work RVUs of 19.75;

- CPT code 93655 - Decrease the RUC recommendation work RVUs from 6.50 to 5.50;
- CPT code 93656 – Maintain the current work RVUs of 19.77 instead of the RUC recommendation of 20.00
- CPT code 93657 – Accept the RUC recommendation of 5.50

(34) 3D Imaging of Cardiac Structures (CPT code 933X0)
CMS is not proposing any refinements to the direct PE inputs, but is requesting additional information about the 3D echocardiography probe equipment item. The RUC recommended that a 3D probe was required in addition to the base echocardiography machine; CMS received an invoice for $31,754.30 for this item. **CMS seeks information clarifying if this equipment item reflects both the probe and the base machine or only the probe.**

(37) Remote Therapeutic Monitoring (CPT codes 989X1-989X5)
The RTM codes is a family of five codes that includes three PE-only codes and two codes that include professional work. CMS notes the new five RTM codes have similar services and code structure as the existing seven Remote Physiological Monitoring (RPM) codes. CMS discusses two primary differences: (1) according to RUC documents, primary billers of RTM codes are projected to be nurses and physical therapists and are considered general medicine codes (RPM services are considered to be E/M codes) and (2) RTM codes monitor health conditions and allow non-physiologic data collected.

Based on its review of the RTM codes, CMS believes they are "incident to" services and cannot be billed independently by physical therapists and other practitioners who are not physicians or non-physician practitioners (NPPs).[27] "Incident to" serves are an integral part of the physician's professional service and only physicians and certain other practitioners are authorized to furnish and bill incident to services.[28] In addition, because the RPM codes are considered care management services (E/M codes), CMS allows general supervision rather than the direct supervision requirement for incident to services. **CMS seeks comments on how to remedy the issues related to the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill these codes.**

CMS also discusses the data collection for the RTM codes which includes musculoskeletal system status, respiratory system status medication adherence and other non-physiologic data to be self-reported as well as digitally uploaded. In contrast, RPM requires the data be physiologic and digitally uploaded. CMS notes that for both code sets, the device must meet the FDA definition of a medical device.[29] **CMS seeks comments on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors for the RTM services.**

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[27]Non-Physician Practitioners (NPPs) include certified nurse midwifes (CNMs), certified nurse specialist (CNSs), nurse practitioner s(NPs) and Physician Assistant (PA)s.
[28] The CMS Benefit Policy Manual, Chapter 15 (sections 60.1A and 60.1B) defines "incident to" services as services that are an integral, although incidental, part of the physician's professional service; commonly rendered without charge or included in the physician's bill; of a type that are commonly furnished in physician's offices or clinics; and furnished by the physician or by auxiliary personnel under the physician's direct supervision.
[29] Federal Food, Drug, and Cosmetic Act (FFDCA) section 201(h)

(38) Principal Care Management (PCM) and Chronic Care Management (CCM) (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22-99X25)
CMS proposes the RUC-recommended values for work RVUs and direct PE inputs (Table 12 reproduced below). **CMS seeks comments on whether the professional PCM and CCM work RVU value create an incentive to bill CCM instead of billing PCM when appropriate.**

Table 12: 2022 CCM/CCCM/PCM Proposed Values				
CPT Code	**Short Descriptor**	**Current Work RVUS**	**RUC-recommended Work RVUs**	**CMS Proposed Work RVUs**
99490	CCM clinical staff first 20 min	0.61	1.00	1.00
99439	CCM clinical staff each add 20 min	0.54	0.70	0.70
99491	CCM physician or NPP work first 30 min	1.45	1.50	1.50
99X21	CCM physician or NPP work each add 30 min	new	1.00	1.00
99487	CCCM clinical staff first 60 min	1.00	1.81	1.81
99489	CCCM clinical staff each add 30 min	0.50	1.00	1.00
99X22 (G2064)	PCM physician or NPP work first 30 min	new	1.45	1.45
99X23	PCM physician or NPP work each add 30 min	new	1.00	1.00
99X24 (G2065)	PCM clinical staff first 30 min	new	1.00	1.00
99X25	PCM clinical staff each additional 30 min	new	0.71	0.71

CMS also discusses the requirements for obtaining beneficiary consent for these services. Before the PHE, beneficiary consent was required to be obtained either by or under the direct supervision of the physician and during the PHE, beneficiary consent was allowed by general supervision**. CMS seeks comments on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services.**

(39) Moderate Sedation (HCPCS code G0500)
CMS does not agree with a stakeholder's request to increase the intraservice work time for moderate sedation. **CMS seeks comments about the typical use of this procedure.**

(40) Payment for Synthetic Skin Substitutes (HCPCS code GXXAB-GXXAI)
In the 2021 OPPS final rule,[30] CMS finalized payment for C1849 (Skin substitute, synthetic, resorbable, per square centimeter) and allowed it to be billed with graft skin substitute CPT codes 15271-15271. This policy provides a mechanism to pay for graft skin substitute application services performed with synthetic graft substitute products that is comparable to payment for skin graft substitute application services performed with graft skin substitutes regulated by the FDA under its regulatory framework for human cells, tissues and cellular and tissue-based products (HCT/Ps).[31] CMS clarifies that the availability of a HCPCS code for a particular HCT/P does not mean that this product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. CMS states that manufacturers of HCT/Ps should consult

[30] 85 FR 86064-86067
[31] Section 361 of the Public Health Services (PHS) Act

with the FDA Tissue Reference Group (TRG) to obtain a determination on whether their HCT/Ps are appropriately regulated solely under the PHS Act and the FDA regulations.[32]

Under the PFS, graft skin substitute application services are paid separately form the HCT/PS skin substitutes. To reconcile the gap in payment for synthetic products in the physician office setting, CMS is proposing to create eight HCPCS codes (parallel to CPT codes 15172-15278) that would include the synthetic graft skin substitute product as a supply cost in determining the PFS rate. The long descriptors of these codes are included in the proposed rule; briefly the codes are:

- GXXAB: Application of graft to trunk, arms, legs, total wound surface area up to 100 cm^2; first 25 cm^2 or less wound surface area
    - GXXAC: each additional 25 cm^2 or part thereof
- GXXAD Application of graft to trunk, arms, legs, total wound surface area up to 100 cm^2; first 100 cm^2 or 1% of body area of infants and child
    - GXXAE: each additional 100 cm^2 or each additional 1% body area
- GXXAF: Application of graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, multiple digits; trunk, arms, legs, total wound surface area up to 100 cm^2; first 25 cm^2 or less wound surface area
    - GXXAG: each additional 25 cm^2 or part thereof
- GXXAH: Application of graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, multiple digits; trunk, arms, legs, total wound surface area up to 100 cm^2; first 100 cm^2 or 1% of body area of infants and children
    - GXXAI: each additional 100 cm^2 or each additional 1% of body area of infants and children

For 2022, CMS is proposing contractor pricing for these codes. CMS notes there is limited data available on the cost of synthetic skin substitute products in physician offices.

CMS also discusses an alternate approach to pricing that would crosswalk values for these codes with the rates paid under the OPPS. Based on 2020 OPPS claims data, CMS estimated hospital outpatient department costs for graft synthetic skin substitute products averaged $1500. Under this alternative, the cost of the supply would be included in the primary codes (HCPCS GXXAB, GXXAD, GXXAF, and GXXAH); the add-on codes would continue to be reported and paid separately (GXXAC, GXXAE, GSSAG, and GXXAI). CMS would directly crosswalk the work RVUs, MP RVUs, and facility PE RVUs from the surgical application codes. CMS notes, however, that the PE methodology which relies on the allocation of indirect costs based on the magnitude of direct costs, may not be appropriate for these services because the specialists that typically furnish these services do not typically have significant supply costs. To address this issue, CMS considered other services that have a significant proportion of supply costs and furnished by specialists who typically have higher supply costs as potential crossswalks for the nonfacility PE RVUs. CMS considered CPT code 21461 (Open treatment of mandibular fracture, without interdental fixation) for HCPCS codes GXXAB and GXXAF, and a crosswalk to CPT code 21462 (Open treatment of mandibular fracture; with interdental fixation) for HCPCS codes GXXAD and GXXAH.

[32]85 FR 86058

CMS seeks comments on the following:

- The proposal to treat synthetic skin substitute product as incident to supplies in the physician office;
- The proposal to have contractor pricing;
- Other ways to obtain detailed and reliable cost information on synthetic skin substitutes provided in the non-facility setting;
- The alternative CMS pricing methodology; and
- Potential ways to reconcile these coding and payment differences across settings to yield a more consistent and rational payment approach for synthetic and HCT/P graft skin substitutes.

(41) External Extended ECG Monitoring (CPT codes 93241-93248)

CMS discusses the conflicting cost information it continues to receive about the supply item "extended external ECG patch, magnetic tape recorder" (SD339). **CMS repeats its request for comments and information, including invoices and proxy supply items, to support future rulemaking to establish a uniform national payment that appropriately reflects the PE used to furnish these services.** In the absence of this information, CMS proposes to maintain contractor pricing for these codes.

(42) Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

CMS discusses the many concerns raised by stakeholders about the additional costs that physicians and NPPs have incurred due to the PHE, including the higher costs due to additional supplies such as personal protective equipment and increased time spent with patients to mitigate further spread of infection. CMS continues to think about the types of resource costs that may not be fully reflected in payment rates for existing services or costs that could be accounted for by establishing new payment rates for new codes.

CMS seeks comments about:

- Additional strategies to account for PHE-related costs, including information about the specific types of services and costs that may benefit from further review, such as infectious disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services.
- Whether CMS should consider making changes to payments for existing services or develop separate payment for services in future rulemaking.

(43) Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management

CMS discusses the challenges for adequate treatment of pain, including information from the CDC, HHS and the National Academy of Medicine. The SUPPORT Act[33] outlines national strategies to help address the opioid and substance use disorders (SUD) and policies to improve the treatment of pain and SUD.

CMS acknowledges there are no existing codes that specifically describe the work of the clinician involved in performing the tsks necessary to perform pain management care. CMS

[33]Pub. L. 115-271, October 24, 2018

notes that CCM supports chronic disease management but it believes the complexity and resources required for pain management may not be adequately captured and paid through these codes.

CMS is considering creating separate coding and payment for medically necessary activities involved with chronic pain management and effective dose reduction of opioid medications. CMS suggests that activities included in codes could include diagnosis; assessment and monitoring; development and maintenance of a person-centered care plan; treatment management; crisis care; specialty care coordination such as complementary and integrative pain care, and SUD care; and other aspects of pain and/or behavioral health services, including care rendered through telehealth.

CMS is interested in feedback regarding whether the resource costs involved in furnishing these activities would be best captured through an add-on code to be billed with an E/M visit or as a standalone code. CMS states it is considering reimbursement based on crosswalking to CPT code 99483 (Assessment of and care planning to patient with cognitive impairment), HCPCS code G2064 (CCM, at least 30 minutes), HCPCS code G0180 (Diabetes outpatient self-management training services, or other services paid under the PFS with similar resource costs.

CMS also seeks comments on the following issues for consideration for 2022 or for future rulemaking:

- Which healthcare settings and what stages in the treatment are transitions from opioid dependence occurring and which types of practitioners are furnishing these treatments?
- What additional activities should be considered for new codes?
- How could CMS define and value separate coding or an E/M add-on code?
- Are there services that could be provided "incident to" the services of the billing physician who is managing the beneficiary's care (similar to the structure of the Behavior Health Integration codes)?

F. Evaluation and Management (E/M) Visits

As part of the process to update coding and payment for office/outpatient E/M visits, CMS is continuing to review other E/M visit code. For 2022, CMS proposes refinements to policies regarding split (or shared visits), critical care services, and teaching physician visits.

1. Split (or Shared) Visits

a. Background

A split (or shared visit) refers to an E/M visit that is performed (split or shared) by both a physician and a NPP who are in the same group. The Medicare statute provides a higher PFS payment rate for services furnished by physicians than services furnished by NPPs. For visits in the non-facility (e.g., office) setting, when a E/M visit is performed in part by a physician and a

NPP, the physician is permitted to bill for the visit as long as the visits meets the conditions for services furnished "incident to" a physician's professional services.[34]

In the facility setting (e.g., hospital), for E/M visits furnished by both a physician and a NPP who are in the same group, CMS' longstanding split billing policy allows a physician to bill for an E/M visit when both the billing physician and an NPP in their group each perform portions of the visit, but only if the physician performs a substantive portion of the visit. This policy was incorporated in several provisions of the Medicare Claims Policy Manual.[35] In May 2021, in response to a petition submitted under The HHS Good Guidance Practice Regulation, CMS withdrew these sections from the Claims Policy Manual and review of these services is limited to the applicable statutory and regulatory requirement.[36] CMS also indicated that it would address split (or shared) visits through rulemaking.

The list of applicable statutory and regulatory requirements for split (or shared) visits includes the 2021 PFS final rule (85 FR 84549) where CMS generally adopted new CPT prefatory language and code descriptors for office/outpatient E/M visits. CMS notes the CPT E/M Guidelines define a split visit[37] but do not address the various PFS payment issues related to split visits, such as which practitioner should report the visit, whether practitioners need to be in the same group to bill a split visits, or the setting of care when a split visit may be furnished and bill. CMS discusses these issues below.

b. Definition of Split (or Shared) Visit

CMS proposes to define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group, in accordance with applicable laws and regulations. In addition, CMS proposes to define split (or shared) visits as those that are:

- Furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited (§ 410.26(b)(1)).
- Furnished in accordance with applicable law and regulation, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit).

CMS proposed to revise its regulations at § 415.140 to codify this definition.

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[34] § 410.26(b)(1)
[35] Sections 30.6.1(B) and 30.613(H) of the Medicare Claims Policy Manual
[36] CMS' response to the petition is available as Transmittal 19742 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10742cp. CMS' enforcement instructions are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Evaluation-and-Management-Visits.
[37] 2021 CPT Codebook, p.7.

CMS also proposes to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility/Nursing Facility (SNF/NF) E/M visits (discussed below).

CMS notes that it does not need a split (or shared) visit billing policy in the office setting, because the "incident to" regulations govern situations where an NPP works with a physician who bills for the visit, instead of billing under the NPP's own provider number.

c. Definition of Substantive Portion

1. More Than Half of the Total Time. Only the physician or NPP who performs the substantive portion of the split (or shared) visit can bill for the visit. CMS proposes to define "substantive portion" as more than half of the total time spent by the physician and NPP performing the visit.

CMS discusses that the withdrawn manual instructions contained several definitions of "substantive portion" that included any face-to-face portion of the visit or the key component of the E/M visit. Given the recent changes in the CPT E/M Guidelines, the visit can now be selected based on either medical decision making (MDM) or time. CMS believes that time is a more precise factor than MDM to use as a basis for deciding which practitioner performs the substantive portion of the visit. CMS acknowledges that the billing practitioner could select the level for the split (or shared) visit based on MDM, but it believes the definition of substantive portion should be based on time. CMS does not think determining the time is a substantial new burden since the E/M level a physician bills can also be time based.

(2) Distinct Time. CMS proposes that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time and who provided the substantive portion. CMS notes this is consistent with CPT E/M Guidelines for split (or shared) visits that state when two or more individuals jointly meet with or discuss the patient only the time of one individual should be counted.[38] CMS provides examples for counting time.

(3) Qualifying Time. Based on the CPT E/M Guidelines, CMS proposes a list of activities that could count toward total time for purposes of determining the substantive portion. For visits, excluding critical care services, CMS proposes the same listing of activities that can count when time is used to select E/M visits.[39]

CMS seeks comments on whether there should be a different listing of qualifying activities for determining the qualifying time of split (or shared) emergency department visits.

(4) Application to Prolonged Services. CMS proposes a practitioner can bill for a prolonged E/M visit as a split (or shared) visit. The physician and NPP would sum their time together, and whomever furnished more than half of the total time (which included the prolonged time) would report both the primary service code and the prolonged service add-on codes(s).

[38] 2021 CPT Codebook, p.7.
[39] 2021 CPT Codebook, p.8.

d. New And Established Patients, and Initial and Subsequent Visits

CMS proposes to permit the physician or NPP to bill for split (or shared) visits for both new and established patients for initial and subsequent visits.

e. Settings of Care

CMS proposes to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting.[40] This proposal would allow billing for split (or shared) visits for the subset of SNF/NF visits that are not required by regulations to be performed in their entirety by a physician.[41]

f. Same Group

CMS proposes that a physician and a NPP must be in the same group in order for the physician and NPP to bill for a split (or shared) visit.

CMS seeks comments on whether it should further define "group" for purposes of split (or shared) visit billing. CMS discusses several options it has considered for defining group. One option would be the approach outlined in the CPT E/M Guidelines that the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working.[42] Another option would be to align the definition of "group" with the definition of "physician organization at § 411.35 (for purposes of the physician self-referral law).[43] CMS also considered practitioners with the same billing tax identification number (TIN) but acknowledges this may be too broad a definition for some multi-specialty groups or health care systems.

g. Medical Record Documentation

CMS proposes that documentation in the medical record must identify the two individuals who performed the visit. The individual who performed the substantive portion would be required to sign and date the medical record.

2. Critical Care Services (CPT codes 99291-99292)

CMS proposes to adopt the CPT prefatory language for critical care services as currently described in the CPT Codebook[44], except as otherwise specified below. CMS states if CPT makes changes to the guidance for critical care services in a subsequent edition of the CPT Codebook, it could revisit these policies in future rulemaking.

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[40] Section 410.26(a)(6) defines the non-institutional settings as all settings other than a hospital or SNF.
[41] The Conditions of Participation in 42 CFR 483.30 lists the SNF/NF visits that are required to be performed in their entirety by a physician.
[42] 2021 CPT Codebook, p.6.
[43] The term "physician organization" is defined at § 411.35 for purposes of section 1877 of the Act and CMS regulations in 42 CFR part 411, subpart J, and explained further at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysiciansSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.
[44] 2021 CPT Codebook, pp. 5-9 and pp. 31-33.

a. Definition of Critical Care

CMS proposes to adopt the CPT prefatory language as the definition of critical care.[45] This language includes care delivered by a physician or other qualified healthcare professional (QHP). Medicare policy considers a QHP as an individual who is qualified by education, training, licensure/regulation (when applicable), facility privileging (when applicable), and the applicable Medicare benefit category to perform a professional service within their scope and can independently report that service.[46] To be consistent with the CPT definition, CMS proposes that critical care services may be reported by a physician or NPP who is a QHP, consistent with Medicare policy.

CMS proposes to also adopt the following CPT prefatory language:

- The practitioner cannot provide services to any other patient during the same period of time providing critical care services.
- The list of bundled services that are part of critical care visits.
- Time spent performing separately reportable procedures or services should be reported separately and not be included in the time reported as critical care time.

b. Critical Care by a Single Physician or NPP

The CPT codebook indicates that CPT code 99291 is used to report the first 31-74 minutes of critical care on a given date, and that the code should be used only once per day even if the time spent by the practitioner is not continuous on that date. CMS proposes to adopt this rule for critical care services furnished by a single physician or NPP. CMS notes that the CPT codebook does not indicate how practitioners should report critical care when a service lasts beyond midnight. **CMS seeks comments about how to report CPT codes 99291 and 99292 (additional 30-minute time intervals) when a service extends beyond midnight to the following calendar day.**

c. Critical Care Services Furnished Concurrently by Different Specialties

CMS proposes that critical care may be furnished as concurrent (or concurrently) to the same patient on the same day by more than one practitioner in more than one specialty (e.g., an internist and a surgeon, a neurosurgeon and a NPP), regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services. **CMS seeks comments on when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care services.**

[45] 2021 CPT Codebook, p.31.
[46] See 80 FR 70957; 85 FR 83543, 84593.

d. Critical Care Furnished Concurrently by Practitioners in the Same Specialty and Same Group (Follow-Up Care)

CMS discusses how as part of continuous staff coverage, physicians or NPPs in the same specialty and in the same group may provide concurrent follow-up care, such as a critical care visit subsequent to another practitioner's critical care visit. According to CPT coding and billing conventions that CMS generally follows, a practitioner who furnishes a timed service typically reports the primary service or procedure code before reporting an add-on code.

CMS proposes that when critical care is furnished concurrently by two or more practitioners in the same specialty and in the same group to the same patient on the same day, the individual physician or NPP providing the follow-up or subsequent care would report their time using the code for subsequent time intervals (CPT code 99292) and would not report the primary service code (CPT code 99291). Under this proposal, CPT code 99291 would not be reported more than once for the same patient on the same day by these practitioners.

CMS also proposes to allow critical care time spent by more than one practitioner in the same group to be added together for purposes of meeting the time requirement to bill for the initial critical care service using CPT code 99291. CMS believes this proposal recognizes that multiple practitioners in the same specialty and group can concurrently furnish critical care services to a patient on a single day. Under this proposal, the time spent by these practitioners would be aggregated. **CMS seeks comments on when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or different group, to provide critical care services to a patient on a single day.**

e. Split (or Shared) Critical Care Services

CMS proposes that the total critical care service time provided by a physician and NPP in the same group on a given calendar date to a patient would be summed, and the practitioner who furnishes the substantive portion of the cumulative critical care time would report the critical care service.

When critical care services are furnished as a split (or shared) visit, CMS proposes to define the substantive portion as more than half the cumulative total time in qualifying activities that are included in CPT codes 99291 and 99292. For critical care services furnished as a split (or shared) visit, CMS proposes when two or more practitioners spend time jointly meeting with or discussing the patient, the time may be counted only once for purposes of reporting the split (or shared) critical care visit. CMS also proposes that the documentation and other rules proposed for split (or shared) E/M visits (discussed above) would also apply to critical care services.

f. Critical Care Visits and Same-Day Emergency Department, Inpatient or Office Outpatient Visits

The CPT Codebook states that critical care and other E/M services may be provided to the same patient on the same date by the same individual. CMS is concerned that adopting the CPT rule that critical care and other E/M visits may have unintended consequences for the Medicare

program. CMS discusses it general policy that physicians in the same group who are in the same specialty must bill and be paid for services under the PFS as though they were a single physician.[47]

CMS proposes that no other E/M visit can be billed for the same patient on the same day as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty in the same group. CMS acknowledges that this proposal may be appropriate only in certain clinical situations. **CMS seeks comments on this proposal to better understand clinical practice for clinical care, whether and how CMS could pay for E/M services furnished on the same date as critical care services when provided by the same practitioner or practitioners in the same specialty within a group, while also reducing the potential for duplicative payment.**

g. Critical Care Visits and Global Surgery

CMS discusses ongoing work to assess values for global surgery procedures, including the number and level of preoperative and postoperative visits, which can include critical care services. Because critical care visits are included in some 10- and 90-day global packages, CMS proposes to bundle critical care visits with procedure codes that have a global surgical period.
h. Documentation

In addition to documentation supporting the medical necessity of the service, CMS proposes to require practitioners to document in the medical record the total time that critical services were provided by each reporting practitioner (not necessarily the start and stop times).

3. Payment for the Services of Teaching Physicians

Section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. In addition, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician (with exceptions as specified in regulatory provisions in part 415). Medicare separately pays for the time spent by the resident through GME under Medicare Part A.

a. General Policy for E/M Visits

Absent a PHE, CMS' regulations at § 415.172, state that if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. For residency training sites located outside a MSA, PFS payment may also be made if a teaching physician is present through audio/video real-time communications presence (CMS considers this a "virtual presence"). For E/M services,

[47] Medicare Claims Processing Manual, Chapter 12, Section 30.6.5

the teaching physician must be present during the portion of the service that determines the level of service billed.

CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included.

b. Primary Care Exception Policy

Under the primary care exception (§ 415.174), PFS payments are allowed in certain teaching hospital primary care centers for certain lower and mid-level complexity services furnished by a resident without the physical presence of a teaching physician. During the PHE, CMS expanded the list of services that resident could furnish without the physical presence of the teaching physician to include level 4 and 5 office/outpatient E/M visits. When the PHE ends, level 4 and 5 office/outpatient E/M visits will no longer be included in the primary care exception.

CMS proposes that under the primary care exception, only MDM can be used. CMS is concerned that selecting an E/M visit level is not appropriate because residents may be less efficient relative to a teaching physician in providing care. CMS states that using the MDM as the criteria for level of the E/M visit, reduces the possibility of residents furnishing visits that are more than lower and mid-level complexity based on time.

CMS seeks comments about the following issues related to the primary care exception:

- Whether its assumption that MDM is a more accurate indicator of the appropriate level of the visit.
- Whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select office/outpatient E/M visit level using time.

G. Billing for Physician Assistant Services

Section 403 of the CAA, 2021 amends section 1842(b)(6)(C)(i) of the Act to remove the requirement to make payment for physician assistant (PA) services only to the employer of a PA effective January 1, 2022. With the removal of this requirement, PAs will be authorized to bill the Medicare program and be paid directly for their services in the same way that nurse practitioners (NPs) and clinical nurse specialists (CNSs) do. PAs also may reassign their rights to payment for their services and may choose to incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program, in the same way that NPs and CNSs may do. CMS notes that this amendment only changes the statutory billing construct; it does not change the statutory benefit category or the requirement that PA services are performed under physician supervision.

CMS proposes to amend its regulations to reflect the changes made by the CAA by amending §410.74(a)(2)(v), §410.150(b)(15)(i), §410.150(b)(15)(ii), and §410.150(b)(16). Effective for services furnished on or after January 1, 2022, payment is made to a PA for their professional services, including services and supplies furnished incident to their services. Further, payment will be made to a PA for professional services furnished by a PA in all settings in both rural and non-rural areas; and that payment is made only if no facility or other provider charges or is paid

any amount for services furnished by a PA. CMS also intends to update its program manual instructions to reflect the statutory change made by section 403 of the CAA and the changes to its regulations.

H. Therapy Services

CMS is implementing the final part of section 53107 of the Bipartisan Budget Act (BBA) of 201848. 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 (physical therapy assistant (PTA) and occupational therapy assistant OTA)) effective January 1, 2022. Section 1834(v)(2) of the Act requires that: (1) by January 1, 2019, CMS must establish modifiers to be used on claims to identify therapy services furnished in whole or in part by a therapy assistant and, (2) beginning January 1, 2020, each claim for a therapy service furnished in whole or in part by a PTA or an OTA must include the modifier.

In the 2019 PFS final rule,[49] CMS established the CQ and CO modifiers to be used by the billing practitioner or therapy provider to identify therapy services provided in whole or in by PTAs and OTAs, beginning January 1, 2020. CMS requires these payment modifiers to be appended on claims for therapy services, alongside the GP and GO therapy modifiers used to indicate the services are furnished under a PT or OT plan of care, respectively. The CQ and CO modifiers are defined as follows:

- CQ modifier: PT services furnished in whole or in part by PTAs.
- CO modifier: OT services furnished in whole or in part by OTAs.

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 NPPs 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.

In the 2020 PFS final rule,[50] CMS finalized a *de minimis* standard to identify when the CQ/CO modifiers apply and when they do not apply:

- Portions of a service furnished by the PTA/OTA independent of the PT/OT, as applicable, that do not exceed 10 percent of the total service (or 15-minute unit of a service) are not considered in whole or in part by a PTA/OTA, so are not subject to the payment reduction;
- Portions of a service that exceed 10 percent of the total service (or 15-minute unit of a service) when furnished by the PTA/OTA independent of the therapist must be reported with the CQ/CO modifier, alongside the corresponding GP/GO therapy modifier; are considered to be furnished in whole or in part by a PTA/OTA, and are subject to the payment reductions; and

[48] Pub. L. 115-123, February 9, 2018
[49] 83 FR 59654-59660
[50] 84 FR 62702-62708

- Portions of a service provided by the PTA/OTA together with the PT/OT are considered for this purpose to be services provided by the therapist.

Under this policy, CQ/CO modifiers and the *de minimis* standard apply to both untimed and timed codes. The untimed codes are evaluation and reevaluation codes, group therapy and supervised modalities, and when these are billed, only one unit is reflected in the units portion of the claim. When the PTA/OTA provides more than 10 percent of the service, the code is billed with the CQ/CO modifier. CMS did not finalize a requirement that the therapist and therapy assistant minutes be provided in the documentation. CMS expects the documentation in the medical record to be sufficient to know whether a specific service was furnished independently by a therapist or a therapist assistant, or was furnished "in part" by a therapist assistant, in sufficient detail to determine whether the *de minimis* standard was exceeded.

CMS discusses how it provided multiple typical clinical billing scenarios to illustrate when the CQ/CO modifiers would and would not be applicable. In early March 2021, CMS posted general guidelines on how to assign the CQ/CO modifiers for multiple billing scenarios.[51] This guidance included general examples of eight different billing scenarios in which multiple units of 15-minute codes are provided by therapist and therapy assistants and one billing example that used the untimed code for a group therapy performed by a PT and PTA. CMS discusses two of these examples in this rule, including "two remaining unit" cases.

CMS discusses the comments it received from therapy stakeholders indicating the guidance has created confusion. Stakeholders stated that some aspects of the billing scenarios contradict their interpretation of the *de minimis* standard, especially as it applies to a final unit of a multiple-unit timed service. CMS believes that the stakeholder's interpretation of the *de minimis* standard is not consistent with the policy finalized in the 2020 PFS final rule. After discussions with stakeholders, CMS identified policy refinements to address stakeholder's concerns.

CMS proposes to revise the *de minimis* standard to determine whether services are provided "in whole or in part" by PTAs or OTAs. Specifically, CMS proposes to revise the *de minimis* policy to allow a timed service to be billed without the CQ/CO modifier in cases when a PTA/OTA participates in providing care to a patient with a PT or OT, but the PT/OT meets the Medicare requirements for a times service without the minutes furnished by the PTA/OTA by providing more than the 15-minute midpoint (also known as the 8-minute rule). Under this proposal, any minutes that the PTA/OTA furnish in the preceding scenario, would not matter for purposes of billing Medicare.

This revision would apply to cases where one remaining unit of a multi-unit therapy service is billed and would also apply to a limited number of cases where more than one unit of therapy, a total time of 24-28 minutes is being provided. For these limited cases, CMS proposes to allow one 15-minute unit to be billed with the CQ/CO modifier and one 15-minute unit to be billed without the CQ/CO modifier in the scenario where there are two 15-minute units to bill and both the PT/OT and the PTA/OTA each provide between 9 and 14 minutes of the same service. CMS discusses billing scenarios in the rule (Tables 19 and 20).

[51] The guidance is available at https://www.cms.gov/Medicare/Billing/TherapyServices.

CMS states the *de minimis* standard would continue to be applicable in the following scenarios:

- When the PTA/OTA independently furnish a service, or a 15-munute unit of a service "in whole" without the PT/OT furnishing any part of the service.
- In instances where the service is not defined in 15-minute increments including supervised modalities, evaluations/reevaluations and group therapy.
- When the PTA/OTA furnishes eight minutes or more of the final unit of a billing scenario in which the PT/OT furnish less than eight minutes of the same service.
- When both the PTA/OTA and the PT/OT each furnish less than eight minutes for the final 15-minute unit of a billing scenario.

CMS notes it neglected to revise its regulations for purposes of determining when the *de minimis* standard applied, and is proposing to amend its regulations to reflect these changes.

CMS plans to issue instructions to MACs to pay the reduced amount for therapy services furnished in whole or in part by PTA or OTA, beginning with services furnished on January 1, 2022. CMS will also issue an MLN article after the 2022 PFS final rule is issued.

Regulatory Impact
CMS acknowledges there may be a cost implication to its proposal as fewer billing scenarios may result in application of the CG/CO modifiers and consequent payment reduction. It believes its proposal could eliminated the PT's/OT's financial incentive to not provide appropriate therapy to an individual patient furnished by the PTA/OTA. CMS concludes it is uncertain how to gauge the overall costs of this policy because of the possible altered PT/OT behavioral change.

I. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Medicare pays 100 percent of the payment amount for certain colorectal cancer screening tests that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Thus, a beneficiary pays no cost-sharing (and the application of the deductible is waived) for these screening tests.

When the colorectal cancer screening test benefit category was enacted into law, the statute specifically provided that if, during the course of a screening flexible sigmoidoscopy or screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but rather shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. The result was that beneficiaries faced unexpected coinsurance charges because the procedure was classified as a diagnostic test instead of a preventive service screening test.

Section 4104 of the ACA addressed this issue with respect to the deductible but not for any coinsurance that may apply. Section 122 of the CAA addresses this issue for the coinsurance by successively reducing, over a period of years, the percentage amount of coinsurance for which

the beneficiary is responsible so that for services furnished on or after January 1, 2030, the coinsurance will be zero. The phased-in increases in the amount the Medicare program pays for these services on or after January 1, 2022 are as follows:

Year	Medicare Payment %	Beneficiary Coinsurance %
2022	80	20
2023 through 2026	85	15
2027 through 2029	90	10
2030 and subsequent years	100	0

CMS proposes to codify its regulations to implement the changes to the Medicare statute.

J. Vaccine Administration Services: Comment Solicitation: Medicare Payments for Administering Preventive Vaccines

CMS highlights the importance of preventive vaccines for the health of Medicare beneficiaries, but stakeholders are concerned with low Medicare payment rates for vaccine administration services. Noting that 2021 national average payment rate of $16.94 (geographically adjusted) for vaccine administration services by suppliers (such as physicians, NPPs, and mass immunizers) is the same as in 2019, the agency seeks feedback on how it should update the payment rate for administration of these preventive vaccines under Medicare Part B under 1861(s)(10) of the Act.

1. Medicare Part B Payment for Vaccines

CMS reviews the history for the payment rates for Part B vaccines (i.e., influenza, pneumococcal, HBV, and COVID-19 vaccines) and their administration. Vaccine administration services under 1861(s)(10) of the Act are not technically valued or paid under the PFS, but payment rates have been historically based on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that is used to establish PFS payment rates. For administration of influenza, pneumococcal, and HBV vaccines, CMS generally establishes rates by crosswalking HCPCS codes G0008, G0009, and G0010 to CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) which resulted in a reduction over time of the valuation of the vaccine administration codes. CMS established administration rates for the COVID-19 vaccines furnished on or after March 15, 2021 of $40 per dose which was a significant increase over early rates.

CMS seeks detailed feedback to support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act for physicians, NPPs, mass immunizers and certain other providers and

suppliers. The following is a list of comment topics that is largely unedited from the proposed rule.

- What are the different types of providers and suppliers that furnish preventive vaccines, and have these types of providers/suppliers changed as a result of the PHE for COVID-19? (CMS is particularly interested in understanding additional, specific characteristics of the providers and suppliers that may not be distinguishable under the more general Medicare enrollment data.) It is also interested in whether different providers and suppliers furnish different aspects of the vaccine administration for the same beneficiary.

- What are the differences in incurred costs of furnishing flu, pneumonia and HBV vaccines compared to furnishing COVID-19 vaccines? Are there differences in the costs (per dose or otherwise) of furnishing a one-dose vaccine product vs. a two-dose vaccine product? Also, are there differences in cost of administering preventive vaccines furnished under the Part D benefit, such as the shingles vaccines, compared to those furnished under Part B?

- What are the resource costs that physicians, NPPs, mass immunizers and certain other suppliers incur when furnishing vaccines safely and effectively? CMS is interested in specific information on costs related to staffing/labor, infrastructure, patient onboarding/enrollment, vaccine storage and handling, vaccine procurement and coordination, supplies, CDC and state reporting requirements, patient counseling about safety and efficacy, and other costs it may not have considered. It is also interested in specific resource costs per vaccine dose within each cost category, if available.

- What are the impacts of the PHE for COVID-19 on resource costs incurred by vaccination providers, and do stakeholders envision that these impacts will continue after the PHE has ended? Following the end of the PHE, do you expect that the same types of vaccination providers and suppliers will continue to administer vaccines, or do you envision that this will change (if so, how, and what would be the primary factors driving the change)?

- Medicare has generally relied on the PFS methodology for setting payment rates for HCPCS codes G0008, G0009 and G0010. How should Medicare assess costs associated with furnishing these preventive vaccines outside of the physician office setting, such as in pharmacies, mass immunization sites, mobile vaccine clinics or other locations? In addition, there may be administrative burdens associated with the routine collection of cost data to support more accurate rate-setting for suppliers that are vaccinating patients. Are there other ways to update and validate costs for a broader range of entities using existing data?

- Payment rates for vaccine administration currently vary by setting. For HCPCS codes G0008, G0009 and G0010, the 2021 national average payment rate for physicians, practitioners and other suppliers is $16.94, which is geographically adjusted, while for hospital outpatient departments it is $40. However, for COVID-19 vaccine

administration, Medicare now pays $40 per administration in all settings, unless the vaccine in administered under certain circumstances in the beneficiary's home or residence (as discussed in more detail below). Should Medicare continue to pay differently for non-COVID-19 preventive vaccines furnished in certain settings or under certain conditions? If not, what factors contribute to higher costs for administration of non-COVID-19 vaccines that are not currently reflected in the Medicare payment rates?

- Should CMS use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis?

- In the last few years CMS has also crosswalked vaccine administration CPT codes 90460 (Administration of first vaccine or toxoid component through 18 years of age with counseling), 90461 (Administration of vaccine or toxoid component through 18 years of age with counseling), 90471 (Administration of 1 vaccine), 90472 (Administration of vaccine), 90473 (Administration of 1 nasal or oral vaccine), and 90474 (Administration of nasal or oral vaccine) to the same rate used by G0008, G0009 and G0010. How should Medicare address payment rates for these CPT codes under the PFS?

- Are there major differences between what Medicare pays physicians, NPPs and mass immunizers for non-COVID-19 preventive vaccine administration and what commercial insurers pay? To the extent possible CMS is also interested in feedback on specific rates used by other insurers.

2. Payment for COVID-19 Vaccine Administration in the Home

Effective June 8, 2021, CMS announced a new add-on payment (HCPCS code M0201) with a national rate of $35.50 when a COVID-19 vaccine is administered inside the beneficiary's home[52] if either of the following applies:

A. The patient has difficulty leaving the home to get the vaccine; difficulty leaving the home could mean any of the following:
   - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;
   - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19; or
   - They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort.

B. The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.

[52] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment

Payment for HCPCS code M0201 is made if the sole purpose of the visit is to administer the COVID-19 vaccine. The patient's home may include a private residence temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient's home that is made provider-based to a hospital during the PHE for COVID-19. However, the following locations are not considered to be the patient's home for this purpose:

- Communal spaces of a multi-unit living arrangement.
- Hospitals, Medicare SNFs, and Medicaid NFs, regardless of whether they are the patient's permanent residence.
- Assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program.

In the proposed rule, CMS clarifies that an institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act (relating to hospitals, skilled nursing facilities, and most Medicaid nursing facilities) is not considered a patient's home under this policy.

Additionally, HCPCS code M0201 may only be billed once per individual home per date of service. If more than one Medicare beneficiary lives in the same individual home, the additional payment for COVID-19 vaccine administration in the home is limited to one time in that home on that day. Any additional COVID-19 vaccine administration services for other individuals in that same home would be paid at the generally applicable rate of approximately $40 (i.e., without the additional in-home add-on payment amount).

In setting the rate for HCPCS code M0201, CMS used the home health low utilization payment adjustment (LUPA) add-on factor for skilled nursing as a proxy for the increased resource costs above the costs reflected in the base payment rate for COVID-19 vaccine administration involved in arranging and furnishing COVID-19 vaccine administration services in the home. The payment rate for in-home COVID-19 vaccine administration is roughly $74 ($40 for the COVID-19 vaccine administration base rate plus $34 as the additional proxy payment for administration in the home). CMS also notes that the national payment rate for HCPCS code M0201 for all providers and suppliers not paid on the basis of reasonable cost is $35.50 (based on the hospital OPPS APC national payment rate for New Technology APC 1494).

CMS is interested in feedback generally on its requirements as well as on the following specific topics:

- The definition of the "home" and the types of clinical and non-clinical circumstances that make it difficult for a beneficiary to receive a COVID-19 vaccine outside the home. Do the requirements strike the appropriate balance of ensuring access to vaccines for vulnerable beneficiaries while also protecting against potential fraud? Should CMS maintain these requirements during the PHE as-is, or should it consider changes? Outside of the circumstances of the PHE that create a need for beneficiaries to be vaccinated as quickly and broadly as possible, under what circumstances do health care providers, suppliers, or others find particular need to vaccinate people at home rather than periodically in association with routine in-person visits?

- The add-on payment of $35.50 was based on applying the LUPA add-on factor for skilled nursing to the national $40 payment rate for the base service as a proxy to reflect the additional resources involved in furnishing services in the home setting. CMS seeks detailed feedback on the costs associated with furnishing COVID-19 vaccines in the home, and how these costs differ from costs of furnishing vaccines in traditional locations, such as a physician's office or mass immunization site.

- What other steps should CMS take related to program integrity and beneficiary protection with this new add-on payment for administering the COVID-19 vaccine in the home? What documentation should providers and suppliers that furnish vaccines in the home be required to maintain and/or provide?

- CMS believes the add-on payment is only appropriate for COVID-19 vaccines due to the unique circumstances of the PHE, as well as the upfront fixed costs and prolonged visit lengths that exemplify and constitute the increased resource costs involved in arranging and furnishing COVID-19 vaccine administration services in the home. However, it seeks feedback on whether the same barriers that could prevent a beneficiary from obtaining a COVID-19 vaccine would also prevent them from obtaining other preventive vaccines, whether Medicare should make a similar add-on vaccine administration payment in those circumstances, and whether the costs to furnish other preventive vaccines in the beneficiary's home would be consistent with the costs to furnish the COVID-19 vaccine.

3. Monoclonal Antibodies Used to Treat COVID-19

When monoclonal antibody products were authorized during the PHE for COVID-19, CMS decided to cover and pay for them under the COVID-19 vaccine benefit in section 1861(s)(10) of the Act meaning, among other policy considerations, that beneficiaries did not have any cost-sharing for either the product or its administration. It also allowed almost all Medicare enrolled providers and suppliers, as permitted by state law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care.

As of June 15, 2021, the EUAs require at least one hour of post-infusion monitoring for all of the products available. On May 6, 2021, CMS increased the payment rate for administration to $450.00 and established a separate payment rate of $750.00 when a monoclonal antibody product used to treat COVID-19 is administered in a home or residence.

Generally, CMS considers monoclonal antibody products that are used in the treatment of other health conditions to be "biologicals," and they are paid based on the methodology in section 1847A of the Act when they are furnished in physician offices, ambulatory infusion clinics and under a similar methodology under the hospital OPPS.

CMS notes that a number of rapid changes with respect to monoclonal antibody products for COVID-19, including revocation of one EUA and revisions to others, and the addition of more products to the market may result in a decision by the federal government to no longer acquire

the products and make them available at no charge to providers and suppliers. **CMS seeks feedback on a number of issues, including the following:**

- Its coverage and payment policies for monoclonal antibody products used to treat COVID-19.
- Whether to align payment and coverage of these products with other biologicals after the end of the PHE (which would mean beneficiaries would be subject to cost-sharing requirements).
- The impact of different coding and payment rules for tocilizumab when used to treat COVID-19 and other clinical purposes.
- Resource costs to administer COVID-19 monoclonal antibody products, such as costs associated with infrastructure, clinical labor, and equipment, including personal protective equipment.
- How the costs to furnish monoclonal antibodies used to treat COVID-19 compare with infusions of other complex biologics, and how the costs to furnish these products may be different when these products are administered in the home.

K. Payment for Medical Nutrition Therapy Services and Related Services

Registered dietitians and nutrition professionals may bill Medicare and be paid directly for Medical Nutrition Therapy (MNT) services under Part B if they are enrolled in accordance with regulations at 42 CFR 414.64 and 424.510. If they are employees or independent contractors of a hospital or physician group, they may reassign their benefits to that hospital or physician group. The Medicare specialty code for "dietitian/nutritionist" is 71.

Stakeholders express concern for the low utilization rate for MNT services by Medicare beneficiaries. CMS notes that it previously modified its telehealth policies by adding MNT services to the telehealth services list and recognized that registered dietitians and nutrition professionals may furnish and bill for these services as distant site practitioners. Additionally, pursuant to section 4104 of the ACA, there is no beneficiary cost-sharing imposed for MNT services. In implementing the ACA policy, CMS neglected to update its payment regulations for MNT services at §414.64(a) to reflect the congressionally mandated policy; it proposes to do so now.

Registered dietitians and nutrition professionals are the only practitioners listed at section 1842(b)(18)(C) of the Act without a specific regulatory provision addressing them as a type of practitioner and specifying payment policies for their services; CMS proposes to do so by creating a new section §410.72 to reflect these policies. Through cross-references to other regulations, the agency would (1) address the qualifications for registered dietitians and nutrition professionals; (2) include requirements for referrals for MNT services from a physician (an M.D. or D.O.); and (3) clarify that MNT services must be personally performed by the registered dietitian or nutrition professional in a face-to-face encounter (except when furnished as a telehealth service).

CMS also proposes to include diabetes self-management training (DSMT) services in proposed new §410.72(b)(2) as an "other service" that registered dietitians and nutrition professionals can provide where (1) the registered dietitian or nutrition professional is a certified provider of DSMT services as specified at section 1861(qq)(2)(A) of the Act and (2) they have submitted necessary documentation to, and are accredited by, a CMS-approved accreditation organization, for DSMT services. Additionally, the current requirement that DSMT services require a referral from the physician or qualified NPP who is treating the beneficiary's diabetes condition would be added. Proposed new section §410.72 would also specify that MNT and DSMT services cannot be furnished together on the same date of service[53] and that neither MNT nor DSMT services can be furnished incident to the professional services of a physician or other practitioner.

CMS emphasizes that neither MNT services nor DSMT services may be provided incident to the services of a billing physician because both types of services are separate, distinct Part B benefits. If a physician is qualified to bill for MNT services, the physician (not any auxiliary personal) would have to personally provide those services. Approved DSMT entities are separately recognized programs, rather than individuals or practitioners, that provide DSMT services in accordance with their accreditation; a physician or other practitioner can only provide the DSMT services directly if they are also an approved DSMT entity.

Proposed new section §410.72 would also incorporate current rules that prohibit payment for MNT services furnished to beneficiaries who are inpatients in Part A stays in hospitals and skilled nursing facilities and that prohibit coverage of MNT services for beneficiaries receiving services from an ESRD facility.

Finally, CMS proposes to add regulatory text stating that services of a registered dietitian or nutrition professional are provided on an assignment-related basis. It is also considering whether additional cross-references to its regulations on assignment should be included for clarity. **The agency seeks comments on its proposals**.

Section III. H. of the proposed rule also includes a number of policy proposals with respect to MNT services, including removing the requirement that the referral be made by the treating physician. See below for a summary of those proposed policies.

III. Other Provision of the Proposed Rule

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

1. RHC and FQHC Payment Methodologies

RHCs and FQHCs are paid a single amount for each face-to-face encounter. RHCs are paid based on an all-inclusive rate (AIR) that equals the RHCs reasonable cost per visit subject to a national limit. FQHCs are paid under a PPS. Both the RHC AIR and FQHC PPS payment rates

[53] See national coverage determination for MNT services (see https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?ncdid=252).

are designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day.

2. RHC Payment Limit Per-Visit

Freestanding or independent RHCs are paid based on the AIR subject to a limit increased annually by the Medicare Economic Index (MEI). The 2021 limit on the AIR is $87.52 prior to April 1, 2021.

Section 130 of the Consolidated Appropriations Act, 2021 (CAA 2021) increases the per visit payment limit for independent RHCs beginning April 1, 2021 according to the following schedule:

- 2021, after March 31, $100 per visit;
- 2022, $113 per visit;
- 2023, $126 per visit;
- 2024, $139 per visit;
- 2025, $152 per visit;
- 2026, $165 per visit;
- 2027, $178 per visit; and
- 2028, at $190 per visit.

For 2029 and later years, the RHC limit is increased by the MEI. The above limits will apply to all new RHCs including new RHCs (enrolled after December 31, 2020) that are provider-based to hospitals with less than 50 beds.

Existing RHCs (enrolled on or before December 31, 2020) that are provider-based to hospitals with less than 50 beds are paid reasonable costs not subject to a limit through April 1, 2021. CMS waived the 50-bed limit during the COVID-19 PHE. Beginning April 1, 2021, section 130 of the CAA 2021 establishes a per visit payment limit for RHCs that are provider-based to hospitals with less than 50 beds as of December 31, 2020. The limit is the higher of the RHC's reasonable cost per visit in 2020 increased by the MEI or the national per visit limit for the year.

The proposed CY 2022 MEI update is 1.8 percent. CMS will update the MEI for 2022 based on later data. If the RHC does not have a calendar year cost report, the 2020 reasonable cost per visit will be from the cost report that ends in 2020.

"Existing" RHCs provider-based to hospitals under 50 beds must have either: 1) Been enrolled in Medicare as of December 31, 2020; or 2) Submitted an application for enrollment in Medicare that was received not later than December 31, 2020. These provisions apply to provider-based RHCs that were temporarily enrolled or applied for temporary enrollment as of December 31, 2020 to meet the needs of the PHE that later apply for permanent enrollment.

The hospital to which the RHC is provider-based must also continuously maintain less than 50 beds (except as provided during the PHE) after December 31, 2020 to qualify for the higher

limit. If the hospital's number of beds increases to 50 or above, the provider-based RHC will be subject to the same limits as freestanding RHCs and will not be able to regain the higher limit.

To determine if an RHC was in a hospital with less than 50 beds as of December 31, 2020, the MAC generally does ongoing review two times per year. The rules for counting beds are described in §412.105(b).[54] In response to the PHE for COVID-19, CMS will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for 2020.

For multi-facility RHC systems, CMS has allowed for consolidated cost reports. Beginning with RHCs enrolled in Medicare as of January 1, 2021, CMS will no longer allow new provider-based RHCs to file consolidated cost reports as these RHCs will be subject to lower national limits while other provider-based RHCs may be subject to higher limits based on 2020 reasonable costs per visit increased by the MEI.

3. Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients

To be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual's prognosis is life expectancy of 6 months or less if the terminal illness runs its normal course. While working for the RHC or FQHC, physicians, nurse practitioners and physician assistants are not currently authorized under the statute to serve in the role of an attending physician.

Section 132 of the CAA 2021 provides authority for FQHCs and RHCs to receive payment for hospice attending physician services on or after January 1, 2022. Therefore, beginning January 1, 2022, a physician, NP, or PA who is employed by or working under contract with an RHC or FQHC may provide hospice attending physician services during a time when they are working for the RHC or FQHC. The RHC or FQHC would bill for these services as they would for any other qualified service to be paid at the RHC AIR or the FQHC PPS rate. When the RHC/FQHC furnishes a hospice attending physician service that has a technical component, the provider furnishing the technical component would go to the hospice for payment. CMS is proposing to change the regulations to conform with these statutory changes.

4. Concurrent Billing for Care Management Services

CMS describes chronic care management, transitional care management (TCM), general behavioral health integration, and the psychiatric collaborative care model. These services are collectively described as "care management services." Effective January 1, 2020, CMS allows suppliers paid under the PFS to concurrently bill care management services that were previously restricted from being billed with TCM. However, CMS did not extend this policy to care management services furnished in RHCs or FQHCs. For 2022, CMS is proposing to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same

[54]Total number of beds equals bed days available to provide care under the IPPS during the hospital's cost reporting period divided by the number of days in the cost reporting period.

beneficiary during the same service period, provided that all requirements for billing each code are met.

B. RHCs and FQHCs - Telecommunications Technology

RHCs and FQHCs can serve as originating sites for telehealth services paid under the physician fee schedule to distant site practitioners. However, the law does not authorize them to receive payment as distant site practitioners directly except during the PHE. During the PHE, the statute permits RHCs and FQHCs to serve as the distant site for a telehealth service and be paid a special rate CMS set at $99.45 (the weighted average of all services paid as telehealth under the PFS). Once the PHE expires, the temporary statutory authority that allows RHCs and FQHCs to be paid for furnishing distant site Medicare telehealth services will also expire.

CAA 2021 section 123 added the home of the individual as a permissible originating site for telehealth services billed under the PFS when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. This provision does not apply to RHCs and FQHCs. However, CMS has limited authority to define services which may be covered under the RHC and FQHC benefit categories.

Using this authority, CMS is proposing to allow RHC or FQHC mental health visits to include encounters furnished through interactive, real-time telecommunications technology in addition to those furnished through a face-to-face visit. The proposal would be limited to services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. Consistent with its PFS policy, CMS is also proposing to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. CMS adds that the decision as to whether a mental health service is face-to-face or via a telecommunications system should be based on the clinical judgment of the practitioner, in consideration of patient needs and preferences.

CMS proposes that RHCs and FQHCs would append the 95 modifier (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) where the service was furnished using audio-video communication technology. It will develop a new service level modifier in cases where the service was furnished audio-only.

Consistent with the requirements of CAA section 123, CMS would require that there be an in-person service within 6 months prior to or after the furnishing of the telehealth service. CMS seeks comment on whether there should be a similar requirement for mental health services furnished by RHCs and FQHCs via telecommunications technology.

C. Payment for Tribal FQHCs- Comment Solicitation

1. Tribal Outpatient AIR and Grandfathered Tribal FQHCs

Medicare pays for outpatient services provided by Indian Health Service (IHS) and tribal hospitals using an AIR set by IHS. For 2021, the AIR is $662 in Alaska and $414 elsewhere (85 FR 86940).

A "grandfathered tribal FQHC" is a FQHC that is operated by a tribe or tribal organization under the Indian Self Determination Education and Assistance Act; was billing as if it were provider-based to an IHS hospital on or before April 7, 2000 and is not currently operating as a provider-based department of an IHS hospital. CMS distinguishes grandfathered tribal FQHCs from freestanding tribal FQHCs and provider-based tribal clinics that may have begun operations subsequent to April 7, 2000. Grandfathered tribal FQHCs—there are currently 7—are paid based on the AIR while all other FQHCs (including tribal FQHCs) are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate of $176.45.

2. The Tribal Technical Advisory Group (TTAG)

The TTAG advises CMS on policy and program issues impacting American Indians/Alaska Native (AI/AN) populations served by CMS programs. The TTAG requested that CMS amend Medicare regulations to make all IHS and tribally-operated outpatient facilities eligible for payment at the AIR. They believe CMS' policy varies Medicare's rates by regulatory definition, rather than the actual costs of the outpatient clinic. CMS responds that rate differentials are not unique to tribal and IHS facilities. Statutory and regulatory definitions govern differential payment among many provider types (for example, ambulatory surgical centers and hospital outpatient departments) that provide the same or similar services.

The TTAG also questioned the need for grandfathered tribal FQHCs to file cost reports arguing that FQHC cost reports have no relationship to the AIR paid to grandfathered tribal FQHCs as hospital cost reports are used in setting the rate. Therefore, they stated, the FQHCs should only need to file a cost report to the extent necessary to support payment for non-FQHC services that are not included in the AIR. CMS responded that FQHC cost reports are needed to determine reasonable costs of the influenza and pneumococcal vaccines and their administration, allowable graduate medical education costs, and bad debts. The FQHC market basket also uses information from the FQHC cost report to determine the cost share weights, which reflect the relative costs of input expenses that FQHCs face in order to provide FQHC services.

3. Comment Solicitation

CMS solicits comment on the TTAG's request specifically asking commenters to address:

- The types and number of facilities or clinics that could potentially enroll in Medicare as an FQHC, or are already an FQHC paid under the FQHC PPS, and if these clinics are freestanding or provider-based;
- The relative operating costs of IHS and tribally operated outpatient clinics compared to non-tribal FQHCs and supporting evidence to address whether or why payment set at the

AIR would be more appropriate than the payment rate under the FQHC PPS;
- How the AIR, which is based upon a limited number of hospital cost reports, relates to costs in such clinics and the kinds of services that the clinics furnish; and
- Concerns that the AI/AN community may have regarding access or equity in situations where a payment differential exists.

CMS further requests information that it does not have (other than from provider-based clinics and grandfathered FQHCs that submit cost reports) as follows:
- If a facility is not enrolled in Medicare as an FQHC or is not provider based to a hospital, is it a physician practice?
- Are there other options for enrolling as different types of providers or suppliers?
- How much would payments increase from changing policy as requested by the TTAG?
- Would there be program integrity concerns with increased payment?
- How would Medicare pay for services that are currently paid through the cost report if tribal FQHCs did not submit cost reports?

The proposed rule also seeks comment on whether it can use the section 1834(o)(1)(A) of the Act statutory authority to adopt the TTAG's request:
- Would the TTAG's request be an expansion of the payment policy that CMS adopted for 2016 to create tribal FQHCs?
- Could CMS develop a payment adjustment applicable to IHS and tribally operated outpatient clinics based on the cost differential reported in their cost reports when compared to non-IHS outpatient clinics, or non-provider-based clinics?
- Are there other potential ways to determine whether the costs associated with furnishing services to AI/AN are uniquely greater than other clinics within the confines of the FQHC PPS outlined in section 1834(o)(1) of the Act?

D. Reporting Average Sales Price (ASP) for Self-Administered Drug Products

1. Requiring Certain Manufacturers to Report Drug Pricing Information for Part B

Under current law and regulations, only manufacturers with a Medicaid drug rebate agreement are required to report ASP data to CMS. Other manufacturers of drugs and biologicals without Medicaid drug rebate agreements may voluntarily report ASP data. If a drug manufacturer does not report ASP data for a single source product, Medicare payment is based on wholesale acquisition cost (WAC) which is generally higher than ASP because it is not reported net of price concessions.

Section 401 of Division CC, Title IV of the CAA, 2021 (section 401):
- Requires manufacturers of Medicare Part B drugs without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022;
- Provides discretion for CMS to exclude repackagers from the definition of "manufacturer" for purposes of the ASP reporting;
- Adds parallel provisions addressing confidentiality, audit and verification provisions;

civil money penalties for misrepresentation, late reporting, and reporting of false information; and increasing oversight and enforcement provisions to those in existence for drug manufacturers with Medicaid drug rebate agreements; and

- Requires the Office of the Inspector General (OIG) to submit a report on the accuracy of ASP submissions to Congress by January 1, 2023.

To implement the first provision, CMS proposes to amend the definition of the term "drug" at § 414.802 require ASP reporting for any product that is paid under Part B as a drug or biological irrespective of whether the manufacturer has a Medicaid drug rebate agreement.

With respect to repackagers, CMS does not see a need to exempt repackagers from reporting ASP. There is no such exemption under current policy. CMS provides an analysis that demonstrates approximately the same percentage of drug products would be reported by repackagers under current reporting policies and the more expansive reporting policies under section 401. Further, CMS believes exempting repackagers from reporting would distort ASP and create administrative burden for the agency in its validation of ASP reporting.

Under current policy, if the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. These policies only apply to manufacturers of Part B drugs with Medicaid drug rebate agreements. Section 401 applies these same penalties to manufacturers of Part B drugs that do not have Medicaid drug rebate agreements. CMS proposes to make conforming changes to the regulations consistent with the new statutory requirements (and also to make other editorial improvements to the regulations that do not change any policy).

2. Determination of ASP for Certain Self-administered Drug Products

ASP is determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. Therefore, all versions of a single source drug or biological product marketed under the same FDA approval number are considered the same drug or biological for determining the ASP for the billing and payment code. This means that a self-administered version of a drug marketed under the same FDA approval is subject to ASP reporting requirements and not excluded from the payment limit calculation, even though Medicare does not make separate Part B payment for it.

Section 405 directs OIG to conduct periodic studies to identify self-administered drug products that should be excluded from the determination of ASP. The law directs OIG to inform the Secretary of these products at such times as the Secretary may specify. Then the Secretary shall, to the extent appropriate, determine the ASP as the lesser of the amount including or excluding the self-administered drug or biological products.

Although the law is permissive with regard to future products identified by the OIG, the law is mandatory on the Secretary to apply the lesser-of methodology to the two billing and payment codes identified in the OIG's July 2020 report titled, "Loophole in Drug Payment Rule Continues to Cost Medicare and Beneficiaries Hundreds of Millions of Dollars" beginning July

1, 2021. Consistent with the statutory requirements, CMS already applied the lesser-of methodology to determine the ASP for Cimzia® (certolizumab pegol) and Orencia® (abatacept) for the July 2021 ASP Drug Pricing Files and crosswalks.

If OIG identifies additional self-administered drugs and biologicals that should be excluded from ASP determinations, CMS is proposing that it would apply the lesser of methodology beginning two quarters following the OIG study publication. For example, if the OIG study becomes available to the public in the first quarter of the calendar year, the lesser-of methodology would be applied to the payment limit calculation of the applicable billing and payment code in the third quarter ASP pricing file (the July ASP pricing file) and each quarter thereafter.

CMS also proposes:

- The manufacturer must continue to report pricing and volume information for self-administered versions of Part B drugs even when this information is excluded from ASP pricing determinations;
- Not to apply the lesser of policy if a drug is on the FDA's drug shortage list. However, this exception will not apply to certolizumab pegol and abatacept because the law mandates that lesser of policy apply to these two drugs; and
- To continue applying the lesser of policy when the drug's NDC has changed but the product is the same; and
- To not extend the "lesser of" policy to subsequent FDA approvals of products with the same active ingredient unless specifically identified by OIG. Such subsequent FDA approvals could be for new syringe sizes, new types of injector syringes, generic formulations, biosimilar biological products, or interchangeable biological products.

E. Medicare Part B Payment for Section 505 Drugs

Medicare Part B drugs fall into two broad, mutually exclusive categories: (1) multiple source drugs, and (2) single source drugs. For multiple source drugs, all of the same drug products are assigned to a single billing and payment codes and the ASP is an average of the prices of all of the products assigned to that code. For single source drugs, only one product is assigned to the billing and payment code and the ASP reflects the average sales price of only that one product.

In most cases, the distinction between multiple source drugs and single source drugs is straightforward. However, there is a subset of drugs approved by the FDA under section 505(b)(2) of the Federal Food, Drugs and Cosmetics Act (section 505 drugs). For these drugs, the approval application may rely on the findings for an already approved drug product or on published literature. Unlike a generic drug, a section 505 drug is not required to have the same FDA labeling as the already approved drug. For these drugs, assignment to a single source or multiple source drug code is not as straightforward.

CMS is concerned about growth in the number of section 505 drugs paid under Medicare Part B and spending on them. In some cases, the payment rate for these products is multiples of the payment rate for the analogous products paid under a multi-source drug code. The section 505 drug may even share substantial portions of the FDA-approved labeling including prescribing

information on safety, efficacy, and pharmacokinetics as the source drug product paid in a multi-source drug code.

In the 2021 PFS proposed rule, CMS proposed to codify its long-standing approach to determining whether a section 505(b)(2) drug product would be assigned to single or multi-source drug code.[55] However, CMS did not finalize its proposal.

CMS is now soliciting comments on a more detailed framework. The framework aims to build off the current policy for assigning drug products to billing and payment codes by describing detailed standards for determining whether a section 505 drug corresponds to an existing multiple source drug code. CMS is not proposing to adopt the framework at this time but seeks comment to inform future policy making.

The framework will provide guidance for when a section 505 drug product without an FDA therapeutic equivalence rating will be assigned to an existing multiple source drug code. The first portion of the framework would compare:

1. Active ingredient(s);
2. Dosage form (if part of the drug product name);
3. Salt form; and
4. Other ingredients in the drug product formulation.

If there is a match in the first part of the framework, CMS would compare the pharmacokinetic and clinical studies of the section 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code. Finally, a determination would be made as to whether the section 505(b)(2) drug product could be assigned to the existing multiple source code. For full details on the framework, please see: Decision Framework for Section 505(b)(2) Drug Products (cms.gov).

CMS seeks comment on:

- The framework and how it aligns with the statutory definitions of single source and multiple source drugs;
- How the framework distinguishes situations in which a section 505 drug is not described by an existing multiple source drug code; and
- The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

[55] CMS' policy on this issue was part of sub-regulatory guidance in 2007 (see: As announced in late 2006, after carefully examining Section 1847A of the Social Security Act, as added by the Medicare Modernization Act of 2003, CMS has been working further to ensure that more accurate and, as appropriate, separate payment is made for)

F. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (PAMA)[56] added section 1834(q) to the Act which directed the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Section 1834(q)(4) of the Act requires ordering professionals to consult with a specified applicable AUC through a qualified clinical decision support mechanisms (CDSMs) for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system. Payment for such services may only be made if the claim for the service includes information about the ordering professional's consultation of a specified applicable AUC through a qualified CDSM.

CMS discusses the steps it has taken to implement the AUC program (codified at 42 CFR 414.94). Under the AUC program, when a professional orders an advanced diagnostic imaging service for a Medicare beneficiary, the professional or clinical staff acting under the professional's direction, will be required to consult a qualified CDSM. The CDSM provides a determination of whether the order adheres to AUC, or if the AUC consulted was not applicable (e.g., no AUC is available to address the patient's clinical condition). The AUC program impacts all physicians and practitioners[57] that order advanced diagnostic imaging services and facilities that furnish advanced diagnostic imaging services in a physician's office, hospital outpatient department (HOPD) (including the emergency department), and ambulatory surgical center (ASC) or an IDTF whose claims are paid under the PFS or hospital outpatient/ASC prospective payment system.

In 2020, CMS began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020. Furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020. In response to the PHE, the educational and operational testing period was extended through 2021.

The payment penalty phase of the AUC is scheduled to begin January 1, 2022. As discussed below, CMS proposes to begin the payment penalty phase of the AUC on the later date of January 1, 2023, or the January 1 that follows the declared end of the PHE.

1. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification

[56] Pub. L. 113-93, April 1, 2014
[57] Physicians and practitioners as defined in 1862® or 1842(b)(18)(C) of the Act.

of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)).

CMS has addressed the first, second and third components of the Medicare AUC program in prior rulemaking. CMS will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services. CMS acknowledges the AUC program has been significantly delayed.

2. Proposals for Continuing Implementation

CMS provides clarification and proposals relating to updates or modifications to orders for advanced diagnostic imaging and the extreme and uncontrollable circumstances hardship exception. CMS proposes several claims processing solutions to ensure identification of claims that are and are not subject to the AUC program requirements. CMS discusses identifying the ordering professional claims that fail AUC claims processing edits, including whether it should deny or return claims that fail these edits. CMS proposes to begin the claims processing system edits and payment penalty phase on the later of January 1, 2023, or the January of the year after the year in with the PHE ends.

CMS will continue to post information about the AUC program on its website at www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Programs/index.html.

a. Proposed Clarification of AUC Program Scope

i. Modified Orders

CMS discusses when updates or modifications to orders for advanced diagnostic imaging services may be necessary once the beneficiary is under the care of the furnishing professional. The Medicare Benefit Policy Manual (BPM)[58] states that when an interpreting physician determines that a different or additional imaging service that is not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician has been received. The manual includes circumstances under which the interpreting physician or testing facility may furnish the additional imaging services. CMS believes under these circumstances, the interpreting physician/practitioner is exercising their professional judgement to provide the ordering professional with additional diagnostic test results for managing the patient's care and it would not be appropriate to consider the interpreting professional as acting as the ordering professional.

CMS proposes that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described in chapter 15, section 80.6.2-4 of the BPM, neither the ordering professional nor the furnishing professional are required to consult the AUC for the additional services(s). In these situations,

[58] Benefit Policy Manual, Chapter 15, sections 80.6.1-4.

the AUC consultation information from the original order should be reported on the claim line for the additional service(s). CMS expects situations where AUC consultations do not occur for new or modified orders to be infrequent.

ii. Extreme and Uncontrollable Circumstances Hardship Exception

In the 2019 PFS final rule, CMS described extreme and uncontrollable circumstances to include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. CMS includes areas where events occur that have been designated by FEMA as a major disaster or a PHE declared by the Secretary. CMS clarifies that these circumstances are events that are entirely outside the control of the ordering professional that prevent the ordering professional from consulting AUC through a qualified CDSM.

CMS discusses the challenges related to resource reallocation during the PHE that stakeholders have described to prepare for the payment penalty phase of the AUC program. CMS stresses that stakeholders may continue to attest to a significant hardship under the AUC program due to extreme and uncontrollable circumstances related to the PHE and such an attestation may be used as needed throughout the PHE. CMS acknowledges that ordering professional may experience significant hardships resulting from the PHE beyond the date the PHE expires and that AUC program exceptions will continue to be available for such hardships as defined in §414.94(1)(3).

b. Claims Processing

CMS discusses the operational and administrative issues related to implementation of the payment penalty phase and its proposals for addressing them. CMS states that full implementation of the AUC program requires edits in the claims processing system to deny Medicare claims that fail to report the required AUC consultation information. CMS notes it needs workable solutions that allow the AUC program to accurately pay and deny claims using available claim's information, while working within the limitations of the Medicare claims processing system. CMS acknowledges that the inadvertent denial of claims would disproportionately impact radiologists, HOPDs, and freestanding imaging centers. In addition, the AUC requirement for providing AUC consultation information to the furnishing professional falls on the ordering professional, yet claims that are denied for failing to report this information are for services furnished and billed by the professionals and facilities that furnish the advanced diagnostic imaging.

CMS needs to develop edits for the two main Medicare claims types subject to claims processing edits in the AUC program: (1) CMS-1500 submitted by physicians and practitioners, ASCs, and IDTFs, and (2) UB-04 (also called the CMS-1450 and referred to as the institutional claim) submitted by HOPDs and on-campus and off-campus provider-based departments. Because these claims types have different data elements, claims processing edits cannot be identical across claim types.

CMS reviews the partial claims process instructions issued to support the educational and operations testing period.[59] Instructions include HCPCS G-codes to indicate whether or not the CDSM was consulted and a procedure code list that identifies advanced diagnostic imaging codes subject to the AUC program.

Based on a review of 2020 Medicare claims (the education and operations testing phase), CMS estimates between 9-10 percent of all claims subject to the AUC program reported sufficient information to be considered compliant with the program. An additional 6-7 percent of claims included some relevant information, indicating some awareness of the AUC program, but these claims lacked sufficient information required for payment.

Below, CMS discusses specific circumstances requiring additional consideration for implementation of the payment penalty phase. **CMS solicits comments on whether additional circumstances require consideration and whether the proposals discussed adequately address these issues. CMS also seeks any additional information to assist in developing claims processing system edits or other measures to ensure that only appropriate claims are subject to AUC claims processing edits.**

i. Ordering Professional NPI

CMS needs to establish a claims processing edit to require the fields for reporting the NPI (available on both claims types), to be populated on all advanced diagnostic imaging claims subject to the AUC program.

CMS also discusses the situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim3. This will not work for reporting AUC consultation information because the referring professional field is reported at the claim-level and not at the claim line or service line. For the AUC program, only one ordering professional can be reported per claim.

ii. Critical Access Hospital

Advanced diagnostic imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program.[60] CMS must identify these claims and allow them to bypass program claims processing edits. For institutional claims, CMS intends to apply the claims processing edits to type of bill 13x (outpatient hospital settings); type of bill 85x is used by CAHs.

CMS discusses the requirement to report AUC consultation information on the claims from both professionals and facilities.[61] CMS believes, however, if advanced diagnostic imaging services are not entirely furnished in an applicable setting, neither the PC nor TC claims should be required to include AUC consultation information. CMS proposes that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC

[59] CR 11268, Transmittal 2404 available at https://www.cms.gov/files/document/r2404otn.pdf.
[60] In accordance with section 1833(q)(1)(D) of the Act, a CAH is not an applicable setting under the AUC program.
[61] In the 2019 PFS final rule (83 FR 59694) CMS discussed the requirements of section 1834(q)(4)(B) of the Act. CMS revised its regulations at § 414.94(k) to specify that AUC program requirements apply to claims from both furnishing professionals and facilities.

was not furnished in an applicable setting it would not be subject to the AUC program. In these situations, the TC of the image services furnished is not subject to the AUC program.

For advanced imaging services with the TC performed as an outpatient CAH service, CMS has not yet identified a way to allow a claim for the corresponding PC service to bypass AUC program claims processing edits. As discussed below, CMS proposes to establish a separate HCPCS modifier that will be used to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program.

iii. Maryland Total Cost of Care Model

CMS discusses concerns raised by stakeholders about whether advanced diagnostic imaging services furnished in hospitals participating in the Maryland Total Cost of Care Model would be subject to the AUC program. Advanced diagnostic imaging services furnished in HOPDs of hospitals participating in the Maryland Total Cost of Care Model are not subject to the AUC because these services are not paid under an applicable payment system. Consistent with the proposal discussed above, CMS proposes that the PC's of these advanced diagnostic imaging services, when billed separately, are also not required to include AUC consultation information.

CMS believes it has the ability to identify situations in which the imaging service was furnished in a HOPD paid under the Maryland Total Cost of Care Model and exclude those claims from the AUC program claims processing edits. CMS thinks this can be accomplished by using the CMS Certification Number (CCN) in box 32 of the CMS 1500 claims form. CMS plans to determine if a list of CCNs can be used as the source of its edits.

iv. Inpatients Converted to Outpatients

CMS discusses the uncommon situations where a beneficiary's hospital inpatient status changes to outpatient and the criteria that must be met. When these criteria are met, condition code 44 (inpatient admission changed to outpatient) is appended to the institution claim.[62] CMS proposes to allow institutional claims meeting these requirements to use condition code 44 to bypass AUC claims processing edits. CMS believes that any professional claim would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is in inpatient status.

CMS expects less than half of one percent of claims will include condition code 44.

v. Deny or Return Claims that Fail AUC Claims Processing Edits

CMS is considering whether claims that do not pass the AUC processing edits, and therefore will not be paid, should be initially returned to the health care provider so they can be corrected and resubmitted, or should they be denied so they can be appealed.

CMS seeks comments on whether claims should be initially paid or denied and whether the payment penalty phase should begin first with returning claims and then transition to denying claims. CMS notes that a transition may be helpful as professionals and facilities submit claims under the AUC program.

[62] https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r299cp.pdf.

vi. Medicare as a Secondary Payer
CMS discusses stakeholders concerns that in some EHRs, the secondary payer information is typically not available. CMS notes that when Medicare is the secondary payer no Medicare payment would be made after the primary payer makes payment. Medicare is reported as the secondary payer for the approximately 1.5 percent of advanced diagnostic imaging service subject to the AUC program.

CMS proposes to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic practitioner claim or FL 50/52 of the electronic institutional claim) to bypass the AUC program claims processing edits.

vii. Date of Service and Date of Order
CMS will specify a start date for when the AUC program claims process edits become effective. Because CMS cannot identify the order date for an advance diagnostic imaging service based on claims information, CMS proposes that the AUC program claims processing edits for the payment penalty phase will be applicable for services furnished on or after the effective date of the claims edit. For imaging services order prior to, but furnished on or after the effective date of the edits, the furnishing professional would apply a separate HCPCS modifier (discussed below) to indicate that the claim is not subject the AUC claims processing edits.

viii. HCPCS Modifiers
CMS established two primary sets of HCPCS modifiers for the AUC program. One set is included on the same claim line as the G-code identifying the CDSM that was consulted:

- Modifier ME indicates the imaging service adheres to the AUC,
- Modifier MF indicates the imaging service does not adhere to the AUC, and
- Modifier MG indicates the qualified CDSM does not contain AUC that applies to the order.

CMS intends for these modifiers to be continued to be used during the payment penalty phase. CMS notes reporting these modifiers should be limited to one per qualified CDSM G-code since these modifiers are mutually exclusive.

The second set of HCPCS modifiers are used when the ordering professional does not consult a qualified CDSM. Three HCPCS modifiers describe the significant hardship exceptions:

- Modifier MB indicates insufficient internet access,
- Modifier MC indicates EHR or CDSM vendor issues, and
- Modifier MD indicates extreme and uncontrollable circumstances.

In addition, modifier MA is available to identify claims for patients with a suspected or confirmed emergency medical condition. These codes are also mutually exclusive and CMS expects only one to be reported per procedure code-level claim line.

CMS created modifiers for use during the educational and operations testing phase:

- Modifier QQ indicates that the ordering professional consulted a qualified CDSM for the service and the related information was provided to the furnishing professional and

- Modifier MH indicates the AUC consultation information was not provided to the furnishing professional and furnishing facility.

CMS intends to end the current uses for modifier QQ and modifier MH at the end of the educational and operations testing period. Beginning for services furnished on and after the effective date of the AUC program claims processing edits, CMS proposes to redefine modifier MH to describe situations where the ordering professional is not required to consult AUC and the claim is not required to report the AUC consultation. CMS notes this could be repurposed for CAH and other circumstances that fall outside the scope of the AUC program requirements.

ix. Additional Claims Processing Information
CMS believes it will be able to use place of service codes to identify the applicable settings for the AUC program. CMS proposes to limit AUC processing edits to apply only to the following:

- Institutional claims to type of bill 13x (hospital outpatient);
- Practitioner claims with place of service codes 11 (office), 15 (mobile units), 19 (off campus outpatient hospital), 23 (emergency room) and 24 (ASC)

c. Timing of Payment Penalties

Given the many complexities around the scope and application of AUC program claims processing edits, CMS believes that notice and comment rulemaking is the most appropriate means to discuss implementation of the payment penalty phase.

CMS believes the earliest that the claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. CMS does not think it would be possible for it to finalize implementation and claims processing plans in this final rule as implementing these types of claims processing edits generally require a long lead time. To align the effective date for the claims processing edits, CMS believes the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

CMS proposes a flexible effective date for AUC claims processing edits and payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE.

Regulatory Impact
In the 2019 PFS final rule,[63] CMS performed a comprehensive regulatory impact analysis for this program. CMS notes it does not have sufficient reason to change any of the assumptions finalized in the 2019 final rule. CMS updates the analysis to reflect 2019 Medicare claims data. CMS identifies four incremental changes from the 2019 PFS final rule estimates due to updated claims data: (1) impact of required AUC consultations by ordering professionals; (2) impact to Medicare beneficiaries: (3) process efficiencies to potentially offset the estimated burden on Medicare beneficiaries; and (4) impact on transmitting orders for advanced diagnostic imaging services. Table 125, reproduced below, summaries the substantive changes from the 2019 PFS

[63] 83 FR 60034-60044

final rule to the 2022 proposed rule impact estimates. Each of these incremental changes results in a lower estimate.

Table 125: AUC Program Related Activities with Changes in Impact Estimates Resulting From a Three-Year Delay		
AUC Program Related Activity	**CY 2022 PFS Proposed Rule Impact Estimate**	**Change from CY 2019 PFS Final Rule (as a function of the discount rate)**
Impact of required AUC consultations by orderingprofessional	$51,039,109	- $4.3 million (3%) - $9.4 million (7%)
Impact to Medicare beneficiaries	$54,789,518	- $4.6 million (3%) - $10.1 million (7%)
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192	- $8.0 million (3%) - $17.4 million (7%)
AUC automated solution	$1,851,356,888	- $157.1 million (3%) - $340.1 million (7%)
Medicare program impacts associated with advanced diagnosticimaging services	$700,000,000	- $59.4 million (3%) - $128.6 million (7%)
Total Change Attributable to a Three-Year Delay		- $174.1 million (costs, 3%) - $376.9 million (costs, 7%) - $59.4 million (transfers, 3%) - $128.6 million (transfers, 7%)

G. Removal of Selected National Coverage Determinations

In the 2021 PFS final rule[64], CMS established rulemaking as an appropriate vehicle for receiving public comment on removing outdated NCDs. CMS did not establish an exclusive list of criteria that it would use to identify and evaluate NCDs for removal. CMS will consider proposing the removal of an NCD if:

- It believes that allowing local contractor discretion to make a coverage decision better services the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has superseded by subsequent Medicare policy. The national policy does not meet the definition of an "NCD" as defined in sections 1862(l)[65] or 1869(f)[66] of the Act.

[64] 85 FR 84472

[65] Section 1862(l) of the Act describes the national and local coverage determination process.

[66] Section 1869(f)(1) of the Act defines national coverage determination as ''a determination by the Secretary with

- The benefit category determination is no longer consistent with a category in the Act.

In addition, CMS also considers the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology since the last determination, and the availability and quality of clinical evidence and information to support removal of an NCD.

Table 23, reproduced below, list the two NCD's CMS proposes to review. This list is based on CMS' review, requests from the Medicare Administrative Contractors (MACs) medical directors, and requests received from external stakeholders. Each of the current NCDs may be found in the Medicare National Coverage Determinations Manual.[67]

Table 23: Proposed NCDs for Removal	
NCD Manual Citation	**Name of NCD**
180.2	Enteral and Parental Nutritional Therapy (7/11/1984)
220.6	Positron Emission Tomography (PET) Scans (9/3/2013)

CMS' rationale for proposing the removal of these NCDs is summarized below.

(1). NCD 180.2 Enteral and Parenteral Nutrition Therapy (July 11, 1984)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: External stakeholders suggested that portions of this NCD are outdated and unnecessarily add to patient and provider burden as it requires repeated reviews of medical necessity for individuals who need enteral or parenteral nutrition services as a result of chronic diseases. Local contractors have proposed LCDs, that if finalized, would provide coverage for certain Medicare beneficiaries.

(2). NCD 220.6 Positron Emission Tomography (PET) Scans (September 3, 2013)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: External stakeholders suggested this NCD is outdated. CMS notes that since 2013, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents. CMS believes that local contractor discretion provides potential coverage for appropriate coverage for non-oncologic indications.

CMS solicits comments on its proposal to remove each of these NCDs and any recommendations for other NCDs for consideration in the future. CMS request commenters include a rational to support their comments to help CMS take one of the following actions: remove the NCD as proposed; retain the current NCD; or reconsider revising the NCD. CMS also

respect to whether or not a particular item or service is covered nationally under title XVIII, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.''

[67] The manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items?CMS014961.

requests that comments suggesting a revision include new evidence to support a change in national coverage.

H. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

1. Background

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) established new benefit categories for coverage of cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) under Medicare part B and specified conditions of coverage. In the 2010 PFS final rule, those conditions of coverage were codified in §410.47 (for PR) and §410.49 (for CR and ICR).

PR is covered for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD) when referred by the treating physician and permits additional medical indications to be established through a national coverage determination (NCD). CMS has not expanded coverage of PR further using the NCD process. However, CMS did expand coverage of CR through the NCD process to apply to beneficiaries with stable, chronic heart failure, and coverage of ICR was also expanded to apply to beneficiaries with stable, chronic heart failure by the BBA of 2018.

PR, CR, and ICR are physician-supervised programs furnished in a physician's office, hospital outpatient setting or other settings that CMS determines appropriate. The physician must be immediately available and accessible for medical consultation and medical emergencies, and all three programs must include the following: physician-prescribed exercise, psychosocial assessment, outcomes assessment, cardiac risk factor modification (for CR/ICR) and education or training (for PR), and individualized treatment plans (ITPs) established, reviewed and signed by a physician every 30 days. Physicians who are responsible for these programs must have appropriate expertise.

2. Clarification

Stakeholders have complained that it is difficult for programs to fulfill the requirements for the ITPs on the patient's first day of the PR or CR/ICR program and that there is no separate payment for medical directors or other physicians to develop and sign the ITP. CMS provides the following responses:

- A medical director and any staff physician(s) working in the program involved in the patient's care and who has knowledge related to the patient's condition, or the patient's treating and/or referring physician, may establish, review and sign ITPs.
- When appropriate and when all billing requirements are met, a separately billable evaluation and management (E/M) service may be furnished by the medical director or other PR or CR/ICR staff physician(s) working in the program in connection with establishing and signing the ITP on or before the first day of the program.
- Physicians treating patients for their cardiovascular or respiratory conditions, but who are not staff of the PR or CR/ICR programs, may develop and sign ITPs for their patients

before they begin PR or CR/ICR programs. These ITPs will not require an additional signature from the program's medical director, but the medical director or other physician working in the program may revise the ITP as needed to ensure the plan is appropriately individualized regardless of who developed and signed the ITP.

3. Proposed Revisions

a. Covered Conditions for PR.

CMS proposes to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID-19. Severe manifestations of COVID-19 would be defined as a patient requiring hospitalization in the ICU or otherwise who experiences continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge. Based on information from the CDC and other organizations, CMS has concluded that COVID-19 is chronic when symptoms persist for more than 4 weeks, and symptoms include dyspnea, depression and anxiety which can impair physical function and cause incapacitation.

Acknowledging that there is limited evidence to assess the benefits PR may provide for patients who were diagnosed with COVID-19, CMS notes that early research and consensus statements emphasize the restorative role that PR will likely play in the patient recovering from COVID-19. **CMS seeks comment on the appropriateness of the coverage criteria for PR for beneficiaries diagnosed with COVID-19, including both patient characteristics and the timing of symptoms.**

b. Conforming Changes for Consistency Across Programs

PC and CR/ICR programs are subject to many of the same statutory requirements, but their codification in regulations is not identical across the programs. CMS proposes a number of largely technical changes to the regulation text to establish consistency in terminology, definitions and requirements where appropriate; changes would be made to the regulatory text for PR (§410.47) to align it with the text for CR/ICR (§410.47).

With respect to physician standards, CMS proposes to replace the existing PR section with two separate sections, one for the medical director and the other for the supervising physician, the latter would delineate requirements for physicians fulfilling the supervising physician role when PR items and services are furnished. It also proposes to remove the requirement that a physician have "direct patient contact related to the periodic review of his or her treatment plan" because CMS finds the requirement to be overly burdensome and unnecessary since a physician is already required to, in consultation with staff, review patient ITPs every 30 days. CMS believes that direct physician-patient contact can be written into an ITP for patients who require such attention, but it is not necessary for every patient. The need for it should instead be specified by the clinician. **It seeks comment on whether removing the requirement or direct physician-patient contact every 30 days would be potentially detrimental to PR patients**.

4. Impact

CMS believes the proposed expansion of PR coverage may increase utilization. It estimates the total added cost to the Medicare program to be $2,161,447 annually during and immediately following the COVID-19 PHE. As hospitalizations and COVID-19 cases decline, it expects the annual impact to decrease because eligible patient populations will likely decrease. However, it is unable to estimate the longer-term impact of the proposal due to the unpredictable nature of the PHE and the lack of long-term data on COVID-19. Based on the low utilization rate of the benefit, CMS does not believe the other proposed revisions will significantly impact utilization and the Medicare program.

I. Medical Nutrition Therapy

Under existing law and regulations, Medicare beneficiaries with diabetes or renal disease can receive individualized medical nutrition therapy (MNT) provided by a registered dietitian or nutrition professional if referred by a treating physician. The regulations at §410.132 provide the conditions for coverage of MNT services and the limitations on such coverage and §410.134 identifies the provider qualifications for such services.

a. Removal of Treating Physician Restriction

Under the proposed rule, CMS would increase the flexibility for the provision of MNT services by eliminating the requirements that referrals must be made by a treating physician. The word "treating" would be eliminated from §410.132, permitting referrals from physicians more generally. CMS notes that the requirements for referrals to be made by treating physicians was believed to be needed to ensure coordination of care and improve quality. Now, however, CMS believes that the limitations have contributed to the low uptake of referrals to MNT services. CMS states that the treating physician restriction is no longer necessary to expect care to be coordinated and that care coordination between the hospital or post-acute care provider and the primary care provider is the standard of care in today's medical environment.

CMS also proposes a conforming change to eliminate the definition of a "treating physician" from §410.130.

b. Update the eligibility criteria for patients with CKD

CMS proposes revisions to the eligibility criteria for chronic kidney disease to incorporate current medical practice and an improved understanding of the definitions and staging of chronic kidney disease. Specifically, CMS would revise §410.130 by revising the chronic renal insufficiency definition by removing the GFR eligibility criteria of 13 – 50 ml/min/1.73m^2 and replacing with 15 – 59 ml/min/1.73m^2.

J. Medicare Shared Savings Program

CMS reviews in detail the legislative and regulatory history of the Medicare Shared Savings Program. The program and its Accountable Care Organizations (ACOs) were added as section 1899 of the Act by the Affordable Care Act.[68] CMS notes that a major program redesign was finalized in a December 2018 final rule subtitled "Pathways to Success" (83 FR 67816) to encourage the adoption of two-sided risk by ACOs. As part of the December 2018 redesign, a "glide path" was created on which an ACO's risk-bearing level is automatically advanced annually until sufficient two-sided risk bearing is reached to allow the ACO to qualify as an Advanced Alternative Payment Model (Advanced APM). Glide path advancement also provides an ACO with the potential for larger amounts of shared savings.

In the May 8th COVID-19 IFC, CMS offered certain ACOs the option to freeze their glide path advancement for performance year 2021 (i.e., not automatically advance); nearly three quarters of eligible ACOs chose to freeze their glide path level. This option was finalized in the CY 2021 PFS final rule. In the FY 2022 IPPS proposed rule, CMS has proposed to allow those same ACOs to freeze their advancement along the glide path to increased risk bearing for an additional year (performance year 2022).[69]

1. Quality and Other Reporting Requirements

In this rule, CMS proposes to clarify sampling policies for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey; amend the reporting requirements for ACOs under the APM Performance Pathway (APP) and update the APP's quality measure set; amend the Shared Savings Program's quality performance standard; revise the program's extreme and uncontrollable circumstances policy; and update the definition of primary care services used to assign beneficiaries to the program's ACOs. CMS also solicits comments on several topics including promoting health equity within the Shared Savings Program.

a. CAHPS Survey Sampling

Beginning with performance year (PY) 2021, Shared Savings Program ACOs must report their quality data to CMS via the APP. Under the APP, ACOs must field the CAHPS for MIPS survey in place of the previously required CAHPS for ACOs survey. In response to stakeholder queries, CMS now clarifies that the CAHPS for ACOs minimum sampling thresholds will be replaced beginning with PY 2021 by those of CAHPS for MIPS. Minimum thresholds are set to ensure that survey responses accurately reflect care provided by the ACO's clinicians.

Beneficiary samples will continue to be generated at the ACO level with a target sample size of 860 patients, but minimum sampling thresholds will vary by ACO size: 416 patients for large

[68] Pub. L. 111-148, enacted March 23, 2010. Although it is an alternative payment model (APM), the Shared Savings Program is a separate legislative initiative, distinct from the models tested under the CMS Innovation Center's authority (Section 1115A of the Act).
[69] See 88 FR 25077.

ACOs (100 or more MIPS-eligible clinicians), 255 patients for medium ACOs (25-99 clinicians), and 125 patients for small ACOs (2-24 clinicians). Data analyses by CMS have suggested that very few if any ACOs will fail to meet the MIPS minimum thresholds. The agency will notify ACOs who are falling towards the minimums prior to the deadline for ACOs to contract with CAHPS survey vendors. ACOs not meeting their minimum thresholds will not be scored on the CAHPS survey measure and the absent measure will not impact final scoring. CMS also notes that for the CAHPS survey measure, the MIPS term *performance period* is interchangeable with the ACO term *performance year*, with each meaning one full CY.

b. Amended Quality Reporting under the APP

Beginning with performance year (PY) 2021, Shared Savings Program ACOs must report their quality data to CMS via the APP. For PY 2021, ACOs may choose to continue to report ten measures through the CMS Web Interface or report three specified APP measures using other submission mechanisms (e.g., submitted as electronic clinical quality measures (eCQMs)).[70] With either choice, the ACO must also field the CAHPS for MIPS survey and will be scored directly by CMS on two claims-based measures.

Beginning with PY 2022, CMS had finalized that the Web Interface would no longer be available and Shared Savings Program ACOs would be required to report under the APP using their choice of other data submission types (e.g., eCQM). CMS reports, however, that stakeholders have continued to express serious reservations to the agency, including lack of readiness among ACO clinicians and staff; health IT upgrades that are not yet completed; and insufficient time to execute revised Business Associate Agreements for HIPAA-compliant health information exchange of the all-payer data whose collection is required under the APP.

For PY 2022 and PY 2023, CMS responds to stakeholder concerns by proposing to extend until PY 2024 the time under which ACOs may continue to report quality data via the Web Interface. The proposed transition from Web Interface to APP-based reporting is outlined below.

For PY 2022 CMS proposes to require each ACO to report on either

- 10 Web Interface quality measures, or
- 3 specified APP quality measures, using a submission type other than the Web Interface.

Each ACO would also be required to field the CAHPS for MIPS survey and would be scored directly by CMS on 2 claims-based measures.

For PY 2023 CMS proposes to require each ACO to report on either

- 10 Web Interface quality measures plus 1 of the 3 specified APP quality measures, using a submission type other than the Web Interface, or
- 3 specified APP specified quality measures, using a submission type other than the Web Interface.

[70] The 3 measures are HbA1c Control, Depression Screening and Follow-up, and Control High Blood Pressure; they are also referred to by CMS in this rule as the *eCQM/MIPS CQM measures*.

All reported measures must meet data completion and case minimum requirements. Each ACO would also be required to field the CAHPS for MIPS survey and would be scored directly by CMS on 2 claims-based measures.

For PY 2022 and PY 2023, ACO quality performance scoring would depend upon the reporting option selected by the ACO. If Web Interface reporting is chosen, scoring would be based on 10 measures: 7 scored Web Interface measures,[71] CAHPS for MIPS, and 2 claims-based measures. If another quality data submission mechanism is chosen for APP reporting, scoring would be based on 6 measures: 3 specified APP measures, CAHPS for MIPS, and 2 claims-based measures. An ACO that reports using both options (Web Interface and APP via another submission method) will have two quality scores calculated and be awarded the higher of the two.

New ACOs are scored differently (pay for reporting). CMS proposes that for the first PY of its first Shared Savings Program agreement period, a new ACO must:

- *For PY 2022* – Administer CAHPS for MIPS survey, and report either 10 Web Interface measures or 3 specified APP measures through another submission mechanism
- *For PY 2023* – Administer CAHPS for MIPS and report either 10 Web Interface measures and at least 1 specified APP measure (the latter through another submission mechanism) or 3 specified APP measures through another submission mechanism
- *For PY 2024 and subsequently* – Administer CAHPS for MIPS and report 3 specified APP measures.
- *For all years* – Meet the data completion and case minimum requirements for all measures.

CMS notes that measure replacement beginning with PY 2022 is proposed later in the rule (at section IV.A.3.(c)) for the APP claims-based measure *MCC for ACOs*, to be replaced by claims-based measure *MCC for MIPS*.[72] CMS views this as an opportunity to increase alignment across the agency's quality programs (in this case between MIPS and the Shared Savings Program).

The current and the proposed amended quality reporting requirements for Shared Savings Program ACOs are summarized in the table below. As previously finalized for PY 2021, an ACO may report under option A or B. For PYs 2022 and 2023 CMS proposes ACO reporting under option A or B; for PY 2024 and subsequently, the agency proposes that ACOs must report under option B.

[71] Three Web Interface measures are not scored but must be reported; only the 7 scored measures contribute to the ACO's quality category score (along with CAHPS for MIPS and 2 claims-based measures for a total of 10).
[72] MCC: Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions

Table HPA III.J.1: Amended Shared Savings Program Quality Reporting Requirements for APM Payment Pathway Reporting Options (created by HPA from Table 40 and associated narrative section III.J. of the rule)				
	Reporting Options (A and B) by Performance Year			
Measure	**2021**	***2022 (proposed)***	***2023 (proposed)***	***2024 (proposed)***
Web Interface[a] Screening for Future Fall Risk Prevention Influenza Immunization Colorectal Cancer Screening Breast Cancer Screening Statin for Cardiovascular Disease[b] Depression Remission 12 months[b] Tobacco Screening + Cessation Rx[b]	A	A	A	No longer available
Web Interface[a] Hemoglobin A1c (HbA1c) Control Screening for Depression+ Follow up plan Controlling High Blood Pressure	A	A	A	No longer available
eCQM/MIPS CQM Hemoglobin A1c (HbA1c) Control Screening for Depression+ Follow up plan Controlling High Blood Pressure	B	B	B A – choose at least one[c]	B
CAHPS for MIPS Survey	A and B	A and B	A and B	B
Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	A and B	A and B	A and B	B
Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS[d]	A and B	A and B	A and B	B
# Measures on which Total Score is based (by option A/B)	10 A/6 B	10 A/6 B	11 A/6 B	6 B

[a] For 2021 and 2022, may be used by MIPS Groups, Virtual Groups, Shared Savings Program ACOs; for 2023, use restricted to Share Savings Program ACOs only.
[b] Reporting is required but measure is not scored.
[c] ACOs choosing to report via the Web Interface must report on one or more of these three measures. This measure result is scored and included in the Total Score.
[d] Proposed for PY 2022 to replace the similar Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs measure.

CMS notes that Shared Savings Program clinicians who do not reach Qualifying or Partial Qualifying APM Participant status (QP or Partial QP) under the Quality Payment Program (QPP) are required to report their performance data through MIPS. Those clinicians had been scored using the QPP's MIPS APM scoring standard under which the ACO's quality score also served as its clinicians' quality score. The APM scoring standard has been terminated beginning with PY 2021, and clinicians are now able to report through the APP or traditional MIPS avenues (e.g., individual, group). This change is applicable to clinicians in all Shared Savings Program tracks and levels except those who reach Partial QP or QP status for a PY; the latter are

not subject to MIPS. ACOs may report through the APP on behalf of their clinicians who are subject to MIPS. (The QPP is discussed in detail in section IV of the rule and of this summary.)

c. Amended ACO Quality Standard

Eligibility to receive shared savings is contingent upon meeting the ACO quality performance standard. The quality standard was revised for PY 2021 to align with the transition of Shared Savings Program ACOs from Web Interface reporting to reporting via the APP. In this rule CMS proposes further revisions to reflect the proposed quality reporting described above,/ including delaying adoption of a higher standard (40th percentile) until PY 2024, allowing ACOs additional time to prepare for the transition to APP reporting. To incent transition by ACOs from Web Interface to APP measure reporting, CMS proposes: 1) to apply the standard to only one (of three) specified APP measures for PYs 2022 and 2023 if all three are reported by an ACO, and 2) an ACO who fails to report on at least one specified APP measure for PY 2023 will not meet the quality standard regardless of its performance on the remaining measures. The proposed amended quality standards for Shared Savings Program ACOs are shown in the table below.

Table HPA III.J.2: Shared Savings Program Quality Reporting Standard with Timeline
(modified by HPA from Table 24 in the rule)

	PY 2021	***PY 2022 (proposed)***	***PY 2023 (proposed)***	***PY 2024 and after (proposed)***
Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th percentile** across all MIPS Quality performance category scores[a]	Same as PY 2021, **except** an ACO also meets standard if it reports all 3 specified APP measures and achieves performance score ≥ 30th percentile on at least one measure	Same as PY 2022, **except** an ACO does not meet standard if it does not report at least one of 3 specified APP measures	A quality performance score that is equivalent to or higher than the **40th percentile** across all MIPS Quality performance category scores[b]
Quality Performance Standard - Standard is Met	ACOs are eligible to share in savings at maximum sharing rate; on two-sided tracks, losses if any are reduced per track policy	Shared savings and loss determinations same as PY 2021	Shared savings and loss determinations same as PY 2021	Shared savings and loss determinations same as PY 2021

[a] For Web Interface reporters, there are 7 scored measures; for APP reporters there are 3 scored measures.
[b] Only APP reporting is permissible, under which there are 3 scored measures.

CMS seeks comment on whether the CMS Web Interface collection type should be extended for more than the proposed two years.

d. Extreme and Uncontrollable Circumstances Policy Revisions

For PY 2021, CMS finalized changes to the Shared Savings Program's Extreme and Uncontrollable Circumstances policy to align with revisions being made to the program's quality performance standard and to support the transition from Web Interface to APP-based reporting.

In this rule, CMS proposes further changes, described below, to align the policy with the proposed delay until PY 2024 of the increase of the quality performance standard threshold (from the 30th to the 40th percentile of MIPS Quality performance category scores). Also proposed are conforming changes at §425.512(b).

For PY 2023: CMS proposes to set the minimum quality performance score for an affected ACO to equal the 30th percentile MIPS Quality performance category score for 2023 after excluding entities/providers eligible for facility-based scoring. If the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, CMS would award the higher of the ACO's reported quality score or the equivalent of the 30th percentile MIPS Quality performance category score. ACOs unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements would receive the minimum score (30th percentile). Affected ACOs would be eligible for shared savings at the maximum rate or mitigation of shared losses per the provisions of their respective ACO tracks and levels.

For PY 2024 and subsequently: As proposed for PY 2023, except replacing the 30th percentile with the 40th percentile.

CMS seeks comments on the proposed policy revisions and timelines.

e. Requests for Comments

Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity

CMS is seeking comments and recommendations regarding:

- How can ACOs utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location and/or income status, have access to equal care?
- How can ACOs improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare?
- How can CMS encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives?
    - Should adjustments be made to quality measure benchmarks to take into account ACOs serving vulnerable populations?

CMS states its belief that the ongoing transition of the Shared Savings Program from Web Interface to APP quality measure reporting will help to address health disparities and promote health equity. Web Interface measures are designed for use in Medicare's Shared Savings Program and reflective only of care delivered to the program's assigned beneficiaries, while APP measures must be reported for all patients treated by each ACO's clinicians regardless of payer. The program's evolving APP quality reporting requirements will hold ACO clinicians to a single set of standards for all patients they treat.

Solicitation of Comments on Feasibility of TIN Level Reporting and Sampling for eCQMs/MIPS CQMs

CMS is seeking comment on allowing ACO providers/suppliers to submit eCQMs/MIPS CQM measures to CMS at the ACO participant TIN level from which CMS would calculate an ACO-level score from the aggregate data. CMS offers two alternative approaches for comment and requests suggestions for other approaches.

- Approach 1: CMS would calculate the average decile score for each measure for each TIN within an ACO.
- Approach 2: CMS would calculate an ACO-level numerator (sum of performance met across TINs within the ACO) and divide by an ACO-level denominator (sum of the met and performance not met across all TINs within the ACO) to derive an ACO-level rate.

CMS states that the potentially large quality measure denominator of all patients treated by an ACO's clinicians could be an impediment to all-payer patient inclusion and seeks comment on how the agency might determine appropriate beneficiary populations for individual measures.

- Should CMS develop ACO-level eCQM/MIPS CQM measure sampling specifications? Create one or more specific methodologies for ACO sampling?
    - If yes, should the agency develop one or more phase-in implementation strategies? Tiered implementation strategies?

Comment Solicitation for Reporting Options for Specialist Providers within an ACO

In response to stakeholder concerns that the APP's quality measures are focused on population health and primary care, rendering the measures inapplicable to an ACO's specialist clinicians, CMS is seeking comment on:

- Allowing an ACO's participant TINs to report either the APP's eCQMs/CQMs or MVPs applicable to their specialists; and
- Roles played by ACO specialists;
    - Specialty measures suitable for future inclusion in the Shared Savings Program's measure set;
    - Modifications of the current APP measure set that reinforce specialist roles in population health strategies.

Comment Solicitation on Publicly Displaying Prior Year Performance Scores

CMS seeks comment about the utility of public displayed prior year MIPS Quality category performance scores for use by Shared Savings Program ACOs to estimate the performance levels needed to be eligible for sharing savings (and mitigation of shared losses). CMS gives some examples of 2018 and 2019 MIPS percentile scores and asks for other ways stakeholder concerns could be answered.

The program's proposed amended quality standard requires performance at the equivalent of the 30th or 40th percentile of the MIPS scores for shared savings eligibility. MIPS Quality category scores are calculated based on the actual performance year period and so percentile distributions are not available until after each PY ends. Stakeholders want to have performance level

information prior to the start of a PY in order to monitor their quality improvement efforts and outcomes during the year and make adjustments as needed to meet the shared savings threshold. (See Table 24 in the rule and Table III.J.2 above in this summary, and their preceding narratives, for discussion of the proposed amended standard.)

2. Revisions to the Definition of Primary Care Services used in Shared Savings Program Beneficiary Assignment

a. Background

CMS reviews the evolution of beneficiary assignment to ACOs, beginning with the November 2011 rule in which assignment based upon primary care services delivered was established and the initial list of primary care services adopted for that purpose (76 FR 67853). Periodic updates of the list have been made to reflect changing service codes (e.g., addition of chronic care management services) and approaches to beneficiary assignment (e.g., addition of voluntary assignment). The most recent changes have involved responses to COVID-19 PHE impacts (e.g., shift to non-face-to-face services and to telehealth) and expanded E/M services (e.g., non-complex chronic care management).

b. Primary Care Service List Updates Beginning with PY 2022

CMS proposes updates to the list of primary service codes to be used beginning with PY 2022 for beneficiary assignment to Shared Savings Program ACOs; changes to the applicable dates for use of telephone evaluation and management (E/M) for assignment; and a policy for expedited adoption of replacement service codes. For assignment purposes, CMS uses both CPT codes and G-codes.[73]

The finalized list for *PY 2021* is shown below as CPT and HCPCS G-codes with brief descriptors; services new for PY 2021 are indicated by asterisks (*).

CPT Codes:

- 96160 and 96161 (administration of health risk assessment).
- 99201 through 99215 (office or other outpatient visit for the evaluation and management of a patient).
- 99304 through 99318 (professional services furnished in a nursing facility; services identified by these codes if furnished in a skilled nursing facility are excluded).
- 99319 through 99340 (patient domiciliary, rest home, or custodial care visit).
- 99341 through 99350 (E/M services furnished in a patients' home for claims identified by place of service modifier 12).
- 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).

[73] Current Procedural Terminology (CPT) codes are maintained by the American Medical Association (© American Medical Association, used by CMS with permission). Healthcare Common Procedure Coding System (HCPCS) G-codes are maintained CMS.

- 99421 through 99423 (online digital E/M).*
- 99439 (non-complex chronic care management).*
- 99483 (assessment and care planning for patients with cognitive impairment).*
- 99484, 99492, 99493 and 99494 (behavioral health integration services).
- 99487, 99489, 99490, *99491** (chronic care management services).
- 99495 and 99496 (transitional care management services).
- 99497 and 99498 (advance care planning; *excluded when provided in inpatient settings**).

HCPCS codes:

- G0402 (Welcome to Medicare visit).
- G0438 and G0439 (annual wellness visits).
- G0442 (alcohol misuse screening service).
- G0443 (alcohol misuse counseling service).
- G0444 (annual depression screening service).
- G0463 (services furnished in Electing Teaching Amendment hospitals).
- G0506 (chronic care management).
- G2010 (remote evaluation of patient video/images).*
- G2012 (virtual check-in, 5-10 minutes).*
- G2058 (non-complex chronic care management).*
- G2064 and G2065 (principal care management services).*
- G2214 (Psychiatric collaborative care model).*

CMS proposes to add for *PY 2022* the following services and provides rationales for the additions. Conforming changes would be made to §425.400(c)(1)(v).

CPT codes

- 99X21 (add-on code for chronic care management beyond the typical service time of the primary procedure; when the base code is also a primary care service code).
    - Companion code to existing 99487, 99489, 99490, and 99491 series for chronic care management.
- 99X22 through 99X25 (principal care management)
    - New codes for principal care management by physician or by clinical staff under physician supervision; replace and further define G2064 and G2065.

G-codes

- G2212 (prolonged office or other outpatient E/M)
    - For Medicare patient billing in place of CPT 99417.
- G2252 (virtual check-in, 11-20 minutes; if payment is made permanent through CY 2022 PFS rulemaking).
    - Provides for longer service than G2012.

Extended Applicability of Primary Care Services for the COVID-19 PHE

For 2021, CMS updated the status of G2010, G2012, and CPT codes 99421 through 99243 as permanent additions to the assignment list instead of being limited to the duration of the PHE. At that time, CMS did not extend CPT codes 99441 through 99443 (telephone E/M) for use beyond the PHE. The agency now proposes to extend the duration of use of the telephone E/M codes for beneficiary assignment until utilization analyses can be conducted and a decision reached about permanently adding these formerly non-covered services as covered services to the Medicare telehealth list. CMS accomplishes the extended duration by revising §425.400(c)(2)(i)(A)(2) to specify that the telephone codes will continue to be used for beneficiary assignment until they are determined to no longer be payable under Medicare FFS telehealth policies.

Expediting Incorporation of Replacement Codes into the Beneficiary Assignment List

CMS notes that G-codes are often replaced by CPT codes for the same or similar services that a gap may occur between the time the CPT code becomes available and the effective date of the final rule in which the replacement CPT code is incorporated into the assignment list. To shorten the gap, CMS proposes that the assignment list would include any CPT code that directly replaces a CPT or G-code already on the list, whenever a benchmark or performance year's assignment window includes any day on or after the effective date of the replacement code for Medicare payment. This change is proposed for PY 2022 and subsequent years; the determination that a new CPT or G-code is a replacement code would be made by CMS. The permanent beneficiary assignment primary care services list would be amended with the expedited, incorporated, replacement codes during the next PFS annual rulemaking cycle.

3. Repayment Mechanisms

a. Background

An ACO participating in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in §425.204(f), and through additional program guidance. CMS established the repayment mechanism requirements through earlier rulemaking, and most recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938).

Based on operational experience, CMS has found that the repayment mechanism amounts for most ACOs are much larger than needed to cover actual losses. For example, some ACOs have been required to establish repayment mechanisms with amounts that are 9 times greater than their shared losses. In addition, of the 35 times that ACOs have owed shared losses, only one ACO has neglected to repay. CMS discusses four proposed changes regarding required repayment mechanism amounts in this section. This includes a proposal to

- Modify the methodology for calculating repayment mechanism amounts to reduce the required amounts;

- Specify how CMS identifies the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation;
- Permit eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to reduce the amount of their existing repayment mechanisms if their recalculated repayment mechanism amount for performance year 2022 is lower than their existing repayment mechanism amount; and
- Modify the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its ACO's agreement period.

b. Proposed Revisions

(1) Repayment Mechanism Amount Calculation

CMS is considering two options for modifying the calculation of repayment mechanism amounts to result in lower amounts: (1) reducing the percentages used in the existing repayment mechanism amount calculations (as specified in §425.204(f)(4)(ii)); or (2) revising the methodology to use a per beneficiary dollar amount estimation methodology.

CMS proposes the first option which would lower the repayment mechanism amounts by reducing the percentages used in its current methodology. Specifically, CMS proposes to calculate the amount as the lesser of the following: (1) one-half (0.5) percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.[74] Under this proposal, ACOs would receive a 50 percent decrease in their repayment mechanism amounts compared to the current methodology. CMS' review of its data indicates that if this repayment mechanism were in place for PY 2021, the mean repayment mechanism savings would be $297,665 for low revenue ACOs and $2.31 million for high revenue ACOs.

The alternative approach CMS considered would be to estimate the repayment mechanism amount using a per beneficiary dollar amount that would be multiplied by an estimate of the size of the ACO's assigned population. To calculate a per beneficiary amount, CMS analyzed data from the 35 instances where ACOs in two-sided models incurred shared losses. CMS determined that median per beneficiary shared losses were $100.90 and calculated per beneficiary dollar amounts projected to cover 5 to 25 percent of shared losses for ACOs (e.g., $5.05 for 5 percent and $35.23 for 25 percent). CMS notes that it would support using separate per beneficiary dollar amounts for low and high revenue ACOs. It believes that high revenue ACOs are typically larger and better capitalized than low revenue ACOs. CMS' review of its data indicates that if this repayment mechanism were in place for PY 2021, the mean repayment mechanism savings would be $410,682 for low revenue ACOs and $3.84 million for high revenue ACOs.

[74] This would revise the regulations in §425.204(f)(4)(ii), §425.204(f)(4)(ii)(A), and §425.204(f)(4)(ii)(B).

CMS discusses the advantages and disadvantages of the alternative approach. It finds aspects of the alternative approach favorable because it offers low revenue ACOs additional relief, aligns with the existing repayment mechanism amount calculation, uses a simpler method to calculate the repayment amount, and lowers the mean repayment mechanism amount more than under the CMS proposal to lower the percentages used in the existing calculating methodology. CMS also has several significant concerns including that there would be a significant repayment amount difference for ACOs near the 35 percent threshold that differentiates low and high revenue ACOs and the determination of whether an ACO is low or high revenue may change during the application cycle or between performance years. It also considered using a single per beneficiary dollar amount for all ACOs, but was unable to identify an amount that would account for historically higher per beneficiary shared losses owed by high revenue ACOs, while resulting in lower repayment amounts for low revenue ACOs compared to the existing approach.

CMS notes that these modifications would be effective and applicable on January 1, 2022, and that it would communicate to ACOs their final repayment mechanism amounts after the issuance of the final rule. This is important to align with the application cycle for new, renewing, and re-entering ACOs and the change request cycle.

CMS seeks comments on its proposal and its alternative approach for calculating repayment mechanism amounts. It also seeks comments on applying different per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs and the per beneficiary dollar amounts that would be appropriate. CMS also invites comments about whether a single per beneficiary dollar amount would work and how frequently the amount should be updated.

(2) Repayment Mechanism Amount Calculation

CMS proposes to modify the methodology for the annual repayment mechanism amount recalculation to more clearly specify the assigned population used as a multiplier in calculating the repayment mechanism amount. It further proposes to determine the size of the ACO's assigned population based on the number of beneficiaries assigned to the ACO at the beginning of the performance year.[75] This population of assigned beneficiaries is specified in the ACO's initial assignment list report for the performance year. For all ACOs, this population is identified based on an assignment window that is offset from the calendar year (that is, from October 1 through September 30 prior to the start of the performance year), and which is the basis for determining prospective assignment for the performance year. CMS would no longer be using an assignment growth factor as a multiplier for the population size since it would no longer be using historical data. Under this proposed approach, CMS will perform the recalculation of the repayment mechanism once the initial assignment list report is available, which is typically delivered to ACOs in the early winter (around mid-December), prior to the start of the relevant future performance year. CMS proposes that these modifications would be effective and applicable on January 1, 2022.

[75] This would revise the regulations at §425.204(f)(4)(ii), §425.204(f)(4)(ii)(A), and §425.204(f)(4)(ii)(B). CMS also proposes technical and conforming changes to §425.204(f)(4)(iii).

CMS provides illustrative examples in the proposed rule that describe the calculation and recalculation of the repayment mechanism amounts under the proposal (pages 501-504 of the display copy). The number of assigned beneficiaries is used as a multiplier in step 3 of 4 in the expenditure-based amount and revenue-based amount calculations.

(3) Optional One-time Repayment Mechanism Decrease for Eligible ACOs

CMS proposes to allow certain ACOs (i.e., those already in two-sided participation agreements) a one-time opportunity to decrease the amount of their repayment mechanism. Specifically, CMS proposes to amend §425.204 to add paragraph (f)(4)(v) to establish the policy and relevant procedure that would allow eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to lower the amount of their repayment mechanism arrangements. This allows any ACO that established a repayment mechanism to support its participation in a two-sided model an opportunity to reduce its repayment mechanism.

Under this proposal, CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. It anticipates that this would occur after the start of performance year 2022 and that any such election would have to follow the documentation, in a form and manner, and by a deadline specified by CMS. It anticipates that the deadline would be 30 days from the date of the written notice from CMS.

(4) Threshold for Increasing Repayment Mechanism Amounts

To avoid burdensome repayment mechanism modifications for relatively small dollar amounts, CMS proposes to amend the regulations at §425.204(f)(4)(iii)(A) to remove the 50 percent threshold from the annual repayment mechanism increase threshold, such that if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, CMS would notify the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. It anticipates that this approach would reduce the number of ACOs required to annually increase their repayment mechanism amounts and would further simplify the repayment mechanism amount calculations. It also believes that this would reduce the burden on low revenue ACOs (i.e., the ones most affected by the 50 percent threshold).

CMS proposes that this modification would be effective and applicable on January 1, 2022. If finalized as proposed, the revised threshold would be used in determining required repayment mechanism increases for performance year 2022, and subsequent performance years.

4. Reducing Shared Savings Program Application Burden

To participate in the Shared Savings Program, a prospective ACO must submit an application and certify that it satisfies the eligibility and other requirements, including regulatory requirements to disclose prior participation. In conducting application reviews, CMS has found that the document submission requirements substantially increase applicant burden without lending significant value to review of an organization's application to confirm that the ACO

meets the eligibility requirements for participation. CMS proposes to revise three provisions at §§425.204(b) and (c)(6), and §425.116(c).

First, CMS proposes to modify §425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS during the application process—rather than as a mandatory submission with the ACO's initial or renewal application. CMS notes that during the application cycle and for purposes of evaluating program eligibility, CMS already determines prior participation for initial and re-entering ACO applicants by reviewing ACO- and ACO participant-level information. Under this proposal, CMS would continue review of an ACO's history of compliance with the Shared Savings Program regulations and the ACO's quality and financial performance results in accordance with §425.224(b), at CMS' request.

Second, CMS proposes to modify §425.204(c)(6) to remove provisions requiring an ACO to submit sample ACO participant agreements during the application process. Under this proposal, sample ACO participant agreements and the first and signature pages of each executed ACO participant agreement would need to be submitted during the application process only if requested by CMS, rather than as a mandatory submission with the ACO's initial or renewal application. CMS notes that it is ultimately the ACO's responsibility to ensure that all its ACO participant agreements comply with the Shared Savings Program requirement. The ACO must still certify that all its ACO participant agreements comply with the regulatory requirements of the Shared Savings Program. CMS would retain the discretion to request ACO participant agreement documentation at any time during an agreement period.

Third, CMS proposes to modify §425.116(c) to remove provisions requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application or participation agreement renewal process. It would retain the requirement that an ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants. CMS also notes that although ACOs may request additions to an ACO participant list at specified times during the performance year, all approved ACO participant list additions become effective on January 1 of the following performance year.

CMS believes these three proposals will collectively reduce the administrative and programmatic burden for ACOs significantly without sacrificing program integrity and reinforce that ACOs are responsible for ensuring their ACO participant agreements meet the necessary requirements.

5. Beneficiary Information Notice for ACOs with Prospective Assignment

After consideration of the beneficiary notice requirement, CMS concluded that the current requirement to provide beneficiary notifications prior to or at the first primary care visit of the performance year is overly broad with respect to ACOs that have selected the prospective assignment methodology. Such ACOs are currently required to provide the beneficiary notice to beneficiaries who will never be assigned to the ACO for the performance year. This can also cause unnecessary confusion for beneficiaries because the notice describes details that will not apply to them (for example, information on data sharing and the SNF 3-day rule waiver).
In contrast, for ACOs under preliminarily prospective assignment with retrospective reconciliation, the preliminary prospective assignment list provided to the ACO at the beginning

of the performance year does not include all FFS beneficiaries who may ultimately be assigned to the ACO. As such, CMS continues to believe all FFS beneficiaries receiving primary care services from ACO providers and/or suppliers should receive the notice. This ensures that all beneficiaries ultimately assigned to the ACO would be informed of their right to decline data sharing.

Thus, CMS proposes to amend §425.312(a)(2) to set forth different beneficiary notification obligations depending on the assignment methodology selected by the ACO. Specifically, CMS proposes at §425.312(a)(2)(ii) to provide that, in the case of an ACO that has selected preliminary prospective assignment, the ACO or ACO participant must provide the standardized written beneficiary notice to each FFS beneficiary prior to or at the first primary care visit of the performance year. CMS also proposes to add at §425.312(a)(2)(iii) that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year.

CMS seeks comment from stakeholders on whether it should modify the frequency with which the beneficiary information notice must be furnished, for example, by reducing the frequency of the existing requirement from annually to once per agreement period. CMS has received feedback from program stakeholders that the current annual requirement is too frequent, potentially confusing beneficiaries, and increasing burden on ACOs. On the other hand, CMS expresses a concern that reducing the frequency to once per agreement period may ultimately be too infrequent, given the many changes a beneficiary may experience with their health and life in general in that span of time.

6. Seeking Comment on Considerations Related to the Use of Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACOs' Historical Benchmark.

a. Request for Comment on Calculation of the Regional Adjustment and Blended National-Regional Growth Rates for Trending and Updating the Benchmark

In calculating the historical benchmark for ACOs participating in the Shared Savings Program, CMS uses historical expenditures for the ACO's assigned beneficiaries, as well as factors based on regional FFS expenditures, national FFS expenditures, and a blend of national and regional FFS expenditures.[76] CMS believes incorporating regional expenditures into benchmark calculations makes the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region (see for example, 81 FR 37950, 37951 and 37955).

In determining regional FFS expenditures, CMS uses average county FFS expenditures for assignable beneficiaries, including the ACO's assigned beneficiaries, in each county in the ACO's regional service area for the 12-month calendar year corresponding to the relevant benchmark or performance year. CMS weights these county-level FFS expenditure amounts by

[76] Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program.

the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type.[77]

ACOs and other program stakeholders have expressed concerns with the approach to determining regional FFS expenditures using a population of assignable beneficiaries that includes the ACO's assigned beneficiaries. In areas where an ACO has high market penetration in their regional service area, as the ACO reduces the costs of its own assigned beneficiaries it also reduces the average regional costs. This could result in reducing savings for efficient ACOs and could potentially be more problematic in rural areas where ACOs may care for a greater portion of their region's total beneficiary population than an urban ACO. Stakeholders have suggested that CMS exclude an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures.

CMS puts forth a suggested approach that it states would pose relatively limited operational burden and would leverage data elements already computed under the current benchmarking methodology. This approach relies on the premise that per capita risk-adjusted regional FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk-adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk-adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share and the weight on (c) is one minus the ACO's regional market share.

Shown as an equation this is:

(a) = [(b) x (ACO's regional market share)] + [(c) x (1 – ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, CMS inserts the applicable values into the above equation and solves for (c) by rearranging the equation as follows:

(c) = {(a) – [(b) x (ACO's regional market share)]} / (1 – ACO's regional market share).

CMS states that this approach, using such ACO- and regional-level values and performed separately by Medicare enrollment type, would avoid the need to calculate individualized ACO county-level risk-adjusted expenditures.

During simulated use of this approach, CMS found that the estimated average increase in the updated benchmark by quintile ranged from 0.1 percent to 1.4 percent. ACOs with higher market shares tended to see slightly higher average increases than ACOs with lower market shares, and rural ACOs saw slightly higher average increases than non-rural ACOs. Some ACOs experienced decreases in their benchmarking amounts, ranging from -0.2 percent to -1.5 percent.

[77] See §425.601(c) (calculating county expenditures) and (d) (calculating regional expenditures).

CMS seeks comment on several issues related to the use of regional FFS expenditures in benchmarks.

- CMS' approach or alternative approaches to calculating regional FFS expenditures without including an ACO's assigned beneficiaries. It is looking for specific approaches that balance achieving the desired outcome of removing the ACO's assigned beneficiaries from program calculations and can be understood by ACOs without adding too much complexity and minimizing the potential for calculation errors.
- Whether market penetration should be considered in benchmark calculations and what constitutes heavy penetration in the ACO's regional service area.
- Possible unintended consequences that could result from removing an individual ACO's assigned beneficiaries from regional calculations. For example, could this lead to ACOs seeking out healthier beneficiaries and avoiding at-risk or higher-cost beneficiaries, incent the formation of large ACOs, or create instability in regional FFS expenditures from removal of an individual ACO's assigned beneficiaries.
- Whether removal of an ACO's assigned beneficiaries from regional FFS calculations brings about a need to remove ACO assigned beneficiaries from other Shared Savings Program financial calculations.
- Other approaches to calculating benchmarks that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure calculations, such as basing these expenditures on a larger geographic area, including using state-level data, Core-Based Statistical Area, or some other combination.

CMS notes that for each calendar year it releases two public use files that could be helpful to inform these issues: (1) County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries PUF, and (2) Number of ACO Assigned Beneficiaries by County PUF. These files are available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/SSP_Benchmark

b. Request for Comment on the Shared Savings Program's Risk Adjustment Methodology

In its risk adjustment methodology, CMS takes into account changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark and when adjusting the benchmark each performance year. CMS makes separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). CMS uses CMS-HCC prospective risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period. This cap is the maximum increase in risk scores allowed for each agreement period, such that any positive adjustments between Benchmark Year (BY) 3 and any performance year in the agreement period cannot be larger than 3 percent.

ACOs and other stakeholders have expressed concerns that the program's methodology for capping any increase in the risk adjustment to the historical benchmark does not account for risk score growth in the ACO's regional service area, and thereby penalizes ACOs.

CMS seeks comment on the following issues:

- Approaches, generally, to improving the risk adjustment methodology and specifically for ACOs with medically-complex, high-cost beneficiaries.
- Approaches to risk adjustment that would balance the need for accurate and complete coding, while protecting against incentivizing coding intensity initiatives by ACO participants and ACO providers/suppliers.
- Alternate approaches that would increase the cap on an ACO's risk score growth in relation to risk score growth in the ACO's regional service area, such as:
    - Allowing the ACO risk score growth cap to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area.[78]
    - Setting the ACO risk score growth cap at some level between the existing 3 percent risk score cap and the regional risk score growth, which would account for a portion of the regional risk score growth that exceeds the current cap.
- Potential interactions between policies to remove assigned beneficiaries from the assignable beneficiary population used to calculate regional FFS expenditures and growth rates, and policies addressing regional risk score growth.

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

1. Background on Ground Ambulance Data Collection

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 to CMS. The Secretary was required to specify the data collection system by December 31, 2019, and to identify a random sample of providers and suppliers that would be required to submit information. Beginning January 1, 2022, the Secretary is required to apply a 10 percent penalty to a ground ambulance organization's payment for failure to sufficiently submit data.

Table 27 from the proposed rule reproduced below provides an overview of the elements of the data collection instrument.

Table 27: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
General survey instructions (1)	Information on background and motivation for data collection, instructions for navigating the instrument, and links for questions and other resources.
Ground ambulance organization characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other

[78] In this alternate approach, the percentage applied would be equal to 1 minus the ACO's regional market share. CMS states this alternative approach would raise the existing cap while limiting the ability for ACOs with high penetration in their region to increase their cap by engaging in coding intensity initiatives that raise the regional risk score.

Table 27: Components for the Data Collection Instrument	
Component (Data Collection Instrument Section)	**Broad Description**
	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)	Hours and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; annual cost of ownership, insurance, maintenance, and utilities.
• Vehicles (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual cost of ownership; total fuel, maintenance, and insurance.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (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.

CMS is proposing changes and clarifications to the survey instrument based on questions it has received from the public.

2. Proposed Revisions to the Medicare Ground Ambulance Data Collection Instrument

a. Shared Services

Section 2, questions 7-9 are designed for the respondent to describe their ground ambulance operation and whether operational costs are shared with another entity or other operations (e.g., a provider-based ambulance may share costs with a hospital). Question 9 asks the respondent to select "one of the following" for the type of operation with whom costs are shared and lists six choices. Respondents indicate that multiple selections may be relevant. CMS proposes to revise the question to allow the respondent to select multiple other organizations or operations rather than a single one.

b. Average Trip Time

Questions 3 and 6 ask ground ambulance organizations to report their "average trip time" defined as "the time the ambulance leaves the station to when that ambulance is available to take another call." Based on the literal wording of the question, it is not clear whether and if so, how ground ambulance organizations should report trip times for responses not originating at a station. CMS proposes to revise "average trip time" as "the time an ambulance begins its response to the time when the ambulance is available to respond to another call (that is, time on task)."

c. Secondary Service Area

Section 3, question 4 instructions define the secondary service area for an organization as "outside [its] primary service area, but one where [it] regularly provide[s] services through mutual or auto-aid arrangements. The instruction directs organizations to "not include areas where [they] provide services only under exceptional circumstances." Some ground ambulance organizations are unsure how to report areas where they (a) did have mutual or auto-aid arrangements in place but where (b) they responded to calls only very rarely. CMS proposes changes to the text of the question to make clear that the respondent can use judgment to determine whether the organization regularly serves a secondary service area.

d. 90th Percentile Emergency Response Time

Section 4, question 3 asks ground ambulance organizations to report the 90th percentile emergency response time, which the question defines as the time separating the quickest 90 percent of responses from the longest 10 percent of responses. The goal of the question is to understand whether the organization has some response times that are much longer than its typical response time. Several ground ambulance organizations are misinterpreting this question. CMS proposes to revise the question to ask: "what is your best estimate of the share of responses (enter percentage) that take more than twice as long as the average response time as reported in the prior question?"

e. Reporting Paid Ambulance Transports

CMS proposes to revise questions in section 5 to clarify that its interest is in the number of transports furnished during the data collection period that were paid either by a patient or 3rd party. Respondents are not being asked to report transports that occurred in a prior period that were paid during the data collection period.

f. Labor Hours

The instructions in section 7 were intended to identify staff hours worked on ground ambulance operations versus other activities but respondents are misinterpreting "unrelated" to mean "related" hours. The absence of total hours may be contributing to this misinterpretation. CMS proposes to change the instructions in section 7 to ask respondents to report hours worked on different activities in such a way that the sum of hours worked across different activities equals total hours worked annually.

g. Facility, Vehicle, and Equipment Expenses

The purpose of sections 8 (Facilities Costs), 9 (Vehicles Costs), and 10 (Equipment, Consumable, and Supply Costs) is to collect total expenses during the data collection period related to facilities, vehicles, and equipment and supplies, respectively. Respondents that do not currently depreciate facilities, vehicles, and/or equipment for accounting purposes report that they are unsure where to report some components of total expenses in these categories.

CMS proposes to add screening questions asking individually whether the organization depreciates facilities, vehicles, and equipment. Further, CMS proposes to add new columns to the survey for facilities and vehicles purchased outright during the data collection period for organizations that do not depreciate these expenses. In addition, CMS proposes to change the instructions to refer to broad types of equipment that are typically considered capital medical and non-medical equipment. Respondents will then be asked to report relevant annual expenses for qualifying equipment, regardless of whether the expenses are annual depreciation expenses or purchase costs (for organizations not calculating depreciation).

h. National Provider Identifier's (NPIs) Under Broader Parent Organizations

Some ground ambulance NPIs are part of broader parent organization companies that own and/or operate multiple ground ambulance NPIs. Section 2, question 2 asks, "Did your organization use more than one NPI to bill Medicare for ground ambulance services during the data collection period?" This question has confused some respondents who are unsure whether the survey responses are for just the NPI surveyed or the entire organization. CMS is proposing to clarify that it is requesting an allocated share of parent organization expenses for each NPI surveyed in each section of the instrument where this issue is relevant.

i. Other Clarifications

CMS is making 11 other minor clarifications and updates to the instrument. Of these, the most significant are:

- Section 5, question 3a. This question asks respondents to report the percentage of ground ambulance responses that involve a non-transporting agency and the percentage of ground ambulance transports in which the non-transporting agency continues to provide medical care in the ambulance during a transport. CMS acknowledges that this data is hard to collect and is clarifying that estimated percentages are acceptable.
- Section 13, question 3. Organizations may report revenue from specific payers that include patient cost-sharing amounts. To ensure patient cost-sharing is not reported twice, CMS is clarifying patient self-pay amounts are only reported if not previously reported.

3. Collection and Reporting of Information under the Data Collection System

In the 2020 PFS final rule (84 FR 62893), CMS finalized a policy to select a 25 percent stratified sample in each of the first four years of data collection. The data collection period was finalized as a continuous 12-month period, which is either the calendar year aligning with the data collection year, or the organization's annual accounting period. The collection period would be selected by the sampled ambulance organization. Organizations are required to report data during a 5-month data reporting period starting immediately following the end of the data collection period.

CMS originally required ground ambulance organizations to collect data between:

- January 1, 2020 and December 31, 2020 (year 1);

- January 1, 2021 and December 31, 2021 (year 2);
- January 1, 2022 and December 31, 2022 (year 3);
- January 1, 2023 and December 31, 2023 (year 4)

Due to the PHE, CMS delayed year 1 and year 2 reporting until 2023. As a result, ground ambulance organizations selected in year 1, 2, and 3 will have the same data collection periods beginning between January 1, 2022 and December 31, 2022.

Prior to the delay, CMS anticipated approximately equal shares of ground ambulance organizations (25 percent) would collect and report data in four consecutive periods. However, as a result of the delays, there will now be approximately 75 percent of the ground ambulance organizations that will have data collection periods in the same year and 25 percent one year later.

CMS is proposing to revise the data collection period for year 3 sampled ambulance organizations to be between January 1, 2023 and December 31, 2023. This timeline would align with the data collection period and data reporting period requirements for selected ground ambulance organizations in year 4.

As a result, there would be approximately 50 percent of ground ambulance organizations selected in year 1 and 2 with data reporting periods beginning between January 1, 2022 and December 31, 2022 and approximately 50 percent of ground ambulance organizations selected in year 3 and 4 with data reporting periods beginning between January 1, 2023 and December 31, 2023. This proposal will allow data to be collected for multiple years after PHE from 50 percent of ambulance organizations in each year without further additional delays in providing ambulance data to MedPAC for its report to Congress, which is required by March 15, 2023.

4. Notification Process for Selected Ground Ambulance Organizations Required to Report

CMS' regulations require that it notify an eligible ground ambulance organization that it has been selected to report data for a year at least 30 days prior to the beginning of the calendar year. Within 30 days being notified, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date to its MAC. CMS is proposing that the selected ground ambulance organization provide the start date of the data collection period to CMS or its contractor instead of the MAC. This change will provide CMS with flexibility to have the MACs or other contracted entities provide written notifications and collect information from the selected ground ambulance organizations. If CMS finds the response rate is low, having the flexibility to contract with other entities that could employ additional outreach resources may be useful.

5. Payment Reduction for Failure to Report

As a result of the collection and reporting delays due to the PHE, CMS is clarifying the timing of when a penalty would apply to an ambulance organization for failure to report information required by the survey. As previously indicated, the penalty will apply if data is not reported

within 3 months after the end of the data reporting period. For example, if a selected ground ambulance organization's data collection period is based on a calendar year, that is, January 1, 2022 through December 31, 2022, CMS will allow a ground ambulance organization 5 months to report the data collected during the data collection period. The data reporting period for this organization is January 1, 2023 – May 31, 2023. The organization would be subject to the 10 percent payment reduction for the following calendar year if data is not reported by August 31, 2023.

6. Public Availability of Data

Due to the PHE, CMS is proposing to modify the date when data collected from the surveys will be publicly available. Instead of data being publicly available in 2022, it would now be publicly available in 2024.

L. Medicare Diabetes Prevention Program (MDPP)

The Medicare Diabetes Prevention Program (MDPP) expanded model is a structured intervention that aims to prevent or delay the onset of type 2 diabetes among eligible Medicare beneficiaries diagnosed with pre-diabetes. MDPP services are furnished in community and health settings by organizations that enroll as a new supplier type, MDPP supplier. MDPP services furnished under this model are covered as a preventive service with no cost-sharing under Medicare.

To increase beneficiary participation and access these services, CMS proposes changes to the MDPP to facilitate provider enrollment. CMS notes that more than 1,000 organizations nationally are eligible to become MDPP suppliers however, only 27 percent of eligible organizations are participating in the MDPP. An analysis of the National Health and Nutrition Examination Survey (NHANES),[79] estimates 16.4 million people are eligible for MDPP; to date, approximately 2,600 beneficiaries are participating in the MDPP expanded model.

CMS does not anticipate these proposals would impact its ability to complete an evaluation of the MDPP expanded model; the evaluation would incorporate any finalized changes. CMS anticipates these proposals would result in more MDPP suppliers, increased beneficiary access to MDPP services and a reduction in the incidence of diabetes in eligible Medicare beneficiaries in both urban and rural communities.

1. Proposed Changes to the Ongoing Maintenance Session (§ 410.79(b), (c), and (e))

CMS discusses challenges recruiting suppliers to participate in the MDPP expanded model, including the length of the set of MDPP services and the payment timing. MDPP suppliers are required to offer up to 2 years of MDPP services (§ 410.79(b)). Unlike the 12-month CDC National Diabetes Prevention Program (National DPP), MDPP suppliers are required to offer up to 2 years of MDPP services to eligible MDPP beneficiaries. CMS notes that based on analysis of FFS claims approximately 10 percent of MDPP beneficiaries continue with the ongoing

[79] Lee AK., Warren B, Liu C, Foti K, Selvin E. (2019) Number and Characteristics of US Adults Meeting Prediabetes Criteria for Diabetes Prevention Programs: NHANES 2007-2916, J Gen Intern Med 34(8):1400-2.

maintenance sessions phase and the majority of MDPP beneficiaries achieve the 5 percent weight loss milestone within the first 6 months of the program.

CMS proposes to amend § 410.79(c)(1)(ii) to preclude coverage of ongoing maintenance sessions unless the MDPP beneficiary has started their first core session on or before December 31, 2021. This proposal would make the MDPP timeframe consistent with the National DPP for MDPP service periods that begin on or after January 1, 2022.

In conjunction with the proposed change to shorten the MDPP program to 12-months, CMS proposes to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance sessions provided. CMS proposes to increase performance payments for MDPP beneficiaries achievement of the 5 percent weight loss goal, as well as continued attendance during each core maintenance interval.

CMS proposes a maximum performance payment of $661.00. CMS notes that this proposed payment is less than the current maximum payment of $704.00 under the 2-year payment structure, but it believes this proposed payment would have a net positive effect on MDPP suppliers. In addition, this proposed payment is more than the 2021 National Average Facility Payment of $528.00 for the face-to-face intensive behavior counseling for obesity (IBT-Obesity) for individuals.[80] The Office of the Actuary estimated that the average payment for an MDPP supplier would increase by $100 with the elimination of the second year of MDPP.

Table 28 in the rule, shows the current 2021 non-cumulative performance payments and the proposed performance payments for MDPP beneficiaries who started their first core services on or after January 1, 2022. CMS notes it is not proposing to change the payment rates for ongoing maintenance sessions in cases where a beneficiary remains eligible for them; CMS proposes to maintain those payment rates until ongoing maintenance sessions are phased out.

CMS proposes a change to its emergency policy at § 410.79(e)(3)(v)(C) to account for the proposed elimination of ongoing maintenance sessions for MDPP beneficiaries who start the MDPP services on or after January 1, 2022. Only beneficiaries who start the MDPP between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event may either resume or restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event if they elect not to continue with MDPP services virtually during the applicable 1135 waiver event.

Table 29, reproduced below, summarizes CMS' proposals for the MDPP services period based on beneficiary start date.

[80] The IBT-Obesity is a Medicare preventive service benefit whose goal is to promote sustained weight loss among Medicare beneficiaries with a BMI of 30 $kg.m^2$ or higher.

Table 29: Summary of the MDPP Service Period Based on Beneficiary Start Date	
Beneficiary MDPP Status	**MDPP Services Period**
Beneficiary starts MDPP set of services on or before December 31, 2021	• Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. • Ongoing Maintenance Services Period, consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period
Beneficiary starts MDPP set of services on or after January 1, 2022	• Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

2. Proposed Updates to Performance Payments (§ 414.84(b) and (c))

CMS proposes to amend § 414.84(b) and (c) to update the amount of the performance payment and this change applies to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022.

For MDPP beneficiaries starting the first core session on or before December 31, 2021, CMS proposes that MDPP suppliers continue to submit claims for the ongoing maintenance sessions attended using the appropriate HCPCS codes (G9891-G9885).

3. Proposal to Waive the Provider Enrollment Medicare Application Fee (§ 424.205(b)

CMS discusses stakeholders that the enrolment application fee factors into an organization's decision to participate in MDPP. Although MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee, many would not qualify. For 2021, the provider/supplier enrollment fee is $599.

On April 9, 2020, CMS waived all provider enrollment application fees as part of the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. CMS notes it saw an increase in MDPP supplier enrollment in Q2 2020, the quarter the blanket waivers were announced. CMS believes that granting a waiver of the enrollment fee for MDPP supplies beyond the PHE may increase MDPP supplier enrollment.

CMS proposes to utilize its waiver authority under section 1115A(d)(1) of the Act to waive the provider enrollment Medicare application fee for all organizations that submit an application to enroll in Medicare as an MDPP supplier on or after January 1, 2022. CMS proposes to amend the regulations at § 414.205(b) to reflect this waiver.

4. Proposal to Remove MDPP Suppliers From the List of Institutional Providers Required to Pay the Enrollment Fee (§ 414.502).

CMS proposes to amend § 414.502 to remove the reference to the Medicare Enrollment Application (CMS-20134) thereby removing MDPP suppliers from the list of institutional providers required to pay the Medicare enrollment fee under § 414.514. As proposed, § 414.514 would no longer be applicable to organizations enrolling as an MDPP supplier.

Regulatory Impact
CMS estimates that these proposed changes would reduce Medicare spending over 10 years, with potential savings starting in 2026 (Table 126). Increasing the first-year payment amounts to suppliers and waiving the Medicare enrollment fee should increase access to MDPP, resulting in more utilization of the MDPP set of services. These estimates do not consider waiving the Medicare enrollment fee as a direct cost and assume there will be an additional 500 beneficiaries per year participating in MDPP. CMS notes this assumption has a high level of uncertainty; Table 127 shows the 10-year impact estimates for different levels of additional beneficiary participation as a result of the proposed changes.

M. Laboratory Specimen Collection and Travel Allowance

1. Nominal Fee for Specimen Collection

In the March 2020 COVID-19 IFC (85 FR 19256), CMS established a nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients for the duration of the PHE. The fee is generally $23.46 for individuals in a SNF or $25.46 for individuals whose samples will be collected by laboratory on behalf of a home health agency. CMS indicated that the specimen collection fee will end once the PHE for the COVID-19 pandemic has ended.

In the 2021 PFS proposed rule, CMS requested comments on whether to terminate the COVID-19 specimen collection fees once the PHE for COVID-19 ends (85 FR 50211). CMS expressed particular interest in why separate, increased payment for specimen collection, specifically for COVID–19 tests, in contrast to other tests, may be needed following the end of the PHE. Commenters expressed support for permanently authorizing the specimen collection fees to compensate for the supplies, equipment, and sterilization protocols required for safe and uncontaminated specimen collection and handling in the presence of COVID-19.

After considering these comments, CMS believes that the increased fees were intended to address additional resources needed specifically during the PHE for the COVID-19 pandemic. Given the advances in the types of COVID-19 clinical diagnostic laboratory tests (CDLTs) available to the public and the reduced need for specimen collection by trained laboratory professionals, CMS believes that the increased laboratory professional resources needed for COVID-19 specimen collection will no longer be necessary after the PHE for the COVID-19 pandemic ends. CMS further anticipates that widespread vaccination of both medical professionals as well as the general population will likely reduce the need for intensive personal protective equipment.

2. Specimen Collection Fee and Travel Allowance for Clinical Diagnostic Laboratory Tests

Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. The travel allowance is intended to cover the estimated travel costs of collecting a specimen from a Medicare beneficiary and reflects the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable and is not available if the technician is merely performing a messenger service to obtain a specimen drawn by a physician or nursing home personnel.

Although CMS expects the increased specimen collection fees for COVID-19 CDLTs will end at the termination of the PHE for the COVID-19 pandemic, **CMS seeks broad comment on specimen collection fees and the travel allowance. Specifically, CMS seeks comment on how specimen collection practices may have changed as a result of, or from insight gained during, the PHE for the COVID-19 pandemic in terms of changes to supplies and staffing resources as well as related costs. CMS also seeks comments on the methodology for calculating the travel allowance, including calculation of mileage specific to per mile or flat rate and proration when there are multiple patients or specimens.**

3. Electronic Travel Logs

The methodology for determining the travel allowance varies depending on the round trip mileage to patients' homes. For instance, a per mile travel allowance methodology applies when the round trip to a patients' home is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip is less than 20 miles.

In the March 2020 COVID-19 IFC (85 FR 19258), CMS indicated that, for the duration of the PHE for the COVID-19 pandemic, paper documentation of miles traveled would not be required and that laboratories could maintain electronic logs if they preferred. CMS proposes to make permanent the option for laboratories to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample.

This policy is for all CDLTs and is not limited just to COVID-19 specimen collection. CMS will provide guidance in future instructions via forthcoming Change Requests and other materials such as MLN Matters® Articles. Laboratories will need to be able to produce electronic logs in a form and manner that can be shared with MACs and should continue to consult with their local MACs regarding the format and process for ongoing submission of this information.

N. Medicare Provider and Supplier Enrollment

1. Enrollment Process

The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare meet federal and state requirements to do so. The process helps prevent unqualified and potentially fraudulent individuals and entities from being able to enroll and inappropriately bill Medicare. The provisions outlined below largely codify in

regulations policies that were previously only found in sub-regulatory guidance (except as noted).

2. Proposed Provisions

a. Expansion of Authority to Deny or Revoke Based on OIG Exclusion

CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is excluded by the OIG. CMS proposes to expand these denial and revocation provisions to include excluded administrative or management services personnel who furnish services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist. This change would align with existing OIG guidance stating that providers and suppliers may not employ excluded persons to provide management or administrative services that are payable by a federal health care program.

b. Deny or Revoke Enrollment for Surrender of Drug Enforcement Administration (DEA) Certificate of Registration in Response to Show Cause Order

CMS has existing authority to deny a physician's or other eligible professional's enrollment if his or her DEA certificate of registration to dispense a controlled substance is currently suspended or revoked. CMS proposes to expand these authorities to include situations where the physician or other eligible professional surrenders his or her DEA certificate in response to an order to show cause.

c. Creation of Specific Rebuttal Rights for Deactivations

Deactivation means that the provider's or supplier's billing privileges are stopped (but not revoked or terminated). Deactivation rebuttal procedures are provided only in sub-regulatory guidance. CMS proposes to revise 42 CFR part 424, subpart P to incorporate the existing sub-regulatory process into regulations.

CMS proposes the following policy changes to the rebuttal process:

- If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS. CMS may, at its discretion, extend the 15-day time-period.
- Any rebuttal must: (1) be in writing; (2) specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or effective date, as well as the reasons for disagreement; (3) submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation; and (4) be submitted in the form of a letter that is signed and dated by the individual supplier, the authorized official or delegated official or a legal representative.
- The provider's or supplier's failure to submit a rebuttal that is both timely and fully

compliant constitutes a waiver of all rebuttal rights.

- Upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date are correct.
- The filing of a rebuttal and the review period does not suspend or postpone the deactivation's implementation.
- A rebuttal determination is an initial determination and is not appealable. Rebuttal is the only administrative remedy available for a deactivation.

d. Modernizing Enrollment for Emerging Technologies in Independent Diagnostic Testing Facilities (IDTFs)

IDTF standards for enrollment were designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. Yet, some health care entities have developed or utilize diagnostic tests via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. These entities often cannot meet certain IDTF requirements (and thus cannot enroll in Medicare) strictly because of the test's indirect nature.
To address this issue, CMS proposes exempting IDTFs that provide services that do not require direct or in-person beneficiary interaction from specific IDTF requirements.

CMS proposes that any nonphysician personnel performing a test in an exempted IDTF must meet all applicable state licensure requirements (if any). The IDTF must maintain documentation available for review that these requirements have been met. CMS also proposes that the following IDTF certification standards would not apply to exempted IDTFs:

- Having comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF;
- Maintenance of a beneficiary's written clinical complaint at the physical site of the IDTF.
- Openly posting enrollment standards for review by patients and the public.

With respect to a liability insurance policy, CMS acknowledges the possibility that an exempted IDTF could provide incorrect diagnostic results. **CMS solicits comment on the types of situations where this could arise as well as: (1) whether exempted IDTFs should be required to maintain a $300,000 liability policy; (2) whether a liability amount of less than $300,000 is warranted (and, if so, a suggested amount) and (3) whether no liability policy should be required**.

e. Revocation Proposals

CMS may revoke a provider's or supplier's enrollment if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. The purpose of this provision is to place providers and suppliers on notice that they are legally obligated to always submit correct and accurate claims and that failing to do so could lead to the revocation of their enrollment. CMS has recently encountered situations where providers and suppliers have engaged in periods of non-compliant billing that, though comparatively brief,

have or could have harmed the Medicare program but CMS has been unable to take revocation actions because of limitations in the regulations.

To increase its flexibility to address periods of abusive billing irrespective of their duration, CMS proposes to:

- Revise the revocation provisions to focus on the percentage of denials during the timeframe under consideration rather than the entire period of the provider's or supplier's enrollment.
- Delete a provision of the regulations that requires the enforcement authority to consider the reason for the claim denial in whether to invoke revocation.
- Add consideration of the specific facts (to the extent this can be determined) and type of billing non-compliance.

With respect to the 2nd proposal above, CMS indicates that even if a period of erroneous claim submissions reflected no nefarious intent by the provider, the provider still failed to comply with Medicare billing requirements and this presented a risk to the Medicare program.

3. Provider/Supplier Medical Review Requirements

CMS identifies improper payments in the Medicare FFS program through a variety of program integrity-related activities and a network of contractors to carry out program integrity initiatives. Despite the statutory authority authorizing contractors' activities, CMS does not have regulatory provisions governing certain medical review activities, specifically prepayment and post-payment medical reviews. To ensure consistency across prepayment and post-payment reviews and to establish clear requirements, CMS proposes adding the following key terms and their definitions:

- "Additional documentation" means the information requested by a contractor when conducting a prepayment review or post-payment review;
- "Additional Documentation Request (ADR)" means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review;
- "Post-payment medical review (or post-payment review)" means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate; and
- "Prepayment medical review (or prepayment review)" means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

These definitions are longstanding provisions of the Program Integrity Manual and have been in common use by Medicare contractors.

CMS proposes to add new §405.903 to outline the prepayment medical review provisions codifying:

- Contractor authority to conduct prepayment medical review on selected claims in order to determine whether and how much payment should be made.

- Contractor authority to request additional documentation while conducting a prepayment review.
- Providing a provider or supplier 45 calendar days to submit additional documentation in response to a contractor's request (with exceptions for good cause). For a Unified Program Integrity Contractor, the deadline is 30 calendar days except for good cause.
- Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.
- A contractor's prepayment review will result in an initial determination.

These provisions reflect longstanding requirements Medicare contractors have used in conducting prepayment reviews. CMS proposes parallel requirements for post-payment reviews except that when conducting a post-payment review, a contractor's review will result in either no change or a revised determination

CMS proposes new §405.930 to clearly outline contractor authority to deny a claim should a provider or supplier fail to convey the additional documentation in response to a request. The proposed language clarifies that the contractor must give the provider or supplier notice and time to respond to the additional documentation request. Contractors also have the authority to deny additional time and the associated claim(s) when the additional documentation is not received within the requested timeframe.

O. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services

In the 2020 and 2021 PFS final rules, CMS implemented Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. That law called for a new Part B benefit category for OUD treatment services furnished by Opioid Treatment Programs (OTPs) beginning January 1, 2020.

The rules established:

- A methodology for determining bundled payments for episodes of care;
- Codes for payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care; and
- Add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, additional counseling, and for take home supplies of nasal naloxone and injectable naloxone.

Current payment rates for OUD treatment services provided by OTPs can be found on the CMS OTP website under Billing and Payment at https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf. The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for 2022, will be made available at the time of publication of the 2022 PFS final rule.

Geographic Adjustment & Updates. The 2020 and 2021 PFS final rules applied a geographic adjustment to the non-drug component of the OTP bundled payments and to the add-on payment adjustments for non-drug services, using the Geographic Adjustment Factor (GAF), and an annual update based on the MEI to the non-drug component of the bundled payment. CMS did not, however, address geographic adjustments or annual updates for the non-drug component for take-home supplies of opioid antagonist medications. To address this, CMS proposes to revise §410.67(d)(4)(ii) to apply a geographic adjustment using the GAF and §410.67(d)(4)(iii) to provide for an annual update using the MEI.

Duplicative Payments. The 2021 PFS final rule establishes that a payment to an OTP for naloxone is duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Duplicative payments are not permitted and if a duplicative payment is identified, CMS may recoup that payment. The rules, however, do not specifically reference payments for medications that are furnished as part of an adjustment to the bundled payment. Accordingly, CMS proposes to revise §410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS notes that this provision applies to take-home supplies of naloxone as well as to take-home supplies of other medications under §410.67(d)(4)(i)(D).

Coding for New Nasal Naloxone Product. At the time that CMS finalized payment for HCPCS code G2215 (Take-home supply of nasal naloxone), it did not have pricing information for a new, higher dose naloxone hydrochloride nasal spray. While CMS still does not have the pricing information, it proposes to create a new G-code for this higher-dose product. The new add-on code would use the same methodology for take-home supplies of other opioid antagonist medications and would include both a drug and non-drug component. The drug component would be determined using a methodology consistent with that used for HCPCS code G2215 except that payment amounts based on ASP or wholesale acquisition costs would not include add-on percentages. It would be based on a typical take-home supply of a box of two 8mg nasal sprays and would be limited to one add-on code every 30 days except when medically reasonable and necessary.

Counseling and Therapy Furnished via Audio-Only Telephone. The 2020 PFS final rule permitted the use of two-way interactive audio/video communication technology for the counseling and therapy services in the weekly bundle as well as for additional counseling and therapy services. During the COVID-19 PHE, CMS has permitted those services to be provided using audio-only telephone calls. The flexibility was intended to ensure that beneficiaries with OUDs continue to receive services during the PHE even while self-isolating or social distancing whether or not they have access to audio/video communications technology.

After consideration of comments in response to the 2021 PFS proposed rule and feedback from other stakeholders, CMS proposes to extend the flexibility permanently where two-way audio/video communication technology is not available provided all other applicable requirements are met. It notes that during the PHE, the ability to use telephone calls is permitted

whether or not audio/video communication is available. Further, CMS interprets "not available to the beneficiary" to include circumstances where the beneficiary is not capable of or has not consented to use two-way audio/video devices.

Under the proposed rule, CMS also requires OTPs, when providing additional counseling and therapy billed under the add-on code after the end of the PHE, to use the modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System). In addition, after the end of the PHE, OTPs providing services using audio-only telephone calls would be required to document in the beneficiary's medical record that the counseling or therapy was provided via telephone call and the rationale for doing so.

In addition, CMS proposes the use of a new service-level modifier on claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when furnished via an audio-only interaction. Use of the modifier would be required beginning January 1, 2022 but is applicable only after the conclusion of the PHE. The modifier indicates that the practitioner had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. This will enable CMS to track use of the flexibility and potentially refine the benefit in the future.

CMS defers to providers to use clinical judgement in determining whether in-person counseling or therapy, rather than audio-only telephone calls would be most appropriate for the patient in their circumstances. **It seeks comment on whether there should be additional conditions to ensure program integrity, and to ensure patient safety and access to appropriate care.**

P. Physician Self-Referral Updates

CMS reviews the history of its implementation of the physician self-referral law under section 1877 of the Act by providing a chronology of its significant rulemaking, including its most recent final rule entitled "Modernizing and Clarifying the Physician Self-Referral Regulations" (the "MCR final rule") (85 FR 77492). The MCR final rule established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as "value-based arrangements," established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law; for example, it revised the definition of "indirect compensation arrangement."

1. Indirect Compensation Arrangements (§411.354(c)(2))

CMS proposes revisions to §411.354(c)(2) (relating to the conditions for an indirect compensation arrangement) to correct what it describes as an inadvertent omission in its changes to this section in the MCR final rule. Specifically, the proposal would amend §411.354(c)(2)(ii) (which identifies unbroken chains of financial relationships that constitute "indirect compensation arrangements") to include as a potential indirect compensation arrangement "any

unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that he or she personally performs." This is intended to ensure that its long-standing prohibition on certain per-unit of service compensation formulas for determining charges for the rental of office space and equipment remains in place. Additionally, in response to inquiries from stakeholders, CMS proposes to define the term "unit" for purposes of applying this provision of the regulations.

a. Definition of "Indirect Compensation Arrangement"

CMS explains that its changes to the regulations that identify indirect compensation arrangements under the physician self-referral law were made in response to comments that were primarily in the context of compensation paid to physicians for their personally performed services. The revisions were intended to permit parties to more precisely identify arrangements that pose a risk of abusive conduct at the earlier stage of the analysis. However, the changes in the MCR final rule omitted certain arrangements involving unit of service-based payment for the rental of office space or equipment from the definition of "Indirect Compensation Arrangement."

CMS reiterates its long-standing belief that unit of service-based compensation formulas in arrangements for the lease of space and equipment are inherently susceptible to abuse because physician lessors have an incentive to profit from referring a higher volume of patients to their lessees. Among the fraud and abuse concerns the agency has previously articulated, CMS believes that unit of service-based compensation formulas (especially for equipment leases) (i) create incentives for overutilization of services; (ii) create incentives for physicians to narrow their choice of treatment options to those for which they will realize a profit; (iii) influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different technology; (iv) result in physicians steering patients to equipment they own; and (v) increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider. However, CMS believes that as a general matter, indirect compensation arrangements under which a physician (or immediate family member) is paid solely for services that he or she personally performs do not raise significant program integrity concerns, provided that the compensation is consistent with fair market value for the personally performed services. As finalized in the MCR final rule, §411.354(c)(2)(ii) is not limited to indirect compensation arrangements under which a physician (or immediate family member) is paid solely for services that he or she personally performs.

CMS proposes to revise §411.354(c)(2)(ii) to require a two-step analysis of any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything other than services personally performed by the physician. It would modify the condition at §411.354(c)(2)(ii)(A) to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of § 411.354(c)(2)(i) through (iii) to be an indirect compensation arrangement for purposes of the physician self-referral law if the unit of compensation received by the physician (or immediate family member) is payment <u>for anything other than services personally performed by the physician</u> (or immediate family member).

CMS would consider services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member) not to be personally performed by the physician. CMS proposes to add this clarification to §411.354(c)(2)(ii)(B)(*3*).

b. Definition of "Unit" for Purposes of Applying §411.354(c)(2)(ii)(A)

After the publication of the MCR final rule, stakeholders have questioned how to apply §411.354(c)(2)(ii)(A) where compensation does not appear to be unit-based or is calculated using two or more units or different types of units (e.g., annual salaries and performance bonuses). Noting that all compensation is essentially unit based, CMS states that an underlying unit may be a discrete item, a unit of service, a unit of time, or a unit that results from combining different types of units into a single unit used to calculate the compensation. The individual unit of compensation is the smallest unit of time for which the compensation is entirely paid per hour, per day, per month, per year, or per similar period of time. It believes that compensation that has both a time-based unit component and a service-based unit component is appropriately analyzed by converting it to compensation for a unit of time in applying §411.354(c)(2)(ii).

CMS proposes to add a new provision to §411.354(c)(2)(ii)(B)(*2*) that will identify the unit to consider for purposes of applying the regulation at §411.354(c)(2)(ii)(A) and determining the existence of an indirect compensation arrangement that must satisfy the requirements of an applicable exception. The proposed the individual units are as follows:

- Time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided;
- Service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided; and
- Time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

CMS seeks comment on its proposals as well as whether additional guidance would be necessary to determine whether an indirect compensation arrangement exists.

2. Exception for Preventive Screening Tests, Immunizations, and Vaccines (§411.355(h))

Vaccines are included in the definition of outpatient prescription drugs; thus, they are considered designated health services (DHS) under the physician self-referral law. Because Medicare does not currently pay for COVID-19 vaccines, they are not included per se in the definition of DHS. However, if the federal government stops purchasing COVID-19 vaccines, they would be paid for under the Medicare program and thus be considered DHS.

The regulations at §411.355(h) provide an exception for preventive screening tests, immunizations, and vaccines. In the 2021 PFS final rule, CMS added COVID-19 vaccines to the

list of immunization and vaccine codes to which this exception applies. However, one of the conditions for this exception is compliance with frequency limits established in statute or by CMS. Neither the statute nor the agency has established any frequency limits for COVID-19 vaccines. CMS proposes to waive the frequency limit condition for COVID-19 vaccines until such time as any such limits are established. **It seeks comment on the proposal and whether it should limit the waiver to the period of the COVID-19 PHE or some other period of time.** In the alternative, CMS proposes to waive CMS-mandated frequency limits for all vaccines; **it seeks comment on whether it should include alternative program integrity requirements**.

CMS does not propose to waive the frequency limit requirement for preventive screening tests. It also proposes to change its terminology to refer to "vaccinations" in lieu of "immunizations" throughout §411.355(h).

3. Annual Update to the List of CPT/HCPCS Codes

CMS specifies that the entire scope of designated health services (DHS) for purposes of the physician self-referral prohibition is defined in a list of CPT/HCPCS codes (the Code List) which is updated annually to account for both changes in the most recent CPT and HCPCS publications and changes in Medicare coverage policy and payment status.

Noting that coding changes have become more frequent, effective January 1, 2022, CMS proposes to update the Code List each calendar quarter. The first quarterly update would be April 1, 2022. CMS would provide advance notice of the updates on its website on March 1, June 1, September 1, and December 1 of each year, with corresponding Code List updates effective on April 1, July 1, October 1, and January 1, respectively. It would also provide a 30-day public comment period following each advance notice posted on the website. Instructions for submitting comments, and CMS' responses to comments, would also be posted on the website. It anticipates that most comments would be addressed within 90 calendar days of the effective date of the Code List update to which they pertain though CMS notes that complex comments or issues may require a longer timeframe.

CMS will include the Code List that is effective January 1, 2022 in the 2022 PFS final rule. Thereafter, the Code List would only be published on the CMS website. The website is http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

CMS seeks comments on its proposals including whether to update the Code List more or less frequently.

Q. Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

1. Background

Section 2003 of the SUPPORT Act mandates that, beginning January 1, 2021, the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically, with certain exceptions specified in the SUPPORT Act as well as any additional exceptions as

specified by HHS. CMS finalized this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022. CMS described this delay as necessary to recognize the unique challenges that prescribers are facing during the COVID-19 PHE. Based in part on consensus among stakeholders, CMS required Part D prescribers to use the NCPDP SCRIPT 2017071 standard for electronic prescriptions for controlled substances.

2. Proposed Timeframe for EPCS Adoption

CMS proposes to delay the January 1, 2022 compliance date for the EPCS requirements for most prescribers by one year. For Part D controlled substance prescriptions written for beneficiaries in long-term care facilities, the compliance date is delayed until January 1, 2025. CMS notes that the January 1, 2025 compliance date extension would not apply to beneficiaries who are residents of nursing facilities and whose care is provided under Part A.

The rationales for these proposals include concerns from prescribers about the rapid implementation of the EPCS requirements, the impact of the COVID-19 pandemic, and the Department of Justice rulemaking currently underway that will facilitate EPCS requirements. CMS believes that long-term care (LTC) facilities face additional barriers that other prescribers do not; one such barrier is the NCPDP SCRIPT 2017071 standard which lacks appropriate guidance for LTC facilities. The agency declines to establish a specific LTC waiver or exception to the EPCS requirement, and it does not anticipate extending the compliance date for LTC facilities beyond January 1, 2025.

3. Proposed Compliance Threshold

Citing the authority under section 1860D-4(e)(7)(B) of the Act for the Secretary to specify appropriate penalties for noncompliance, CMS believes it may also establish a threshold for when it would penalize noncompliance. It proposes to establish a threshold of 70 percent, meaning that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances must be done electronically per calendar year. Any prescriptions issued while a prescriber falls within an exception or a waiver would be excluded from the calculation. CMS would examine PDE data at the end of the calendar year and divide the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed.

The statute authorizes the Secretary to make an exception for a prescription issued for a drug for which the FDA requires a prescription to contain elements that cannot be included in electronic prescribing. However, CMS was unable to identify any such prescription under the current standard. While there may be other reasons that could make EPCS infeasible for prescribers who currently conduct EPCS (e.g., temporary technological failures or cases where it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition), CMS does not propose a specific exception for these cases. This is because it believes that EPCS is infeasible in no more than an estimated 30 percent of instances due to circumstances such as the ones described previously. Thus, CMS believes the proposed 70 percent threshold is achievable without posing undue burdens on prescribers.

CMS seeks comments on the proposal and on what circumstances would make EPCS not feasible.

4. Proposed Classes of Exceptions

Section 1860D-4(e)(7)(B) of the Act permits the Secretary to establish exceptions to the EPCS requirements and includes some examples. CMS proposes three classes of exceptions.

a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy are Same Entity

Section 1860D-4(e)(7)(B)(i) of the Act lists a possible exception for when the practitioner issuing the prescription and dispensing pharmacy are the same entity. Citing widespread support for this exception, CMS proposes to add it to its regulations at 423.160(a)(5)(i). Stakeholders believe it would promote patient safety, workflow efficiency, and health IT performance; further, failure to provide this exception might result in unwarranted artificial workflow structures for these prescribers. **Comment is sought on the proposal**.

b. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

Based on stakeholder feedback, CMS believes it is appropriate to specify circumstances for a waiver of the EPCS requirement in cases where a prescriber issues a very low volume of controlled substance prescriptions for Part D drugs. This is because the cost of installing EPCS equipment and software may be unduly burdensome relative to its benefit in terms of improving the security of prescriptions for controlled substances.

CMS proposes to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year. The exception would be given to individual prescribers, regardless of the size of the group practice to which they belong. CMS would implement this exception by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within the exception for the year involved.

CMS believes prescribers working under most research protocols would fall under this proposed exception for small prescribers; **however, it seeks comments on its assumption**. CMS declines to provide a specific exception for prescribers working under a research protocol in the regulations because it presumes that researchers would be included either in the exception for small prescribers or in the exception for cases where the prescriber and dispenser are the same entity. It believes that very few researchers would fall outside of the other exceptions.

CMS seeks comments on its proposals and its assumptions with respect to researchers. It is interested in feedback on the maximum number of Part D controlled substance prescriptions a prescriber can issue to be still considered a small prescriber.

c. Cases of Recognized Emergencies and Extraordinary Circumstances

CMS proposes two exceptions for extraordinary circumstances: recognized emergency areas and other extraordinary circumstances.

The first exception would be for prescribers who issue prescriptions in areas that are affected by a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. The agency would determine whether there is an emergency or disaster declared by a federal, state, or local government entity for the geographic area associated with the prescriber's address in the NCPDP database.

The second would permit prescribers who are not in an emergency or disaster area to seek a CMS waiver if they are facing extraordinary circumstances outside their control (e.g., a lack of broadband access). Prescribers would submit a waiver request that describes and documents the extraordinary circumstances beyond their control and states that the circumstances prevent them from conducting EPCS. The prescriber would submit an attestation (using a CMS form available on the CMS website) thereby allowing them to submit waiver requests through an online portal. The attestation must provide minimum information, including first and last name, NPI, TIN, contact information, and a description of the extraordinary circumstances. After receipt of the attestation, CMS would provide written notice of receipt of the waiver request and a decision on the request. Additional details would be provided in subsequent rulemaking.

CMS seeks comments on its proposals.

d. Individuals in Hospice and Nursing Facilities

The SUPPORT Act required the Secretary to consider whether prescriptions for individuals under the Part D benefit for an individual enrolled in the Medicare Part A Hospice benefit should be exempt from the EPCS requirement. CMS does not believe an exception should be made for these circumstances. Part of the rationale for its position is there may be very few instances in which a controlled substance prescribed for a Part D enrollee who has elected hospice could be covered under Part D, and an exception that would apply only in these rare instances could be confusing and burdensome for prescribers. Additionally, beneficiaries may cancel a hospice election at any time thereby creating operational complexities if an exception were established.

The SUPPORT Act also required the Secretary to consider whether prescriptions for individuals under the Part D benefit for an individual who is a resident a nursing facility and eligible for Medicare and Medicaid benefits warrants an exception. Noting that none of the feedback it received provided any compelling reason to do so, CMS declines to create this exception.

CMS seeks comment on these decisions.

7. Fraud and Abuse Law

Some Prescription Drug Plans (PDPs), MA-PD plans, or other organizations with which prescribers are affiliated may provide technology and services to prescribers that are necessary to carry out electronic prescribing of covered Part D drugs in order to satisfy the mandate for electronic prescribing of controlled substances for those drugs. This assistance may implicate the payment and fraud and abuse laws, including the physician self-referral law and the federal anti-kickback statute.

CMS notes that there is an exception to the physician self-referral law's prohibition and a corresponding safe harbor under the federal anti-kickback statute that permits certain donations in the form of items or services (not including cash or cash equivalents) that are necessary and used solely to receive and transmit electronic prescription information. All the requirements of the applicable exception or safe harbor must be satisfied. In addition, there may be other exceptions to the physician self-referral law and safe harbors under the federal anti-kickback statute that may apply.

8. Penalties

For the first compliance year (2023), CMS proposes to limit its compliance actions to sending letters to prescribers that may be in violation of the EPCS requirements during that year. The letters would notify prescribers that they are violating an EPCS requirement; provide information on how to come into compliance with the requirement; describe the benefits of EPCS; include an information solicitation as to why they are not conducting EPCS; and provide a link to the CMS portal to request a waiver. It will consider additional compliance actions in future rulemaking, and **comment is sought on appropriate types of compliance actions after 2023, including whether any penalties should be phased in over time**.

R. Open Payments

CMS proposes to make a number of changes and additions to its Open Payments requirements which it believes will clarify existing requirements and improve the quality of data. It proposes the following policies.

1. Mandatory Payment Context Field for Records to Teaching Hospitals

CMS proposes to add a mandatory context field for payments or transfers of value attributed to teaching hospitals. The field would contain information to better identify the payment as deemed appropriate by the applicable manufacturer or GPO. This is in response to concerns from teaching hospitals that Open Payments submissions do not contain sufficient information to identify reported payments or transfers of value in their own records; teaching hospitals must dispute the record to get additional information to verify those payments or transfers which adds unwarranted burden on those hospitals.

2. Option to Recertify Annually Even When No Records Are Being Reported

In response to feedback from companies that would like to attest they have no reportable events for a year, CMS proposes to add an option for a company that does not have reportable payments or transfers of value for the program year to recertify their registration in Open Payments and attest that it does not have any records to submit. CMS proposes specific language for the attestation.

3. Definition for a Physician-Owned Distributorship

While the Open Payments final rule (78 FR 9458) discussed physician-owned distributorships (PODs) as a subset of group purchasing organizations (GPOs), it did not specifically define this type of entity. CMS believes that the disclosure of an entity's status as a POD is essential and that it will also help clear up confusion about whether PODs must report. Thus, it proposes to include the definition of a POD as set out at §403.902 as a subset of either an applicable manufacturer or applicable GPO. CMS would also require PODs to self-identify when registering or recertifying.

CMS also proposes to align the updated definition of "ownership and investment interest" under the physician self-referral regulations to the Open Payments program; thus, it would include the exceptions for titular ownership and employee stock ownership programs (ESOPs) that are qualified under IRS regulations for consistency in application. The updated definition would not include publicly traded securities or mutual funds.

CMS emphasizes that its proposed definition of POD for the Open Payments program does not apply for purposes of any other law or regulation. It also emphasizes a number of additional points, including the following:

- To be considered a physician owner, the owner must hold at least one active professional license to practice as a physician issued by a U.S. state or territory.
- If a company with common ownership reports in a consolidated report with the POD, the reporting company would only be required to register as a POD if it meets the 5 percent ownership requirement when ownership of all entities in the report is calculated.
- Five percent interest would be calculated as 5 percent of the total dollar value in USD of all ownership in the POD as of December 31, or the latest date that the ownership was held, as of the calendar year proceeding the Program Year.
- The POD would have to report ownership and investment interest (as defined at §403.902) as required by existing Open Payments requirements.
- The POD would have to identify as a POD whether or not the physician has a controlling interest in the reporting entity.
- Indirect ownership interest would also have to be reported as required by §403.902.
- Any entity meeting this definition would have to identify itself as a POD when submitting and attesting to its records.

CMS does not believe the proposed definition would increase industry burden because it is a subset of existing definitions.

4. Disallowing Record Deletions Without a Substantiated Reason

CMS is concerned that entities could be compliant with Open Payments program requirements by reporting and attesting to records, and then deleting those records so that they are never publicly available. While it does not have any evidence of this behavior, it proposes to add a new policy at §403.904(a)(3) that states that an entity that has reported payments or transfers of value under the scope of the Open Payments rule may not remove, delete, or alter the records in the Open Payments system. The previous prohibition would not apply if the entity discovered an error in the information furnished, or the record is otherwise believed to meet existing exceptions for reporting that were previously unknown.

5. Disallowing Publications Delays for General Payment Records

The Open Payments program permits delays in the publication of certain information in the record details that may reveal proprietary information about a company's research activities. CMS notes that as of December 26, 2020, there were 20,930 general records with a value of roughly $26 million that were delayed from publication for at least one Program Year for which the agency could not verify the connection with research or clinical activities. This was because the information provided in the format for submission of general records was inadequate for that verification.

CMS proposes to eliminate the ability to delay general payments from publication and only permit publication delay of research payments, whose formatting does require the appropriate information to be provided.[81]

6. Short Term Loans

An exception currently applies for reporting short term equipment loans. The regulations define a short-term medical supply or device loan as the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient. The regulations also clarify that for a single product the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days were consecutive. CMS proposes wording changes to its definition to clarify its intent that the loan period is 90 days and to disallow a new loan to start at the end of the previous loan period within the same year.

7. Removal of General Ownership Records

There are two ways for entities to report ownership: they may submit an ownership record or a general record with a Nature of Payment category of "Ownership." CMS proposes to remove the "Ownership" Nature of Payment category because this category does not include certain

[81] See 42 CFR 403.904(f).

information associated with reporting ownership interest (e.g., dollar amount invested and the value of interest).

8. Updated Contact Information

CMS proposes to require companies that have had reportable payments or transfers of value within the past 2 calendar years to keep their contact information current within the Open Payments system. It provides the following example for clarification:

> [I]f an applicable manufacturer or group purchasing organization had reported records in Program Years 2018 and 2022, but did not have records for Program Years 2019, 2020, or 2021, it would be required to keep updated contact information in the system during Program Years 2019 and 2020. The applicable manufacturer or group purchasing organization would not have to update its contact information for Program Year 2021. In Program Year 2022, since it once again had reportable records, it would be required to recertify and update its contact information as usual.

The agency believes the proposed changes would increase the usability of the data, address stakeholder concerns, and give reporting entities sufficient time to prepare for changes to their data collection and reporting procedures.

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 states that its estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2021 with proposed payment rates for 2022 using 2020 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 and amended section 1848(d) of the Act. This provision requires

an update of 0.0 percent for 2022, before applying any other adjustments. In addition, the expiration of the 3.75 percent increase to PFS payments for 2021 from the Consolidated Appropriations Act (CAA) will result in the 2022 conversion factor being calculated as though the 3.75 percent increase for the 2021 conversion factor had never been applied. In addition to the update factor, the CF calculation for 2022 takes into account an RVU budget neutrality adjustment.

The proposed CF for 2022 is $33.5848, which reflects the expiration of the 3.75 percent increase for services furnished in 2021, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality (BN) adjustment of -0.14 percent. The 2022 proposed anesthesia conversion factor is $21.0442, which reflects the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for anesthesia specialty. See Tables 121 and 122 from the proposed rule, reproduced below.

Table 121: Calculation of the Proposed 2022 PFS Conversion Factor

2021 Conversion Factor		**$34.8931**
Conversion Factor without 2021 Consolidated Appropriations Act Provision		$33.6319
Statutory Update Factor	0.00 percent (1.0000)	
2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
2022 Conversion Factor		**$33.5848**

Table 122: Calculation of the Proposed 2022 Anesthesia Conversion Factor

2021 National Average Anesthesia Conversion Factor		**$21.5600**
Conversion Factor without 2021 Consolidated Appropriations Act Provision		$20.7807
Statutory Update Factor	0.00 percent (1.000)	
2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
2022 Practice Expense and Malpractice Adjustment	1.41 percent (1.0141)	
2022 Conversion Factor		**$21.0442**

Table 123 (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. This includes changes to RVUs for specific services and other proposals including CMS' proposed update to clinical labor pricing. The table, however, **does not** show the impact of the expiration of the 3.75 percent increase to PFS payments for 2021 from the CAA. Thus, the combined effect of RVU changes and the conversion factor is much larger than what CMS displays in Table 123. If, for example, CMS specifies a -2 percent reduction in Table 123 for a given specialty, the combined effect of RVU changes with the CF reduction from the CAA would be roughly -6 percent.

2022 PFS Impact Discussion

The most widespread specialty impacts of RVU changes in most years is related to changes to RVUs for specific services, including RVUs for new and revised codes. CMS's proposed update to clinical labor pricing, however, appears to be the primary cause of redistributive effects for certain specialties. Specialties that rely primarily on clinical labor rather than supply or equipment items, such as portable x-ray (+10%), endocrinology (+2%), family practice (+2%), general practice (+2%), geriatrics (+2%) and hand surgery (+2%) would receive the largest increases relative to other specialties.[82] In contrast, specialties that rely primarily on supply or equipment items, such as interventional radiology (-9%), vascular surgery (-8%), radiation oncology and radiation therapy centers (-5%), and oral/maxillofacial surgery (-4%), would receive the largest decreases relative to other specialties. Other factors that could impact changes include proposed revaluation of individual procedures based on reviews by the AMA RUC and CMS, the continued phase-in of the previously finalized updates to supply and equipment pricing, and previously finalized phased-in code-level reductions that are being phased-in over several years.

Column F of Table 123 shows the estimated 2022 combined impact on total allowed charges by specialty of all the proposed RVU and other changes.

TABLE 123: 2022 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	$220	0%	-2%	0%	-2%
Anesthesiology	$2,755	0%	1%	0%	1%
Audiologist	$58	0%	-1%	0%	-1%
Cardiac Surgery	$203	0%	-1%	0%	-1%
Cardiology	$6,119	0%	-1%	0%	-2%
Chiropractic	$617	0%	0%	0%	0%
Clinical Psychologist	$814	0%	0%	0%	0%
Clinical Social Worker	$873	0%	0%	0%	0%
Colon And Rectal Surgery	$144	0%	0%	0%	0%
Critical Care	$367	0%	0%	0%	0%
Dermatology	$3,454	0%	-1%	0%	0%
Diagnostic Testing Facility	$682	0%	0%	0%	0%
Emergency Medicine	$2,525	0%	0%	0%	0%
Endocrinology	$506	0%	2%	0%	2%
Family Practice	$5,725	0%	2%	0%	2%
Gastroenterology	$1,476	0%	0%	0%	0%
General Practice	$368	0%	1%	0%	2%
General Surgery	$1,738	0%	0%	0%	0%
Geriatrics	$175	0%	1%	0%	2%

[82] Since PE the component maintains budget neutrality, increased pricing for clinical labor holds a corresponding relative decrease for other components of PE such as supplies and equipment. The portable x-ray specialty may have seen a large increase because one code Q0092 (set-up portable Xray equipment) relies primarily on clinical labor – the time of a radiology technologist – and accounts for almost 40 percent of allowed charges.

(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
Hand Surgery	$222	0%	2%	0%	2%
Hematology/Oncology	$1,737	0%	-2%	0%	-2%
Independent Laboratory	$552	0%	-2%	0%	-2%
Infectious Disease	$639	0%	-1%	0%	-1%
Internal Medicine	$9,906	0%	1%	0%	1%
Interventional Pain Mgmt	$900	0%	1%	0%	1%
Interventional Radiology	$480	0%	-9%	0%	-9%
Multispecialty Clinic/Other Phys	$138	0%	0%	0%	0%
Nephrology	$2,303	0%	0%	0%	0%
Neurology	$1,354	0%	0%	0%	1%
Neurosurgery	$708	0%	0%	0%	0%
Nuclear Medicine	$50	0%	-2%	0%	-2%
Nurse Anes / Anes Asst	$2,092	0%	1%	0%	1%
Nurse Practitioner	$5,288	0%	1%	0%	1%
Obstetrics/Gynecology	$558	0%	1%	0%	1%
Ophthalmology	$4,365	0%	0%	0%	0%
Optometry	$1,108	0%	0%	0%	1%
Oral/Maxillofacial Surgery	$70	0%	-4%	0%	-4%
Orthopedic Surgery	$3,273	0%	1%	0%	1%
Other	$52	0%	-1%	0%	-1%
Otolarngology	$1,037	0%	-1%	0%	-1%
Pathology	$1,061	0%	-1%	0%	-1%
Pediatrics	$55	0%	1%	0%	1%
Physical Medicine	$1,030	0%	0%	0%	0%
Physical/Occupational Therapy	$3,976	-1%	-1%	0%	-2%
Physician Assistant	$2,810	0%	1%	0%	1%
Plastic Surgery	$319	0%	1%	0%	1%
Podiatry	$1,847	0%	1%	0%	1%
Portable X-Ray Supplier	$84	0%	10%	0%	10%
Psychiatry	$1,040	0%	1%	0%	1%
Pulmonary Disease	$1,471	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,660	0%	-5%	0%	-5%
Radiology	$4,397	0%	-2%	0%	-2%
Rheumatology	$541	0%	-1%	0%	-1%
Thoracic Surgery	$302	0%	-1%	0%	-1%
Urology	$1,677	0%	0%	0%	0%
Vascular Surgery	$1,144	0%	-8%	0%	-8%
Total	$89,065	0%	0%	0%	0%

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

The following is an explanation of the information for Table 123:

- 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 2020 utilization and 2021 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 2022 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 2022 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 2022 impact on total allowed charges of the proposed changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2022 combined impact on total allowed charges of all the changes in the previous columns.

To illustrate how impacts can vary within specialties, CMS created a public use file that models the expected percentage change in total RVUs per practitioner.[83] Based on its analysis of 2020 utilization data, CMS found that total RVUs change between -1 percent and 1 percent for more than 52 percent of practitioners, representing about 48 percent of changes in total RVUs for all practitioners. Some specialties, such as emergency medicine, exhibit very little variation in changes in total RVUs per practitioner whereas diagnostic testing facilities exhibit more variation.

B. 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 related to proposed clinical labor updates, telehealth services, revisions to the current *de minimis* policy for services furnished in whole or part by PTAs/OTAs, proposals related to RHCs and FQHCs, requiring certain manufacturers to report drug pricing information, appropriate use criteria for advanced diagnostic imaging services, modifications to the MSSP quality reporting requirements, among others.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 50 percent of the nearly 1.6 million clinicians billing to Part B (809,625) will be assigned a MIPS score for 2024 because others will be ineligible for or excluded from MIPS. Table 129, reproduced below, provides the details of clinicians' MIPS eligibility status for 2024 MIPS payment year (2022 MIPS performance year). CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed

[83] See https://www.cms.gov/files/zip/cy-2022-pfs-proposed-rule-specialty-impacts-practitioner-2019-vs-2020-claims.zip

policy; CMS continues to assume 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria would elect to opt-in to the MIPS program.

TABLE 129: Description of MIPS Eligibility Status for CY 2022 Performance Period/2024 MIPS Payment Year Using the 2022 PFS Proposed Rule 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	184,773	$45,007
	Do not participate in MIPS	27,015	$6,313
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria and submit as a group)	Submit data as a group	594,578	$15,195
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	3,259	$77
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**809,625***	**$66,592**
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	411,872	$10,529
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	100,501	$565
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	303,873	$14,951
Total Number of Clinicians Not MIPS Eligible		816,246	26,045
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,871	92,638

*Estimated MIPS Eligible Population
** Table 129 does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 6,000 clinicians and $527 million in PFS allowed charges).
*** Allowed charges estimated using 2019 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 2024 payment year, it would redistribute about $587 million in payment adjustments on a budget neutral basis and that $425 million would be distributed to MIPS eligible clinicians who meet or exceed the additional performance threshold. CMS notes that an increase in funds are available for redistribution due to the increase in clinicians with final scores below the performance threshold. The maximum positive payment adjustments are 14.0 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance, a significant increase in the maximum

positive payment adjustment. The overall proportion of clinicians receiving a positive or neutral payment adjustment decreases from 91.7 percent to 67.5 percent with the implementation of the proposed policies that shift away from MIPS transition policies. Clinicians receiving a negative adjustment is expected to increase from 8.3 percent to 32.5 percent.

Table 131, reproduced below, shows the impact of payments by practice size, and based on whether clinicians are expected to submit data to MIPS. As compared to past years, CMS notes that it no longer observes large difference in performance across practice sizes due to the shift from MIPS transition policies, though differences remain. For instance, 35 percent of clinicians in small practices (1-15 clinicians) are expected to receive a negative payment adjustment compared with about 30 percent for clinicians in very large practices (100+). CMS notes that it is using 2019 MIPS performance period submissions data for estimation purposes and that it cannot account for at this time certain changes such as services and payment disrupted by the PHE and/or clinicians changing behavior to avoid a negative payment adjustment.

Table 131: MIPS Estimated 2022 Performance Period/2024 Payment Year Impact on Total Estimated Paid Amount by Participation Status and Practice Size*

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS 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	107,712	64.8%	23.7%	35.2%	1.6%
2) 16-24	36,819	60.6%	18.8%	39.4%	0.7%
3) 25-99	174,803	64.7%	19.5%	35.3%	1.1%
4) 100+	463,183	69.7%	15.1%	30.3%	1.2%
Overall	**782,517**	**67.5%**	**17.4%**	**32.5%**	**1.3%**
Among those not submitting data					
1) 1-15	23,056	0.0%	0.0%	100.0%	-8.4%
2) 16-24	1,200	0.0%	0.0%	100.0%	-8.5%
3) 25-99	2,206	0.0%	0.0%	100.0%	-8.5%
4) 100+	646	0.0%	0.0%	100.0%	-8.7%
Overall	**27,108**	**0.0%**	**0.0%**	**100.0%**	**-8.4%**

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

** 2019 data used to estimate 2022 performance period/2024 payment year payment adjustments. Payments estimated using 2019 dollars trended to 2024.

***Includes facility-based clinicians whose cost and quality data are submitted through hospital programs.

CMS estimates that approximately 225,000 to 290,000 eligible clinicians will become QPs for the 2024 and a total of $600-$750 million in total lump sum APM incentive payments will be made.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. Due to the PHE, CMS states that it is aware that there may be changes in health care delivery and billing patterns that will impact results for the 2020 performance year/2024 payment year that it was not able to model with its historic data sources. The scoring model results presented in the proposed rule assume that 2019 Quality Payment Program data submissions and performance are representative of 2022. CMS also anticipates that clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. Likewise, CMS states that it is difficult to predict whether clinicians will elect to opt-in to participate into the MIPS program. CMS states that given these limitations and others, there is considerable uncertainty around its estimates.

D. Alternatives Considered

The proposed rule contains a range of potential policies, and CMS provides a discussion of alternatives considered for some of these policies. These are discussed in previous sections of this summary, but we highlight two of particular significance.

As discussed earlier in section II.C.1 in the proposed rule (Changes in Relative Value Unit (RVU)), CMS estimates changes in Medicare expenditures using CY 2020 utilization data for purposes of determining 2022 RVUs and determining other factors. Due to the PHE for COVID-19, CMS considered using CY 2019 data, but found that using 2020 data as opposed to 2019 data had relatively little differential impacts on payment (despite the 20 percent decrease in overall service utilization). Table 134 illustrates specialty-specific impacts using 2019 data. Specifically, the majority of specialties experienced of shifts less than one percent.

As discussed in the PE section of this rule (Section II.B. of this proposed rule), CMS is proposing to update the clinical labor pricing for 2022. As an alternative to fully implementing this policy in one year, CMS considered, as an alternative, the use of a similar 4-year transition to implement the pricing update for affected stakeholders. Table 135 illustrates the specialty-specific impacts using the first year of a potential 4-year phase-in for clinical labor pricing. This would smooth out the increases/decreases but would delay the full implementation of updated pricing. CMS does not project any changes to the CF if it were to use a 4-year transition for clinical labor pricing.

E. Impact on Beneficiaries

CMS does not believe these provisions will have a negative impact on beneficiaries given overall PFS budget neutrality. CMS believes proposals related to the Medicare Diabetes Prevention Program will have a positive impact on eligible beneficiaries. With respect to QPP, there are several changes in this rule that CMS expects to have a positive effect on beneficiaries. CMS

believes the MVP and subgroup proposals, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians.

CMS also welcomes specific comments on several provisions for which it was unable to predict the direction or magnitude of specific or aggregate effects. This includes provisions requiring certain manufacturers to report drug pricing information for Part B that would reduce the reliance on payments based on Wholesale Acquisition Cost (WAC) that is sometimes significantly, higher than ASP. For single source drugs, these changes may result in lower payment limits because, typically, the WAC plus 3 percent is higher than ASP plus 6 percent. Similarly, payment limits for multiple source drugs could increase or decrease, and CMS is unable to predict the direction or magnitude of specific or aggregate effects at this time. **CMS welcome comment on: (1) the likely costs or savings to beneficiaries; and (2) other related impacts of this provision.**

Similarly, this proposed rule includes provisions requiring determination of ASP for certain self-administered drug products. For example, the OIG's July 2020 report determined that the inclusion of self-administered versions of certolizumab and abatacept in their respective volume-weighted, average ASPs, alone, has resulted in $173 million in additional Medicare beneficiary coinsurance between 2014 and 2018. **CMS welcomes comment on: (1) the likely costs or savings to beneficiaries; and (2) other related impacts of this provision.**

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 $114.24 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 $913.92 (8.0 hours x $114.24) and the total cost of reviewing this regulation is about $38.5 million ($885.92 x 40,227 reviewers on last year's proposed rule).