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CY 2022 Physician Fee Schedule Final Rule 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 Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-payment Medical Review Requirements
[CMS-1751-F]

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2022[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the November 19, 2021, issue of the *Federal Register*. Policies in the final rules will go into effect on January 1, 2022, unless otherwise specified.

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 final rule updates the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The final rule modifies current policies for split (or shared) E/M visits, critical care services, and services furnished by teaching physicians involving residents. CMS also finalizes policies for services added to the Medicare telehealth list during the COVID-19 PHE and policies for telehealth services used for the diagnosis, evaluation, or treatment of a mental health disorder.[2]

The final conversion factor for 2022 is $33.5983, which reflects the expiration of the 3.75 percent increase for services furnished in 2021[3], the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a budget neutrality adjustment of -0.10 percent.

[2] These policies 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.

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 update to clinical labor pricing appears to be the primary cause of redistributive effects for certain specialties. CMS finalizes the implementation of the clinical labor update over 4 years to transition from current prices to the final updated prices in 2025. Specialties that rely primarily on clinical labor rather than supply or equipment, such as diagnostic testing facilities (+6%) and portable x-ray (+2%), will receive the largest increases relative to other specialties. In contrast, specialties that rely primarily on supply or equipment items, such as interventional radiology (-5%), and vascular surgery (-5%), 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. Thus, the combined effect of RVU changes and the conversion factor is much larger than these impacts.

II. Provisions of the Final Rule

A. Background

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

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

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

1. Practice Expense Methodology

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

For 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).[4] CMS finalizes its proposal to use proxy practice expense per hour (PE/HR) values for these new specialties by crosswalking the PE/HR from specialties that furnish similar services in the Medicare claims data. MDS would use PE/HR data from dermatology, and ACHD would use PE/HR data from

[4] These became recognized Medicare specialties in 2020.

cardiology. The relevant PE/HR data can be found in the 2022 PFS Final Rule PE/HR file published on CMS' website.[5]

CMS did not make any proposals associated with the list of expected specialty assignments for low volume services, but it received comments on this topic from stakeholders. Several commenters provided an analysis to identify all codes that meet the criteria to receive a specialty override. CMS acknowledges the submission and after reviewing this information makes 82 additions to the list of expected specialty assignments for low volume services (Table 1 and Table 2 in final rule). It does not finalize commenters' recommended changes in expected specialty assignment for the CPT codes associated with the thoracic surgery specialty (Table 3). CMS also notes that HCPCS codes and expected specialty assignment remain on the list from year to year and will be applied should the volume fall below 100 services in any calendar year (there is no need to "reactivate" individual codes as some commenters indicated in their submissions).

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 for 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

[5] https://www.cms.gov/files/zip/cy-2022-pfs-final-rule-direct-pe-inputs.zip

codes. These lists are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

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

For 2022, CMS corrects 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 finalizes its proposal 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. The commenters stated that they appreciated and agreed with the correction in calculation.

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 finalizes its proposal 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 sought comment to help it discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083.

Several commenters supported the proposal to maintain the currently assigned specialty (all physicians) for indirect PE allocation for HCPCS codes G2082 and G2083. Others argued that esketamine services were best identified as procedures assigned to the specialty of psychiatry noting that utilization data from CMS indicated that nearly 75 percent of providers in the non-facility setting fall within the psychiatry specialty for both codes. Another commenter suggested a blend of the psychiatry (2/3) and all physicians (1/3) designations. In response, CMS believes that the "all physicians" specialty most accurately captures the indirect PE allocation associated with these services. CMS notes that it does not assign a blended combination of specialties for any other services and commenters did not provide new data to support this change in specialty assignment. It also reiterates its perspective that that it would not 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).

For CPT code 35860 (Exploration of for postoperative hemorrhage, thrombosis or infection; extremity), CMS finalizes its proposal 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.

CMS indicates that due to a technical error, the utilization for anesthesia services was unintentionally duplicated in the files associated with the proposed rule. It apologizes for any confusion and has corrected this issue in the files for the final rule.

c. Updates to Prices for Existing Direct PE Inputs

For 2022, CMS updates the prices of six supplies and two equipment items in response to the public submission of invoices. The 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,[6] the new pricing for these items would take effect for 2022 as there are no remaining years of the transition. See Table 23 in the final rule for details on the updated prices, CPT codes affected, and number of services impacted. In response to comments, CMS also received invoices for negative pressure wound therapy (NPWT) devices; specifically, CMS finalized a price of $263.25 based on the median of the five submitted invoices from one commenter (kit is currently priced at $208).

[6] 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.

The full list of updated supply and equipment pricing as it was implemented over the 4-year transition period is available on the CMS website: https://www.cms.gov/files/zip/cy-2022-pfs-final-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.

For 2022, CMS discusses autologous platelet-rich plasma supply inputs. Stakeholders 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 finalizes its proposal, 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 did not receive any comments on this issue.

d. Clinical Labor Pricing Update

CMS finalizes its proposal to update the clinical labor pricing for 2022 in conjunction with the final year of the supply and equipment pricing update with modifications. Instead of implementing the clinical labor pricing update in one year (2022), CMS finalizes the implementation of the update over 4 years to transition from current prices to the final updated prices in 2025. CMS provides an example of how this transition would be implemented in Table 10 in the final rule (shown below).

Table 10: Example of Clinical Labor Pricing Transition		
Current Price	$1.00	
Final Price	$2.00	
Year 1 (2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (2025) Price	$2.00	

CMS also make additional technical changes to how the rates are calculated and how certain clinical labor types are priced when Bureau of Labor Statistics (BLS) data were not available. CMS will use the median BLS wage data rather than the proposed average or mean wage data for calculation of clinical labor rates. Other technical changes are discussed below.

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). 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 will generally 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 Radiologic Technologists and Technicians as the best proxy category.
The cost per minutes for each clinical labor staff type will be derived by dividing the median hourly wage rate by 60 to arrive at the per minute cost.7 CMS chose to switch from the mean to the median because it notes the median value is less susceptible to outlier values and therefore, better captures the "typical" case. To account for the employers' cost of providing fringe benefits, such as sick leave, CMS proposed to use the same benefits multiplier of 1.366 as used in 2002. Based on comments received, CMS will use the fringe benefits multiplier of 1.296 for employees in private industry based on a BLS release from June 17, 2021 (USDL-21-1094). 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.

Table 12 in the final rule list the updates to CMS' clinical labor prices for the 50 clinical labor types, the year one phase-in rate per minute, and the total percent change (excerpt of this table is reproduced below). On average, the updated final rates are more almost 50 percent more than their current value, but the range of update varies widely from 0 percent for behavioral health care manager to a 105 percent increase for an orthoptist. CMS' decision in the final rule to use the median instead of the average to calculate the wage rate has resulted in smaller increases compared with the proposed rule. For example, the updated rate per minute for an RN was 67% higher than the current rate in the proposed rule, and in the final rule, the RN rate is 49% higher.

[7] 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.

Excerpt of Selected Labor Categories from Table 12: Finalized Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	Y1 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.24	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.29	38%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.35	38%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.41	46%
L038B	Cardiovascular Technician*	BLS 29-2031	0.38	0.60	0.44	58%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.47	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.48	52%
L043A	Mammography Technologist*	BLS 29-2034	0.43	0.63	0.48	47%
L045A	Cytotechnologist*	BLS 29-2035	0.45	0.76	0.53	69%
L046A	CT Technologist*	BLS 29-2035	0.46	0.76	0.54	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.54	62%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.60	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.57	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.58	51%

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

To examine the anticipated effects of the clinical labor pricing update on specialty payments, CMS compared the 2022 rates with and without the clinical labor pricing updates in place. Table 13 (excerpt of this table is reproduced below) shows the specialty impact of both the fully implemented pricing update and the first year of a 4-year transition. 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, show decreases based on updating the clinical labor prices. In contrast, the family practice specialty has a higher share of direct costs associated with clinical labor compared to diagnostic testing facilities and will receive a 2 percent increase compared with a 7 percent decline for diagnostic testing facilities when fully updated. The year one specialty impacts with the 4-year transition are relatively small –the largest percentage decline is 2 percent for interventional radiology and diagnostic testing facilities.

Excerpt of Anticipated Final Clinical Labor Pricing Effect on Specialty Impacts from Table 13†

Specialty*	Allowed Charges (mil)	Fully Updated	Y1 Phase-In Transition
Portable X-Ray Supplier	$86	9%	2%
Endocrinology	$508	2%	0%
Family Practice	$5,765	2%	0%
General Practice	$375	1%	0%
Hand Surgery	$222	1%	0%
Nurse Practitioner	$5,323	1%	0%
Geriatrics	$177	1%	0%
Internal Medicine	$9,979	1%	0%
Orthopedic Surgery	$3,286	1%	0%
Pediatrics	$56	1%	0%
Physician Assistant	$2,825	1%	0%
Pulmonary Disease	$1,478	1%	0%
Psychiatry	$1,053	1%	0%
Optometry	$1,116	1%	0%
Neurology	$1,362	1%	0%
Rheumatology	$543	-1%	0%
Otolaryngology	$1,041	-1%	0%
Pathology	$1,069	-1%	0%
Interventional Pain Mgmt	$897	-1%	0%
Infectious Disease	$644	-1%	0%
Nuclear Medicine	$50	-1%	0%
Radiology	$4,417	-1%	0%
Dermatology	$3,462	-1%	0%
Allergy/Immunology	$221	-1%	0%
Other	$54	-2%	0%
Audiologist	$58	-2%	-1%
Hematology/Oncology	$1,742	-2%	-1%
Independent Laboratory	$557	-2%	-1%
Radiation Oncology and Radiation Therapy Centers	$1,666	-3%	-1%
Oral/Maxillofacial Surgery	$73	-3%	-1%
Vascular Surgery	$1,149	-5%	-1%
Interventional Radiology	$482	-6%	-2%
Diagnostic Testing Facility	$689	-7%	-2%
*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 finalized in this rule.

The following is a summary of the overall comments on the clinical labor pricing, how clinical labor prices are determined, and the pricing of individual clinical labor types.

Commenters were mixed in their overall support of updating the clinical labor rates and its proposed implementation in one calendar year. Those in support cited that after almost 20 years an update to clinical labor pricing was long overdue. Moreover, commenters pointed out that inaccurate prices for PE inputs could lead to distortions in the PE RVUs as updating prices for

equipment and supplies, but not clinical labor could lead to undervaluing of services that use a high share of clinical labor. Others supported the update but stated that it should be phased in using a 4-year transition consistent with previous PE updates, such as the market-based supply and equipment pricing update. They argued that the transition would minimize the reimbursement reductions to services which rely heavily on supply and equipment costs that otherwise could negatively impact beneficiary access to these services. Those in support overwhelmingly agreed that the BLS was the most accurate source of wage data and best source to use for updating the clinical labor pricing. Many also requested that CMS update pricing data on a more frequent basis so that adjustments will not be as dramatic.

Many commenters, however, disagreed with the proposal to update clinical labor pricing and urged that the policy should not be finalized, with or without a 4-year transition. They specifically objected to proposed reductions in many types of services including those in the fields of radiation oncology, peripheral arterial disease, PT/INR home monitoring, flow cytometry, cardiovascular disease, and many others. They expressed concern that the clinical labor pricing update would limit access to Medicare beneficiaries and force many Medicare beneficiaries into the facility-based system resulting in a significantly higher cost to Medicare and its beneficiaries.

CMS agrees with stakeholders that the use of a multi-year transition will help smooth out the changes in payment resulting from the clinical labor pricing update, avoid potentially disruptive changes in payment for affected stakeholders, and promote payment stability from year-to-year. It states that a 4-year transition would be consistent with other broad-based updates and is finalizing the implementation of the clinical labor update over 4 years to transition from current prices to the final updated prices in 2025. In response to those who disagreed with updating the clinical labor prices, CMS states that it recognizes that payment for some services will be reduced as a result of the pricing update due to the budget neutrality requirements of the PFS. However, it does not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs. It notes that other services, such as those primarily furnished by family practice and internal medicine specialists, will be positively affected by the pricing update and thus this change could increase access to care for disadvantaged groups such as women and racial minorities. CMS also agrees that pricing updates should occur more frequently but does not discuss a potential timeframe for periodic updates.

Stakeholders also had specific concerns about the disproportionate negative impact of the clinical labor pricing update on codes with high supply and equipment costs. Many commenters stated that the proposed policy would place a huge and unfair burden on specialties that require expensive supplies and equipment. Many referenced the reduction of the direct scaling factor used in the calculation of PE RVUs noting that updating the clinical labor rates increases direct PE costs by 30 percent. Due to budget neutrality requirements, this results in a reduction of the direct scaling factor of 24 percent from 0.5916 to 0.4468 in 2022 – the net effect that Medicare will now reimburse 44 cents on the dollar instead of 59 cents on the dollar for direct costs. Commenters suggested that if CMS finalized its proposal to update the clinical labor rates it should explore options to adjust the direct scaling factor, maintain the 2021 PE direct scaling factor of 0.5916, or even spread out the cost of the clinical labor update across both the direct and indirect PE pools.

CMS replies that under its current PE methodology it calculates a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs does not vary from the aggregate pool of direct PE costs for the current year. If it maintained the direct scaling factor from a previous calendar year, the amount of PFS spending allocated to direct PE would increase at the expense of all other spending. This would negatively affect the valuation of services that have few or no direct PE inputs and would also result in a substantial negative adjustment to the PFS conversion factor under the statute's budget neutrality requirements as the total number of PE RVUs would increase and would need to be offset through the conversion factor. It also disagrees with commenters that it would be appropriate to spread the increased spending from the clinical labor pricing update across the direct and indirect PE pools as it would have a similar effect to continuing to maintain the direct scaling factor from the previous calendar year. Services that have a higher proportion of indirect PE would be negatively affected as increases in the direct PE pool would be subsidized by the indirect PE pool. It also notes that it did not propose to update its PE methodology and is not finalizing any changes in the methodology.

Several commenters recommended that CMS address the problems related to high-cost supplies by establishing HCPCS Level II codes for supplies that exceed $500. They stated that the establishment of individual coding for high-cost supplies would help maintain patient access to care in the office setting. CMS notes that it did not make any proposals to establish HCPCS Level II codes for high-cost supplies and has addressed this issue in prior rulemaking. It believes that this option presents a series of potential problems in the context of broader challenges regarding its ability to price high-cost disposable supply items (references the 2011 PFS final rule with comment period, 75 FR 73251).

CMS also addresses in its comments how the clinical labor prices are calculated. CMS agrees with commenters that the use of median BLS wage data would be more appropriate than average or mean wage data and it better captures the "typical case" and is not as susceptible to outlier values. It will use the median wage data when finalizing the pricing for the clinical labor update. It also agrees with commenters that it should use a more recent fringe benefits multiplier than the multiplier utilized during the previous clinical labor pricing in 2002. It will use the current fringe benefits multiplier for employees in private industry of 1.296 (instead of 1.366) based on the BLS release from June 17, 2021 (USDL-21-1094).

CMS also received comments regarding the pricing of individual clinical labor types. These changes are as follows:

- Crosswalk of the Angio Technician to the Lab Tech/Histotechnologist (L035A) clinical labor type with a median hourly rate of $26.63 (or an annual rate of $55,390).
- Maintains the RN/OCN clinical labor types rate proposed. In the absence of additional information , it believes the proposed use of BLS category 29-2033 (Nuclear Medicine Technologists) at $37.48 remains the most appropriate pricing for L056A.
- Changes the crosswalk of Histotechnologists (L037B) to BLS category 29-2010 (Clinical Laboratory Technologists and Technicians), which has an updated median hourly wage rate of $25.54.

- Changes the crosswalk of Orthoptists to BLS category 21-1021 (Child, Family, and School Social Workers).
- Changes the crosswalk for the Cardiovascular Technician (L038B) clinical labor type to the BLS category 29-2031 (Cardiovascular Technologists and Technicians).
- Changes the crosswalk for Mammography Technologist (LO43A) clinical labor type to BLS category 29-2034 (Radiologic Technologists and Technicians).
- Changes the crosswalk for Certified Retinal Angiographer (L039A) to the BLS category 29-2057 (Ophthalmic Medical Technician) at a median hourly wage of $23.93.
- Changes the calculate labor rate for physicists based on 2020 salary data submitted by the American Association of Physicists in Medicine (AAPM). CMS arrives at a final adjusted clinical labor rate of $2.14 per minute based on average salary of $205,838 for certified Medical Physicists with a Masters or Ph.D. degrees and its fringe benefits multiplier.

The finalized clinical labor prices are shown in Table 12.

e. Establishment of 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 Codes involving 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.[8] This section discusses two specific innovative technologies and the approach CMS finalizes to account for their resource costs as well a summary of general comments CMS received about accounting for innovative technology in its PE methodology.

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

CMS finalizes its proposal to establish values for remote retinal imaging (CPT code 92229) using its crosswalk approach, and thus this service would no longer be contractor-priced. Specifically, CMS proposes a crosswalk of remote retinal imaging (CPT code 92229) 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

[8] 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.

crosswalk because the total resource costs are similar even if the services provided are very different. CMS states it uses 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.

Many commenters supported CMS' crosswalk proposal as it better reflects the overall relative resource costs for this service. They believed that national pricing for CPT code 9229 helps provide transparency and facilitates beneficiary access to care and that current MAC pricing negatively impacts provider and beneficiary access to novel and vision-saving technologies. Several commenters expressed concern that CMS repeatedly stated that software and analysis fees are not direct expenses. Commenters stated that software directly attributable to a specific physician service is a direct expense and provide multiple examples. CMS acknowledges that although it has typically considered software costs to be indirect PE under its methodology, there have been exceptions to this general principle where software costs have been included directly in the service under review. At the moment, however, CMS believes that the use of this crosswalk and similar crosswalks are the best way to value services that make use of software, licensing, and analysis fees while it explores ongoing potential updates to the PE methodology.

(2) Fractional Flow Reserve Derived from Computed Tomography

CMS sought 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 sought comment on whether CPT code 93455 and CPT code 93458 would be appropriate crosswalks for FFRCT.

CMS finalizes national pricing for CPT code 0503T, based on a valuation crosswalk to the TC for CTP code 93457. CMS explains that it changed the proposed crosswalk because it had intended in the 2022 PFS proposed rule to reference and use the OPPS payment rate but due to a technical error inadvertently referenced the cost information to identify potential resource-based crosswalks under the PFS.

Many commenters supported the proposal to use a crosswalk to recognize resource costs and appropriately pay for CPT code 0503T. Other commenters, including the AMA RUC, expressed concern about CMS' reliance on data from the OPPS in establishing relative values for the PFS. Some commenters requested that CMS use submitted invoice information, which included a price of $1,100 for furnishing the whole service described under CPT code 0503T, as a direct expense input to establish national payment for CPT code 0503T. In response to commenter's concern about its potential use of OPPS cost data, CMS notes that section 1848(c)(2)(N) of the Act authorizes alternative approaches to establishing PE relative values using cost, charge, or other data from suppliers or providers of services in order to ensure accurate valuation of services under the PFS. CMS continues to believe that the costs in the physician office setting are similar to costs reflected under the OPPS (85 FR 84630).

(3) Comment Solicitation for Evolving Innovative Technology

CMS more broadly solicited 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. Overall, commenters were appreciative of CMS' effort to understand and proactively engage on AI topics as well as the acknowledgement that these are not well accounted for in the current PE methodology. A synopsis of those comments follows:

- AI-enabled technology or software algorithms are more likely recurring, and thus CMS should consider these technologies a direct PE instead of an indirect PE.
- Costs should be considered indirect costs and that the PPI survey should be updated more frequently to accurately capture these indirect costs.
- Flexibility is needed in how CMS considers costs to allow for a range of cost structures, such as subscription models, per-use costs, device/supply purchases, and AI service purchases, when determining its approach.
- Three broad categories were identified by some commenters when describing the different roles these technologies play in physician work: (1) assistive, which enhances clinical management, but does not generate additional physician work; (2) automated, which provides additional insight that informs the physician's actions); and (3) autonomous, which provides diagnosis or clinical management decisions, but does not require physician intervention.
- Technologies have the potential to facilitate more efficient and timely care and increase access. Beneficiaries in rural areas, however, with limited broadband access could face barriers.

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.

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

In the proposed rule, CMS discussed the submissions nominating codes for review under the potentially misvalued code initiative. CMS did not propose any of these codes as potentially misvalued. For 2022, CMS finalizes CPT code 49436 as a potentially misvalued service.

Table 14: 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
*Finalizes as a potentially misvalued service for 2022	

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 was concerned that the associated services are misvalued. CMS noted that the stakeholder's determination that the code and common related services are potentially misvalued was based on the billing patterns for the two methods of a procedure.

CMS finalizes its proposal that CPT code 2251 will not be considered as potentially 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 noted 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 was solely performed in the facility ambulatory surgical center (ASC) setting. CMS did not propose CPT code 49436 as potentially misvalued.

The nominator provided additional information about the benefits of providing this service in the nonfacility setting including a reduction in burden to both the practitioner and the patient and promotion of home peritoneal dialysis. The nominator also provided documentation demonstrating the procedure can be safely performed in the nonfacility setting. After considering this additional information CMS believes the code's typical site of service may have changed since it was last valued and finalizes this code as potentially misvalued for 2022.

CPT code 55880 (Ablation of malignant prostate tissue with high intensity-focused ultrasound (HIFU)
A stakeholder nominated CPT code 55880 as misvalued because it was not valued for payment in the non-facility-setting. CMS noted 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 was equally effective and as safe as the cryoablation procedure (CPT code 55873) which is valued in the non-facility setting. CMS noted that CPT code 55880 was reviewed and valued in the 2021 PFS final rule and was only valued for the facility setting.[9] CMS states it does not have enough claims to make an accurate comparison to similar codes furnished in the non-facility setting.

A commenter informed CMS that this service is slated for review by the AMA RUC in 2022 with possible recommendations to CMS in 2024. CMS finalizes its proposal not to consider this code 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 noted that the stakeholder had requested a Level II HCPCS code for Dilapan-S, but that request was not approved. CMS did not make any determination about this nomination.

A few commenters did not agree that Dilapan-S should be added as a supply item. CMS finalizes its proposal not to consider this code as potentially misvalued.

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. Based on CMS' review of claims data in 2018 and 2019 these services were almost always performed in

[9] 85 FR 84614-84615

the ASC facility setting and in 2020 they were performed in the hospital impatient or hospital outpatient facility setting.

CMS finalizes its proposal not to consider these codes as potentially misvalued.

CMS received several comments recommending additional codes as potentially misvalued. CMS suggests commenters consider nominating the code as potentially misvalued services for 2023.

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.[10]

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.

[10] 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 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.

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 15, reproduced with modifications below). CMS finalizes its proposal not to approve the addition of any of these requests to the Medicare telehealth list.

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

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.[11] CMS believes the patient would need to be in the same location as the service.

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.

[11] See discussion in previous rulemaking, 83 FR 59483.

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.[12] 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 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.

Personal Care (98960-98962)
CMS notes that these services are not separately payable when furnished in-person and thus are not separately payable when furnished as telehealth services. These services are always bundled into the payment of other services (Table 16).

Psychotherapy (90849)
CMS notes that this service is not separately payable when furnished in-person and thus are not 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 (Table 16).

Neurostimulators and Neurostimulators, Analysis-Programming. 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 (Table 17). 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 concluded they do not have

[12] 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.

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 finalizes its proposal not to add these services as a Category. CMS notes it added services temporarily to the telehealth services list on an emergency basis to provide access to medically necessary services while avoiding risks for infection during the COVID-19. Commenters did not provide sufficient clinical information to support adding these services to the telehealth list. CMS invites stakeholders to provide additional information and to submit requests for addition to the telehealth list through its usual process.

Some commenters requested CMS add all the codes added to the Medicare telehealth services list on an interim basis during the PHE to the Medicare telehealth list on a Category 3 basis (Table 18). Commenters did not provide any additional clinical information. Absent any additional clinical information, CMS does not believe these services are appropriate for inclusion as a Category 3.

CMS does not agree with comments stating that CMS should maintain payment for telehealth services at the non-facility, rather than facility payment rates. CMS states that payment for telehealth services using the facility PE is consistent with its belief that direct PE costs are generally incurred at the originating site where the beneficiary is located.

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

In the 2021 PFS final rule[13], 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 finalizes its proposal 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.

CMS discusses the requests for consideration as Category 3 services. CMS finalizes the addition of cardiac and pulmonary rehabilitation services to the telehealth list on a Category 3 basis.

Therapy, Audiology and Speech-Language Pathology Services. Commenters requested the addition on these services as Category 3. Commenters did not provide additional information and CMS does not finalize addition of these services.

[13] 85 FR 84507

Cardiac and Pulmonary Rehabilitation. CMS agrees with commenters that it would be appropriate to add these codes to the telehealth list on a Category 3 basis.

Telephone E/M Services. In response to comments that these codes are important for providing mental health services, CMS notes it is finalizing its proposal to revise the definition of "telecommunication system" to allow audio-only technology for certain medical conditions (discussed below). For telehealth services other than mental health care, CMS continues to believe that audio-only telecommunications are appropriate after the PHE.

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
*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[14] 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.

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

- 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.

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.[15]

In the proposed rule, CMS requested comments on 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 and how to distinguish these services.

To implement the statutory requirement for an in-person service, CMS proposed 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 noted 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 discussed 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.[16] In the proposed rule, CMS requested comments on this requirement and how often a patient 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.

To implement the statutory requirement for subsequent in-person services, CMS proposed 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 would distinguish between mental health services furnished for a diagnosed SUD or co-occurring

[15] 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.

[16] 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.

mental health disorder and those furnished to beneficiaries without a SUD diagnosis based on ICD-10 diagnosis codes on claims.

As discussed below in this section, CMS also proposed 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 proposed 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.

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.

Commenters generally supported CMS' proposals to implement these provisions of the CAA, 2021. Many commenters agreed with CMS' alternative policy to allow the required in-person, non-telehealth to be furnished by another practitioner of the same specialty and subspecialty in the same group as the practitioner who would normally furnishes the telehealth service if that practitioner is not available. CMS appreciates suggestions related to claims processing and will consider these in future rulemaking.

Many commenters opposed the proposal to require an in-person, non-telehealth visit every 6 months for beneficiaries receiving mental health services in their home under the CAA, 2021. Commenters was concerned this requirement was excessive and would limit access to services, particularly given the shortage of mental health practitioners. Some commenters stated the practitioner should determine when an in-person interaction is necessary; other commenters stated that if CMS was going to require an in-person visit, it should be extended for as long as possible. Some commenters, including MedPAC supported CMS' proposal because a 6-month requirement would minimize the risk of program integrity issue.

CMS agrees with MedPAC and others that requiring an in-person, non-telehealth service may help reduce program integrity issues, but it is also concerned about access to services. CMS also agrees with commenters that there may be specific circumstances when an in-patient visit requirement may be inadvisable or impracticable for the beneficiary .After consideration of comments, CMS finalizes the proposed in-person visit requirement of 6 months with modifications:

- The in-person, non-telehealth service must be within 12 months of each mental telehealth service; and
- Allow for limited exceptions to this requirement. Specifically, if the patient and practitioner agree that the benefits of an in-person, non-telehealth visit are outweighed by risks and burdens, associated with an in-person service, the in-person visit requirement for that particular 12-month period will not apply.
    - This decision must be documented in the medical record.

CMS notes there is no exception to the statutory requirement that the practitioner must furnish an in-person, non-telehealth service with 6 months prior to the initiation of telehealth for mental health services.

A few commenters requested CMS implement a broad definition of the term "home" as a mental health delivery site because a strict definition would exacerbate existing socioeconomic barriers and reduce access to care. Commenters also pointed out that for privacy reasons, a beneficiary may not wish to receive mental health services in their home and may use a temporary location such as a car or other private location. CMS states that its definition of home, both in general and for this purpose, can include temporary lodging, such as hotels and homeless shelters. CMS clarifies the circumstances when the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth services will still be considered to be furnished "in the home of the individual".

CMS finalizes the proposed amendments to its regulation at §410.78. CMS finalizes:

- The addition of the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders;
- That the geographic restrictions do not apply to these services;
- The conditions of payment requiring an in-person, non-telehealth visit within 12 months of the mental health service in the patient's home; and
- An exception for the subsequent mental health services when the risks and burdens outweigh the benefits of this requirement.

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.

To expand access to mental health services, CMS finalizes its proposal 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. CMS limits this policy 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 finalizes its proposal 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 finalizes its proposal to use a service-level modifier to identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology.

Commenters were very supportive of CMS' proposal to cover mental health services furnished using audio-only communications technology. Some commenters requested CMS allow office/outpatient E/M services furnished via telehealth to be conducted via audio-only communications technology, at least through the end of the year in which the PHE ends. Some commenters requested coverage of audio-only communications for other services. A few comments suggested CMS remove the requirement that the practitioner have access to two-way, audio/video communications technology in order to furnish audio-only telehealth services because practitioners in rural areas may not have access to reliable broadband.

In response, CMS reiterates its belief that mental health services are different from most other services on the Medicare telehealth list in that they primarily involve verbal conversation. CMS clarifies that SUD services are considered mental health services for the purposes of the expanded definition of "interactive telecommunications system" to include audio-only services under §410.78(a)(3). CMS continues to believe that distant site practitioners must have the technical capability to use an interactive telecommunications system that includes two-way, real-time, interactive audio and video communications when an audio-only telehealth service is provided. .

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.[17]

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.

In the proposed rule, CMS solicited 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?

Several commenters stated that CMS should permanently modify the definition of direct supervision to be met through virtual presence using telecommunications technology; other commenters thought CMS should permanently modify the definition of direct supervision for only certain cases. Some commenters supported the use of a service-level modifier to identify services when the supervising physician was available through two-way audio/video communications technology. MedPAC was concerned about making this policy permanent because of potential safety risks with the clinician not being physically available and the possibility that virtual supervision could allow a clinician to supervise many individuals at multiple locations at the same time. CMS will consider these issues in future rules or guidance, as appropriate.

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.[18] HCPCS code G2252 was valued through a direct crosswalk to CPT code 99442.

CMS finalizes its proposal to permanently adopt HCPCS code G2252 and continue to crosswalk payment to CPT code 99442.

Some commenters recommended CMS create a parallel code to HCPCS code G2252 billable by those practitioners who cannot independently bill for E.M services. Commenters noted CMS implemented a similar policy for HCPCS code G2010 and G2012. CMS will consider these comments for future rulemaking.

[17] 85 FR 19245-19245 and 85 FR 84538-84540.
[18] 85 FR 84533-84536

2. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00. For services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act.

The originating fee for telehealth services furnished in 2021 is $27.02 and for services furnished in 2022 is $27.59 (Table 18).

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. According to a report prepared by the Assistant Secretary for Planning and Evaluation (ASPE),[19] 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 final work RVUs, work time and other payment information for all the payable codes in 2022 are available on the CMS website under downloads for the PFS final rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the final rule provide additional details about the 2022 valuation of specific codes:

Table 20	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 21	Direct PE Refinements
Table 22	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 23	Invoices Received for Existing Direct PE Inputs
Table 24	New Invoices
Table 25	No PE Refinements

[19] Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic (hhs.gov)

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.[20] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values.[21]

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 20 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2020. In response to comments, CMS notes that consistent with the policy finalized in the 2015 PFS final rule[22], it will formally review the

[20]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[21]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.
[22] 79 FR 67602 through 67609

recommendations from the April 2021 RUC meeting next year as part of the 2023 PFS rulemaking cycle.

Commenters raised several concerns about the methodologies used for work valuation. Several commenters disagreed with CMS' reference to older work time sources and stated it was invalid to draw comparisons between current work times and work RVUs that were not based on surveyed data and newly survey work time and work RVUs recommended by the RUC. CMS disagrees and states that its operating assumption about the validity of the existing values as a point of comparison is critical to the integrity of the relative value system. CMS notes that if it assumed that previously recommended work times were routinely overestimated, this would undermine the relativity of the work RVUs and also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. CMS believes it is irresponsible to ignore changes in time based on the best available data and that it is statutorily obligated to consider both time and intensity in establishing work RVUs.

CMS also disagrees with comments stating that the use of time ratios is not a valid methodology. CMS reiterates it is statutorily obligated to consider both time and intensity in establishing work RVUs and provides examples of services with identical intraservice and total work time but have different work RVUs. CMS uses time ratios to identify potentially appropriate work RVUs and then uses other methods, including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes, to validate RVUs.

In response to comments that CMS did not consider compelling evidence that services had changed, CMS states this concept was developed by the RUC as part of its process to justify an increase in valuation. The RUC's compelling evidence criteria includes documented change in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the services. CMS considers changes in technology, patient population, and other compelling evidence criteria as they may affect the time and intensity of a service but, it is under no obligation to adopt the same review process of compelling evidence criteria as the RUC.

CMS disagrees with a commenter that there has been a disparate impact on the valuation of cardiothoracic services. CMS states there is no prejudicial approach to the valuation of services from the cardiothoracic specialty or any other specialty.

In response to commenters recommending CMS resume using the refinement panel, CMS states the refinement panel was established to assist CMS in reviewing public comments on CPT codes and not established as an appeals process or reconsideration process for stakeholders. CMS continues to believe the refinement panel was not achieving its intended purpose, but it notes it did not eliminate the refinement panel and could convene panels.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with

recommendations about PE inputs for new, revised, and potentially misvalued codes. Table 21 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 22 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:

- 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 (Tables 23 and 24). 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 increases 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 23 and 24.

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 (77089-77092); capsule endoscopy (91113); and 3D echocardiographic imaging (93319).

4. 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 final rule for more specific details.

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Proposed RVUs	
			Work	PE	Work	PE
1	Anesthesia for Cardiac Electrophysiologic Procedures	00537	No	Yes	Yes	Yes
2	Anesthesia Services for Image-Guided Spinal Procedures	01937-01942	No	Yes	Yes	Yes
3	Closed Treatment of Nasal Bone Fracture	21315 & 21320	No	Yes	Yes	Yes
4	Insertion of Intralaminar/Interspinous Device	22867	Yes	NA	Yes	NA
5	Treatment of Foot Infection	28001-28003	No	Yes	Yes	Yes
6	Percutaneous Cerebral Embolic Protection	33370	Yes	NA	Yes	NA
7	Exclusion of Left Atrial Appendage	33267-33269	Yes	Yes	Yes	Yes
8	Endovascular Repair of Aortic Coarctation	33894, 33895, & 33897	No	NA	Yes	NA
9	Harvest of Upper Extremity Artery†	33509 & 35600	No	NA	Yes	NA
10	Needle Biopsy of Lymph Node	38505	Yes	Yes	Yes	Yes
11	Drug Induced Sleep Endoscopy	42975	Yes	Yes	Yes	Yes
12	Per-Oral Endoscopic Myotomy (POEM)	43497	No	Yes	Yes	Yes
13	Placement-Removal of Seton	46020 & 46030	No	No	Yes	Yes
14	Periurethral Balloon Continence Device Procedures	53451-53454	NA*	NA*	NA*	NA*
15	Intracranial Laser Interstitial Thermal Therapy†	61736 & 61737	No	No	Yes	Yes
16	Arthrodesis Decompression	63052 & 63053	No	NA	No	NA
17	Hypoglossal Nerve Stimulator	64582-64584	No	Yes	Yes	Yes
18	Destruction by Neurolytic Agent	64633-64636	No	Yes	No	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Proposed RVUs	
			Work	PE	Work	PE
19	Destruction of Intraosseous Basivertebral Nerve	64628 & 64629	No	Yes	Yes	Yes
20	Dilation of Aqueous Outflow Canal	66174 & 66175	No	Yes	Yes	Yes
21	Cataract Removal with Drainage Device Insertion	66989, 66991, 6692, 66984,66987, 66988, & 0671T	No	Yes	No	Yes
22	Retinal Detachment Prophylaxis	67141 & 67145	Yes	Yes	Yes	Yes
23	Strabismus Surgery	67311-67320, 67331-67335, & 67340	Yes	Yes	Yes	Yes
24	Lacrimal Canaliculus Drug Eluding Implant Insertion	68841	Yes	No	Yes	Yes
25	Transcutaneous Passive Implant-Temporal Bone	69714, 69716, 69717, 69719, 69726 & 69727	Yes	No	Yes	Yes
26	X-Rays at Surgery Add-on	74301	Yes	NA	Yes	NA
27	Trabecular Bone Score†	77X089-77092	Yes	No	Yes	Yes
28	Pathology Clinical Consult†	80503-80506	No	No	Yes	No
29	ESRD MCP	90954	NA#	NA	Yes	NA
30	Colon Capsule Endoscopy	91110, 91111 & 91113	No	No	Yes	No
31	External Cardiovascular Device Monitoring†	93228 & 93229	No	No	No	No
32	Electrophysiologic Evaluation	93621	No	NA	Yes	NA
33	Cardiac Ablation Services†	93653-93657	No	NA	Yes	NA
34	3D Imaging of Cardiac Structures	93319	Yes	NA	Yes	NA
35	Cardiac Catheterization for Congenital Defects	93593-93598	No	NA	Yes	NA
36	Outpatient Pulmonary Rehabilitation Services	94625 & 94626	No	No	Yes	Yes
37	Remote Therapeutic Monitoring†	98975-98981	Yes	No	Yes	Yes
38	Principal Care Management & Chronic Care Management	99490, 99439, 99491, 99437,	Yes	Yes	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed RVUs Agrees with RUC Recommendations		CMS Finalizes Proposed RVUs	
			Work	PE	Work	PE
		99487, 99489, 99424-99427				
39	Moderate Sedation[#]	G0500	NA	NA	NA	NA
40	Payment for Synthetic Skin Substitutes[†]	HCPCS Level II Codes	NA*	NA*	NA*	NA*
41	External Extended ECG Monitoring	93241-93248	NA*	NA*	NA*	NA*
42	Comment Solicitation for Impact of Infectious Diseases on Codes[†]	NA	NA	NA	NA	NA
43	Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management[†]	NA	NA	NA	NA	NA
[†]Discussed in HPA summary *Contractor Priced Codes [#]Stakeholder request						

(9) Harvest of Upper Extremity Artery (CPT codes 33509 and 35600)
In the proposed rule, CMS discussed 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 noted 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 an 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 proposed to assign the ZZZ-day global period to these codes.

Commenters stated that an XXX global period would allow the individual who performs the harvest of an upper extremity procedure to report it under their National Provider Identification (NPI) number; the individual performing this procedure can be different than the surgeon performing the base CABG procedure and is not the first assistant to the CABG procedure. CMS does not believe the solution to a billing issue should be a change in the global period codes. CMS suggests stakeholders consider using modifiers that describe when a different practitioner is performing the add-on procedure consistent with the same way the practitioner performing the preoperative or postoperative care during the global period can be distinguished from the practitioner performing the surgery.

(15) Intracranial Laser Interstitial Thermal Therapy (LITT) CPT codes 61736 and 61737)
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.[23] CMS did not believe the RUC correctly applied this policy. CMS was also concerned that the RUC recommended 90-day preservice times despite surveying the service as a 00-day service. CMS disagrees with comments supporting the RUC recommendations and finalizes its proposed RVUs for these codes.

(27) Trabecular Bone Score (TBS) (CPT codes 77089-77092)
CPT codes 77089 and 77091 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. In the proposed rule, CMS discussed 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 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 proposed 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.

In response to comments, CMS reiterates it considers most computer software and associated analysis and licensing feeds to be indirect costs linked to costs for the associated hardware that is considered to be medical equipment.

(28) *Pathology Clinical Consult (CPT codes 80503-80506)*
In the proposed rule, CMS discussed 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 requested comments on how these codes would most typically be billed relative to use of existing pathology codes.

In response to comments, CMS maintains that there is not sufficient information provided to support the level of decision making associated with these code descriptors. Based on the additional information provided, CMS does agree that the use of the EP024 microscope would be typical for these codes and restores the RUC-recommended equipment time for EP024 to this policies. CMS notes it will monitor the use of these replacement codes to ensure appropriate billing and inform future rulemaking as needed.

(31) External Cardiovascular Device Monitoring (CPT code 93228 & 93229)
CMS proposed to reduce the RUC recommended work RVUs to account for efficiencies gained by technologic advances. CMS acknowledged that the number of ECG tracings and daily reports

[23] 75 FR 73226

has 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 proposed a lower work RVU (0.43) than recommended by the RUC (0.52). CMS also proposed a reduction in the RUC recommended PE. CMS discussed 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 proposed 0 minutes for this Clinical Activity Code

CMS also requested additional information about the acquisition costs for equipment item EQ340 Patient Worn Telemetry System. CMS noted 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 noted 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.

Commenters disagreed with the proposed work RVUs for CPT code 93228; they stated the use of the intraservice time ratio used to value the code disproportionately decreased the work RVU by 17 percent when the total time only decreased by 8 percent. CMS reiterates its belief that that the intensity of the work has decreased but acknowledges commenters' concerns that the proposed work RVU was disproportionately decreased compared to the decrease in total time and finalizes a work RUV of 0.48. Commenters provided additional information about the quality assurance "overread" done by a second, senior technician, and CMS finalizes the RUC-recommended 24 minutes for this clinical labor activity for CPT code 93229.

Commenters reiterated the uniqueness of mobile cardiac telemetry (MCT) and agreed that invoices were unattainable because companies that furnish MCT manufacture their own devices and systems; the equipment is not bought or sold in the marketplace. Commenters also stated that EQ340 has a relatively short lifespan because it is continuously worn for several weeks which results in wear and tear. CMS maintains the current price of $23,494 and useful life of 3 years for the EQ340 equipment.

(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 believed 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 resurvey and review at the April 2021 RUC meeting. CMS reviewed the initial survey information and it agreed 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 proposed 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

Commenters were concerned that the proposed RVU reductions in Cardiac Ablation codes would reduce the number of providers of these services and impact beneficiaries' access to atrial fibrillation treatments. Some commenters requested that CMS and AMA withdraw the restructuring of these codes because they did not agree that these services should be bundled.

CMS notes that the AMA CPT restructured these codes because evidence from claims indicated that procedures were frequently bundled together on the same day, with the same practitioner, for the same beneficiary. The CPT panel decided to retain the old procedure code and only adjust its descriptor; this appears to have created misunderstanding with the survey respondents. CMS concludes that unbundling these services is not possible and finalizes its proposal to maintain the current values until it has new RUC recommendations for next year. CMS acknowledges that these codes were resurveyed and discussed at the RUC April 2021 meeting. CMS' established policy is that recommendations from the RUC April meeting, along with recommendations from the subsequent October and January meetings, are considered part of the next PFS rulemaking cycle. CMS will consider the recommendations from April 2021 as part of the 2023 PFS proposed rule.

(37) Remote Therapeutic Monitoring (CPT codes 98975-98981)
The RTM codes is a family of five codes that includes three PE-only codes and two codes that include professional work. In the proposed rule, CMS noted the new five RTM codes have similar services and code structure as the existing seven Remote Physiological Monitoring (RPM) codes. CMS discussed 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 believed 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).[24] "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.[25] 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 also discussed the data collection for the RTM codes which includes musculoskeletal system status, respiratory system status medication

[24]Non-Physician Practitioners (NPPs) include certified nurse midwifes (CNMs), certified nurse specialist (CNSs), nurse practitioner s(NPs) and Physician Assistant (PA)s.
[25] 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.

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 noted that for both code sets, the device must meet the FDA definition of a medical device.[26]

The majority of commenters disagreed with CMS' determination that physical therapists cannot bill RTM codes. Although the services may be performed incident to the services of a billing physician or practitioner, commenters did not believe the codes represent "incident to" services when billed by PT. CMS continues to view the clinical labor described in the RTM codes as being services incident to the billing practitioner's services. Because it believes these services are important to beneficiaries, it finalizes that non-E/M billing practitioners (e.g., therapists) and other qualified health care professionals can bill the RTM codes. When the practitioner's Medicare benefit does not include services incident to their professional services, the items and services described by these codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the PT's or OT's supervision. CMS will also designate the five RTM codes as "sometimes therapy" codes which means that the services can be billed outside a therapy plan of care provided by a physician and certain NPPSs but only when appropriate.

Commenters made several recommendations addressing the supervision status of these codes, including designating the RTM treatment management codes as care management services or alternatively developing HCPCS G codes as designated care management services to allow general rather than direct supervision. CMS also acknowledges comments received about the RTM device-supply code. CMS appreciates comments and will continue to work with stakeholders to address these issues.

(40) Payment for Synthetic Skin Substitutes

CMS discusses its payment policy for synthetic skin substitutes in the OPPS. In the 2021 OPPS final rule,[27] 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. CMS notes that under the OPPS, payment for C1849 is packaged into payment for the graft substitute procedure, and its costs are incorporated into the payment rate for these services. CMS explained 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).[28]

Under the PFS, graft skin substitute application services are paid separately from the HCT/PS skin substitutes. To reconcile the gap in payment for synthetic products in the physician office setting, CMS proposed to 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 codes were based on the body area of the application and surface area of the wound. CMS

[26] Federal Food, Drug, and Cosmetic Act (FFDCA) section 201(h)
[27] 85 FR 86064-86067
[28] Section 361 of the Public Health Services (PHS) Act

proposed contractor pricing for these codes. CMS noted there is limited data available on the cost of synthetic skin substitute products in physician offices.

CMS discussed an alternate approach to pricing that would involve crosswalking 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 noted, 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 crosswalks 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.

A commenter supported the proposed eight HCPCS codes; this proposal was consistent with the commenter's belief that CMS should consider separately identifying and paying for services with disposable supplies over $500. The commenter disagreed with the proposed alternative to crosswalk values to OPPS rates and asserted this would be inconsistent with the statutory authorities for the PFS. CMS responds that section 1848(c)(2)(N) of the Act authorizes CMS to use alternative approaches to establishing or adjusting RVUs using cost, charge, or other data from suppliers or providers of services to ensure accurate values under the PFS.

Several commenters appreciated CMS' recognition of the need to develop appropriate payment mechanisms for synthetic skin substitute products but urged CMS not to finalize its proposal to treat these products as incident to supplies in the physician office and not distinguish between products. Commenters recommended CMS pay separately for the procedure using the existing skin substitute application codes (CPT codes 15271-15278) and establish specific HCPCS codes for each distinct synthetic skin substitute product. Commenters noted that synthetic skin substitutes have variable costs and pricing. A few commenters stated that alternatively, CMS could mirror the outpatient department methodology by assigning skin substitutes to a high or low-cost category and establish a single payment rate for each category.

After consideration of comments, CMS finalizes establishing a unique HCPCS code for each of the 10 products it has received a HCPCS Level II coding application and also finalize that these products will be payable in the physician office setting as contractor price products that are billed separately from the procedure to apply them (CPT codes 15271-15278). The ten products are: NovoSorb SynPath, Restrata Wound Matrix, Symphony, InnovaMatrix AC, Mirragen Advanced Wound Matrix, bio-ConneKt Wound Matrix, TheraGenesis, XCelliStem, Microlyte Matrix, and Apis. CMS indicates that it will post information about this new HCPCS Level II codes in

November on its website at https://www.cms.goc/medicare/coding/medhcpcsgeninfo. CMS finalizes these codes will be contractor priced.

Commenters also urged CMS to re-evaluate the OPPS payment policy and made other suggestions for improving payment for all types of skin substitutes across all settings. CMS plans to further evaluate this issue in future rulemaking.

(41) External Extended ECG Monitoring (CPT codes 93241-93248)
In the proposed rule, CMS discussed 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 proposed to maintain contractor pricing for these codes.

Several commenters submitted invoices for use in pricing the SD339 supply items which ranged from a price of $179.80 to a maximum of $241.99. Based on the ten invoices submitted, CMS finalizes an updated price of $200.15 for the "extended external ECG patch, magnetic tape recorder" (SD339) supply. Because these services have a high utilization and would impact budget neutrality adjustments for 2022, CMS believes that a proposal to establish national payment for these services should take into account stakeholder feedback. Therefore, CMS does not finalize national pricing at this time and finalizes maintaining contractor pricing for these codes for 20222. CMS continues to encourage stakeholders to provide invoices or other additional information for pricing SD339 supplies to assist CMS in setting national prices for 2023.

(42) Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting
In the proposed rule, CMS discussed 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 sought comments about additional strategies to account for PHE-related costs and whether CMS should consider making changes to payments for existing services or develop separate payment for services in future rulemaking.

Many commenters suggested the use of a new modifier for use with E/M codes to ensure that resources are available for the increased work associated with care during an outbreak. Commenters recommended establishing a permanent policy to reimburse clinicians for managing future infectious disease outbreaks. Many commenters recommended CMS implement and pay for CPT code 99072 (additional supplies, materials and clinical staff time when performed with a PHE). CMS will consider this feedback in future rulemaking.

(43) Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management
In the proposed rule, CMS discussed the challenges for adequate treatment of pain, including information from the CDC, HHS and the National Academy of Medicine. The SUPPORT Act[29] 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 tasks necessary to perform pain management care. CMS 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 requested 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 also sought 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)?

CMS appreciates the comments (over 1,900) it received and will consider these for future rulemaking.

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 proposed refinements to policies regarding split (or shared visits), critical care services, and teaching physician visits.

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

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.[30]

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.[31] 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.[32] 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[33] 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.

As discussed below, CMS finalizes the following policies for split (or shared) E/M visits:

- A split (or shared) visit is a visit billed by the physician or practitioner who provides the substantive portion of the visit.
- For 2022, the substantive portion of the visit can be history, physical exam, medical decision making (MDM), or more than half of the total time (except for critical care which can be more than half of the total time).
- Split (or shared visits) can be reported for new as well as established patients, initial visits, subsequent visits, and prolonged services.
- A claim modifier will be required to identify these services.

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[30] § 410.26(b)(1)
[31] Sections 30.6.1(B) and 30.613(H) of the Medicare Claims Policy Manual
[32] 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.
[33] 2021 CPT Codebook, p.7.

- Documentation in the medical record must identify the individuals who performed the visit and the individual providing the substantive portion must sign and date the medical record.

CMS codifies these policies at §415.140.

b. Definition of Split (or Shared) Visit

CMS finalizes its proposal 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 finalizes the definition of a 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 also finalizes its proposal 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 believes a split (or shared) visit billing policy is not needed 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.
Commenters were generally supportive of the definition. A few commenters stated that "incident to" policies exclude new patient visits in the office setting and recommended CMS allow billing of split (or shared) visits in all settings, both institutional and non-institutional. CMS is considering addressing requirements for new and established patients in future rulemaking and it does not think it should address this issue through the split (or shared) visit policy.

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 proposed to define "substantive portion" as more than half of the total time spent by the physician and NPP performing the visit.

In the proposed rule, CMS discussed 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.

Approximately half of the commenters supported this proposal and half recommended alternative definitions of substantive portion. Commenters provided a wide range of recommendations for the definition of substantive portion including a lower percentage of time (25 to 30 percent of the total time); MDM; choice of MDM or time; one of the three key components of history, exam, or MDM; and working with the AMA to revise CPT E/M Guidelines.

CMS does not believe MDM is necessarily the most critical component of the E/M visit and it does not believe that MDM can be readily attributed to only the physician or the NPP, or definitely divided between them. CMS also does not believe that the higher physician payment rate should be made when the physician performs less than half of the visit.

CMS believes commenters overestimate the administrative burden of tracking and attributing time but understands an adjustment period might facilitate this activity. CMS finalizes its proposed policy with a modification to provide a one-year transition period. For 2022, except for critical care visits, the substantive portion will be defined as one of the three key components or more than half of the total time spend by the physician and NPP performing the split (or shared) visit. CMS states that the practitioner who spends more than half of the total time, or performs the history, exam, or MDM can be considered to have performed the substantive potion and can bill for the split (or shared) E/M visit. CMS clarifies that when one of the three key components is used as the substantive portion in 2022, the practitioner who bills the visit must perform that component in its entirety to bill. For critical care visits, starting in 2022, the substantive portion will be more than half of the total time. Table 26, reproduced below summarizes this policy.

Table 26: Final Definition of Substantive Portion for E/M Visit Code Families

E/M Visit Code Family	2022 Definition of Substantive Portion	2023 Definition of Substantive Portion
Other Outpatient*	History, or exam, or MDM, or more than half of total time	More than half of total time
Inpatient/Observation/Hospital/Nursing Facility	History, or exam, or MDM, or more than half of total time	More than half of total time
Emergency Department	History, or exam, or MDM, or more than half of total time	More than half of total time
Critical Care	More than half of total time	More than half of total time
*Office visits will not be billable as split (or shared) services.		

(2) Distinct Time. CMS finalizes its proposal 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.[34] CMS provides examples for counting time.

[34] 2021 CPT Codebook, p.7.

(3) Qualifying Time. Based on the CPT E/M Guidelines, CMS proposed a list of activities that could count toward total time for purposes of determining the substantive portion. For visits, excluding critical care services, CMS proposed the same list of activities can count when time is used to select E/M visits.[35] CMS sought comments on whether there should be a different listing of qualifying activities for determining the qualifying time of split (or shared) emergency department visits.

Commenters were generally supportive of this proposal. For ED visits, some commenters thought the proposed activity list could apply to both office outpatient and ED visits; other commenters recommended the CPT Editorial Panel address this issue. One commenter recommended several revisions to the list to remove time-based activities and focus MDM as the determining component of an ED visit. After reviewing the comments and consulting with the CMS medical officers, CMS does not believe an alternative listing for ED visit is necessary. CMS agrees with commenters that this issue should be considered by the CPT Editorial Panel.

In response to comments requesting clarification of the requirement for face-to-face contact with the patient, CMS cites the current CPT E/M Guidelines, "The E/M services for which these guidelines apply require a face-to-face encounter with the physician or other qualified health care professional. A shared or split visit is a visit in which a physician and other qualified health care professional (s) jointly provide the face-to-face and non-face-to-face work related to the visit."[36] CMS believes that in this context face to face means in-person. CMS notes that its intent was that only one of the practitioners must perform the in-person part of an E/M visit when it is split (or shared) and finalizes as proposed that the substantive portion can be comprised of time that is with or without direct patient contact.

CMS finalizes its proposal to use the CPT listing of qualifying activities for time for E/M visits, including ED visits. CMS also finalizes its proposal that for all split (or shared) visits, one of the practitioners must have face-to-face (in-person) contact with the patient, but it does not necessarily need to be the provider who performs the substantive portion and bills for the visit. The substantive portion could be entirely with or without direct patient contact and will be determined by the proportion of total time, not whether the time involves direct or in-person patient contact.

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

CMS notes that during the 2022 transition year, when practitioners use a key component as the substantive portion, a different approach will be necessary for billing a prolonged E/M visit as a split (or shared) visit. CMS finalizes that for shared office/outpatient visits when practitioners use a key component as the substantive portion, prolonged services can be reported by the

[35] 2021 CPT Codebook, p.8.
[36] 2021 CPT Codebook, p.7.

practitioner who reports the primary service when the combined time of both practitioners needs the threshold for reporting prolonged office/outpatient services (HCPCS code G2212). CMS notes this is a complex approach, but prolonged services are not frequently reported. Table 27, reproduced below), summarizes these policies.

Table 27: Reporting Prolonged Services for Split (or Shared) Visits

E/M Visit Code Family	2022		2023
	If Substantive Portion is a Key Component…	**If Substantive Portion is Time…**	**Substantive Portion Must Be Time**
Other Outpatient*	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212
Inpatient/Observation/ Hospital/Nursing Facility	Combined time of both practitioners must meet the threshold for reporting CPT 99354-9 (60+ minutes > typical)	Combined time of both practitioners must meet the threshold for reporting CPT 99354-9 (60+ minutes > typical)	Combined time of both practitioners must meet the threshold for reporting prolonged services
Emergency Department	N/A	N/A	N/A
Critical Care	N/A	N/A	N/A
*Office visits will not be billable as split (or shared) services.			

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

CMS finalizes its proposal 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 finalizes its proposal to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting.[37] This allows 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.[38]

f. Same Group

CMS finalizes its proposal 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 sought comments on whether it should further define "group" for purposes of split (or shared) visit billing. CMS discussed 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.[39]

[37] Section 410.26(a)(6) defines the non-institutional settings as all settings other than a hospital or SNF.
[38] 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.
[39] 2021 CPT Codebook, p.6.

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).[40] CMS also considered practitioners with the same billing tax identification number (TIN) but acknowledged this may be too broad a definition for some multi-specialty groups or health care systems.

Commenters agreed that the physician and NPP should be in the same group. Commenters had various recommendations about how CMS should define group, including that CMS work with the AMA Workgroup on E/M to create a proposal for the CPT Editorial Panel to consider. After consideration of comments, CMS decides not to further define "group".

g. Medical Record Documentation

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

h. Claims Identification

CMS finalizes its proposal to create a modifier to describe split (or shared visits) that must be appended to claims for split (or shared) visits.

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

CMS finalizes its proposal to adopt the CPT prefatory language for critical care services as currently described in the CPT Codebook[41], 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 might revisit these policies in future rulemaking.

As discussed below, CMS finalizes the following policies for critical care services:

- Critical care services are defined in the CPT Codebook prefatory language.
- The CPT codebook listing of bundled services are not paid separately.
- When medically necessary, critical dare services can be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty and can be split (or shared) visits.
- Critical care services may be paid on the same day as other E/M visits by the same practitioner or another practitioner in the same group of the same specialty. The medical record must document that the E/M visit was provided prior to the critical care services and the patient did not require critical care. Practitioners must report modifier -25 on the claim when reporting critical care services.
- Critical care services may be paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure. CMS will create a

[40] 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.
[41] 2021 CPT Codebook, pp. 5-9 and pp. 31-33.

new modifier for use on claims to identify that the critical care is unrelated to the procedure. If care is fully transferred from the surgeon to an intensivists (and the critical care is unrelated) the appropriate modifier must also be reported to indicate the transfer of care.

a. Definition of Critical Care

CMS finalizes its proposal to adopt the CPT prefatory language as the definition of critical care.[42] 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.[43] To be consistent with the CPT definition, CMS finalizes that critical care services may be reported by a physician or NPP who is a QHP, consistent with Medicare policy.

CMS finalizes its proposal 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 finalizes its proposal to adopt this rule for critical care services furnished by a single physician or NPP.

CMS noted that the CPT codebook does not indicate how practitioners should report critical care when a service lasts beyond midnight. CMS sought 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. Commenters provided a range of suggestions about reporting services beyond midnight. CMS notes that since the publication of the proposed rule, it has identified CPT guidance about this issue. According to the CPT introductory language, "Some services measured in units other than days extend across calendar days. When this occurs, a continuous service does not reset and create a first hour. However, any disruption in this service does create a new initial service." [44] CMS adopts this rule for critical care services that cross midnight.

[42] 2021 CPT Codebook, p.31.
[43] See 80 FR 70957; 85 FR 83543, 84593.
[44] 2021 CPT Codebook page xvii.

c. Critical Care Services Furnished Concurrently by Different Specialties

CMS finalizes its proposal 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 an NPP), regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services.

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 finalizes its proposal 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 report their time using the code for subsequent time intervals (CPT code 99292) and do not report the primary service code (CPT code 99291). Under this policy, CPT code 99291 will not be reported more than once for the same patient on the same day by these practitioners.

CMS also finalizes its proposal 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 policy 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 policy, the time spent by these practitioners would be aggregated.

e. Split (or Shared) Critical Care Services

CMS finalizes its proposal 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 will be summed, and the practitioner who furnishes the substantive portion of the cumulative critical care time will report the critical care service.

When critical care services are furnished as a split (or shared) visit, CMS finalizes its proposal 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 finalizes that 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 finalizes that the documentation and other rules finalized for split (or shared) E/M visits (discussed above) 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 was concerned that adopting the CPT rule that critical care and other E/M visits may have unintended consequences for the Medicare program. CMS discussed 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.[45]

CMS proposed 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 acknowledged that this proposal may be appropriate only in certain clinical situations.

CMS received many comments opposing this proposal. Commenters stated the proposal was contrary to the CPT Codebook and did not provide the flexibility to allow practitioners to provide an E/M service on the same day as a critical care service when both services are medically necessary. Commenters provided examples when both services are medically necessary.

After consideration of comments, CMS finalizes that an E/M service can be provided prior to the critical care service, if at a time the patient did not require critical care and the service was separate and distinct from the critical care service provided later in the day. Practitioners must use modifier -25 on the claim when reporting these critical care services.

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 proposed to bundle critical care visits with procedure codes that have a global surgical period. CMS received many comments opposing this proposal. Commenters stated that policy would have a significant negative impact on the quality and safety of patient care.

After consideration of comments, CMS does not finalize this policy. CMS will create a new modifier to identify that the critical care is unrelated to the procedure. If care is fully transferred from the surgeon to an intensivist (and the critical care is unrelated), modifiers -54 (surgical care only) and -55 (postoperative management only) must also be reported to indicate the transfer of care. CMS notes it may consider in future rulemaking an MPPR-like adjustment to identify critical care billed in conjunction with a global surgery procedure and discount one of the services instead of paying both in their entirety.

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

h. Documentation

In addition to documentation supporting the medical necessity of the service, CMS finalizes its proposal 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, the teaching physician must be present during the portion of the service that determines the level of service billed.

CMS finalizes its proposal 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. In response to comments, CMS clarifies that only time spent by the teaching physician performing qualifying activities listed by CPT (with or without direct patient contact on the date of the encounter), including time the teaching physician is present when the resident is performing those activities, may be counted for purposes of the visit level selection. This time excludes teaching time that is general and not limited to discussion that is required for the management of a specific patient.

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 finalizes its proposal that under the primary care exception, only MDM can be used. CMS is concerned that selecting an E/M visit level based on time 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.

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 proposed 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.

There were public comments both in support of and opposed to this proposal. In response to comments opposed to the proposal, CMS reiterated that it is merely implementing requirements of the CAA, 2021 and it has no independent authority to continue the prior policy that required Medicare payment be made to the PA's employer.

H. Therapy Services

CMS implements the final part of section 53107 of the Bipartisan Budget Act (BBA) of 201846. 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.

[46] Pub. L. 115-123, February 9, 2018

In the 2019 PFS final rule,[47] 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,[48] 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
- 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.

In the proposed rule, CMS discussed 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

[47] 83 FR 59654-59660
[48] 84 FR 62702-62708

scenarios.[49] 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 discussed the comments it received from therapy stakeholders indicating that the March 2021 guidance had 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 finalizes its proposal to revise the *de minimis* standard to determine whether services are provided "in whole or in part" by PTAs or OTAs. Specifically, CMS finalizes revision of 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, will not matter for purposes of billing Medicare.

In addition, this revision will 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 finalizes its proposal 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 when the total time is at least 23 minutes and no more than 28 minutes. CMS discusses several billing scenarios in the rule (Tables 28 and 29).

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 15-minute 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 will 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.

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

Many commenters, including the major therapy stakeholders, appreciated the updated interpretation of the *de minimis* standard. Many commenters requested a delay of the therapy assistant payment policy until 2023 to allow time to provide education to practitioners and provide time for providers to recover financially from the COVID-19 pandemic. Commenters also asked for an exemption of the 15 percent payment differential for rural and underserved areas because OTAs and PTAs provide a disproportionate amount of therapy services in these areas. CMS responds that it does not have the authority to change the statute. Section 1834(v)(1) of the Act does not provide CMS with flexibility to change either the implementation date or exempt rural or other underserved areas from the 15 percent payment differential for therapy services provided in whole or in part by PTAs and OTAs.

CMS also received many comments about other therapy, including supervision of PTAs and OTAs, telehealth, and RTM services. CMS notes that the supervision requirements were not addressed in the proposed rule and it will consider these issues in future rulemaking. CMS reiterates that the virtual presence definition for direct supervision is effective until the later end of the calendar year in which the PHE ends or December 31, 2021.

CMS finalizes payment for RTM services and designates the five RTM codes as "sometimes therapy" codes (discussed in section II.E). As sometimes therapy codes, the RTM services can be billed outside a therapy plan of cate when provided by a physician and certain NPPs, but only when appropriate. CMS notes that RTM services that relate to an RTM device that is specific to therapy services, such as the ARIA Physical Therapy device supply in CPT code 98977, must also be furnished under a therapy plan of care when furnished by physicians and NPPs. RTM services must be provided under direct supervision when not directly performed by physicians, NPPs, or therapists; and RTM services delegated by PTs and OTs to PTAs and OTAs are subject to the *de minimis* standard. To accommodate the two 20-min CPT codes 98980 and 98981 under the *de minimis* policy, CMS is making a technical amendment to the regulatory text to recognize this 20-minute time interval as an "other time interval."

2. Therapy KX Modifier Threshold Amounts

The KX modifier thresholds were established through section 50202 of the BBA of 2018. These per-beneficiary amounts are updated each year based on the MEI. For 2022, the targeted medical review (MR) threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Under the targeted review process, some, but not all claims exceeding the MR threshold amount are reviewed.[50]

Regulatory Impact
CMS acknowledges there may be a cost implication to the revised *de minimis* standard definition as fewer billing scenarios may result in application of the CG/CO modifiers and consequent payment reduction. It believes this might eliminate the PT's/OT's financial incentive to not limit appropriate therapy to an individual patient when services are furnished by the PTA/OTA. CMS

[50] Information on the targeted medical review process is available at https://www.cms.gov/ResearchStatistics-Data-and-Systems/MonitoringPrograms/Medicare-FFSCompliancePrograms/Medical-Review/TherapyCap.html.

concludes it is uncertain how to gauge the overall costs of this policy because of this 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. Instead, payment 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 rectifies the coinsurance issue 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 modifies its regulations to implement the changes to the Medicare statute.

A commenter believed that a beneficiary may still be subject to coinsurance for anesthesia services when screening flexible sigmoidoscopy or screening colonoscopy becomes a diagnostic test in the case of a biopsy or removal of the lesion or growth; CMS was urged to modify its regulations to hold the beneficiary harmless for any coinsurance for these anesthesia services. CMS notes it previously modified its definition of colorectal cancer screening tests for screening colonoscopy to include anesthesia furnished in conjunction with the colonoscopy, but it failed to make a corresponding modification to the definition applicable to flexible sigmoidoscopy. It notes that the CAA did not make any changes to these definitions, and CMS did not include any such proposal in its proposed rule. It will take this comment into consideration for future rulemaking.

In response to a commenter who suggested allowing providers to voluntarily waive beneficiary coinsurance for colorectal cancer screening tests before 2030, CMS notes that any such waiver must comply with applicable fraud and abuse laws, including the AKS and the CMP for beneficiary inducements. CMS received other comments that were out of scope but which the agency may take into consideration for future rulemaking on issues such as coverage of bowel preparation products, coverage of non-invasive screening tests that require a follow-up colonoscopy, and cost-sharing for new colorectal screening technologies.

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 the 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 preventive vaccines under Medicare Part B under 1861(s)(10) of the Act. Table 32 in the final rule (reproduced at the end of this section) shows the payment amounts for administering preventive vaccines.

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 sought detailed feedback on a variety of policy questions 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.

a. Comments.

Commenters noted the importance of vaccination for positive health outcomes for Medicare beneficiaries, the falling rate of immunizations, and disparities in vaccination among racial and ethnic minorities. CMS received feedback on specific types of expenses incurred by providers of

COVID-19 and other preventive vaccines (noting higher costs for administration of the COVID-19 due to factors like storage, filling, scheduling of second doses, monitoring, patient education and outreach, staffing and training, PPE, and additional paperwork burdens). Other input highlighted costs of vaccine administration during the pandemic generally and costs associated with establishing outreach clinics and mass immunization sites.

While commenters support the $40 per dose payment rate for COVID-19 vaccines, they believe the lower reimbursement rate of $16.94 for other preventive vaccines may discourage many providers, especially smaller, independent practices and those in underserved areas from offering vaccines to their patients. Some commenters supported the RUC recommendation that CMS crosswalk HCPCS codes G0008-10 to CPT code 90471, using inputs that would result in a payment rate of roughly $21 per dose. The RUC also recommended crosswalking codes for COVID-19 vaccine administration to CPT code 90460 (result in a payment of roughly $30 for the vaccine administration codes) and an additional payment of roughly $10 for the duration of the PHE for new CPT code 99072 (*Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease*) to reflect the additional PEs associated with administration of the COVID-19 vaccines during the PHE.

Other commenters recommended decoupling payment for preventive vaccine administration from the crosswalk to a code valued under the PFS; they favor a site-neutral payment rate of $40 per dose for administration of all Part B preventive vaccines. Other comments suggested crosswalking vaccine administration services to CPT code 36000 (*Introduction of needle or intracatheter, vein*).

b. Response and Final Policy.

CMS concurs with commenters who suggested decoupling payment for vaccine administration from the crosswalk to the PFS and treating them independently. CMS believes that the service to administer the vaccines is essentially the same and does not vary significantly across different provider types. While CMS agrees that the PHE poses unique challenges for the administration of the COVID-19 vaccines, it anticipates that after the end of the PHE costs will decrease. It believes patient volumes will stabilize; providers will incorporate schedule and reporting into the routine clinical practice; and providers will have already made capital investments for COVID-19 vaccines.

Thus, CMS will continue the payment of $40 per dose for COVID-19 vaccines until January 1 of the year that begins after the termination of the PHE when the payment rate for administration of the COVID-19 vaccines will be the same as the payment rate for administration of the other Part B preventive vaccines.

With respect to payment for the administration of the other Part B preventive vaccines, CMS establishes a uniform payment rate of $30 for 2022. It finds that this amount is roughly equivalent to the 2021 valuation of CPT code 36000 adjusted for inflation to 2022. The agency declines to establish payment rates that address unique costs experienced across the wide variety

of providers and suppliers that administer vaccinations because it believes such a policy would require unnecessarily complex payment methodology and might delay implementation. Noting that the statute operates such that payment rates for vaccines administration services are independent of the PFS, it notes that the payment rates finalized above will be updated as necessary independently of the valuation of any specific codes under the PFS. Nonetheless, CMS continues to seek feedback on an appropriate methodology to update the rates. CMS will monitor immunization rates among Medicare beneficiaries to discern the impact of the payment policies it finalizes in this rule.

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[51] 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.

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. In a change of policy, effective August 24, 2021, CMS announced that the following two locations will be considered to be the patient's home for this purpose.

- Communal spaces of a multi-unit living arrangement.
- Assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program.

However, hospitals, Medicare SNFs, and Medicaid NFs, regardless of whether they are the patient's permanent residence, are not considered to be the patient's home for this purpose. CMS

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

clarified in the proposed rule 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.

In the proposed rule, CMS stated that 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). CMS announced a policy clarification effective August 24, 2021, under which Medicare will pay the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; however, this only applies when fewer than 10 Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living location. When 10 or more Medicare patients receive a COVID-19 vaccine dose at a group living location on the same day, the additional payment may only be billed once per home—whether the home is an individual living unit or a communal space.

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 sought feedback on its policies for vaccine administration in the home.

Commenters supported the additional payment of $35.50 for the administration of the COVID-19 vaccine in the home and recommended that the policy continue after the end of the PHE; many also suggested extending this policy to other Part B preventive vaccines citing the importance of increasing immunizations and the increased costs of furnishing these services in the home. Some commenters objected to what they describe as overly restrictive conditions for eligibility for the additional in-home payment, such as the policy that the payment will not be made if another Medicare service is provided on the same day (e.g., a home health visit). Others believed CMS failed to take into account unique cultural dynamics of households in Indian Country.

CMS finalizes its policy to extend the additional payment of $35.50 when a COVID-19 vaccine is administered in a beneficiary's home (under certain circumstances) until the end of the year in which the PHE expires. CMS notes that while it has not established any specific medical record documentation requirements, it has issued guidance on the circumstances where payment is available; the agency advises vaccine providers to ensure that the medical record documentation is sufficient to support payment.

3. Monoclonal Antibodies Used to Treat COVID-19

When monoclonal antibody products were authorized during the PHE for COVID-19, CMS covered and paid 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. It also noted that tocilizumab was previously FDA approved for several indications which means there are separate coding and payment rules for the product when furnished to patients with COVID-19 and when furnished for other clinical purposes. CMS sought feedback on its coverage and payment policies for these monoclonal antibody products.

Some commenters encouraged the agency to continue to cover monoclonal antibodies for the treatment of COVID-19 under the Part B vaccine benefit, some urging CMS to extend that payment rule beyond the end of the PHE. Others supported the transition to payment as biologics though they encouraged the agency to develop policies that mitigate beneficiary out-of-pocket expenses. Still other commenters who cited patient safety concerns recommended against in-home administration of these products.

CMS finalizes a policy to transition to treating COVID-19 monoclonal antibody therapies as biologicals that are paid under section 1847A of the Act following the end of the calendar year in which the PHE expires. This policy decision parallels the two finalized policies described above to maximize access to vaccines in the home during the PHE. CMS notes that after the termination of the PHE, EUAs issued under that authority will no longer apply. It further believes that after the end of the PHE, the public health needs that prompted coverage and payment of COVID-19 monoclonal antibody therapies (and their administration) under the Part B vaccine benefit will gradually restabilize. Before the transition to payment as a biological, payment will continue to be made to providers and suppliers for the products themselves at 95 percent of AWP except when they are provided for free by the government. CMS will also maintain the $450 payment

rate for administering a COVID-19 monoclonal antibody in a healthcare setting and the $750 payment rate for administering a COVID-19 monoclonal antibody therapy in the home.

Table 32 in the final rule (reproduced below) shows the payment amounts for administering preventive vaccines.

	Current	**Effective Jan. 1, 2022**	**Effective Jan. 1 of the year following the year in which the PHE expires**
Administration of influenza, pneumococcal and HBV vaccines	$16.94/dose	$30/dose	
Administration of COVID-19 vaccines	$40/dose	$40/dose	
Additional payment when a COVID-19 vaccine is administered in the home setting	$35.50	$35.50	
Payment for COVID-19 monoclonal antibody products	95% of AWP except when provided for free by the government	95% of AWP except when provided for free by the government	Section 1847A of the Act
Payment for COVID-19 monoclonal antibody administration	$450 in the healthcare setting; $750 in the home setting	$450 in the healthcare setting; $750 in the home setting	Suppliers and providers paid under the applicable payment system

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 of 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 finalizes its proposed changes to do so as well as the other proposals made with respect to policies for registered dietitians and nutrition professionals in the proposed rule.

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 creates a new section §410.72 to reflect these policies. Through cross-references to other regulations, the agency (1) specifies qualifications for registered dietitians and nutrition professionals; (2) includes requirements for referrals for MNT services from a physician (an M.D. or D.O.); and (3) clarifies that MNT services must be directly performed by the registered dietitian or nutrition professional in a face-to-face encounter (except when furnished as a telehealth service). CMS had proposed to require that the services be "personally performed" by the registered dietitian or nutrition professional; however, it concluded that the reference to "personally performed" could be confusing since that term describes services that may be furnished both directly and incident to the services of other practitioner types. The statute does not authorize registered dietitians or nutrition professionals to furnish and bill for services incident to their professional services. The reference to "directly perform" in the regulations as finalized is intended to clarify that registered dietitians and nutrition professionals may only bill Medicare for professional services that they furnish directly to the beneficiary. In response to a question, CMS clarifies that the referral for MNT services must be from an M.D. or D.O.; the physician may not co-sign an MNT referral made by an NPP.

CMS includes diabetes self-management training (DSMT) services in new §410.72(b)(2) as an "other service" that registered dietitians and nutrition professionals may provide subject to certain conditions. These conditions include requirements that (1) the registered dietitian or nutrition professional be 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 condition that DSMT services require a referral from the physician or qualified NPP who is treating the beneficiary's diabetes condition is added. New section §410.72 also specifies that MNT and DSMT services may not be furnished together on the same date of service[52] and that neither MNT nor DSMT services may 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) must personally furnish 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.

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

Section §410.72 also incorporates current rules that prohibit payment for MNT services furnished to beneficiaries who are inpatients in Part A stays in hospitals, skilled nursing facilities, nursing facilities or hospice as well as those rules that prohibit coverage of MNT services for beneficiaries receiving services from an ESRD facility or in an RHC or FQHC.

Finally, CMS adds regulatory text stating that services of registered dietitians or nutrition professionals are provided on an assignment-related basis and that they may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. Any impermissible charges must be refunded to the beneficiary. CMS makes minor technical changes to the language of the regulation as proposed.

Section III. I. of the final 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 policies.

III. Other Provisions of the 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 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).[53] 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.

In response to public comments, the final rule clarifies or confirms the following policies:

- RHCs that are provider-based to hospitals under 50 beds that did not have an AIR established for services furnished in 2020 will have their payment limit per visit

[53]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.

established based on their AIR determined by MACs using the RHC's final settled cost report ending in 2021. The interim rate estimate will be reconciled at cost report settlement for the cost reporting period ending in 2021 which is used to establish the RHC's payment limit per visit for services furnished in 2021.

- Provider-based RHCs whose enrollment application was received by CMS as of December 31, 2020 will not be required to complete their certification process by the end of 2021 to qualify for the higher limit on the AIR applicable to RHCs provider-based to hospitals under 50 beds.
- To receive the higher limit on the AIR applicable to RHCs provider-based to hospitals under 50 beds, the RHC must have submitted the enrollment application. It is insufficient to qualify for this higher limit with documentation of a material effort to have applied by the deadline.
- The temporary policy that allows an increase in beds over 50 for provider-based RHCs applies during the COVID-19 PHE only. It does not apply to future PHEs. Once the COVID-19 PHE ends, RHCs must be provider-based to hospitals under 50 beds to retain the special higher limit on the AIR.
- Protocols are already in place to determine how the MACs establish the bed count. The MAC reviews the number of beds twice a year to determine whether the provider-based RHC meets the requirements for the special higher limit on the AIR applicable to RHCs provider-based to hospitals under 50 beds.
- Standard cost reporting reconciliation rules will apply when establishing the AIR for provider-based RHCs. Audit adjustments will be reconciled at cost report reconciliation and cannot be recouped through future reductions in payment. As with all other cost report appeals, RHCs may appeal audit adjustment to the Provider Review Reimbursement Board.
- Change of Hospital Ownership (CHOW) rules will govern the provider-based RHC's status as being subject to a higher limit on the AIR. If the acquiring owner accepts assignment of the Medicare provider agreement, the special payment rules for provider-based RHCs associated with that provider agreement would apply to the new owner.
- A change of address, updates to a facility (for example, cosmetic improvements), or altering of a specified provider-based enrollment record are not likely to affect an RHC's status as long as it continues to meet all rules that allow it to qualify for that special status.

There were comments that objected to CMS' proposal to disallow consolidated cost reports for all multi-facility RHCs. These comments suggested CMS should only prohibit consolidated cost reports for multi-facility RHCs when the RHCs are not all subject to the same AIR limit. CMS agrees and will permit new RHCs (that is, enrolled under section 1866(j) of the Act on or after January 1, 2021) to file consolidated cost reports with:

- New RHCs that are provider-based;
- New RHCs that are independent;
- Existing independent RHCs; and/or
- Existing provider-based RHCs that are in a hospital that has greater than 50 beds.

One commenter requested that CMS clarify whether a hospital that acquires a new RHC that is subject to the national statutory payment limit may still include the new RHC on the consolidated cost report. CMS indicated that the hospital cost report provides the ability to identify a group of RHCs as consolidated and identify an individual RHC. More information on identifying provider-based RHCs on the hospital cost report (FORM CMS-2552-10) is available in PRM 15-2, Chapter 40, section 4010.

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 proposed to change the regulations to conform with these statutory changes.

There were comments that asked CMS to clarify that a patient electing hospice can change their attending physician to an RHC/FQHC practitioner after their initial hospice election. These commenters requested that CMS eliminate the phrase "at the time of election" from the regulatory text. The commenters indicated that this language implies that an RHC/FQHC practitioner would have to selected at the time of election of hospice benefits and could not be selected at any other time. CMS agreed and is finalizing the regulatory change as requested by the commenters.

In response to a comment about revenue codes for billing as an RHC hospice attending physician, CMS indicates a new revenue code is not needed for RHCs to bill this service. HCPCS modifier, -GV, defined as "attending physician not employed or paid under arrangement by the patient's hospice provider" provides the necessary information for RHCs and FQHCs to bill.

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 proposed to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided that all requirements for billing each code are met. Commenters supported the policy that CMS is finalizing without change.

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 proposed 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 policy would be limited to services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. Public comments were supportive of this proposal A few commenters requested that this flexibility be extended to medical visits furnished at RHCs and FQHCs, not just mental health visits. However, CMS responded that this comment was outside the scope of its proposal.

MedPAC commented that FQHC and RHC-provided telehealth services should be paid at rates comparable to those under the PFS. CMS responded that payment for virtual communications and care management services furnished at RHCs and FQHCs are paid based on PFS rates; however, these services describe non-face-to-face encounters between a patient and an RHC or FQHC practitioner and are paid outside of the AIR or PPS. CMS is finalizing this proposal without modification.

Consistent with its PFS policy, CMS proposed 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. Public comments supported this proposal that CMS is finalizing. 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 proposed 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. There were no comments on this proposal that CMS is finalizing without modification.

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 sought comment on whether there should be a similar requirement for mental health services furnished by RHCs and FQHCs via telecommunications technology.

Comments both supported and opposed this proposal. Opponents said that the policy could negatively impact access to care and recommended CMS defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate. Supporters said that requiring an in-person visit every 6 months ensured some level of physical proximity between the patient and provider. CMS is persuaded by the comments related to ensuring access in the event of in-person needs and alignment with requirements under Medicare FFS but is modifying the policy in the final rule. Under the final rule policy, CMS will require an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service. CMS is modifying its proposal for an in-person visit following the telehealth services in the final rule to at least every 12 months.

CMS will allow for limited exceptions to the requirement that there be an in-person, non-telehealth service every 12 months in circumstances where the patient and practitioner consider the risks and burdens of an in-person service to outweigh the benefits. The practitioner must document the basis for that decision in the patient's medical record. Situations in which the risks and burdens associated with an in-person service may outweigh the benefit could include, but are not limited to instances when:

- An in-person service is likely to cause disruption in service delivery or has the potential to worsen the patient's condition(s);
- A patient receiving services is in partial or full remission and only requires a maintenance level of care;
- The clinician's professional judgment is that the patient is clinically stable and/or that an in-person visit has the risk of worsening the beneficiary's condition, creating undue hardship on self or family, or if it is determined that the patient is at risk for disengagement with care that has been effective in managing the illness.

CMS further stresses that patients and providers should determine the frequency of in-person meetings as driven by clinical needs and they may occur at any frequency level.

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 solicited 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 requested 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 requested comment on whether it can use the section 1834(o)(1)(A) of the Act as 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?

CMS summarized a variety of comments on the issue noting that many did not agree that billing as an FQHC is the only or best solution since so few clinics elect to enroll as an FQHC due to the burden of submitting cost reports. Comments suggested that all outpatient Indian Health programs qualify for reimbursement at the AIR regardless of how they are enrolled in Medicare. CMS responded that although it did not receive specific information on costs or specific types of clinics, it will consider making all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR for future rulemaking.

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 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; civil money penalties for misrepresentation, late reporting, and reporting of false information; and increasing oversight and enforcement 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 proposed to amend the definition of the term "drug" at § 414.802 to 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. In response to a comment, CMS stated that the ASP reporting requirement does not apply to radiopharmaceuticals as they are not paid under section 1847A of the Act that applies only to drugs and biologicals (even though radiopharmaceuticals may be paid based ASP when ASP is reported).

Some commenters asked CMS to be more specific on the definition of "drug" that requires manufacturer ASP reporting. CMS was emphatic in responding that further specificity is unneeded and the manufacturer of any product paid under Part B as a drug or biological must report ASP beginning January 1, 2022. CMS is finalizing its proposed definition of drug.

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. Public commenters agreed with this proposal that CMS is finalizing without change.

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 proposed 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). There was one public comment supporting these proposals that CMS is finalizing without modification.

CMS received a number of comments outside the scope of the proposed rule. Of these, the one of most interest asked CMS to publish an ASP limit for all codes for which ASP is reported. Commenters supported this request by stating that products with a published ASP have an advantage over those without one. CMS did not respond to the request other than to say that it was out of scope of the proposed rule and not required by section 401 of the CAA, 2021.

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, 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 proposed 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 had also proposed:

- 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.

CMS finalized all of these policies. Public comments expressed a variety of concerns about the above proposals including:

- Neither CMS nor the OIG has specified details about future OIG studies, what criteria the OIG will use to initiate a study, how often such studies will be conducted, if external stakeholders will be able to request a study; and factors that the OIG will use when determining which NDCs are "self-administered";
- CMS does not specifically define the term "self-administered" for purposes of the lesser-of methodology nor describe whether CMS and/or the OIG will refer to contractor self-administered drug lists to determine if a drug should be studied;
- Not applying the lesser of methodology to certolizumab pegol and abatacept billing and payment codes as they may negatively impact patient access to the most appropriate treatment for their disease; and
- Requesting CMS to abandon the lesser-of methodology in favor of a model that works to provide appropriate reimbursement for all drugs including consideration that including non-covered NDCs may reduce the volume-weighted ASP leading to disincentives in the marketplace for those drugs and again impacting patient access.

CMS responded to the first two of the above comments by stating that it cannot reply because the statute assigns responsibility for future studies of this issue to the OIG. With respect to not applying the lesser of policy to certolizumab pegol and abatacept, CMS responds that policy is required by statute. On the last comment, CMS responds that paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment amount for a single-source drug or biological be determined using all of the NDCs assigned to it. Further, section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

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 code 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.[54] However, CMS did not finalize its proposal.

CMS solicited comments on a more detailed framework in the proposed rule. 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 did not propose to adopt the framework but requested comment to inform future policy making.

The framework intends to 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 requested 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

[54] 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)

- The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

Several commenters noted that CMS lacks the statutory basis for the framework. Others commented that framework does not result in meaningful differences between drug products. There were comments expressing concern that implementation of the framework would slow innovation by discouraging manufacturers from using the section 505(b)(2) pathway for drug approval. The commenters also stated that payment for section 505(b)(2) drug products as multiple source drugs could result in inadequate reimbursement, and subsequently, may limit access to patients in the physician office setting. There were also comments in support of the framework and/or assigning these products to multiple source drug codes. CMS will take these comments into consideration for future rulemaking.

F. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (PAMA)[55] 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[56] 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.

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

The payment penalty phase of the AUC was scheduled to begin January 1, 2022. As discussed below, CMS finalizes its proposal 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 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. Continuing Implementation

CMS provides clarification and finalizes proposals related to updates or modifications to orders for advanced diagnostic imaging and the extreme and uncontrollable circumstances hardship exception. CMS finalizes several claims processing solutions to ensure identification of claims that are and are not subject to the AUC program requirements. CMS finalizes its proposal 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. 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)[57] 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

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

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 finalizes its proposal that when the furnishing professional for an advanced diagnostic imaging service modifies an order for advanced diagnostic imaging services with a replacement and/or additional imaging service, and is unable to reach the order professional for a new order as 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, 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.

Commenters generally supported this policy. A few commenters stated that the proposal conflicts with a prior response to public comments in the 2018 PFS final rule addressing order modifications. One commenter stated the proposals for modified orders are confusing and require furnishing professionals to report erroneous information.

CMS disagrees that the proposal conflicts with prior guidance and explains that the commenters did not reference the CMS response in its entirety. CMS believes the proposal provides further clarification that when the furnishing professional is unable to reach the ordering professional to obtain a new order and proceeds with additional or different imaging as described in the BPM, the AUC consultation information for the original order is to be appended to the claim for the service(s) ultimately furnished.

CMS also disagrees that the proposal results in reporting of erroneous information on the Medicare claims. CMS notes that in the situations described in the BPM, no other AUC consultation takes place and the furnishing physician does not become the ordering physician. In these situations, the only AUC consultation information pertinent to the specific patient for the specific clinical scenario was obtained when the ordering professional consulted the AUC for the original order and is the only AUC consultation information that could be appended to the claim. CMS may consider in future rulemaking whether an additional modifier should be appended to all modified orders for which new orders are not submitted by the original ordering professional to ensure that furnishing professionals are not furnishing services unilaterally and without the acknowledgement of the ordering professional. CMS notes that the AUC program is designed to improve ordering patters of ordering professionals, and this may not be achieved if orders are frequently modified without the involvement of the ordering professional.

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).

In response to commenters requesting various additional exceptions, CMS notes its authority to include exceptions to the AUC is limited to those specified in section 1834(q)(4)(C) of the Act. Thus, the AUC program does not include exceptions similar to the QPP. CMS also notes that imaging ordered pursuant to a clinical trial protocol is not excluded from the AUC requirements. CMS states that claims for clinical trials covered by Medicare require the national clinical trial (NCT) identifier number, HCPCS modifiers Q0 or Q1 and ICD-10 diagnosis code Z00.6 on the claim form.

In response to commenters requesting clarification about the requirements for second opinions under the AUC program, CMS states the AUC consultation and reporting requirements apply to second opinions in the same way they apply to original patient assessments and resulting orders for advanced diagnostic imaging services. CMS notes that second opinions are different from modified orders, so if new or additional orders result from the second opinion review, there should be new, subsequent orders that would be subject to the AUC program requirements.

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 processing instructions issued to support the educational and operations testing period.[58] 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.

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. In the proposed rule, CMS also discussed situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim. CMS did not think this would be possible 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.

In response to a comment referencing different sections of the 837 professional claim form, CMS further reviewed this form and agrees with the commenter that the practitioner who orders the advanced diagnostic imaging service can be identified at the line level. This means that 837 professional claims will not be required to be submitted separately for each ordering professional. CMS notes this will minimize the burden concerns raised by other commenters. CMS will continue to evaluate which line-item field is most appropriate for this information.

After consideration of comments, CMS will develop claims processing instructions that will allow more than one ordering professional of advanced diagnostic imaging services to be reported on the practitioner 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.[59] CMS must identify these claims and allow them to bypass program claims processing edits. For institutional claims, CMS intends to

[58] CR 11268, Transmittal 2404 available at https://www.cms.gov/files/document/r2404otn.pdf.
[59] In accordance with section 1833(q)(1)(D) of the Act, a CAH is not an applicable setting under the AUC program.

apply the claims processing edits to type of bill 13x (outpatient hospital settings); type of bill 85x is used by CAHs.

In the proposed rule, CMS discussed the requirement to report AUC consultation information on the claims from both professionals and facilities.[60] 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 proposed that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting 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. CMS had not yet identified a way to allow a claim for the corresponding PC service to bypass AUC program claims processing edits. CMS proposed 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.

CMS finalizes its proposal that claims submitted by physicians or practitioners for the PC of an advanced diagnostic image service when the TC was not furnished in an applicable setting are not subject to the AUC program. CMS also finalizes its proposal to use a modifier to identify practitioner claims that are not subject to the AUC program (discussed below)

iii. Maryland Total Cost of Care Model

In the proposed rule, CMS discussed 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. CMS proposed that the PC's of these advanced diagnostic imaging services, when billed separately, are not required to include AUC consultation information.

One commenter was concerned that excluding HOPDs participating in the Maryland Total Cost of Care Model would provide an incentive for ordering professionals to send Medicare patients to hospitals instead of non-hospital entities which would disrupt existing referral patterns and have financial impacts. CMS appreciates these concerns, but it is unable to modify the AUC statutory provisions. Since services furnished under the Maryland Total Cost of Care Model are not paid under an applicable payment system, these services are not subject to AUC requirements.

CMS will continue to work to set up claims processing edits using the CMS Certification Number (CCN) in box 32 of the CMS 1500 claim form to identify advanced diagnostic imaging services furnished under the Maryland Total Cost of Care Model for claims that are not subject to the AUC program requirements.

[60] 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.

iv. Inpatients Converted to Outpatients
In the proposed rule, CMS discussed the uncommon situations when a beneficiary's hospital inpatient status changes to outpatient and the criteria that must be met to append condition code 44 (inpatient admission changed to outpatient) to the institution claim.[61] CMS proposed 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.

Some commenters supported this proposal but noted that not all patients moved from inpatient to outpatient will be captured with condition code 44. Commenters recommended CMS create an exception for any inpatient order for advanced diagnostic imaging services furnished within a short period after the inpatient discharge and create a new modifier for instances where inpatient imaging orders are performed in the outpatient setting shortly after discharge. As discussed below, CMS finalizes AUC claims processing edits to apply to all applicable settings under the AUC program.

CMS finalizes its proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits.

v. Deny or Return Claims that Fail AUC Claims Processing Edits
In the proposed rule, CMS discussed 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 noted that a transition may be helpful as professionals and facilities submit claims under the AUC program.

Some commenters recommended that claims should be returned for correction instead of being denied. A few commenters suggested returning claims for a limited time such as one year and then transition to denials. CMS agrees that returning claims for correction and resubmission when the payment penalty phase begins would be most appropriate.

vi. Medicare as a Secondary Payer
In the proposed rule, 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.

In response to a question about AUC requirements for Medicare Managed Care claims, CMS notes that AUC program requirements are specific to fee-for-service Medicare, so Medicare Advantage organizations (MAOs) are not required to follow AUC requirements. Similarly,

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

these requirements do not apply to Medicaid. CMS notes that MAOs might require contacted providers to follow Medicare ACU program procedures.

CMS finalizes its proposal 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. CMS notes that Medicare claims include a date of service but do not include the date the image is ordered.

CMS finalized its proposal 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 ordered 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. This first set is included on the same claim line as the CPT code for the advanced diagnostic imaging.[62]

- 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.

[62]In the proposed rule, CMS incorrectly stated that the first set of modifiers was to be included on the same claim line as the G-code identifying the CDSM.

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 proposed 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 noted this could be repurposed for CAH and other circumstances that fall outside the scope of the AUC program requirements.

Several commenters requested more clarification about the use of modifier MA and one commenter requested information about which modifier to use for the patient in the emergency department who does not qualify for the emergency services exception but whose insurance status is unknown. Another commenter requested that all ED visits be excluded. CMS reiterates that the statute and regulations include the ED visits as an applicable setting under the AUC program; the exception is for applicable imaging services for individuals with an emergency medical condition. As such CMS cannot exclude all services provided in an ED, including those furnished to patients whose insurance is unknown at the time of treatment.

CMS received many comments about the proposals for modifier MH. Comments included supporting the proposal to repurpose modifier MH, suggestions for maintaining modifier MH, and not supporting the proposal because repurposing would create confusion. Commenters recommended CMS should create a new modifier. CMS agrees with commenters that modifier MH should not be repurposed. CMS does not agree with commenters that modifier MH should be maintained during the payment penalty phase because this is not consistent with any provision in the statute. CMS intends to retire modifier MH when the payment penalty phase of the program begins.

In response to concerns that these modifiers could result in claims processing issues with secondary non-Medicare payers, CMS states that the modifiers for the AUC program are valid HCPCS modifiers and all payers are required to accept all HCPCS modifiers. CMS will continue to consider all claims processing options; working with stakeholders, CMS has not yet identified a more streamlined and less burdensome approach.

CMS finalizes the use of both the QQ and MH modifiers will end when the payment penalty begins. Instead of repurposing modifier MH, CMS will establish a new modifier to identify claims where the ordering professional is not required to consult AUC and the already established modifiers do not apply.

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 finalizes its proposal to limit AUC processing edits to apply only to the following:

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

In response to comments, CMS believes that the above list includes all applicable settings, including IDTFs, where advanced diagnostic imaging services must be furnished subject to the AUC program requirements.

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 finalizes its proposal that the 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.

The overwhelming majority of commenters supported CMS' effective date for the payment penalty phase to begin. Several commenters suggested alternative start dates, including 2024, or not until the vast majority of submitted claims include sufficient information for payment. Commenters offered additional opinions on the AUC program and the relationship between the AUC program and quality programs. Commenters suggested aligning the goals of the two programs to minimize burden and duplication. Some commenters suggested alternative options for enforcing compliance with AUC consultation requirements, including allowing the use of qualified clinical data registries and collecting required data directly from CDSMs. One commenter requested an annual attestation and CDSM audit approval. A few commenters recommended that CMS work with Congress to delay the program and re-evaluate the utility of the program.

CMS appreciates the extensive comments and recommendations on the AUC program. CMS reiterates that the program is required by statute. It will continue to explore opportunities to reduce the burden of the AUC program by leverage other quality programs. CMS acknowledges the comments and suggestions for expanded education and outreach efforts.

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

[63] 83 FR 60034-60044

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 138, reproduced below, summaries the substantive changes from the 2019 PFS final rule to the 2022 final rule impact estimates. Each of these incremental changes results in a lower estimate.

Table 138: 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.

[64] 85 FR 84472

- 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.
- 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.

CMS Table 33, reproduced below, lists the two NCD's CMS finalizes for removal. These NCDs were identified 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 33: 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 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.

[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 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.

Commenters supported removal of these NCDs. Several commenters requested that instead of removing NCD 180.2, that CMS update this NCD because they were concerned that MACs would make LCDs that would create discrepancies in the availability of coverage across the country. Some commenters recommended CMS create a new benefit category for enteral and parenteral nutrition to encompass more than the current definition of prosthetic devices.

CMS states it does not have the authority to establish new Medicare benefit categories or to establish coverage through NCDs for items or services that fall outside the scope of the Medicare Part A or Part B benefits prescribed in title XVIII of the Act. CMS covers parenteral and enteral nutrition based on the prosthetic benefit in section 1861(s)(8) of the Act for certain patients.

One commenter suggested that CMS use a "hybrid" approach for removing NCDs that would include an annual review of all NCDs in addition to reviewing NCDs that are 10 years old. The commenter stated that 10 years may be too long to keep pace with current developments. CMS acknowledges the rapid pace of medical changes and will consider these factors as it evaluates whether existing NCDs should be reviewed.

Comments recommended additional NCDs for future removal:

- NCD 20.7 Percutaneous Transluminal Angioplasty (PTA);
- NCD 140.1 Abortion;
- NCD 160.22 Ambulatory EEG Monitoring;
- NCD 220.6.19 PET (Na-F-18) to Identify Bone Metastasis;
- NCD 220.6.20 Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease;
- NCD 220.13 Percutaneous Image-Guided Breast Biopsy;
- NCD 230.2 Uroflowmetric Evaluations;
- NCD 230.11 Diagnostic Pap Smears; and
- NCD 230.16 Bladder Stimulators (Pacemakers).

CMS will take these recommendations into consideration for future review.

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. Revisions

a. Covered Conditions for PR

CMS proposed covering 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.

All commenters supported expanding coverage of PR to include beneficiaries recovering from COVID-19. Commenters had varying opinions about the specific coverage parameters ranging from agreeing with the proposed parameters to not limiting PR to hospitalized patients. Commenters discussed the rapidly evolving evidence and the need to expand coverage.

After consideration of comments, CMS finalizes that PR is covered for beneficiaries who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. CMS states this includes beneficiaries regardless of the setting in which they were treated for COVID-19. Eligible beneficiaries do not need a positive COVID-19 test but they must have had confirmed or suspected COVID-19 and must experience persistent symptoms of COVID-19 that include respiratory dysfunction for at least 4 weeks. CMS notes the 4-week time frame may begin with the onset 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 finalizes 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 finalizes its proposal 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 finalizes the proposal 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.

In response to comments, CMS reiterates that under the statute, PR and CR/ICR programs include individualized treatment that is furnished under a written plan established, reviewed, and signed by a physician every 30 days. CMS does not have the allowing to allow for the ITP to be signed by a physician after the first day services are furnished.

4. Impact

CMS believes the finalized expansion of PR coverage may increase utilization. It estimates the total added cost to the Medicare program to be $8,871,323 annually during and immediately following the COVID-19 PHE. The impact of including all eligible beneficiaries regardless of the treatment setting for COVID-19, increased the number of eligible beneficiaries by 290,555

As COVID-19 cases decline, CMS expects the annual impact to decrease because the eligible patient populations will likely decrease. However, CMS 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.

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

CMS finalizes its proposal to 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 these limitations have contributed to the low uptake of referrals to MNT services. CMS states that the treating physician restriction is no longer necessary; it expects 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 finalizes a conforming change to eliminate the definition of a "treating physician" from §410.130.

b. Update the eligibility criteria for patients with CKD

CMS finalizes its proposed 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.

The majority of commenters supported these proposals. In response to commenters requesting expansion of MNT services to beneficiaries with other diseases and allow NPPs to be considered the ordering physician, CMS states it does not have the authority to extend coverage beyond beneficiaries with diabetes or renal disease as the benefit is defined in statute in section 1861(s)(2)(V) of the Act and section 1861(vv)(1) of the Act required the order of a physician for MNT coverage under Part B.

Several commenters requested the definition of diabetes in §410.130 include Hemoglobin A1C greater than 6.5 percent, the recommended national standard of medical care for diabetes. They noted that both the USPSTF and the American Diabetes Association Standards of Care

recommended the use of any of the following three tests to screen for abnormal blood glucose: fasting plasma glucose; Hemoglobin A1C; and 2-hour plasma glucose. CMS appreciates this additional information, but it believes that changes to coverage provisions need to include notice and comment rulemaking; it will consider this issue for future rulemaking.

CMS disagrees with suggestions that the definition of renal disease should include CKD stage 1 and stage 2. CMS believes chronic renal insufficiency or CKD stages 3 and 4, are the stages when interventions are often initiated to prevent progression of kidney disease to renal failure.

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 final rule, CMS finalizes its proposal 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 finalizes actions to amend the reporting requirements for ACOs under the APM Performance Pathway (APP); update the APP's quality measure set; amends the Shared Savings Program's quality performance standard; revises the program's extreme and uncontrollable circumstances exception (ECE) policy; and updates the definition of primary care services used to assign beneficiaries to the program's ACOs.

CMS clarifies sampling policies applicable to Shared Savings Program ACOs when fielding the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey. CMS also acknowledges comments received in response to requests for comments on multiple topics, including promoting health equity within the Shared Savings Program.

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[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 86 FR 45503.

a. CAHPS Survey Sampling Clarification

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 the 2022 PFS proposed rule, CMS responded to stakeholder queries about CAHPS survey minimum sampling thresholds. In this final rule, CMS notes that commenters have indicated that uncertainty persists about how the CAHPS for MIPS survey thresholds will be applied to Shared Savings Program ACOs.

In this final rule, CMS offers further clarification. Beginning with PY 2021, CAHPS for ACOs minimum sampling thresholds have been replaced by those of CAHPS for MIPS. Beneficiary samples will continue to be generated at the ACO level with a target sample size of 860 patients. Minimum sampling thresholds will vary by ACO size.[70] 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 measure will be excluded from the denominator (number of total measures) during ACO scoring. CMS emphasizes that excluding the CAHPS measure in this way assures that an ACO that cannot meet the survey minimum sampling threshold will not be penalized for its inability to administer a CAHPS for MIPS survey.

CMS also notes that for the CAHPS for MIPS survey measure, the MIPS term *performance period* is considered interchangeable with the ACO term *performance year*, with each meaning one full CY.

b. Amended Quality Reporting under the APP

CMS finalizes with modifications the proposed requirements associated with transitioning from CMS Web Interface quality data reporting to reporting under the APP: 1) the transition timeline is extended through PY 2024 and 2) a requirement that Shared Savings Program ACOs must report at least one of the APP's three electronic clinical quality measures/MIPS clinical quality measures (eCQMs/MIPS CQMs) for PY 2023 is not finalized.[71]

Coincident with requiring Shared Savings Program ACOs to report quality data via the APP, CMS had finalized a transition during which the CMS Web Interface would be phased out as an option for data submission. For PY 2021, ACOs could choose to report using either the Web Interface or APP measure sets; for PY 2022, the only option would be the APP measure set.

In response to strong and persistent stakeholder objections to the transition as finalized during 2021 rulemaking, in the 2022 PFS proposed rule CMS proposed to extend until PY 2024 the

[70] Thresholds are 416 patients for large ACOs (100 or more MIPS-eligible clinicians), 255 patients for medium ACOs (25-99 clinicians), and 125 patients for small ACOs (2-24 clinicians).
[71] The three clinical measures are available in both electronic (eCQM) and non-electronic format (MIPS CQMs).

time under which ACOs may continue to report quality data via the Web Interface. Thereafter the sole reporting option would be the 6 APP measures (3 eCQMs/MIPS CQMs, 2 claims-based measures, and the CAHPS for MIPS survey). CMS also invited comment on an alternative, to extend the availability of the Web Interface reporting option for 2024 and subsequent years.

Commenters continued to be extremely concerned about the transition from the Web Interface to the APP for quality reporting and as the basis for the ACO quality standard requirements. Issues identified include ACO lack of readiness, burden and infrastructure costs of transition, variation in EHR products used by TINs within an ACO, the COVID-19 PHE, and potential HIPAA compliance issues due to the all-payer patient data required for reporting under the APP instead of only assigned Medicare beneficiaries under the Web Interface.

A few commenters supported the transition timeline as proposed. However, most urged further delay at least through PY 2024. They also noted that a proposed interval requirement for PY 2023 – that ACOs report at least one of the APP's three eCQMs/MIPS CQMs – poses the same challenges as the proposed PY 2024 requirement for reporting all three measures, since essentially the same resources are necessary for reporting one measure as for reporting all three. Technical challenges of data aggregation and de-duplication faced by ACOs whose providers use differing EHR products were also cited as reasons for delaying transition.

CMS is persuaded by commenters' concerns and modifies the transition timeline, finalizing that the Web Interface reporting option for Shared Savings Program ACOs will be extended through PY 2024 but no longer be available beginning with PY 2025. CMS is also persuaded that the burden and costs for reporting one eCQM/MIPS CQM are equivalent to those for reporting multiple measures and does not finalize the proposed PY 2023 requirement for ACOs to report at least one such measure.

CMS further responds that HIPAA permits disclosure by Shared Savings Program ACOs of protected health information that is "required by law", such as under the agency's quality reporting regulations, although updates to ACOs' Business Associate Agreements with their providers and suppliers may be needed. CMS also notes that the Quality Reporting Document Architecture (QRDA) I format allows for de-duplicated individual records that can be aggregated for reporting by an ACO to CMS as required and references the *PY 2021 APM Performance Pathway Toolkit* as a resource for ACOs in data submission (available at https://qqq.cms.gov/resources/resource-library).

Reporting requirements by performance year are shown in the table below (modified from table 34 of the final rule).

TABLE HPA II.J-1. APP Reporting Requirements for Shared Savings Program ACOs by Performance Year (PY)		
PY 2021	**PYs 2022, 2023, and 2024**	**PY 2025 and subsequent years**
ACOs are required to report EITHER 1) the 10 CMS Web Interface Measures OR 2) the APP's 3 eCQMs/MIPS CQMs.	Same as PY 2021	ACOs are required to report the APP's 3 eCQMs/MIPS CQMs
ACOs also must administer the CAHPS for MIPS survey.		ACOs also must administer the CAHPS for MIPS survey.
CMS will calculate the results of the APP's 2 claims-based measures.		CMS will calculate the results of the APP's 2 claims-based measures.
The ACO total performance score will be based on either 10 (option 1) or 6 (option 2) measures.		The ACO total performance score will be based on 6 measures.

Reporting Requirements for New ACOs

New ACOs are scored differently (pay-for-reporting rather than pay-for-performance) during the first performance year of their first Shared Savings Program agreement periods. However, they will be subject to the same measure reporting options for PYs 2022-2024 as finalized for established ACOs; namely they will have a choice of reporting either 10 Web Interface measures or 3 APP eCQMs/MIPS CQMs. Beginning with PY 2025, the only option for new ACOs will be reporting the 3 APP eCQMs/MIPS CQMs. For all years they must meet the data completion and case minimum requirements for all measures. For all years they must also field the CAHPS for MIPS survey and CMS will calculate the ACOs' results for the same two claims-based measures as is done for established ACOs.

c. Updating the APP Quality Measure Set

CMS finalizes the APP measure set as proposed, shown in Table 35 of the rule and in the table below. All reported measures must meet data completion and case minimum requirements. (CAHPS survey minimum threshold application is described in more detail earlier in the rule and this summary.)

Commenter support for replacing the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs) with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS (MCC for MIPS) was divided. Those opposed stated that the MCC for MIPS measure does not accurately reflect the provision of care to ACO beneficiaries by ACO providers, since the MIPS measure is not limited to the ACO's assigned beneficiaries.

Commenter support for the measure set as a whole was divided. Some praised the parsimony of the measure set and the associated reduced reporting burden. Others found the measure set to be narrowly-focused and constrained, having too few outcomes-based primary care measures.

CMS states that aligning measures across its quality programs (e.g., the Shared Savings Program and MIPS) is a high priority for the agency and that its preliminary analysis showed results of the two MCC measures to be highly correlated. CMS further states that its goal is a streamlined, primary care-focused APP measure set and believes the finalized set reflects that goal.

TABLE HPA II.J-2: Finalized Quality Measures for CMS Web Interface and APP Reporting
X = Mandatory reporting
(Based on Table 35 in the rule and related material in the preamble)

Measure	Web Interface (PY 2022-2024)	APP (PY 2022 and subsequent)
Survey[a]		
CAHPS for MIPS Survey	Reported by survey vendor	Reported by survey vendor
Administrative Claims-Based[b]		
Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Calculated from claims by CMS	Calculated from claims by CMS
Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS		
Reported by ACOs (Scored)[a]		
Diabetes Hemoglobin A1c (HbA1c) Poor Control	X	X
Screening for Depression and Follow up plan	X	X
Controlling High Blood Pressure	X	X
Screening for Future Fall Risk	X	Not part of APP
Influenza Immunization	X	Not part of APP
Colorectal Cancer Screening	X	Not part of APP
Breast Cancer Screening	X	Not part of APP
Reported by ACOs (Not Scored)[b]		
Statin for Prevention and Treatment of Cardiovascular Disease	XX	Not part of APP
Depression Remission at 12 months	X	Not part of APP
Tobacco Screening and Cessation Intervention	X	Not part of APP

[a] Measures must be reported and performances are scored
[b] Measures lack benchmarks so are not scored but must be reported

d. Amended ACO Quality Standard

Performance by ACOs on the required quality measures is linked to the ACO quality performance standard. Meeting the standard determines whether an ACO is eligible to receive shared savings or have its shared losses mitigated; actual savings or reduced loss amounts are

determined by the terms of each ACO's Shared Savings Program track. Therefore, alignment is necessary between the measures required for reporting and the quality standard's criteria.

CMS finalizes with modifications its proposal for freezing the quality standard for PY 2023 at the 30th percentile across all MIPS Quality category performance measures. Modifications are made to align the quality standard's criteria with the timeline for the transition of reported measures from the Web Interface to the APP. Modifications also are made to resolve potential conflicts with the regulatory criteria that allow most tracks of the Shared Savings Program to qualify as Advanced APMs. Table 35 in the final rule and the table below show the quality standard's criteria by performance year as finalized.

Many commenters were supportive of freezing the quality standard for PY 2023 and some requested additional delay. Other commenters objected to replacing Web Interface measures with which ACOs have considerable experience, with unfamiliar measures from the MIPS inventory. Some argued that comparing ACOs to other MIPS participants, who range from individual clinicians to large groups, is inappropriate. Objections were raised to the small, narrowly-focused APP eCQM/MIPS CQM measure set. Some also were concerned that measure benchmarks would not be known in advance by ACOs since MIPS benchmarks are not set after all data have been submitted and scored.

CMS believes that freezing the quality standard for PY 2023 provides sufficient time for Shared Savings Program ACOs to prepare for the higher PY 2024 standard (i.e., 40th percentile rather than 30th percentile minimum performance). CMS states that aligning quality standards for clinicians, whether Shared Savings Program ACO or MIPS participants, allows comparisons across providers that are meaningful to beneficiaries in healthcare decision making. The agency pledges to release past MIPS measure performance distributions to allow ACOs to estimate future measure benchmarks.

CMS emphasizes that for PYs 2021, 2022, and 2023, an ACO that does not report for a given year any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, will not meet the Shared Savings Program quality standard for that year. For PY 2024 and subsequent years, an ACO that does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP will not meet the Shared Savings Program quality standard. Finally, CMS notes that to satisfy the Shared Savings Program quality standard, ACOs also must satisfy the data completeness and case minimum requirements for all measures for the applicable performance year.

Quality Performance Standard for New ACOs

New ACOs are scored differently (pay-for-reporting rather than pay-for-performance) during the first performance year of their first Shared Savings Program agreement periods. CMS received no comments on its proposal for the quality standard applicable to new ACOs in their first performance years. However, to align with the finalized timeline for transition from Web Interface to APP measures, CMS finalizes with modifications the quality standard applicable to the first performance year of new ACOs, as described below.

PY 2022, 2023, and 2024: the new ACO reports either the 10 Web Interface or 3 APP measures.
PY 2025 and subsequent years: the new ACO reports the 3 APP measures.
For all years: the new ACO must field the CAHPS for MIPS survey.
For all years: the new ACO must meet data completeness and case minimum requirements for all reported measures.

Table HPA II.J-3: Shared Savings Program Quality Performance Standard with Timeline (based on Tables 34-36 in the rule and related preamble material)			
PY 2021	**PY 2022 and PY 2023**	**PY 2024**	**PY 2025 and after**
Web Interface or APP eCQMs/MIPS CQMs	**Web Interface or APP eCQMs/MIPS CQMs**	**Web Interface or APP eCQMs/MIPS CQMs**	**APP eCQMs/MIPS CQMs only**
A quality performance score that is equivalent to or higher than the **30th percentile** across all MIPS Quality performance category scores	1) Same as PY 2021 **OR** 2) APP Only: A quality performance score that is equivalent to or higher than the **10th percentile** of the performance benchmark on at least 1 of 4 APP *outcome* measures **AND** a quality performance score that is equivalent to or higher than the **30th percentile** of the performance benchmark on at least 1 of the remaining 5 APP measures	A quality performance score that is equivalent to or higher than the **40th percentile** across all MIPS Quality performance category scores	A quality performance score that is equivalent to or higher than the **40th percentile** across all MIPS Quality performance category scores
For Web Interface reporters, there are 7 scored measures; for APP reporters there are 3 scored measures (see Table II.J-2 above).			

2. Extreme and Uncontrollable Circumstances Policy Revisions

CMS notes having received only supportive comments about its proposed changes to the Shared Savings Program's Extreme and Uncontrollable Circumstances Policy. It finalizes the proposed changes with modifications to align with the Shared Savings Program's ACO quality standard adopted elsewhere in the rule.

For PY 2023: CMS finalizes setting the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances 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 will 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 will receive the minimum score (30^{th} percentile). Affected ACOs will 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.

3. Primary Care Services Used for Beneficiary Assignment to Shared Savings Program ACOs

CMS finalizes as proposed actions to update the list of primary service codes to be used beginning with PY 2022 for beneficiary assignment to Shared Savings Program ACOs; change the applicable dates for use of telephone evaluation and management (E/M) for assignment; and expedited adoption of replacement service codes. For assignment purposes, CMS uses both CPT codes and G-codes.[72]

a. Primary Care Service List Updates Beginning with PY 2022

Commenters were very supportive of the proposed additions. The finalized additions to the list of primary service codes to be used beginning with PY 2022 for beneficiary assignment to Shared Savings Program ACOs are shown below.

CPT codes

- 99437 Add-on code for chronic care management beyond the typical service time of the primary procedure
- 99424 through 99425 Principal care management by physician or by clinical staff under physician supervision

G-codes

- G2212 Prolonged office or other outpatient Evaluation/Management service, used for Medicare patient billing in place of CPT 99417
- G2252 Virtual check-in, 11-20 minutes (a Communication Technology-Based Service)

CMS also had solicited suggestions for other existing CPT or G-codes that stakeholders believed should be considered for addition to the primary care services list. The sole comment received suggested deletion of G0506 *(Comprehensive assessment and care planning by the physician or other qualified health professional for patients requiring chronic care management services)* from the list because the code has been identified as potentially misvalued.

b. Extended Applicability of Telephone E/M Services for the COVID-19 PHE

CMS finalizes extending the addition of the telephone E/M codes (CPT codes 99441, 99442, and 99443 for use in ACO beneficiary assignment by revising §425.400(c)(2)(i)(A)(2) to specify that the telephone codes will continue to be used for assignment until they are determined to no longer be payable under Medicare FFS telehealth policies. This change functionally allows the agency time to conduct utilization analyses and reach a decision about permanently adding these formerly non-covered services as covered services to the Medicare telehealth list. Stakeholders noted the critical importance of expanded telehealth services during the COVID-19 PHE.

[72] 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.

c. Expediting Incorporation of Replacement Codes into the Beneficiary Assignment List

CMS finalizes as proposed that the list of primary care service codes for beneficiary assignment will include any CPT code identified by CMS as a direct replacement of a CPT code or G-code that is already on the list, whenever the assignment window for a benchmark or performance year includes any day on or after the effective date of that replacement code for payment purposes under FFS Medicare.

Commenters were supportive and CMS notes that this change may expedite the availability of replacement codes for beneficiary assignment purposes.

4. Requests for Comment

a. Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity

CMS requested comments about potential actions by Shared Savings Program ACOs to identify and address healthcare inequities in their patient populations and to how to encourage safety net providers to participate in ACOs and other value-based care initiatives. CMS does not discuss the comments received and indicates that the input may be considered during future rulemaking.

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

CMS requested 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 does not discuss the comments received and indicates that the input may be considered during future rulemaking.

c. Comment Solicitation for Reporting Options for Specialist Providers within an ACO

CMS requested comment about the roles played by specialist providers in Shared Savings Program ACOs and what quality measures could be adopted into the Shared Savings Program that would meaningfully assess specialist performance. CMS does not discuss the comments received and indicates that the input may be considered during future rulemaking.

d. Comment Solicitation on Publicly Displaying Prior Year Performance Scores

CMS requested comment about the utility of publicly displayed prior year MIPS Quality category performance scores for use by Shared Savings Program ACOs to estimate the performance levels they would need to be eligible for sharing savings and mitigation of shared losses per the applicable year's quality performance standard. Commenters were divided about the utility of prior years' MIPS percentile distribution data.

CMS indicates that future years' data will be made available but notes that the data release cannot occur until after all MIPS data have been submitted and scored for each performance year.

5. 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 policy changes regarding required repayment mechanism amounts in this section.

- 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. 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 finalizes, as proposed, the first option which would lower the repayment mechanism amounts by reducing the percentages used in its current methodology. Specifically, CMS will 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.[73] Under this policy, ACOs will 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 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 had several significant concerns about its alternative proposal 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 modifications will be effective and applicable on January 1, 2022, and that it will 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.

Commenters in support of CMS' proposal to lower the repayment mechanism amounts by reducing the percentages used in its current methodology believe this approach would minimize administrative costs of, or reduce administrative barriers for, ACOs participants. Many believe that this would encourage more providers to enter or stay in the program, particularly small and rural providers. Several commenters preferred the alternative approach to utilize a per beneficiary dollar amounts to calculate required repayment mechanism values because they believed this approach would improve transparency and allow ACOs to better predict their repayment mechanism amount prior to moving to two-sided risk. These commenters were not supportive of setting different per beneficiary dollar amounts for high revenue ACOs and low revenue ACOs.

CMS declines to adopt the alternative approach as it believes that there are a number of aspects of such an approach that would require additional time to develop and evaluate. These issues to resolve in the calculation include the variability in per capita costs of Medicare beneficiaries

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

among ACOs, how to identify the population of assigned beneficiaries, and frequency with which modifications would be needed to the per beneficiary dollar amount. CMS finalizes its proposal to lower the repayment mechanism by reducing the percentages used in the current methodology.

(2) Population of Assigned Beneficiaries Used in Calculating and Recalculating Repayment Mechanism Amounts

CMS finalizes its proposal 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 will 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.[74] 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 will no longer be using an assignment growth factor as a multiplier for the population size since it will no longer be using historical data. Under this 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. These modifications will be effective and applicable on January 1, 2022.

CMS provides illustrative examples in the final rule that describe the calculation and recalculation of the repayment mechanism amounts under its policy (pages 863-866 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.

Commenters generally expressed support for CMS' proposals for how to identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and in the annual repayment mechanism amount recalculation. CMS finalizes its proposal and amends its regulations at §§425.204(f)(4)(ii) and (iii).

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

CMS finalizes its proposal 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 amends §425.204 to add paragraph (f)(4)(v)(A) 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.

[74] 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 finalizes technical and conforming changes to §425.204(f)(4)(iii).

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

Commenters were supportive of CMS' proposal to allow a one-time repayment mechanism decrease for eligible ACOs.

(4) Threshold for Increasing Repayment Mechanism Amounts

To avoid burdensome repayment mechanism modifications for relatively small dollar amounts, CMS finalizes its proposal 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 will 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 will reduce the number of ACOs required to annually increase their repayment mechanism amounts and further simplify the repayment mechanism amount calculations. It also believes that this will reduce the burden on low revenue ACOs (i.e., the ones most affected by the 50 percent threshold).

This modification will be effective and applicable on January 1, 2022. The revised threshold will be used in determining required repayment mechanism increases for performance year 2022, and subsequent performance years.

Commenters were supportive of this approach and believed that it would minimize administrative complexity and financial costs for ACO participants.

6. 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 revises three provisions at §§425.204(b) and (c)(6), and §425.116(c) to address application burden.

First, CMS finalizes its proposal 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 policy, CMS will continue its 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 finalizes its proposal to modify §425.204(c)(6) to remove provisions requiring an ACO to submit sample ACO participant agreements during the application process. Under this policy, sample ACO participant agreements and the first and signature pages of each executed ACO participant agreement will 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 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 will retain the discretion to request ACO participant agreement documentation at any time during an agreement period.

Third, CMS finalizes its proposal 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 retains 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 policies 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.

The majority of commenters supported CMS' proposal to reduce the frequency and circumstances under which ACOs must submit sample ACO participant agreements to CMS and noted that this policy refinement reduced administrative burden during the application process. One commenter suggested permitting ACOs to request a CMS review of their sample ACO participant agreements prior to the ACO participant list change request review cycle. CMS notes that it is each ACO's responsibility for ensuring that all of their ACO participant agreements are compliant. CMS finalizes its proposals without modification.

7. 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 finalizes its proposal to amend §425.312(a)(2) to set forth different beneficiary notification obligations depending on the assignment methodology selected by the ACO. Specifically, CMS finalizes its proposal 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 adds 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 sought 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.

Many commenters supported the proposal to amend the beneficiary notification requirements such that ACOs that have selected prospective assignment do not have to send notification to beneficiaries who are not prospectively assigned to them. Other commenters advocated that CMS remove the obligation altogether. Some expressed support for reducing the frequency of beneficiary information notice to once per agreement period stating that notifying beneficiaries annually when there have been no programmatic changes can cause unnecessary confusion and burden on patients. CMS declines to eliminate the requirement that ACOs furnish the standardized written beneficiary notifications as it believes that such notices provide important information about their care and serve to improve transparency. With respect to frequency of the beneficiary information notice, CMS states that it will consider this information in future rulemaking.

8. Comments 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.[75] 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 the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type.[76]

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).

[75] Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program.
[76] See §425.601(c) (calculating county expenditures) and (d) (calculating regional expenditures).

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.

CMS sought 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.

Commenters were mixed in their support of amending the Shared Savings Program benchmarking methodology to remove an ACO's assigned beneficiaries from the assignable population used in determining regional FFS expenditures. Commenters against this approach including MedPAC, believed that such an approach could create a situation that would reward low-spending ACO's without improving their efficiency of care and would reduce incentives for participation among high spending ACOs. Others in favor believes this change is necessary and should be implemented immediately as the current policy on calculating regional expenditures penalizes ACOs when they reduce costs by also reducing the regional costs against which the ACO if compared. Many argued the current approach particularly disadvantages rural ACOs or ACOs with high market penetration in their regional service areas. Other commenters expressed the belief that removing the ACO assigned beneficiaries from regional FFS expenditure calculations would penalize ACOs serving medically complex, high-cost patients in a region.

Commenters suggested alternative approaches for addressing the impact of an ACO's own performance on its benchmark or countering the potentially adverse effects of removing the ACO's assigned beneficiaries from regional expenditure calculations. This includes:

- Expanding the definition of regional service areas in cases where ACO market penetration is high to mitigate concerns about the reference population being too small
- Using geographic units smaller than counties to define an ACO's regional service areas as those geographic units may be more socio-economically homogeneous.
- Altering the calculation of regional spending in the trend factor by extending the ACO's regional service area to a larger market area (from example, CBSAs, health service areas, or hospital referral regions) in lieu of excluding ACO assigned beneficiaries from regional expenditure calculations (a MedPAC comment).
- Using other approaches being used in Innovation Center Models – referenced Direct Contracting Model, Primary Care First Seriously Ill Population model, and Direct Contracting model High Needs track.

b. Comments 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 sought 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.[77]
    - 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.

Commenters recognized the importance of risk adjustment in setting fair benchmarks and evaluating expenditures during the performance year. MedPAC was generally supportive of the current approach and believed that changes in an ACO's population health status would be accounted for by the CMS-HCC model, and the current 3 percent potential increase to benchmarks would likely cover anomalies when ACO populations have deteriorating health status. Concerns about the risk adjustment methodology centered primarily on the 3 percent cap on positive adjustments resulting from risk score increase over the ACO's 5-year agreement period. Many commenters believed the current approach is unfair to ACOs and inadequate and while the 3 percent cap may be reasonable in the early years of a 5-year agreement period, it may not be appropriate in the later years of the agreement period. Others suggested that the existing policy is also driving inequity and may disadvantage ACOs that serve more vulnerable populations or beneficiaries with complex medical needs. Specific suggestions included increasing the cap on risk growth score during an ACO's 5-year agreement period to no less than 5 percent and a floor of no greater than negative 5 percent for risk score decreases. Other risk adjustment suggestions by commenters included the addition of social risk factors (e.g., sociodemographic status, language, and post-discharge support structure) in the risk adjustment models used for ACO benchmarking; a more "veracious" approach to calculating coding intensity adjustment factors; and exploring ways to implement the Innovation Center's concurrent HCC risk adjustment model, among other suggestions.

In its response, CMS states that it will take these comments in consideration for future rulemaking as it contemplates refinements to the Shared Savings Progam's risk-adjustment methodologies.

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 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

[77] 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.

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 38 from the final rule reproduced below provides an overview of the elements of the data collection instrument.

Table 38: 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 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 proposed changes and clarifications to the survey instrument based on questions it has received from the public. Public comments generally supported CMS' efforts to improve the ground ambulance data collection although they remain concerned about complexity that may prevent compliance.

One commenter noted that the data collection is only for the purpose of assessing the adequacy of Medicare payments and the data should not be used for any other purpose. CMS responded that the data collected will provide CMS the information it needs to evaluate the adequacy of Medicare payment rates for ground ambulance services and geographic variations in the costs of furnishing such services, as well as the data MedPAC needs to prepare its statutorily-required report to Congress.

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 proposed to revise the question to allow the respondent to select multiple other organizations or operations rather than a single one. There were no comments on this proposal that CMS is finalizing without modification.

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 proposed 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)."

Public comments indicated that "time on task" could be difficult to calculate when a crew receives a second call before completing the patient care report on the first call. CMS acknowledged that not all ground ambulance organizations track time on task as proposed but that the initial definition of "average trip time" is problematic for other reasons. CMS believes the change will provide organizations with greater flexibility in reporting of time and is finalizing the revision to the question as proposed.

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 proposed 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.

There was one comment in support of the proposed policy that noted not all primary service areas follow county lines or ZIP code designations. The commenter requested additional language in the question where the primary service area is based on the needs of the population. CMS is finalizing the revised question as proposed but will continue to provide education and give opportunities for organizations to ask questions regarding the instructions for the survey.

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 proposed 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?" CMS did not receive any public comments on this change that it is finalizing without modification.

e. Reporting Paid Ambulance Transports

CMS proposed 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.

One commenter supported the question but asked a clarifying question. CMS responded that reporting is for ambulance transports that occurred during the data collection period and paid through at least through the end of the data collection period or before the information is reported.

CMS is finalizing the revision to the question as proposed.

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 proposed 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. CMS did not receive any public comments on this change that it is finalizing without modification.

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 proposed to add screening questions asking individually whether the organization depreciates facilities, vehicles, and equipment. Further, CMS proposed 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 proposed to change the instructions to refer to broad types of equipment that are typically considered capital medical and non-medical equipment. Respondents are then 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). CMS did not receive any public comments on this change that it is finalizing without modification.

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 proposed 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. CMS did not receive any public comments on this change that it is finalizing without modification.

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.

The only public comments were on the above two items and supported CMS' proposed revisions. On the first point above, the commenter stated that costs are incurred by two companies when there is joint response but only the single ambulance providing transport is paid. The commenter requested payment for all agencies involved in the joint transport. CMS did not directly respond to this point but stated its purpose was not in getting a joint response to the survey question but to understand which general types of labor and other inputs are involved when a non-transporting agency is involved in providing ambulance services to the respondent.

CMS is finalizing its proposed revisions without modification.

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 proposed 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 policy 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.

Public commenters supported CMS' proposal. One commenter stated that the proposed timeline is problematic given that CMS did not beta test the data collection system. This commenter recommended a 4-year timeline and a 12-month data reporting period rather than a 5-month data reporting period that begins the day after the last day of the ground ambulance organization's data collection period. According to the commenter, the data collected would be more reflective

of a typical year of costs for ground ambulance organizations rather than be affected by the pandemic.

CMS responded that it plans to conduct beta testing data collection system prior to data reporting. It further indicated its awareness of the tension between the need to begin collecting data and the challenges and threats to generalizability of collecting data through the ongoing pandemic and PHE. Under its proposal, information will be collected from fewer organizations during data collection periods starting in 2022, and from more organizations during data collection periods starting in 2023. CMS is finalizing its proposal for a new data collection period beginning between January 1, 2023 and December 31, 2023 and a new data reporting period beginning between January 1, 2024 and December 31, 2024 for selected ground ambulance organizations in year 3.

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 of 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 proposed 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. CMS did not receive any public comments on this change that it is finalizing without modification.

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. CMS received one public comment in support of its proposal that it is finalizing without modification.

6. Public Availability of Data

Due to the PHE, CMS proposed 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. One commenter requested that CMS provide the data annually (as it does with

Medicare cost report information) and not wait until 2024 to first release the data. CMS is not making any changes to its previously finalized policy of posting summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable every 2 years. It is not following the same process as exists for Medicare cost reporting.

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 finalizes proposed 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),[78] 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 finalized proposals will impact its ability to complete an evaluation of the MDPP expanded model; the evaluation would incorporate any finalized changes. CMS anticipates these changes will 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. 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 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 finalizes its proposal 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 makes 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 proposed to redistribute a portion of the ongoing maintenance sessions phase performance

[78] 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.

payments to certain core and core maintenance sessions provided. CMS proposed to increase performance payments for MDPP beneficiary achievement of the 5 percent weight loss goal, as well as continued attendance during each core maintenance interval. Based on comments, CMS modifies this proposal and finalizes it will redistribute all the ongoing maintenance sessions phase performance payments to certain core and core maintenance sessions performance payments. CMS will also maintain the current 2021 performance payment amount for achievement of the 5 percent weight loss goal, increase the payment amounts to the attendance only goals to incentivize attendance, and increase the total maximum payment to $705.

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. Although the maximum payment to an MDPP supplier will decrease when compared to the original 2-year payment structure, the second year of the MDPP set of services has been far less utilized that first year set of services. CMS notes it is not changing the payment rates for ongoing maintenance sessions in cases where a beneficiary remains eligible for them; CMS will 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 40, reproduced below, summarizes CMS' proposals for the MDPP services period based on beneficiary start date.

Table 40: 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.

Commenters were generally supportive of the proposed changes; a few commenters recommended keeping the second year as an option and others thought the second year should be discontinued for all MDPP beneficiaries. CMS believes it would be overly burdensome and confusing to suppliers, beneficiaries, and the MACs to have some beneficiaries enrolled in MDPP on or after January 1, 2022 continue with a second year. CMS understands that offering certain MDPP beneficiaries ongoing maintenance services after January 1, 2021 may be temporarily burdensome, but it believes it is important to permit all eligible beneficiaries who attended their first core session prior to January 1, 2022 have the opportunity to obtain all the services that existed when they initiated the service.

In response to comments, CMS clarifies that beneficiaries who are eligible to participate in MDPP ongoing maintenance phase sessions between January 1, 2021 and December 31, 2021 but who elect not to participate virtually during the PHE, will have the option to resume or restart the ongoing maintenance session interval. CMS is not imposing a requirement for beneficiaries to restart the MDPP set of services following the end of the PHE, nor is it establishing a deadline for when such beneficiaries must restart because of the uncertainty of the PHE end date.

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).

Many commenters recommended CMS redistribute all, not just a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments. Commenters suggested CMS consider increasing the proposed payment rates to fully cover costs. Commenters also recommended that CMS increase the amount of the performance payment available at the beginning of the MDPP set of services because staff time and programming expenses are highest at the beginning of the MDPP. Commenters provided several alternatives for CMS to consider.

After considering these comments, CMS determined that distributing the current total maximum payment amount will make MDPP more attractive to suppliers and increase beneficiary participation. CMS acknowledges that the final payment structure may remain insufficient to cover the costs of MDPP for some suppliers but hopes that increasing the maximum per beneficiary attendance-based payment by $253 may help address some of the costs associated with serving diverse and low-income participants. CMS discusses stakeholders concerns that diverse and low-income beneficiaries have more barriers to weight loss, and it believes that shifting some of the payment amounts to attendance only performance goals will increase the overall average per-beneficiary payment.

CMS finalizes with modifications the proposed §414.84(b) and (c) to redistribute all the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments (Table 39, reproduced below). Based on this modification, the total maximum payment will increase from the proposed $661 to $705; the current maximum payment amount is $704 under the original 2-year payment structure. CMS also modifies the

proposal to adjust the MDPP payment structure to increase the performance payments available at the beginning of the MDPP set of services. These changes will pay a total of $81 more per MDPP beneficiary who attends at least 9 sessions during the core session ($315 as finalized versus $234 as proposed versus $173 at current 2021 payment rates).

Table 39: MDPP Payment Structure			
Payment Description	**Current**	**Proposed**	**Final**
Core Sessions (Months 1-6)			
Attend 1 Core Session or Bridge Payment	$26	$26	$35
Attend 4 Core Sessions	$52	$78	$105
Attend 9 Core Sessions	$95	$130	$175
Core Maintenance (CM) Sessions (Months 7-12)			
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$15	$52	$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 1 (Months 7-9)	$63	$106	$93
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10-12)	$15	$52	$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 2 (Months 10-12)	$63	$106	$93
5% WL Achieved from baseline weight	$169	$189	$169
9% WL Achieved from baseline weight	$26	$26	$35
Ongoing Maintenance Sessions (Months 13-24)			
Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$53		
Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$53		
Subtotal Maximum Payment – Attendance Only	**$203**	**$338**	**$455**
Total Maximum Payment	**$704**	**$661**	**$705**

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

CMS discusses how 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 finalizes its proposal 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 will 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 finalizes its proposal 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 finalized, §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 140. 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 141 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 sought broad comment on specimen collection fees and the travel allowance.

Commenters expressed appreciation that CMS recognized the need for additional resources required for specimen collection during the PHE and also for the expansion of access to laboratory testing in the home for Medicare beneficiaries. Most believed that CMS should continue increased payments for specimen collection, simplify payments, or provide add-on payments for rural areas. They believed this was justified because the COVID-19 pandemic has permanently altered the public health paradigm necessitating permanent and resource-intensive infection control measures that merit higher specimen collection fees. Specific policy suggestions included the following:

- Expand and permanently authorize the specimen collection payment under HCPCS codes G2023 and G2024.
- Simplify the travel allowance by creating a single per-encounter flat-rate payment for travel to be updated annually by the Consumer Price Index for All Urban Consumers.
- Modify the existing travel allowance payment structure to better account for increased labor and fuel costs and start the mileage calculations at an eligible laboratory or patient location and end when the trained personnel no longer have the specimen in their possession.
- Create a rural add-on payment to supplement the single per-encounter flat-rate payment for travel.

CMS states it appreciates the comments regarding the travel allowance and plans to take this feedback into consideration for possible future rulemaking or guidance.

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 makes 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. 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 finalizes its proposal 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. CMS makes additional technical changes and finalizes its revisions to §§424.530(a)(2) and 424.535(a)(2).

Several commenters expressed concern that providers and suppliers may miss instances where a person they review against the OIG exclusion list has a name that does not exactly match that indicated on the OIG list as an excluded party. The commenters suggested an exception to these OIG provisions if the provider or supplier demonstrated a good-faith effort. CMS was not sympathetic and stated the central principle associated with these provisions involves the provider's or supplier's need to avoid relationships with OIG-excluded parties, not the level of effort the provider or supplier undertook to confirm that no such relationship exists.

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 finalizes its proposal 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 finalizes its proposal to revise 42 CFR part 424, subpart P to incorporate the existing sub-regulatory process into regulations.

Specifically, CMS finalizes 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.

Several commenters supported its proposal to address deactivation rebuttal rights in regulation, but several commenters suggested modifications. These suggestions included that a deactivated provider or supplier have 30 days from its receipt of the deactivation notice to submit is rebuttal. They also asked for a good cause exception for untimely or less-than-fully compliant rebuttals and that CMS should have to make its determination regarding the rebuttal submission within 15 days of receiving it. CMS disagrees with these recommendations stating that a 15-day timeframe is sufficient for a detailed rebuttal; it is the deactivated provider's or supplier's responsibility to ensure that the rebuttal is timely; and it does not believe its timeframe for review should be restricted.

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 finalizes its proposal exempting IDTFs that provide services that do not require direct or in-person beneficiary interaction from specific IDTF requirements.

CMS finalizes its proposal 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 finalizes its proposal 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.

Commenters were generally supportive but offered alternative suggestions in several instances. Several commenters, for example, stated that CMS should create an additional exemption which prohibits a fixed-based IDTF (excluding hospital-based IDTFs) from sharing its practice location with another Medicare provider or supplier. CMS disagrees and believes that the space-sharing prohibition should still apply to exempted IDTFs. It believes each IDTF must independently meet all IDTF requirements on its own merits, rather than in unison with another IDTF or Medicare provider or supplier.

e. Revocation Policies

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 finalizes its proposal 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 policy 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.

Several commenters were concerned about this proposal believing that it gave CMS unfettered discretion to target any short period of non-compliant billing without having to consider the provider's/supplier's behavior during its period of enrollment. For example, they cited erroneous claims can occur for many reasons (i.e., technological, system, or inadvertent mistakes, or changes in CMS or MAC procedures). CMS responds by emphasizing several things (1) its revocation authority is strictly discretionary and not mandatory and that it carefully weighs the facts and circumstances of the situation, (2) providers and suppliers have a responsibility to always submit correct claims, and (3) and it has an obligation to protect the Medicare program and the Trust Funds.

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 finalizes its proposal to add 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 adds 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 finalizes proposed 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 finalizes proposed 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 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.

CMS did not receive any comments on its definitions. All commenters supported its proposals related to prepayment and post-payment medical review and acknowledged CMS's need to conduct oversight activities to protect the Medicare program.

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

In the CY 2020 and CY 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;
- 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 Opioid Treatment Programs (OTPs) Medicare Billing and Payment Fact Sheet (cms.gov). The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2022, will be made available at Opioid Treatment Programs (OTP) | CMS.

Geographic Adjustment & Updates. The CY 2020 and CY 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 proposed 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. Commenters supported the changes and CMS finalizes them without change.

Duplicative Payments. The CY 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 any such 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 proposed 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). Commenters supported the changes and CMS finalizes them without change.

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. In advance of that information becoming available, CMS proposed to create a new G-code for this higher-dose product. In this final rule, the new G-code is finalized as proposed. The new add-on code will 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 will 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 will 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.

For CY 2022, consistent with §410.67(d)(2)(i)(A), the drug component of the new code will be priced at $125 for a 2-pack of the 8mg spray, which is 100 percent of the WAC.

The finalized G-code is:

- G1028: Take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure

In addition, CMS updates the code descriptor for existing G2215 to better distinguish it from the new higher dosage G-code finalized in this rule:

- G2215: Take-home supply of nasal naloxone; 2-pack of 4mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

One commenter raised concerns about up-coding or overutilization of the higher strength naloxone. A few commenters objected to the plan to price the product without the 6 percent add-on and recommended that CMS include a factor to compensate providers for administrative expenses and overhead costs. CMS responds by recognizing the possibility of upcoding but given that the number of overdoses continues to increase, the product should be available. With respect to limiting payment amounts to 100 percent of the ASP, CMS believes doing so will incentivize the use of the most clinically appropriate drug for a given patient. In response to a commenter recommending a rural add-on code, CMS states that since none was proposed, the issue is out of scope.

Counseling and Therapy Furnished via Audio-Only Telephone. The CY 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 finalizes its proposal 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.

CMS finalizes its proposal to require 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).

It does not, however, finalize its proposed requirement that after the end of the PHE, OTPs providing services using audio-only telephone calls document in the beneficiary's medical record that the counseling or therapy was provided via telephone call and the rationale for doing so. It was persuaded by commenters that the requirement would be duplicative because the new

service-level modifier for services furnished via an audio-only interaction will also identify when a service was furnished via audio-only communication.

CMS defers to providers to use clinical judgment in determining whether in-person counseling or therapy, rather than audio-only telephone calls, would be most appropriate for the patient in their circumstances.

Many commenters were supportive of the proposal. In response to a commenter suggesting CMS permanently extend the ability to provide counseling via audio-only telehealth for patients who are compliant with their treatment plan, CMS defers to the judgment of treating clinicians to determine when audio-only or audio/video counseling or therapy are appropriate and whether there are certain circumstances, such as when patients are considered to be high risk, when in-person services are needed.

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 proposed revisions to §411.354(c)(2) (relating to the conditions for an indirect compensation arrangement) to correct what it described as an inadvertent omission in its changes to this section in the MCR final rule. Specifically, CMS excluded from the definition of "indirect compensation arrangement" a subset of unbroken chains including compensation arrangements that it identified as presenting significant program integrity concerns: certain arrangements involving unit of service-based payment for the rental or lease of office space or equipment. CMS proposed amending §411.354(c)(2)(ii) (which identifies when aggregate compensation to a physician results in an indirect compensation arrangement if the other conditions of §411.354(c)(2) are met) 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 was 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 proposed to define the term "unit" for purposes of applying this provision of the regulations.

In the final rule, CMS finalizes some its proposals with modifications, and declines to finalize others.

a. Definition of "Indirect Compensation Arrangement"

(i) Background.
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. CMS believes that program integrity concerns arise when payment for items or services provided as the result of a physician's referrals or the other business the physician generates, rather than the physician's own labor, is included in the calculation of compensation. 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.

(ii) Proposed Rules Policies.
CMS proposed 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, including arrangements for the lease of office space or equipment or for the use of premises or equipment. The condition at §411.354(c)(2)(ii)(A) would have been modified 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 for anything other than services personally performed by the physician (or immediate family member).

CMS would have considered 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 proposed to add this clarification to §411.354(c)(2)(ii)(B)(*3*).

(iii) Final Rule Policies.
CMS finalizes its proposal that is designed to ensure that the prohibition on certain unit of service-based compensation formulas for the lease of office space or equipment or for the use of premises or equipment applies to all compensation arrangements that include them. It does not finalize its proposal regarding payment for anything other than services personally performed by the physician (or immediate family member); commenters complained that this was overly broad and would prohibit all arrangements for services furnished "under arrangement" to a hospital or other entity—typically purchased on a per-service basis—where the entire service is not performed personally by the physician who receives the unit-based compensation. Some commenters also sought clarification on when a service is considered to be personally performed by a physician. While CMS did not finalize this policy, it reiterates what it describes as its longstanding position that an item or service is not personally performed by a physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

CMS also declines to codify its proposed interpretation of services that are personally performed by a physician (or immediate family member). As finalized, §411.354(c)(2)(ii)(A) (i.e., when aggregate compensation to a physician results in an indirect compensation arrangement if the other conditions of §411.354(c)(2) are met) provides as follows:

(A)(1) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and
(2) The amount of compensation that the physician (or immediate family member) receives per individual unit—
(i) Is not fair market value for items or services actually provided;
(ii) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;
(iii) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or
(iv) Is payment for the lease of office space or equipment or for the use of premises or equipment.

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

(i) Background.
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). The determination of whether an indirect compensation arrangement exists requires the evaluation of the individual unit of compensation that the physician (or immediate family member) receives. If the individual unit of compensation does not meet any of the conditions at current §411.354(c)(2)(ii)(A), the unbroken chain of financial relationships does not constitute an indirect compensation arrangement.

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. For example, if a physician is paid on an hourly basis, the unit is an hour; where the physician is paid an annual salary, the unit is a year. Where compensation is entirely paid per service (e.g., a work RVU), the unit is the individual service. CMS believes that hybrid compensation (i.e., 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 also observes that a compensation arrangement may also involve multiple units of the same type (e.g., annual salary as well as payment on an hourly basis or perhaps a monthly fee for supervisory duties). Each unit must be analyzed under §411.354(c)(2)(ii)(A) to determine whether an indirect compensation arrangement exists.

(ii) Proposed Rules Policies.
CMS proposed to add a new provision to §411.354(c)(2)(ii)(B)(*2*) that would 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 individual units were 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.

Some commenters presumed that the inadvertent omission of the prohibition on per-click payments for lease of office space or equipment under §411.354(c)(2) in the MCR final rule did not indicate that CMS was abandoning this longstanding policy; CMS confirms that it in no way intended to change the longstanding prohibition. Some comments expressed concern about the burden of learning how to apply new regulations. CMS responds that for all unbroken chains of

financial relationships where the compensation arrangement closest to a physician (or immediate family member of a physician) is for the lease of office space or equipment or for the use of premises or equipment, the analysis under the physician self-referral law will revert to the two-step analysis in place since the Phase I regulations were finalized in 2004. Thus, when it is determined that an indirect compensation arrangement exists, the requirements of an applicable exception must be satisfied.

(iii) Final Rule Policies.
CMS finalizes its proposal to correct the inadvertent omission of arrangements involving unit of service-based payment for the lease of office space or equipment or for the use of premises or equipment from those unbroken chains of financial relationships that constitute indirect compensation arrangements under §411.354(c)(2).

CMS finalizes its proposed policies with respect to individual units with modifications intended to provide clarity. It finalizes the following individual units for purposes of applying §411.354(c)(2)(ii)(A)(2) (relating to the determination of whether an indirect compensation arrangement exists):

- Item, if the physician (or immediately family member) is compensated solely per item provided.
- Service, if the physician (or immediate family member) is compensated solely per service provided, which includes arrangements where the "service" provided includes both items and services.
- Time, in all other circumstances if the conditions of either of the two preceding bullets are not met.

CMS also makes clarifying, conforming changes to §411.354(c)(2)(ii)(C) to require the analysis of whether the amount of compensation that a physician (or immediate family member) receives per individual unit meets the requirements of §411.354(c)(2)(ii)(A)(2) as finalized (and shown above) in cases of financial relationships between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest. These circumstances require the analysis of nonownership or noninvestment interest closest to the physician to determine whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and whether the amount of compensation that the physician (or immediate family member) receives per individual unit meets the applicable conditions in §411.354(c)(2)(ii)(A)(2).

Finally, CMS declines to delay the effective date of the modifications to the regulations in the final rule. It also declines to grandfather in existing arrangements that may run afoul of the regulations as finalized.

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 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 finalizes its proposal to waive the frequency limit condition for COVID-19 vaccines until such time as any frequency limits are established (which is not limited to the period during which the current PHE is in effect).

In the alternative, CMS proposed waiving the CMS-mandated frequency limits for all vaccines and sought comment on that policy idea. The agency was not persuaded to remove the CMS-mandated frequency limit requirement for all vaccines in part due to concerns about the potential for harm to patients from unnecessary or duplicative vaccinations.

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. List of CPT/HCPCS Codes (§411.351)

a. List of Codes

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 proposed to update the Code List each calendar quarter, with the first quarterly update occurring on April 1, 2022. Some stakeholders expressed concern that more frequent Code List updates would impose a significant burden on the industry and increase its risk of noncompliance with the physician self-referral law. CMS does not finalize this proposal. The Code List that is effective January 1, 2022 is included in this final rule and will continue to be updated on an annual basis as described below.

CMS proposed to publish the Code List only on its website, beginning after the publication of the January 1, 2022 Code List in this final rule. It does finalize this proposal; the list will be available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.

CMS also proposed to provide a 30-day advance notice and public comment for the Code List updates. It finalizes this proposal. The instructions for submitting comments, and CMS' responses to comments, will also be posted on the website. It anticipates that most comments will be addressed within 90 calendar days of the effective date of the Code List update though CMS notes that complex comments or issues may require a longer timeframe.

b. Annual Update

The entire scope of four categories of DHS is defined in the Code List, which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The four DHS categories are as follows:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§411.355(g)).
- Preventive screening tests, immunizations, and vaccines (§411.355(h)).

CMS notes that EPO and any dialysis-related drugs that are paid for under the ESRD PPS are not designated health services (because they are paid for under a composite rate) and do not qualify for the exception at §411.355(g). However, ESRD-related oral-only drugs (i.e., drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form) are not paid under the ESRD PPS and will not be so paid until 2025. Thus, these oral-only drugs are considered DHS and may qualify for the exception at §411.355(g).

CMS reminds readers that it added COVID-19 vaccines to the list of vaccine codes for which the exception at §411.355(h) applies. The 2021 Code List included, and the 2022 Code List will include, a statement indicating that the Stark law prohibitions do not apply to CPT code 90749 (unlisted vaccine/toxoid) when it is used to identify a COVID-19 vaccine or to any future CPT or HCPCS code designated for a COVID-19 vaccine. However, CMS cautions that including CPT code 90749 on the Code List is not intended, and should not be considered, to direct or approve the use of CPT code 90749 for the identification and billing of any COVID-19 vaccine. CMS also notes that it is including in the 2022 Code List the existing specific HCPCS codes for monoclonal antibody products that are covered and paid under the COVID-19 vaccine benefit in section 1861(s)(10) of the Act for which the exception at §411.355(h) is available.

Tables 41 and 42 in the final rule identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2022. These tables also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exceptions for dialysis–related outpatient prescription drugs furnished in or by an ESRD facility and for preventive screening tests, immunizations, and vaccines.

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 that HHS may specify. 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. Timeframe for EPCS Adoption

CMS finalizes its proposal 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 does 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. 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. CMS finalizes the proposals.

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 did 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 70 percent threshold is achievable without posing undue burdens on prescribers.

4. 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 proposed several classes of exceptions.

a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy are Same Entity (§423.160(a)(5)(i))

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 finalizes its proposal to add it to its regulations at §423.160(a)(5)(i).

b. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions (§423.160(a)(5)(ii))

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 finalizes its proposal to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year. The exception will be given to individual prescribers, regardless of the size of the group practice to which they belong. CMS will 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 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, and it was not persuaded to the contrary by the one comment it received on the issue.

c. Cases of Recognized Emergencies and Extraordinary Circumstances (§423.160(a)(5)(iii) and (iv))

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

The first exception is 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 exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring.

The second would permit prescribers who are not in an emergency or disaster area to seek a CMS waiver if they are facing any extraordinary circumstance outside their control such as a lack of broadband access. CMS agrees with commenters that cybersecurity attacks and technological failures could be circumstances that may prevent prescribers from conducting EPCS and that might qualify for a waiver. This exception will not require emergency or disaster declaration from a governmental entity. Prescribers must 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 will 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 will provide written notice of receipt of the waiver request and a decision on the request. Should a waiver be granted, it would be for a term of up to one year. Additional details would be provided in subsequent rulemaking.

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, and it does not establish one in the final rule. 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.

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 finalizes its proposal to limit compliance actions to sending letters to prescribers that may be in violation of the EPCS requirements during that year. The letters will 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. CMS will consider additional compliance actions in future rulemaking.

R. Open Payments

CMS proposed to make the following changes and additions to its Open Payments requirements which it believes will clarify existing requirements and improve the quality of data. It finalizes all of its proposals without modification.

1. Mandatory Payment Context Field for Records to Teaching Hospitals

CMS adds a mandatory context field for payments or transfers of value attributed to teaching hospitals. The field contains information to better identify the payment as deemed appropriate by the applicable manufacturer or GPO. This addition responds 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.

Some commenters opposed the policy believing that the field would increase burden without

decreasing disputes, and the lack of standardization would be problematic since reporting entities would not have direction on what to input and teaching hospitals might not understand the additional context. CMS disagrees; it believes the additional information will help ensure accuracy and the flexibility regarding the field's content will be easier for reporting entities.

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 adds 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 notes that the reporting entity's attestation will not prevent it from submitting later-discovered records.

3. Definition of 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 includes the definition of a POD (as set out at §403.902) as a subset of either an applicable manufacturer or applicable GPO. CMS requires PODs to self-identify when registering or recertifying.

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

CMS emphasizes that the 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 definition will 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 adds 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. This prohibition does not apply if the entity discovers an error in the information furnished or if the record is otherwise believed to meet existing exceptions for reporting that were previously unknown.

5. Disallowing Publications Delays for General Payment

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 eliminates the ability to delay general payments from publication and will only permit publication delay of research payments made in connection with written research agreements, whose formatting requires the appropriate information to be provided.[79]

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 finalizes 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.

[79] See 42 CFR 403.904(f).

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 removes the "Ownership" Nature of Payment category because this category does not include certain information associated with reporting ownership interest (e.g., dollar amount invested and the value of interest).

8. Updated Contact Information

CMS finalizes its proposal 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 changes will 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 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 CF for 2022 is $33.5983, 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 -0.10 percent. The 2022 anesthesia conversion factor is $20.9343, which reflects the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for the anesthesia specialty. See Tables 134 and 135 from the final rule, reproduced below.

Table 134: Calculation of the 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	-0.10 percent (0.9990)	
2022 Conversion Factor		**$33.5983**

Table 135: Calculation of the 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	-0.10 percent (0.9990)	
2022 Practice Expense and Malpractice Adjustment	0.84 percent (1.0084)	
2022 Conversion Factor		**$20.9343**

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 policy to transition the clinical labor pricing over 4 years has mitigated the large negative impacts on certain specialties observed in the proposed rule. In general, specialties with increases furnish services

that involve a higher proportion of clinical labor cost that is reflected in their PE RVUs. Specialties with decreases, on the other hand, furnish services that involve proportionally higher supply or equipment item costs. Column F of Table 136 shows the estimated 2022 combined impact on total allowed charges by specialty of all the RVU and other changes. These impacts range from an increase of 6 percent for diagnostic testing facility, an increase of 2 percent for portable x-ray supplier and a decrease of 5 percent for interventional radiology and vascular surgery.[80]

Table 136 **does not** show the impact of the expiration of the 3.75 percent increase to PFS payments for 2021 from the CAA. CMS explains in the final rule that the expiration of the 3.75 percent CAA provision for 2022 is a statutory change that takes place outside of budget neutrality, and therefore, is not captured in the specialty impacts. Thus, the combined effect of RVU changes and the conversion factor is much larger than what CMS displays in Table 136. If, for example, CMS specifies a -1 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 -5 percent.

TABLE 136: 2022 PFS 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	$213	0%	0%	0%	0%
Anesthesiology	$1,626	0%	1%	0%	1%
Audiologist	$56	0%	0%	0%	0%
Cardiac Surgery	$197	0%	-1%	0%	0%
Cardiology	$5,926	0%	-1%	0%	-1%
Chiropractic	$600	0%	0%	0%	0%
Clinical Psychologist	$791	0%	0%	0%	0%
Clinical Social Worker	$849	0%	0%	0%	0%
Colon and Rectal Surgery	$140	0%	0%	0%	0%
Critical Care	$353	0%	0%	0%	0%
Dermatology	$3,336	0%	0%	0%	1%
Diagnostic Testing Facility	$664	0%	6%	0%	6%
Emergency Medicine	$2,445	0%	0%	0%	0%
Endocrinology	$489	0%	0%	0%	0%
Family Practice	$5,557	0%	0%	0%	1%
Gastroenterology	$1,428	0%	0%	0%	0%
General Practice	$361	0%	0%	0%	1%
General Surgery	$1,688	0%	0%	0%	0%
Geriatrics	$170	0%	1%	0%	1%
Hand Surgery	$214	0%	1%	0%	1%
Hematology/Oncology	$1,679	0%	-1%	0%	-1%

[80] We followed-up with CMS about the large negative decreases for specialties such as vascular surgery and they stated that the combined impact numbers published in Table 136 are correct and that decreases for vascular surgery, for example, are also due to the revaluation of individual procedures based on reviews by the AMA RUC and CMS, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing.

TABLE 136: 2022 PFS 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
Independent Laboratory	$537	0%	0%	0%	0%
Infectious Disease	$620	0%	0%	0%	0%
Internal Medicine	$9,618	0%	0%	0%	0%
Interventional Pain Mgmt	$865	0%	2%	0%	1%
Interventional Radiology	$465	0%	-5%	0%	-5%
Multispecialty Clinic/Other Phys	$133	0%	0%	0%	0%
Nephrology	$2,231	0%	0%	0%	0%
Neurology	$1,313	0%	0%	0%	0%
Neurosurgery	$687	0%	0%	0%	0%
Nuclear Medicine	$48	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$1,036	0%	1%	0%	0%
Nurse Practitioner	$5,130	0%	0%	0%	0%
Obstetrics/Gynecology	$541	0%	0%	0%	0%
Ophthalmology	$4,218	0%	0%	0%	0%
Optometry	$1,075	0%	0%	0%	0%
Oral/Maxillofacial Surgery	$70	0%	-1%	0%	-1%
Orthopedic Surgery	$3,167	0%	0%	0%	0%
Other	$52	0%	0%	0%	0%
Otolaryngology	$1,003	0%	0%	0%	0%
Pathology	$1,030	0%	0%	0%	0%
Pediatrics	$54	0%	0%	0%	0%
Physical Medicine	$999	0%	0%	0%	0%
Physical/Occupational Therapy	$3,850	0%	-1%	0%	-1%
Physician Assistant	$2,723	0%	0%	0%	0%
Plastic Surgery	$311	0%	0%	0%	1%
Podiatry	$1,797	0%	1%	0%	1%
Portable X-Ray Supplier	$83	0%	2%	0%	2%
Psychiatry	$1,015	0%	0%	0%	0%
Pulmonary Disease	$1,424	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,605	0%	-1%	0%	-1%
Radiology	$4,257	0%	-1%	0%	-1%
Rheumatology	$523	0%	0%	0%	-1%
Thoracic Surgery	$293	0%	-1%	0%	-1%
Urology	$1,623	0%	0%	0%	1%
Vascular Surgery	$1,107	0%	-5%	0%	-5%
Total	$84,285	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 136:

- 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 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 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 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.

B. Impacts of Other Policies

The expected impacts of some of the 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 clinical labor updates, telehealth services, revisions to the current *de minimis* policy for services furnished in whole or part by PTAs/OTAs, policies 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 (809,593) will be assigned a MIPS score for 2024 because others will be ineligible for or excluded from MIPS. Table 144, 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; 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 144: Description of MIPS Eligibility Status for CY 2022 Performance Period/2024 MIPS Payment Year Using the 2022 PFS Final 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	185,684	$45,201
	Do not participate in MIPS	26,087	$6,117
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	594,567	$15,194
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	3,255	$77
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**809,593***	**$66,589**
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	411,837	$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		816,211	$26,045
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,804	$92,634

*Estimated MIPS Eligible Population
** Table does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 6,000 clinicians and $531 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 $603 million in payment adjustments on a budget neutral basis and that $360 million will be distributed to MIPS eligible clinicians who meet or exceed the additional performance threshold. CMS notes that an increase in funds is available for redistribution due to the increase in clinicians with final scores below the performance threshold. The maximum positive payment adjustments are 14.4 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 66.8 percent with the implementation of the

policies that shift away from MIPS transition policies. Clinicians receiving a negative adjustment is expected to increase from 8.3 percent to 33.2 percent.

Table 146, 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, 36 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 146: 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	108,274	63.6%	22.4%	36.4%	1.5%
2) 16-24	36,925	56.8%	15.7%	43.2%	0.5%
3) 25-99	174,982	60.7%	15.7%	39.3%	0.9%
4) 100+	463,232	70.6%	12.1%	29.4%	1.1%
Overall	**783,413**	**66.8%**	**14.5%**	**33.2%**	**1.2%**
Among those not submitting data					
1) 1-15	22,475	0.0%	0.0%	100.0%	-8.4%
2) 16-24	1,094	0.0%	0.0%	100.0%	-8.5%
3) 25-99	2,028	0.0%	0.0%	100.0%	-8.5%
4) 100+	583	0.0%	0.0%	100.0%	-8.6%
Overall	**26,180**	**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 final 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 final 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 one of particular significance.

As discussed earlier in section II.C.1 in the final 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 149 illustrates specialty-specific impacts using 2019 data. Specifically, the majority of specialties experienced shifts of less than one percent. CMS received few comments on this alternative considered which CMS believes indicates support for its use of 2020 claims data from the majority of commenters.

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 will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians on the compare tool.

CMS 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 will 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.

Similarly, this final 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.

F. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the final rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on this year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is $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 final 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 $32.38 million ($885.92 x 35,430 reviewers on this year's proposed rule).