CALIFORNIA HOSPITAL ASSOCIATION

Federal Regulatory Summary

as prepared by Health Policy Alternatives, Inc.

SUMMARY OF FINAL RULE — DECEMBER 2020

CY 2021 Physician Fee Schedule Final Rule

Overview

On December 2, the Centers for Medicare & Medicaid Services (CMS) released its final rule updating the Medicare physician fee schedule for calendar year 2021 and other revisions to Medicare Part B policies. The following summary, prepared by Health Policy Alternatives, Inc., provides detailed information on finalized annual payment updates for Medicare Part B clinicians. **The policies in the final rule are effective January 1, 2021.**

In addition to the standard payment updates, CMS finalizes several policies to make some COVID-19 telehealth and scope-of-practice flexibilities permanent and delays clinical laboratory reporting requirements – including for hospital outreach laboratories – until 2022. The summary also details changes related to the Quality Payment Program, including the Merit-Based Incentive Payment System and advanced alternative payment model incentives, as well as the Medicare Shared Savings Program.

Additional information on the final rule is available on the CMS website.

For Additional Information

For questions or additional information related to the final rule summary, please contact Megan Howard, vice president, federal policy, at (202) 488-3742 or mhoward@calhospital.org.

Physician Fee Schedule Final and Interim Final Rules With Comment for 2021
Summary Part I

Medicare Program: 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substance for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program Expanded Model Emergency Policy; Coding and Payment Virtual Check-in Services Interim Final Rule; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September Interim Final Rules in Response to the PHE for COVID-19

[CMS-1734-F, CMS-1734 IFC, CMS-1744-F, CMS 5531-F and CMS-3401-IFC]

On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2021[1] and other revisions to Medicare Part B policies. The final rule is scheduled to be published in the December 28, 2020 issue of the *Federal Register*.

CMS is waiving the 60-day delay in effective date (in accord with the Congressional Review Act). Policies in the final and interim final rules with comment generally go into effect on January 1, 2021, unless otherwise specified.

The comment period for the IFCs ends at close of business on December 28, 2020.[2] CMS issues an IFC to establish coding and payment for virtual check-in services to support the need for longer audio-only services outside the Public Health Emergency (PHE) for COVID-19. CMS is also issuing an IFC to establish coding and payment for personal protective equipment (PPE) as a bundled payment and include certain supply price increases for certain types of PPE.

HPA is providing a summary in two parts. Part I covers all sections of the final and interim final rules except the Quality Payment Program. Part II will cover the updates to the Quality Payment Program (QPP).

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.
[2] This is the date for the comment period on the website: https://www.regulations.gov/document?D=CMS-2020-0088-31356

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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 includes policies for refining the E/M coding and documentation requirements finalized in 2020 for implementation January 1, 2021 including proposals to revalue code sets that rely upon and

are analogous to office/outpatient evaluation and management (E/M) visits commensurate with the increases in values for office/outpatient E/M visits for 2021. CMS continues expand the use of care management services and remote physiologic monitoring services. The rule also finalizes proposals designed to address the expansion of telehealth services covered during the COVID-19 PHE.

The conversion factor for 2021 is $32.4085, which reflects a 0.00 percent update adjustment factor and a budget neutrality adjustment of -10.20 percent (2020 conversion factor of $36.0896*1.000*0.8980). This unusually large budget neutrality adjustment results from the revaluation of the E/M codes and proposed revalue of certain codes analogous to E/M codes. This budget neutrality adjustment reflects the fact that office/outpatient E/M visits are approximately 20 percent of the PFS allowed charges.

Specialty-specific payments impacts vary based on the use and mix of E/M services. Specialties where E/M services represent a greater share of total allowed charges, such as endocrinology (+16%), rheumatology (+15%), hematology/oncology (+14%), and family practice (+13%) would receive the largest increases. In contrast, specialties that have a low use of E/M services such as radiology (-10%), nurse anesthetists (-10%), chiropractor (-10%), pathology (-9%) and physical/occupational therapy (-9%) would receive the largest decrease.[3]

II. Provisions of the Final Rule for PFS

A. Background

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

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

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

1. Practice Expense Methodology

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

[3] These impacts do not take into account CMS' November 20, 2020 IFC (85 FR 76180) that implements the Most Favored Nation) MNF Model for Part B drugs and impacts physician revenues for Part B drugs.

For 2021, CMS makes note and responds to several issues in this section.

Stakeholders have raised concerns about the specialty crosswalk used for home Prothrombin Time (PT)/ International Normalized Ratio (INR) monitoring services used by physicians to determine the time it takes for a person's blood plasma to clot. These services are currently classified under the independent diagnostic testing facilities (IDTF) specialty for PE/HR purposes, but stakeholder do not believe this adequately reflect the indirect costs associated with furnishing these services. CMS sought comments regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services and any additional costs associated with these services not currently reflected in its assigned crosswalk.

Several commenters furnished data indicating that the direct to indirect cost ratio used to furnish home PT/INR monitoring is in the range of 31:69 rather than the approximately 50:50 currently considered in determining the PE RVUs for these services as IDTF. Recognizing these data, CMS finalizes a crosswalk to the General Practice specialty to use for indirect PE, when it comes to home PT/INR monitoring services (HCPCS G0248, G0249, and G0250).

With respect to the formula for calculating equipment cost per minute, CMS finalizes 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. CMS noted in the proposed rule that the equipment formula was designed under the assumption that each equipment item would remain in use for a period of several years and is not designed for use when equipment is being replaced multiple times per year.[4]

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 continues to believe that it does not have sufficient information to determine a variable maintenance factor, though it continues to investigate ways of capturing such information.

Several also commenters requested that CMS review the utilization assumptions for equipment due to decreased practice capacity during the PHE for COVID-19. CMS disagrees and notes in its response that equipment costs under the PFS are amortized across the full useful life of the equipment, such as 5 or 10 years, and thus it would distort relativity to apply a temporary decrease in utilization caused by the PHE.

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

[4] For example, decreasing the useful life of any equipment item from 5 years to 3 months has the same effect as increasing the price of the equipment 20 times over.

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 2021: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

b. Equipment Recommendations for Scope Systems

CMS states that during its routine reviews of direct PE input recommendations, it has regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. It has been exploring this issue since 2017 and has repeatedly expressed its desire to standardize the description of scopes and its pricing. In 2019, CMS delayed proposals for any further changes to scope equipment until 2020, so that it could incorporate feedback from a RUC Scope Equipment Reorganization Workgroup. In 2020, incorporating this feedback, CMS finalized its proposal to establish 23 different types of scope equipment.

For 2021, CMS did not receive any further recommendations from the RUC Scope Equipment Reorganization Workgroup. Prior to the proposed rule, CMS did receive invoices associated with the pricing of the scope video system (monitor, processor, digital capture, cart, printer, LED light) ES031 equipment item as part of its review of the Esophagogastroduodenoscopy with Biopsy and the Colonoscopy code families. CMS finalizes its proposal based on submission of invoices to update the price of the ES031 scope video system equipment to $70,673 from $36,306. The total price of $70,673 is based on the sum of component prices of $21,988.89 for the processor, $16,175.87 for the digital capture device, $6,987.56 for the monitor, $7,922.80 for the printer, $4,945.45 for the cart, and $12,652.82 for the LED light. CMS updates this pricing increase over the remaining two years of the market-based supply and equipment pricing transition: for 2021 the equipment price will be $53,490 before moving to its destination price of the $70,673 in 2022. Although not a scope, CMS also finalizes in this section the price update of a suction machine (Gomco) (EQ235) equipment that would also transition over the remaining 2 years of the market-based supply and equipment pricing update from $1,981.66 in 2021 to $3,195.85 in 2022.

CMS also received invoices associated with three of the eight scope equipment items that still lacked a price. Based on this information, CMS finalizes a price of $7,270.00 for the rigid scope, cystoscopy (ES070) equipment, a price of $22,274.36 for the channeled flexible digital scope, cystoscopy (ES081) equipment, and a price of $19,081.82 for the channeled flexible digital scope, hysteroscopy (ES082) equipment. The total list of scopes and associated pricing is shown in Table 6 in the final rule.

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

For 2021, CMS finalizes its proposal to update the global period for CPT code 0446T (Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator) to add-on status (ZZZ) to more accurately reflect the way in which this service is performed.

CMS also received additional comments on technical corrections to its PE database and made the following changes in its response:

- Finalizes the replacement of the exam table with an exam light (EQ168) at the same equipment time of 36 minutes for CPT code 33202
- Updates supply items in the CMS database that lacked a unit type, such as item or kit) to avoid potential confusion regarding pricing (18 supply items affected listed in Table 7 in final rule).
- Implements a technical change associated with several occupational therapy procedures (CPT codes 97165-97167) (does not describe the nature of that change) to ensure that the three services receive the same allocation of indirect PE. Commenters questioned the proposed RVUs associated with these codes as it was counterintuitive for the PE RVU to go down as the level of complexity increases.
- Finalizes an increase in the work RVU code of G0102 from 0.17 to 0.18 to match the previously finalized crosswalk to CPT code 99211.
- Finalizes an increase in the work RVU for HCPCS code G0106 and G0120 to match the previously finalized crosswalk to CPT code 74280.

d. Updates to Prices for Existing Direct PE Inputs

With respect to updating prices for existing direct PE inputs, 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 2021 for the 2022 Medicare PFS proposed rule). 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 2021, CMS discusses five issues in this section: (1) market-based supply and equipment pricing update, (2) updated supply pricing for venous and arterial stenting services, (3) myocardial PET equipment inputs, (4) Autologous platelet-rich plasma supply items, and (5) adjustment to allocation of indirect PE for some office-based services (fourth and final year of the adjustment).

(1) <u>Market-Based Supply and Equipment Pricing Update</u>

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.[5] These supply and equipment inputs had not been systematically examined since 2004-2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. CMS finalized these pricing recommendations with initial modifications to about 70 supply and equipment codes based on comments and feedback.

Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, CMS finalized a policy to phase in its use of the new direct PE input pricing over a 4-year period. CMS implemented this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for 2019, one third of the difference between the 2019 price and the final price is implemented for 2020, and one half of the difference between the 2020 price and the final price is implemented for 2021, with the new direct PE prices fully implemented for 2022. An example of the transition from the current to the fully implemented new pricing is provided in Table 8 in this rule (reproduced below).

Table 8: Example of Direct PE Pricing Transition		
Current Price	$100	
Final Price	$200	
Year 1 (2019) Price	$125	1/4 difference between $100 and $200
Year 2 (2020) Price	$150	1/3 difference between $125 and $200
Year 3 (2021) Price	$175	1/2 difference between $150 and $200
Final (2022) Price	$200	

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

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

For 2021, CMS received invoice submissions for about a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. Based on comments received and additional invoices submitted, CMS updated many of

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

the supply equipment items. The finalized prices are listed in Table 10 in the final rule (reproduced below).

Table 10: CY 2021 Finalized Market-Based Supply and Equipment Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA026	kit, radiofrequency introducer	$37.080	$24.160	$30.620	$28.575	$32.828
SA074	kit, endovascular laser treatment	$421.165	$323.330	$372.248	$438.600	$429.883
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SC083	tubing set (Liposorber)	$48.840	$47.680	$48.260	$75.710	$62.275
SD089	guidewire, hydrophilic	$39.435	$13.350	$26.393	$20.555	$29.995
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$382.500	$510.000	$487.920	$562.710
SD188	plasma separator (Liposorber)	$94.660	$89.320	$91.990	$131.420	$113.040
SL089	lysing reagent (FACS)	$3.883	$3.280	$3.581	$3.645	$3.764
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period is available on the CMS website: CY 2021 PFS Final Rule Market-Based Supply and Equipment Pricing Update (ZIP) (cms.gov)

(2) Updated Supply Pricing for Venous and Arterial Stenting Services

Regarding supply pricing for certain venous and arterial stenting services, CMS finalizes its proposal to remove the SA103 supply item from CPT codes 37238 (Open/perq place stent same) and 37239 (Open/perq place stent ea add) and replace it with a newly created "venous stent system" (SD340) at the same supply quantity. CMS finalizes a price of $1,750 for this system based on the median price of the ten invoices supplied – it chose to use the median rather than the mean value based on several "outlier" invoices.

(3) Myocardial PET Equipment Inputs

Regarding the direct PE inputs for several codes associated with Myocardial PET services, CMS finalizes its proposal to update the price for the nuclide rod source set (ER044) equipment to $2,081.17 and add the ER044 equipment to CPT codes 78432, 78459, 78491, and 78492 (had been inadvertently excluded from the direct PE recommendations) and assigning the same equipment time utilized by the "PET Refurbished Imaging Cardiac

Configuration" (ER110) equipment in each service. It also updates the useful life of the ER044 equipment to one year from the current useful life of 5 years. CMS notes that these codes are contractor-priced and thus there will be no change in the national pricing of these codes.

(4) Autologous Platelet-rich Plasma (HCPCS Code G0460) Supply Items

Following the publication of the rule, stakeholders contacted CMS regarding the creation of a new 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. This procedure is reported using HCPCS code G0460 and they requested that CMS revalue the service to reflect the increased costs associated with the new patch system supply. CMS shares the stakeholders' concern that patient access to the 3C patch will be materially impacted if it maintains current reimbursement for HCPCS G0460.

CMS notes, however in its response, that it did not propose to increase the price of HCPCS code G0460 in the PFS proposed rule, and has concerns about finalizing a fivefold increase in the pricing of this service without going through notice and comment rulemaking. Therefore, CMS finalizes contractor pricing for HCPCS code G0460 for CY 2021 to allow for increased pricing for this service when it includes the 3C patch system without establishing a new national price. It believes that the use of contractor pricing will allow additional time to determine the most accurate pricing for HCPCS code G0460.

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

As background, CMS allocates indirect costs for each code based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting, and thus indirect PE RVUs allocated to these services are higher in the nonfacility setting than in the facility setting. In cases where direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting. In 2018, CMS finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services (mostly behavioral health services). CMS refers readers to the 2018 PFS final rule (FR 52999 through 53000) for a discussion of this revised methodology. CMS first began implementing this modification in 2018, the first year of a 4-year transition.

For 2021, CMS finalizes its proposal to continue with the fourth and final year of the transition of this adjustment to the standard process for allocating indirect PE. There are 30 codes affected by this policy, and the list is available on CMS' website.[6]

[6] See CY 2021 PFS Final Rule Codes Affected by Alternative Methodology for Indirect PE (ZIP) (cms.gov)

e. Update to Technical Expert Panel Related to Practice Expense

CMS provides an update on the RAND Corporation's efforts on studying potential improvements to CMS' PE allocation methodology and the supporting data. The current system for setting PE values relies in part on data collected in the Physician Practice Information Survey (PPIS) which was administered by the AMA in 2007 and 2008.

In its first phase of its research, RAND concluded that the PPIS data are outdated (e.g., preceded the widespread adoption of electronic health records) and may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries.[7] RAND found, for example, that aggregating Medicare provider specialties into broader categories resulted in small specialty-level impacts relative to the current system suggesting that specialty-specific inputs may not be required.

To follow-up on some of these issues, RAND convened a technical expert panel (TEP) on January 10, 2020 to obtain input from stakeholders, which is available at https://www.rand.org/pubs/working_papers/WR1334.html. Topics included, for example, how best to aggregate PE categories if there were to be new survey instrument; ways to maximize response rate in a potential new survey; and using existing data to inform PFS PE rates. RAND also issued results from its subsequent phase of research.[8]

Based on the results of the TEP and RAND's other ongoing research, CMS states that it is interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. CMS states that stakeholders have expressed an interest in updating the clinical labor data used for direct PE inputs based on current salaries and compensation for the health care workforce. It currently uses data from the Bureau of Labor Statistics (BLS). CMS solicited comments regarding on how it might update the clinical labor data and whether BLS data is the best data source or if there is an alternative.

CMS also indicated an interest in hosting a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders on its ongoing research to potentially update the PE methodology and the underlying inputs.

Commenters encouraged CMS to work with stakeholders on any new PE data collection effort and were supportive of CMS convening a Town Hall meeting. CMS believes that a Town Hall would provide an open forum for discussion and remained interested in hosting this meeting at a date to be determined.

[7] See https://www.rand.org/pubs/research_reports/RR2166.html
[8] See https://www.rand.org/pubs/research_reports/RR3248.html.

C. Potentially Misvalued Services under the PFS

CY 2021 Public Nomination of Potentially Misvalued Services

CMS received multiple submissions nominating CPT code 22867 as a potentially misvalued service. CPT code 22867 describes the insertion of a "interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level." Commenters suggested that the physician work for this code is significantly undervalued when compared to CPT code 63047 ("Laminectomy, facetectomy, and foraminotomy, single vertebral segment; lumbar"). Commenters were also concerned that the malpractice RVUs were not aligned with similar spine procedures

CMS finalizes its proposal to nominate CPT code 22867 as a potentially misvalued code. The AMA RUC commented that this code will be placed on a the "next Level of Interest for review" RUC list.

Comments/Responses: Several commenters nominated CPT code 49436 (Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter) as potentially misvalued because PFS payment for this service is limited to the facility setting. CMS responds it will continue to research the potential impact of valuing this code in the office setting and may consider this for future rulemaking.

CMS reiterates it accepts and reviews all public nomination of services that may be potentially misvalued, including nominations from private commercial insurers. Nominations for 2022 must be received prior to the February 10, 2021 deadline.

D. Telehealth and Other Services Involving Communications Technology and IFC with Comment Period for Coding and Payment of Virtual Check-in Services

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.

The Medicare telehealth services list, including codes added during the PHE, is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. Information about submitting a request to add services to the Medicare telehealth services list is also available on this website. For 2022, requests to add a service to the list must be received by February 10, 2021.

a. Requests to Add Services to the Medicare Telehealth Services List for 2021

In response to the public health emergency (PHE) for COVID-19, CMS undertook emergency rulemaking to add a number of services to the telehealth list on an interim basis.[9] The table below list the additional services CMS finalized to the telehealth list on a Category 2 basis for the duration of the PHE.

Service Type	CPT codes
Emergency Department Visits	99281-99285
Initial and Subsequent Observation and Observation Discharge Day Management	99217-99220; 99224-99226; 99234-99236
Initial hospital care and hospital discharge day management	99221-99223; 99238-99239
Initial nursing facility visits and nursing facility discharge day management	99304-99306; 99315-99316
Critical Care Services	99291-99292
Domiciliary, Rest Home or Custodial Care services	99327-99328; 99334-99337
Home Visits	99341-99345; 99347-99350
Inpatient Neonatal and Pediatric Critical Care	99468-99472; 99475-99476
Initial and Continuing Intensive Care Services	99468-99473; 00475-99476
Assessment and Care Planning for Patients with Cognitive Impairment	99483
Group Psychotherapy	90853
End-Stage Renal Disease (ESRD) Services	90952, 90953, 90959, and 90962
Psychological and Neuropsychological Testing	96130-96133; 96136-96139
Therapy Services, Physical and Occupational Therapy	97161-97168; 07110, 97112, 97116, 97537, 97750, 97755, 97760, 97761, 92521-92524, 92507
Radiation Treatment Management Services	77427

CMS considered which services added to the telehealth services list on an interim basis should remain on the telehealth service list after the end of the PHE. The table below (based on Table 11 in the final rule) lists the services CMS finalizes to add to the Medicare telehealth service list on a Category 1 basis. CMS believes these services are similar to services currently on the telehealth services list.

2021 Proposed Additions to the Medicare Telehealth Services List on a Category I Basis	
HCPCS Code	**Code Description**
G2211	Visit complexity inherent to E/M (Add-on code)
90853	Group psychotherapy
96121	Neurobehavioral status exam (List in addition to primary procedure)
G2212	Prolonged office or other outpatient E/M service (List in addition to E/M service)
99483	Care planning for a patient with cognitive impairment
99334*	Domiciliary or rest home E/M visit for an established patient (15 minutes)

[9] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" interim final rule with comment period (IFC), referred to as the March 31st COVID-19 IFC.

2021 Proposed Additions to the Medicare Telehealth Services List on a Category I Basis	
HCPCS Code	**Code Description**
99335*	Domiciliary or rest home E/M visit for an established patient (25 minutes)
99347*	Home visit for E/M of an established patient (15 minutes)
99348*	Home visit for E/M of an established patient (25 minutes)
*These services can be billed when furnished as a telehealth service only for treatment of a substance use disorder or occurring mental health disorder.[10]	

CMS agrees with a request to add CPT code 96121 to the list since the service would only be considered a telehealth service when billed as an add-on to codes already on the telehealth list.

CMS does not agree with a request to add Medical Genetics services (CPT code 96040 and S0265) to the telehealth list (Table 12). Medical genetic counseling (96040) is bundled into office/outpatient E/M visits which are already on the telehealth list. In addition, genetic counselors are not practitioners who can bill Medicare directly for their professional services. CMS notes that S0265 (Genetic counseling, under physician supervision) is classified as a supply code, and there is no separate payment for this category of codes.

b. Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List

In the May 1st COVID-19 IFC, on an interim basis, CMS removed the requirement that it undertake rulemaking to add or delete services on the Medicare telehealth list to allow it to add additional services on a subregulatory basis. This interim policy expires at the end of the PHE and payment for Medicare telehealth services will be limited by the requirements of section 1834(m) of the Act. At the end of the PHE, CMS will resume the rulemaking process previously established to add services to the telehealth list.

CMS acknowledges that the annual PFS rulemaking schedule may not align with the expiration of the PHE and stakeholders might not have the opportunity to request permanent additions to the telehealth list prior to those services being removed with the end of the PHE. CMS believes this situation is most likely for services considered on a Category 2 basis, which requires supporting information to demonstrate the clinical benefit of a service. To prevent a sudden disruption to clinical practice and beneficiary access to services when the PHE ends, CMS finalizes its proposal to create a third category of criteria for adding services to the Medicare telehealth list on a temporary basis. CMS includes in this category services added during the PHE for which there is likely to be clinical benefit when furnished by telehealth but do not meet the requirements under Category 1 or Category 2. CMS believes the additional time provides the opportunity to both generate evidence and request additions to the telehealth list on a permanent basis.

[10] The SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home as a telehealth originating site for treatment of a substance use disorder or a co-occurring mental health disorder furnished to a patient with a substance use disorder diagnosis.

CMS finalizes its proposal to use 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.

CMS finalizes its proposal that the Category 3 criteria and basis for considering additions to the telehealth list would be temporary and expire at the end of the calendar year in which the PHE expires.

CMS proposed 13 services that it proposed to continue on the telehealth list on a Category 3 basis (Table 13). After consideration of comments, CMS finalizes 63 services on the telehealth list on a Category 3 basis. The table below (based on Table 14 in the final rule) lists the services CMS finalizes to add to the Medicare telehealth service list on a Category 3 basis.

Service Type	CPT Codes
End-Stage Renal Disease Monthly Capitation Payment Services	90952, 90953, 90956, 90959, 90962
Emergency Department (ED) Visits	99281- 99285
Domiciliary, Rest Home or Custodial Care Services, Established patients*	99336 & 99337
Home Visits, Established patients*	99349 & 99350
Nursing Facilities Discharge Day Management	99315 & 99316
Psychological and Neuropsychological Testing	96121, 99130- 99133; 96136- 96139
Therapy Services, Physical and Occupational Therapy, All levels	97161- 97168; 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507
Subsequent Observation and Observation Discharge Day Management	99217; CPT 99224- 99226
Hospital Discharge Day Management	99238 & 99239
Critical Care Services	99291 & 99292
Inpatient Neonatal and Pediatric Critical Care, Subsequent	99469, 99472, 99476
Continuing Neonatal Intensive Care Services	99478- 99480

Comments/Responses: Most commenters supported the proposed timeframe for services added on a Category 3 basis to remain on the Medicare telehealth list. A few commenters stated that adding services on a temporary basis creates unnecessary burden for clinicians. Some commenters suggesting alternative timeframes including time frames ranging between 90 days and 2 years after the end of the PHE or expiration in a specific year, such as 2022. CMS

finalizes the additions in Table 14 to the telehealth list on a Category 3 basis through the later of the end of the year in which the PHE ends or December 31, 2021, as proposed. Any potential expansion of this timeframe would be proposed in future rulemaking.

c. Comment Solicitation on Medicare Telehealth Services Added on An Interim Basis during the PHE that CMS Did Not Propose to Retain After the PHE Ends

Table 15 in the final rule lists the 91 services that commenters requested to be added to the telehealth list on a Category 3 basis; CMS finalizes the addition of 50 services to the telehealth list on a Category 3 basis (see Table 14 in the final rule and summarized above).

CMS did not finalize requests to add 41 services to the telehealth list on a Category 3 basis. CMS' response to these requests is summarized below:

- Initial nursing facility visit. CMS continues to believe that there are components of the initial visit, such as the physical exam, that can only be properly performed in person.
- Audiology services. Based on the information provided, CMS does not agree that these services can be furnished in full by telehealth because it believes the requested services likely require hands-on, clinical assessment and direct, one-on-one interaction/observation.
- Hospital E/M services. CMS finalizes the requests to add E/M services that are furnished in a hospital or ED setting, except for services for new patients. CMS believes that for new patients, an in-person physical exam is necessary.
- Remote monitoring of neuromodulation technologies. Based on the information provided, is not convinced these services can, in most instances, be conducted in full using two-way, audio/video communication technology. CMS also notes it is not within CMS' mandate under the PFS to ensure improved outcomes.
- Radiation treatment management. Based on the information provided, CMS is not convinced the full service elements described by CPT code 77427 could, in most cases, be furnished in full via two-way, audio/video communication technology.

Table 16, reproduced below, summarizes the services added to the Medicare Telehealth list for 2021.

TABLE 16: Summary of CY 2021 Services Added to the Telehealth Services List

Type of Service	Specific Services and CPT Codes
1. Services we are proposing for permanent addition to the Medicare telehealth services list	• Group Psychotherapy (CPT 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334-99335) • Home Visits, Established Patient (CPT 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211) • Prolonged Services (HCPCS G2212) • Psychological and Neuropsychological Testing (CPT 96121)

TABLE 16: Summary of CY 2021 Services Added to the Telehealth Services List	
Type of Service	**Specific Services and CPT Codes**
2. Services finalized as temporary additions to the Medicare telehealth services list through the end of the year in which the COVID-19 ends (Category 3 services), to allow for continued development of evidence to demonstrate clinical benefit and facilitate post-PHE care transitions.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336-99337) • Home Visits, Established Patient (CPT 99349-99350) • Emergency Department Visits, Levels 1-5 (CPT 99281-99285)* • Nursing facilities discharge day management (CPT 99315-99316) • Psychological and Neuropsychological Testing (CPT 96130- 96133; CPT 96136-96139)) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)* • Hospital discharge day management (CPT 99238- 99239)* • Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, and 99476)* • Continuing Neonatal Intensive Care Services (CPT 99477- 99480)* • Critical Care Services (CPT 99291-99292) • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)* • Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224- 99226)*
3. Services not added to the Medicare telehealth services either permanently or as Category 3 services.	• Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Initial hospital care (CPT 99221- 99223) • Radiation Treatment Management Services (CPT 77427) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324-99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Inpatient Neonatal and Pediatric Critical Care, Initial (CPT 99468, 99471, 99475- 99477) • Initial Neonatal Intensive Care Services (CPT 99477) • Initial Observation and Observation Discharge Day Management (CPT 99218- 99220; CPT 99234-99236) • Medical Nutrition Therapy (CPT G0271)
*Services that were not proposed but are Category 3 additions to the Medicare telehealth list.	

2. Analysis and Response to Comment Solicitation on Coding and Payment for Tele-ICU

CMS also summarizes its previous decisions about the addition of critical care services to the telehealth list and notes that two critical care consultation HCPCS codes (G0508 and G0509) are on the telehealth list. CMS continues to believe that the full range of care for critically ill patients cannot be performed via two-way, audio/video telecommunications technology.

CMS sought comment on the definition, potential coding and valuation for remote critical care services. CMS appreciates the feedback it received regarding the different tele-ICU modes. The AMA is currently evaluating coding and valuation for services provided by tele-ICU and it will consider these comments when evaluating any new CPT codes and AMA RUC recommendations as part of future rulemaking.

3. Technical Refinement to the Medicare Telehealth Services List to Reflect Coding

For 2020, the CPT Editorial panel deleted six existing Health and Behavior Assessment and Intervention procedure CPT codes (96150-96155) and replaced them with nine new successor CPT codes (96156, 96158, 96159, 96164-96168, 96170, and 96171). In the 2020 PFS rulemaking, CMS did not make corresponding coding changes on the Medicare telehealth services list. CMS finalizes its proposal to delete the old CPT codes and replace them with the new successor CPT codes on the telehealth list.

CMS finalizes its proposal to amend its regulations to stipulate that when new codes are issued to replace codes that describe the same clinical services that are on the Medicare telehealth services list, it will consider these new codes as successor codes to services on the telehealth list and will update the telehealth list accordingly.

4. Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

During the COVID-19 PHE, CMS waived the requirement for physicians and NPPs to personally perform required visits for nursing home residents and allowed visits to be conducted via telehealth (42 CFR 483.30).[11] In the proposed rule, CMS solicited comments on whether it should maintain this flexibility on a permanent basis when the PHE ends and allow two-way, audio/video telecommunications for required nursing home resident visits when, due to continued exposure risks, or other factors, the clinician determines an in-person visit is not necessary.

In the proposed rule, CMS also discussed requested from stakeholders about frequency limitations for telehealth visits. Stakeholders requested that CMS revise its frequency limitations for telehealth nursing facility visits from once every 30 days to once every 3 days. CMS proposed to revise the frequency limitation from one visit every 30 days to one visit every 3 days.

Stakeholders also requested that CMS revise its frequency limitations which allow telehealth subsequent inpatient visits once every 3 days. CMS disagreed with the request to revise the frequency for inpatient visits and reiterated its prior position that it believes the potential acuity of illness of hospital inpatients and the need for physicians to facilitate the comprehensive, coordinated care for acutely ill patients requires in-person visits.

CMS sought comment on whether frequency limitations are burdensome and limit beneficiary access to necessary care available through telehealth and how to ensure patients receive necessary in-person care.

Comments/Responses: CMS got a wide range of comments about the frequency limitations for subsequent nursing home visits furnished via telehealth; many commenters supported revising

[11] https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers

the frequency limitation to once every 3 days, other commenters urged removal of frequency limitations, and a few commenters thought frequency limitations should be maintained to prevent a disincentive for in-person care. In response, CMS notes that patients in the nursing facility setting tend to have a higher length of stay compared to patients in the inpatient setting and it doesn't think the frequency limitation for nursing facility should be the same as the frequency limitation to once every 3 days as in the inpatient setting. It acknowledges that one telehealth visit every 3 days may be too infrequent and once every 3 days poses a risk of creating a disincentive for in-person care.

Final Decision*:* CMS finalizes the frequency limitation for subsequent nursing facility visits to permit one Medicare telehealth visit every 14 days in the nursing facility setting.

5. Proposed Technical Amendment to Remove References to Specific Technology

CMS' regulation at §410.78(a)(3) state that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system for Medicare telehealth services. CMS does not interpret this to apply to mobile computing devices that include audio and video real-time interactive capabilities, even though they are considered phones and can be used for audio-only telecommunications. CMS believes it is important during the PHE to avoid the potential perception that this language might prohibit use of any device that could otherwise meet the interactive requirements for Medicare telehealth.

On an interim basis during the PHE, CMS revised §410.78(a)(3) to add an exception to this language:

> "*Exception*: For the duration of the public health emergency as defined in §400.200 of this chapter, *Interactive telecommunications system* means multimedia communications equipment 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."

CMS finalizes its proposal to adopt this change on a permanent basis.

6. Communications Technology-Based Services

CMS makes separate payment for communications technology-based services (CTBS); these services are furnished by telecommunications but are not considered Medicare telehealth services. HCPCS codes G2010 and G2020 are for CTBS services provided by physicians or other qualified health care professionals. In the 2020 PFS final rule, CMS finalized separate payment for HCPCS codes G2061-G2063 for CTBS services provided by NPPs consistent with the definition of their respective benefit category.

In the March 31st COVID-19 IFC, CMS established on an interim basis for the duration of the PHE that HCPCS codes G2061-G2063 could be billed by licensed clinical social workers, clinical psychologists, and PTs, OTs, and SLPs who bill directly for their services when the service furnished falls within the scope of their benefit categories. CMS finalizes its proposal to adopt this policy on a permanent basis.

CMS also finalizes its proposal for two additional HCPCS G codes for CTBS services for practitioners who cannot independently bill for E/M services:

- G2250: Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward) including interpretation with follow-up of the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
- G2251: Brief communication technology-based service, e.g., virtual check-in, by a qualified health care professional who cannot report E/M services, provided to an established patient, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

CMS finalizes its proposal to value these services identically to the G2010 and G2020, the codes for CTBS services provided by physicians or other qualified health care professionals. CMS acknowledges it generally differentiates payment for similar services provided by practitioners who can and cannot bill independently for E/M services, but given the relative low values for G2010 and G2020 it does not think there is a significant differential in resource costs to warrant different values.

CMS also finalizes its proposals for the following policies for CTBS:

- Designate G2250, G2251, and G2061-G2063 as "sometimes therapy" services to facilitate billing by therapists.
- Allow consent from the patient to receive these services to be documented by auxiliary staff under general supervision.

Comments/Responses: Many commenters were supportive of CMS' proposals for CTBS. Several commenters urged CMS to increase the values for G2010 and G2012. CMS acknowledges it generally differentiates payment for similar services provided by practitioners who can and cannot bill independently for E/M services, but it does not believe there is a significant differential in the resource costs for these codes to warrant different values. It will consider this issue again in future rulemaking.

7. Continuation of Payment for Audio-only Visits

In the March 31st COVID-19 IFC, CMS established separate payment for audio-only telephone E/M services, CPT codes 99441-99443. CMS believes that these services, previously considered non-covered under the PFS, are an important way to replace a face-to-face visit during the PHE. CMS initially finalized payment based on the RVUs recommended by the RUC. Based on stakeholders' feedback, in the May 1st COVID-19 IFC, CMS established new RVUs for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes. In addition, CMS recognized these services as telehealth services and added them to the Medicare telehealth list for the duration of the PHE. For audio-only E/M services, CMS issued a

waiver[12] of the requirements under section 1834(m) of the Act and its regulation at § 410.78 that Medicare telehealth services must by furnished using video technology.

CMS proposed not to continue to recognize these codes for payment under the PFS after the PHE. CMS acknowledges that the need for audio-only interaction could remain after the PHE as beneficiaries continue to avoid sources of potential infection. CMS sought seeks comments on whether it should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with a higher payment, and whether this should be a provisional policy to remain for some period after the PHE or if it should be a permanent PFS payment policy.

Comments/Responses: Commenters broadly supported maintaining the availability of certain audio-services after the duration of the PHE for COVID-19. Some commenters stated that in the absence of continuing to recognize these codes, CMS should provide coding and payment for a longer virtual check-in. MedPAC suggested that if CMS creates a longer virtual check-in, the policy should be provisional instead of permanent.

CMS disagrees with commenters proposing revisions to the agencies regulation at § 410.78(a)(3) to redefine the longstanding regulatory interpretation of "interactive telecommunications system" to include audio-only services. CMS notes that section 1834(m)(2)(A) expressly provides payment to the distant site physician or practitioner of an amount equal to the amount that provider would have been paid under this title has the service been furnished without the use of a telecommunications system. Section 1834(m)(l) of the Act specifies that telehealth services must be furnished via a "telecommunications system", and it includes an exception to allow "store and forward" technology to be considered a telecommunications system only for purposes of certain federal demonstrations. CMS believes that its longstanding interpretation of "telecommunications system" which includes only technology that enables a visit that is analogous to an in person visit reflects the intent of statute. CMS states that outside of the PHE it continues to believe that audio-only technology is precluded from being a Medicare telehealth service.

Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services (HCPCS code G2252)

In response to comments about the continuing need for audio-only conversations with patients, CMS establishes coding and payment for an extended audio-only assessment service on an interim basis for 2021. CMS establishes the following HCPSC code:

> G2252: Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion

[12] The waiver was issued under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act.

CMS finalizes a direct crosswalk to CPT code 99442.[13] CMS states that because this service is not a substitute for an in-person visit, but rather an assessment to determine the need for one, the restrictions in section 1834(m) of the Act do not apply and the only technological requirement is that the communication technology must be synchronous. CMS considers this a CTBS service. The code will be subject to the same billing requirements as HCPCS code G2012.

CMS finds good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment.

8. Comment Solicitation on Coding and Payment for Virtual Services

CMS discusses how the term "telehealth" is broadly used by the health care community to refer to medical services furnished by communications technology. CMS notes that it generally uses the term "Medicare telehealth services" to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for services, all of which must ordinarily be furnished in-person, when they are not furnished using interactive, real time telecommunications technology.

CMS has been making separate payment for services that use telecommunications technology but are not considered Medicare telehealth services. Although these services are routinely furnished using telecommunications technology, unlike the services specified in section 1834(m) of the Act, they are not ordinarily furnished in person.

In the proposed rule, CMS sought comments about ways it can improve coding and payment for services that utilize telecommunications technology and that are not within the services specified in section 1834(m) of the Act. CMS discusses the comments it received and will consider them for potential future rulemaking or future subregulatory guidance.

9. Clarification of Current PFS Policies for Telehealth Services

In response to the waiver of statutory requirements and the relaxation of regulatory requirements for telehealth during the PHE, CMS received requests to clarify existing PFS policy for telehealth.

CMS finalizes its proposed clarifications:

- Services that may be billed incident to may be provided via telehealth incident to a physicians' (or authorized NPP's) service and under the direct supervision of the billing professional; and
- If audio/video technology is used to provide a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill

[13] For G2252, CMS finalizes a work RVU of 0.5, direct PE inputs of 3 minutes of clinical labor code L037D, and 1 minute, 15 minutes, and 5 minutes of pre, intra and post service time, respectively.

for the service as if the service was furnished in person and the service would not be subject to any of the telehealth requirements under section 1834(m) of the Act or §410.78 of its regulations.

10. Direct Supervision by Interactive Telecommunications Technology

Direct supervision requires that the physician or NPP must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure (§§410.26 and 410.32(b)(3)(ii)). For the duration of the PHE, in order to limit exposure to COVID-19, CMS adopted an interim policy to expand the definition of direct supervision to include the virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology.

CMS finalizes its proposal to revise §410.32(b)(3)(ii) to allow direct supervision to be provided using real-time, interactive audio/video technology (excluding audio-only) through the later of the end of the calendar year in which the PHE ends or December 31, 2021 and subject to the clinical judgement of the supervising physician or other supervising practitioner. CMS clarifies that the requirement could be met by the supervising physician or other practitioner being immediately available to engage in audio/video technology and does not require real-time presence or observation of the service throughout the performance of the procedure.

CMS discusses concerns related to patient safety that preclude it from making direct supervision through audio/video technology a permanent policy. CMS raises concerns that audio/video technology limits a physician or practitioner's ability to recognize important findings on physical examination (such as crystal-mediate acute arthritis or hypoactive delirium) and limits examination of patients with communication disabilities or cognitive impairment. In addition, CMS raises concerns about disruptions of virtual connections making immediate availability impossible.

In the proposed rule, CMS sought comments on whether there should be any additional "guardrails" or limitations to ensure patient safety and clinical appropriateness, as well as restrictions to prevent fraud or inappropriate use if it finalized a policy to permit direct supervision through audio/video telecommunications on an interim or a permanent basis. CMS appreciates the comments received and will consider this information as it determines future policy regarding the use of communication technology to satisfy direct supervision requirements.

11. Comment Solicitation on PFS Payment for Specimen Collection for COVID-19 Tests

In the May 1st COVID-19 IFC, CMS finalized on an interim basis that physicians and NPPs may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for COVID-19 testing, if the billing practitioner does not also furnish a higher level E/M service to the patient on the same day. In the proposed rule, CMS sought comments on whether it should extend the COVID-19 testing policy for a limited period of time or make this policy permanent. CMS appreciates the comments received and will consider this information for potential future rulemaking.

12. Finalization of Interim Final Rule Provisions Related to Requirements of the Substance Use Disorder (SUD) Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

Section 2001(a) of the Support for Patients and Communities Act[14] (the SUPPORT Act) made several revisions to section 1834(m) of the Act. It removed the originating site geographic requirements, added the home of an individual as a permissible originating site, and removed the originating site facility fee when the individual's home is the originating site for telehealth services furnished on or after July 1, 2019 for the purpose of treating individuals diagnosed with a substance use disorder or a co-occurring mental health disorder. Section 2001(b) of the SUPPORT for Patients and Communities Act grants the Secretary specific authority to implement the amendments made by section 2001(a) through an interim final rule.

In the 2019 PFS interim final rule with comment period (83 FR 59452, 59494), CMS implemented these provisions to the regulation text at §§410.78(b)(3) and 414.65(b)(3). After consideration of comments, CMS finalizes the interim revisions in the regulation text.

13. Regulatory Impact

Although CMS expects the changes to the Medicare telehealth list have the potential to increase access to care in rural areas, based on recent telehealth utilization already on the list, CMS estimates there will only be negligible impact on PFS expenditures from the Category 1 and Category 2 additions. Additionally, for services added on a Category 3 basis, outside the PHE, CMS does not anticipate any significant increase in utilization after the PHE ends. CMS states it will need additional analysis, including a full year's worth of claims data, to consider the effect of the PHE on utilization. This analysis would inform CMS about options for adopting any flexibilities on a permanent basis, as allowed by Medicare statute outside of the PHE.

E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

CMS continues to improve payment for care management services. Table 17 (reproduced below) summarizes the care management codes.[15]

Table 17: Summary of Care Management Codes

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS codes G0181, G0182)	Supervision of home health, hospice, per month

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

[15] A list of Care Management Services assigned general supervision is available on the CMS website at https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1734-f. The table is listed as one of the files on the Supporting Documentation Downloads.

Table 17: Summary of Care Management Codes	
Service	**Summary**
ESRD Monthly Services (CPT codes 90951-70)	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013) (CPT codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019, 2020, 2021) (CPT codes 99487, 99489, 99490, 99491, HCPCS code G2058 (99XXX proposed 2021 replacement)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016) (CPT codes 99497, 99498)	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017) (CPT codes 99484, 99492, 99493, 99494, HCPCS code GCOL1 proposed for 2021)	Management of behavioral health conditions(s), timed, per month
Cognitive Impairment Assessment and Care Planning (adopted in 2017) (CPT code 99483)	Assessment and care planning of cognitive impairment, face-to-face visit
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT codes 99358, 99359)	Prolonged non-face-to-face E/M work related to a face-to-face visit (other than office/outpatient visits beginning in 2021), timed
Prolonged Office/Outpatient E/M Visit (adopted for 2021) (CPT code 99XXX)	Prolonged face-to-face and/or non-face to face E/M work related to an office/outpatient E/M visit, timed
Remote Physiologic Monitoring Treatment Management Services (RPM) (adopted in 2020) (CPT codes 99457, 99458)	Development and management of a plan of treatment based upon patient physiologic data
Interprofessional Consultation (adopted in 2019) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation
Principal Care Management (adopted in 2020) (HCPCS codes G2064, G2065)	Management of a single, high risk disease

2. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management

CMS states that remote physiologic monitoring (RPM) involves the collection and analysis of patient physiologic data that is used to develop and manage a treatment plan for a chronic and/or acute illness or condition. CMS finalized payment for seven remote physiologic monitoring (RPM) codes (see table below). CMS notes that stakeholders have repeatedly requested clarification about the CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, 99457 and 99458.

Remote Physiologic Monitoring Codes	
CPT Code*	**Description**
99453	Remote monitoring of physiologic parameter, initial
99454	Remote monitoring of physiologic parameter, each 30 days
99091	Collection & interpretation of physiologic data digitally stored and/or transmitted
99457	Remote physiologic monitoring treatment management services, first 20 minutes
99458	Remote physiologic monitoring treatment management services, additional 20 minutes
99473	Self-measured blood pressure
99474	Separate self-measurements of blood pressure readings
*The order of the codes is consistent with how CMS describes the process of providing RPM services.	

CPT Codes 99453 and 99454. CMS states the RPM process begins with remote monitoring of physiologic parameters (CPT 99453 and 99454). These codes are PE only codes and are valued to include clinical staff time, supplies, and equipment; the equipment includes the medical device used for remote monitoring. The PE value for CPT code 99453 includes clinical staff time for patient and/or caregiver education about using one or more medical devices. CMS clarifies that the PE value for CPT code 99454 includes the medical device or devices supplied to the patient and the programming of the device for repeated monitoring; the medical device or devices supplied to the patient are considered direct PE inputs.

CMS discusses the CPT prefatory language (CPT® 2020 Professional Codebook (hereafter CPT Codebook) for these codes. CMS highlights that the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period and that these codes are not to be reported for a patient more than once during a 30-day period.[16] CMS notes this language suggests that even when multiple medical devices are provided to a patient, the services for all the devices can only be billed once per patient per 30-day period and only when at least 16 days of data has been collected. In addition, CMS emphasizes that CPT 99452 can be billed only once per episode of care and as defined in the CPT Codebook, an episode of care begins "when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment".

CMS also discusses the CPT prefatory language stating that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). CMS clarifies that the medical device should digitally upload patient physiologic data; CMS emphasizes this means the physiologic data is automatically uploaded and not data that is patient self-reported. The device must be used to collect and transmit reliable and valid physiologic data that allows evaluation of a patient's health status for development and management of a treatment plan. CMS notes that the use of these services must meet all the requirements for a Medicare covered service, including being reasonable and necessary for the diagnosis or treatment of the patient's illness or injury.

CMS notes that the RPM codes are included in the E/M section of the CPT Cookbook. CMS clarifies that as E/M codes CPT codes 99453, 99454, 99091, 99457, and 99458 can only be ordered and billed by physicians or nonphysician practitioners (NPPs) eligible to bill for E/M services. Although CMS initially limited RPM services to patients with chronic conditions, CMS expands coverage to include patients with acute and chronic conditions.

CPT Code 99091. CMS states that after the 30-day collection of physiologic date (CPT codes 99453 and 99454), the transmitted physiologic data is analyzed and interpreted by the physician or practitioner (CPT code 99091). CPT code 99091 only includes 40 minutes of professional work time, the reimbursement does not include any direct PE inputs. CMS clarifies the CPT specification in the code descriptor that the service is furnished by a "physician or other qualified health professional (QHCP), qualified by education, training, licensure/regulation." For Medicare purposes, CMS states a physician or other QHCP is an individual whose scope of

[16] This prefatory language is on page 42 of the CPT codebook.

practice and Medicare benefit category includes the service and who is authorized to independently bill Medicare for the service.[17,18]

CPT Codes 99457 and 99458. CMS states that after analysis and interpretation of the physiologic data, the next step is the development of a treatment plan informed by the patient's data. CMS notes that this service includes not only the development of a treatment plan with the patient and/or caregiver but also management of the plan until the treatment goals are attained (the end of the episode of care). In the 2020 PFS final rule (84 FR 62976-62698), CMS designated theses codes as care management services and thus can be furnished by clinical staff under the general supervision of the physician or NPP. CMS clarifies that since RPM services are not considered diagnostic tests and they cannot be furnished and billed by an Independent Diagnostic Testing Facility (IDTF) based on a physician or NPP order.

CMS notes that these services are furnished remotely using "interactive communication", which CMS interprets as real-time interaction between a patient and the physician, nonphysician practitioner or clinical staff providing the service. CMS clarifies that for these codes "interactive communication" involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission.[19] CMS interprets time in the code descriptor to mean the time spent in direct, real-time interactive communication with the patient.

Comments/Responses: CMS disagrees with comments that CPT codes 99091 and 99457 cannot be billed together; CMS states that, if reasonable and necessary, these two codes could be reported for the same patient. CMS believes that as currently described in the CPT Codebook these codes provide different types of services, CPT code 99091 is for "collection and interpretation of physiologic data" and CPT code 99457 is for "remote physiologic monitoring treatment management." CMS agrees with commenters that the CPT Codebook states, "Do not report 99091 in conjunction with 99457" but, notes that in the next section the CPT Codebook states, "Do not report 99091 for time in a calendar month when used to meet the criteria for 99339, 99340, 99374, 99375, 99377- 99830, 99457, and 99491." Based on these two statements, CMS concludes there may be circumstances when both codes could be billed for the same patient in the same month as long as the same time was not used to meet the time criteria for both codes. CMS believes that in some instances when complex data is collected, more time may be necessary for a physician or NPP to exclusively analyze and interpret data such that the criteria for both codes could be met within a 30-day period.

CMS disagrees with commenters that the RPM codes can be ordered and billed only by physicians and NPPs and agrees with some commenters that the CPT Editorial Panel should consider establishing codes for other practitioners. In addition, since RPM services are not considered diagnostic tests they cannot be furnished and billed by an IDTF on the order of a physician or NPP. CMS acknowledges a comment about the coding gap between physiologic and

[17] Additional discussion of this issue is included in the 2016 PFS final rule at 80 FR 70957.
[18] Medicare also covers and makes payments for certain services performed by auxiliary personnel (including clinical staff) "incident to" the professional services of the billing practitioner (§410.26(a)).
[19] CMS believes this remote, non-face-to-face exchange is similar to the exchange provided by HCPCS code G2012, Brief Communication Technology Based Service (83 FR 59483 through 59486).

non-physiologic remote monitoring and indicates it will work with stakeholders to consider coding for services related to remote monitoring for non-physiologic measures of health.

RPM and COVID-19. CMS finalizes its proposal to make permanent two of the interim changes in response to the COVID-19 PHE.[20] CMS finalizes that consent for RPM services can be obtained at the time the services are furnished. For CPT codes 99453 and 99454, CMS finalizes that auxiliary staff (which include clinical staff and other individuals who are employees, or leased or contracted employees) can furnish services under the general supervision of the billing physician or practitioner.

After the PHE ends, CMS will again require that RPM services must be furnished only to an established patient and the remote monitoring must be for 16 or more days of data in a 30-day period for billing.

Need for Additional RPM Services. CMS acknowledges that the current CPT coding may not describe the full range of clinical scenarios for RPM services and notes that some patients may not require 16 days in a 30-day period but instead would benefit from RPM for 8 days within a 30-day period. For example, a post-surgical patient may benefit from remote monitoring of their temperature for assessing infection and managing medications.

In the proposed rule, CMS requested comments, including any additional information about how RPM services are used in clinical practice, and how they might be coded, billed and valued. CMS received general support for a reduction in the number of days of data collected as required for these codes but did not receive any specific clinical examples supporting the need for reduced days for data collection. At the conclusion of the PHE for COVID-19, CMS will require, consistent with the code descriptors, that CPT codes 99453 and 99454 must be furnished only to an established patient and the remote monitoring must be for 16 or more days of data in a 30-day period for billing.

3. Transitional Care Management (TCM)

In the 2020 PFS final rule, CMS modified the billing requirements for TCM services and allowed concurrent billing of TCM services, when reasonable and necessary, with 16 HCPCS codes (84 FR 40549 through 40550). For 2021, CMS finalizes its proposal to remove 15 additional actively priced (not bundled or non-covered) HCPCS codes from the list of services that cannot be billed concurrently with TCM. Specifically, as listed in Table 18 in the final rule, CMS proposes that 14 End-Stage Renal Disease Service codes and the Complex Chronic Care Management Code G2058[21] could be billed concurrently with TCM.

CMS notes that the minutes counted for TCM services cannot also be counted towards other services.

[20] See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications to RPM services during the PHE.
[21] Beginning in 2021, HCPCS code G2058 will be replaced by CPT code 99439.

Comments/Responses: A few commenters disagreed with CMS' proposal and urged CMS to allow the RUC to determine how these codes should be valued/revalued and reported. CMS recognizes that some commenters would prefer it to follow the RUC recommendations for code valuations and billing policies and will continue to consider the RUC recommendations when it develops values and payment policies under the PFS.

4. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS code G2214)

CMS finalizes its proposal to establish a G-code to describe 30 minutes of behavioral health care manager time. The finalized code is:

> G2214: Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.

CMS finalizes that the required elements listed for CPT code 99493, including the CPT time rules, will also be required for billing G2214. CMS also finalizes that this code could be billed during the same month as TCM and CCM services, as long as all of the requirements for each service are met and the time is not double counted. The patient consent requirement will be required for each service. Consistent with other codes in this family, CMS adds G2214 to the list of designated care management services that may be furnished under general supervision.

F. Refinements to Values for Certain Services to Reflect Revisions to Payment for Evaluation and Management (E/M) Visits

1. Background

a. Evaluation and Management (E/M) Visits Overview

Physicians and other practitioners who are paid under the PFS bill for E/M visits using a relatively generic set of CPT codes (Level 1 HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These codes have historically included three key components in their code descriptors: history of present illness (history), physician examination (exam), and medical decision-making (MDM). Currently, there are five levels of office/outpatient E/M visits: five codes for each level for new patients (99201-99205), and five codes for each level for established patients (99211-99215).

Clinicians of nearly every specialty and practitioner type furnish E/M services to Medicare beneficiaries, and E/M services comprise roughly 40 percent of PFS allowed charges. While E/M services are generally furnished by all specialties, there is wide variation in the volume and level of E/M visits billed by different specialties. These services comprise a large share of allowed charges and visits for certain specialties that provide primary care services, such as general practice, internal medicine, and allergy/immunology. In contrast, certain specialties, such as radiology and pathology, bill very few E/M visits based on the nature of diagnostic services they provide. Other specialties, such as podiatry, furnish lower level E/M visits more often than higher level E/M visits.

b. Overview of Policies Finalized in 2020 for 2021

In the 2020 PFS final rule, CMS finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework for the E/M visit code set (99201-99215) issued by the AMA's CPT Editorial Panel.[22] Under this new framework, clinicians will no longer use history and exam to select the level of code for office/outpatient E/M visits, and will, instead, only include a medically appropriate history and exam, when performed.

CMS proposed and finalized in the 2020 Medicare PFS these changes for implementation in 2021 (made no changes in the 2021 Medicare PFS final rule):

- Adopted the revised code descriptors for 99202-99215 as they appear in the CPT 2021 edition, and their associated prefatory language and instructional guidance.
- Deleted CPT code 99201 (Level 1 office/outpatient visit, new patient); the CPT editorial panel decided to eliminate this code because CPT codes 99201 and 99202 are both straight-forward MDM and had significant overlap.
- Finalized separate payment for a new prolonged visit add-on CPT code G2212 (replaces temporary code 99XXX in final rule) and discontinued the use of CPT codes 99358 and 99359 (prolonged E/M visit without direct patient contact).
- Finalized separate payment for HCPCS code G2211 (replaced temporary code GPC1X in final rule) to provide payment for visit complexity inherent to evaluation and management associated with medical services. CMS created this code and disagreed with comments that this code was not necessary or appropriate with the revised E/M codes and increased work RVUs. This code can be reported with all office/outpatient E/M visits.

The AMA RUC resurveyed and revalued the revised office/outpatient E/M visit code set, concurrent with the CPT Editorial Panel redefining the services and associated interpretive guidance and provided CMS with recommendations. CMS finalized new values for CPT codes 99202 through 99215 and assigned RVUs to the new office/outpatient E/M prolonged visit CPT code G2212, as well as the new HCPCS code G2211. These valuations were finalized with an effective date of January 1, 2021. These are described in Table 20 below from the final rule. Work RVUs stayed the same for 99202 and increased for all other E/M codes. This has implications for budget neutrality and the PFS conversion factor given that E/M visits account for a large share of PFS allowed charges (as shown in the regulatory impact section).

Table 20: Summary of Codes and Work RVUs Finalized in the 2020 PFS Final Rule for 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU	2021 Total Time (mins)	2021 Work RVU
99201	17	0.48	N/A	N/A
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6

[22] See https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management

Table 20: Summary of Codes and Work RVUs Finalized in the 2020 PFS Final Rule for 2021				
HCPCS Code	**Current Total Time (mins)**	**Current Work RVU**	**2021 Total Time (mins)**	**2021 Work RVU**
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
99215	55	2.11	70	2.8
G2212	N/A	N/A	15	0.61
G2211	N/A	N/A	11	0.33

c. Continuing Stakeholder Feedback

Since publication of the 2020 PFS final rule, CMS received additional feedback from stakeholders about other services that they believe are analogous to office/outpatient E/M visits and thus these codes should be increased to reflect the underlying changes in the E/M code set. These services, for example, have values that were established relative to values for the office/outpatient E/M visits or contain office/outpatient E/M visits as constituent parts of the bundled services included in the code for the service. CMS addresses many of these requests and sought comment on whether there are additional, similarly situated services for which it should consider similar adjustment or revaluation through future rulemaking. CMS also received questions about the definition and utilization assumptions for the HCPCS add-on code G2211.

2. Revisions for 2021

a. Time Values for Levels 2-5 Office/Outpatient E/M Visit Codes.

CMS notes that the approach used by the AMA RUC to survey the times associated with the office/outpatient E/M visits has resulted in two conflicting sets of times: the component times as surveyed and the total time as surveyed. The sum of the total time as surveyed does not equal the sum of the component time. CMS adopted the RUC recommended times in the 2020 PFS final rule but stated it would continue to consider whether this issue has implications for the PFS broadly. CMS notes that when it establishes pre-, intra-, and post-service times for a service under the PFS, these times always sum to the total time, and would be illogical for it not to do so.

CMS finalizes its proposal beginning for 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. These values are shown in Table 21 in the final rule (shaded below to illustrate what times have been finalized).

Table 21: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC-Recommended Total Times for CPT codes 99202-99215 and Actual Total Time					
HCPCS	**Pre-Service Time**	**Intra-Service Time**	**Immediate Post-Service Time**	**Actual Total Time**	**RUC-recommended Total Time**
99202	2	15	3	20	22
99203	5	25	5	35	40

99204	10	40	10	60	60
99205	14	59	15	88	85
99211		5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

CMS in its response to comments reiterated that it would be illogical for component times not to sum to the total and stated the need to use a consistent methodology across the fee schedule.

b. Revaluing Services that are Analogous to Office/Outpatient E/M Visits

As CMS notes in the 2020 PFS proposed rule, it recognized that there are services for which the values are closely tied to the value of the office/outpatient E/M visit codes. Many of these services were valued via a building block methodology and have office/outpatient E/M visits explicitly built into their definition or valuation. CMS sought comment on these policies and received supportive public comments in revaluing certain services, such as transitional care management services, certain end-stage renal disease (ESRD) services, and others. CMS is dismissive, however, about revaluing the 10-and 90-day global surgical service codes to take into account the new E/M values as it continues to have great concern about whether the E/M services included as part of the global surgical codes are actually provided.

In this section, CMS finalizes its proposals, without modification, to account for the increase in the values for the office/outpatient E/M visits in the following code families: (1) ESRD monthly capitation payment services, (2) transitional care management (TCM) services, (3) maternity services, (4) assessment and care planning for patients with cognitive impairment, (5) Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits, (6) Emergency Department (ED) visits, (7) therapy evaluations and (8) behavioral health care services. CMS also examined but did not revalue certain ophthalmological services. These are discussed in more detail below.

(1) <u>ESRD Monthly Capitation Payment (MCP) services</u>

CMS received supportive comments, particularly from specialty societies representing nephrologists, to revalue the ESRD MCP codes to account for changes in the E/M visit codes. These commenters pointed out that the MCP bundled payments for all ESRD-related care for a month were constructed using a building block methodology and a number of office/outpatient E/M visits were component parts of those bundles; the specified number of visits in the code descriptor must be furnished in order to bill for the service. CMS notes in its response to comments from the proposed rule that it continues to be concerned that the number and level of visits may not reflect what is actually being furnished, and may consider this issue in future rulemaking, as it has for global surgical codes.

CMS finalizes its proposal to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code. These are summarized in Tables 23 and 24 in the final rule and shown below in a combined table

Extract from Tables 23 & 24: 2020 ESRD MCP Work RVUs, Physician and Clinical Time Compared with Final 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Final 2021 Work RVUs**	**2020 Phys. Time**	**Final 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Final 2021 NF Clinical Staff Time**
90951	Esrd serv 4 visits p mo <2yr	18.46	23.92	274	365	60	34
90954	Esrd serv 4 vsts p mo 2-11	15.98	21.44	240	240	60	-
90955	Esrd srv 2-3 vsts p mo 2-11	8.79	10.32	198	227	60	55
90956	Esrd srv 1 visit p mo 2-11	5.95	6.64	148	163	60	59
90957	Esrd srv 4 vsts p mo 12-19	12.52	15.46	253	310	60	53
90958	Esrd srv 2-3 vsts p mo 12-19	8.34	9.87	183	212	60	55
90959	Esrd serv 1 vst p mo 12-19	5.5	6.19	133	148	60	59
90960	Esrd srv 4 visits p mo 20+	5.18	6.77	128	156	60	54
90961	Esrd srv 2-3 vsts p mo 20+	4.26	5.52	113	134	60	54
90962	Esrd serv 1 visit p mo 20+	3.15	3.57	63	70	60	58
90963	Esrd home pt serv p mo <2yrs	10.56	12.09	258	287	60	55
90964	Esrd home pt serv p mo 2-11	9.14	10.25	233	255	60	57
90965	Esrd home pt serv p mo 12-19	8.69	9.8	218	240	60	57
90966	Esrd home pt serv p mo 20+	4.26	5.52	75	96	60	54
90968	Esrd svc pr day pt <2	0.3	0.34	7.8	8.5	2	1.9
90969	Esrd svc pr day pt 2-11	0.29	0.33	7.3	8	2	1.9
90970	Esrd svc pr day pt 12-19	0.14	0.18	2.5	3.2	2	1.8
Notes: Time is in minutes; NF – Nonfacility; Facility clinical staff time for 2020/2021 is the same for these codes: 60 minutes for 90951-90966, and 2 minutes for 90968-90970. CMS also corrected drafting errors in work times for 90966 and 90970.							

(2) Transitional Care Management (TCM) services

CMS began paying for TCM services beginning in 2013 with the goal to improve the health outcomes of patients recently discharged from inpatient and certain outpatient facility stays. CPT code 99495 was valued to include one, level 4 established patient office/outpatient visits while CPT code 99496 was valued to include one, level 5 established patient office/outpatient visit. Given that both include a required face-to-face E/M visit, CMS finalizes its proposal to increase the work RVUs associated with TCM codes commensurate with the new valuations for the level 4 and level 5 E/M visits for established patients. These are summarized in Tables 23 and 24 in the final rule and show below in a combined table. Commenters supported these changes.

Extract from Tables 23 & 24: 2020 TCM Work RVUs, Physician and Clinical Time Compared with Final 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Final 2021 Work RVUs**	**2020 Phys. Time**	**Final 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Final 2021 NF Clinical Staff Time**

99495	Trans care mgmt 14-day disch	2.36	2.78	47.0	54.0	107.0	105.0
99496	Trans care mgmt 7-day disch	3.10	3.74	60.0	75.0	145.0	144.0

Notes: Time is in minutes; NF – Nonfacility; Facility clinical staff time for 2020/proposed 2021 is not applicable for these codes.

(3) Maternity services

CMS states that the maternity packages are unlike other services for which payment is made under the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, including visits, surgical services, and imaging (among other services) and were valued using a building block methodology as opposed to magnitude estimation commonly used to value the 10- and 90-day global services. It states that unlike the global surgical codes it has reason to believe the visits included in the maternity codes are "actually" furnished given the evidence-based standards and professional guidelines for obstetrical care.

CMS finalizes its proposal to revalue these codes based on the valuations recommended by the AMA RUC. CMS is not accepting the AMA RUC recommendations to revalue the 10-and 90-day global surgical packages, as it does not believe all the bundled visits are being furnished. The approach used in revaluing the maternity codes added the marginal differences in work, physician time, and PE in the form of clinical staff time between the current and 2021 E/M values. The revaluations are summarized in Tables 23 and 24 in the final rule and shown below in a combined table.

Extract from Tables 23 & 24: 2020 Maternity Work RVUs, Physician and Clinical Time Compared with Final 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Final 2021 Work RVUs**	**2020 Phys. Time**	**Final 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Final 2021 NF Clinical Staff Time**
59400	Obstetrical care	32.16	36.58	739.5	753.5	N/A	N/A
59410	Obstetrical care	18.01	18.34	398.5	327.5	N/A	N/A
59425	Antepartum care only	6.31	7.8	137.0	180.0	206.0	198.0
59426	Antepartum care only	11.16	14.3	252.0	330.0	386.0	378.0
59430	Care after delivery	2.47	3.22	63.0	77.0	89.0	87.0
59510	Cesarean delivery	35.64	40.39	817.5	818.5	N/A	N/A
59515	Cesarean delivery	21.47	22.13	476.5	392.5	N/A	N/A
59610	Vbac delivery	33.87	38.29	739.5	753.5	N/A	N/A
59614	Vbac care after delivery	19.73	20.06	398.5	327.5	N/A	N/A
59618	Attempted vbac delivery	36.16	40.91	792.5	793.5	N/A	N/A
59622	Attempted vbac after care	22	22.66	451.5	367.5	N/A	N/A

Notes: Time is in minutes; NF – Nonfacility; Facility clinical staff time for 2020/2021 is the same for these codes: 59400, 59410, 59510, 59515, 59610, 59614, 59617, 59622, and no time listed for the remained.

Commenters expressed concern that it was unfair to apply the RUC-recommended E/M value increases to certain global codes, like ESRD and bundled maternity care, but not to E/M visits that are included in the global surgical packages. In response, CMS believes that maternity global surgical packages are distinct from global surgical packages for the reasons discussed above, and that unlike global surgical services, maternity and ESRD bundled services are focused on ongoing, comprehensive medical care similar to the type

of care typically furnished and billed as an office/outpatient E/M visit, and thus making it analogous.

(4) Assessment and care planning for patients with cognitive impairment

In 2018, CMS adopted CPT code 99483 (deleting HCPCS code G0505) to provide payment for cognitive impairment assessment and care planning. The valuation of this service is intended to reflect the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest valued office/outpatient E/M visits (CPT code 99205). CMS finalizes its proposal to adjust the work, physician time, and PE for this service to reflect the marginal difference between the value of the level 5 new office/outpatient E/M visit in 2020 and 2021. The work RVU is adjusted from 3.44 to 3.80. The physician and clinical staff time remain the same.

Commenters were generally supportive of this valuation, while others indicated that the proposed increase to CPT code 99483 would create a rank order anomaly between CPT codes 99205 and 99483 and suggested that this code be referred to the RUC for review. CMS disagrees with this assessment but notes that members of the public can request that the RUC review certain code sets at any time.

(5) Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits

CMS finalizes its proposal to revalue the IPPE and AWV visits as these services were initially valued based on a direct crosswalk to the work, time, and direct PE inputs of E/M codes 99204 and 99214. Details are shown below.

Extract from Tables 23 & 24: 2020 IPPE and AWV Work RVUs, Physician and Clinical Time Compared with Final 2021 Values

HCPCS	Short Descriptor	2020 Work RVUs	Final 2021 Work RVUs	2020 Phys. Time	Final 2021 Phys. Time	2020 NF Clinical Staff Time	Final 2021 NF Clinical Staff Time
G0402	Initial preventive exam	2.43	2.6	45*	60*	62.0	54.0
G0438	Ppps, initial visit	2.43	2.6	45*	60*	62.0	54.0
G0439	Ppps, subseq visit	1.5	1.92	40*	47*	40.0	51.0*

Notes: Time is in minutes; NF – Nonfacility; Facility clinical staff time for 2020/ 2021 is not applicable for these codes. * Updated these times based on work times in published physician time and PE data files. Values in table were inconsistent in final rule.

Commenters were generally supportive of these changes, while others disagreed as it is unclear that the work associated with the services represents work described by a level 4 office/outpatient E/M visit and thought the codes should be reviewed by the RUC. CMS notes in its reply that these services are reported using Medicare-specific HCPCS G codes and thus do not need to be reviewed by the RUC.

(6) ED Visits

The ED visit codes have been revalued under the PFS in 1997, 2007, and most recently in 2019 as part of the misvalued code initiative for 2020 rulemaking. In the 2020 PFS final rule, CMS finalized the RUC-recommended work RVUs. In response to the comment solicitation, the American College of Emergency Physicians (ACEP) submitted a public comment stating that relativity between the ED visits and office/outpatient E/M visits should be maintained and provided specific recommendations regarding CPT codes 99283-99285. CMS finalizes its proposal to adopt the values recommended by ACEP (shown in table 25 in the final rule). The work RVU values will increase from 1.42 to 1.60 for 99283; 2.60 to 2.74 for 99284; and 3.80 to 4.00 for 99285.

CMS also received additional comments that it should consider nursing facility visits, domiciliary visits, and home visits to be analogous to the office/outpatient E/M visits. CMS disagrees and notes that the setting of care indicates that these visits involve different resources. It may address these issues in the future based on any changes recommended by the CPT Editorial Panel and the AMA RUC.

(7) Therapy Evaluations

CMS states that therapy evaluation services and psychiatric diagnostic evaluation services are similar in many respects to the office/outpatient E/M visit code set, but do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits. The practitioners who furnish these services are prohibited by CMS from billing E/M services due to the limitations of the Medicare benefit categories. CMS states, that although these services are billed using specific, distinct codes relating to therapy evaluations and psychiatric diagnostic evaluations, it believes that a significant portion of the overall work in the codes is for assessment and management of patients, as it is for the office/outpatient E/M visit codes.

CMS finalizes its proposal to adjust the work RVUs for these services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits. CMS calculated an adjustment of about 28 percent based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from 2020 to 2021. It applies that percentage increase to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes. The change in work RVU values are shown in Table 25 and reproduced below.

Extract of Table 25: Current and Final Work RVUs for Therapy and Psychotherapy Services			
HCPCS Code	**Short Descriptor**	**Current Work RVU**	**Work RVU**
90791	Psych diagnostic evaluation	3.00	3.84
90792	Psych diag eval w/med srvcs	3.25	4.16
97161	Pt eval low complex 20 min	1.2	1.54
97162	Pt eval mod complex 30 min	1.2	1.54
97163	Pt eval high complex 45 min	1.2	1.54
97164	Pt re-eval est plan care	0.75	0.96
97165	Ot eval low complex 30 min	1.2	1.54

Extract of Table 25: Current and Final Work RVUs for Therapy and Psychotherapy Services			
HCPCS Code	**Short Descriptor**	**Current Work RVU**	**Work RVU**
97166	Ot eval mod complex 45 min	1.2	1.54
97167	Ot eval high complex 60 min	1.2	1.54
97168	Ot re-eval est plan care	0.75	0.96
92521	Evaluation of speech fluency	1.75	2.24
92522	Evaluate speech production	1.5	1.92
92523	Speech sound lang comprehen	3	3.84
92524	Behavral qualit analys voice	1.5	1.92

Commenters were mixed in their support. Some supported these changes and urged CMS to implemented similar increases to the work RVUs of additional therapy services. CMS disagreed with the additional suggestions noting that the CPT codes commenters identified involve work that is not similar to that captured by the office/outpatient E/M codes, such as various types of therapeutic treatment. Other commenters disagreed with the proposal stating that these services are misvalued and that this change would amplify this issue. CMS notes that the commenters can nominate and code(s) as potentially misvalued through the usual misvalued code process.

(8) Behavioral health care services

The psychotherapy code set is divided into psychotherapy that can be furnished as a standalone service and psychotherapy furnished in conjunction with an office/outpatient E/M visit. The standalone psychotherapy codes are CPT codes 90832, 90834, and 90837. As the values for the office/outpatient E/M visits are increasing, there will necessarily be an increase in the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits. To maintain relativity within the code family, CMS believes it is appropriate to increase the values for the standalone psychotherapy services. Thus, CMS finalizes its proposal to increase the work RVU for CPT codes 90832, 90834, and 90837. For example, the work value RVU for CPT code 90834 would increase from 2.00 to 2.25 based on the marginal increase in work value for CPT code 9214 from 2020 to 2021. The change in work RVU values are shown in Table 21=5 and reproduced below.

Extract of Table 25: Current and Final Work RVUs for Therapy and Psychotherapy Services			
HCPCS Code	**Short Descriptor**	**Current Work RVU**	**Final Work RVU**
90832	Psytx w pt 30 minutes	1.50	1.70
90834	Psytx w pt 45 minutes	2.00	2.24
90837	Psytx w pt 60 minutes	3.00	3.31

Some commenters supported the increases, but also wanted CMS to make commensurate relativity adjustments for all Psychotherapy, Psychological and Neuropsychological Testing, and Health and Behavior Assessment and Intervention (HBAI) codes. CMS notes in its reply that its rationale for proposing proportionate adjustments to the stand-alone psychotherapy services does not apply to the wider psychotherapy code set.

(9) Ophthalmological services

CMS also received a request to revalue four ophthalmological services (CPT codes 92002, 92004, 92012, 92014); it did not propose to revalue these codes. CMS states that given the revised code set and framework for level selection for office/outpatient E/M visits, the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is no longer obvious. CMS also indicates that it is aware the ophthalmologists report office/outpatient E/M visits as well as these ophthalmologic-specific evaluation codes and it is not clear to CMS the reason for relying on both.

In addition, CMS observes that the four ophthalmological evaluation codes are reported with modifier -25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service) approximately 4 to 14 percent of the time (depending on the code in question). CMS is in the process of analyzing these data further to assess how often the accompanying service is a minor procedure rather than a visit. After consideration of comments, CMS finalizes its decision to not revalue the ophthalmological evaluations commensurate with the changes to the office/outpatient E/M visit valuations for 2021. CMS did not agree with commenters that the resource costs for these services were closely tied to office and outpatient E/M visits and also emphasized that the level of visit for which the ophthalmological visits might be analogous is not apparent.

c. Comment Solicitation on the Definition of HCPCS code G2211

CMS believes that while the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, it continues to believe the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. In the 2020 PFS final rule, CMS finalized the HCPCS add-on code G2211 (which replaces the temporary HCPCS add-on code GPC1X) to account for "visit complexity inherent to evaluation and management associated with medical care services." CMS does not restrict billing based on specialty, but it did assume that certain specialties furnished these types of visits more than others.

Some specialty societies have stated that its definition of this service, as articulated in the code descriptor and the associated preamble discussion, is unclear. For example, some stakeholders have suggested that HCPCS add-on code G2211 as currently described, could be applicable for every office/outpatient E/M visit. They have also expressed concerns regarding utilization assumptions, since CMS assumed that specialties that predominantly furnish the kind of care described by the code would bill it with every visit. Therefore, CMS solicited comment that would provide additional, more specific information regarding what aspects of the definition of the add-on code are unclear, how it might address those concerns, and how it might refine its utilization assumptions for the code.

Analysis of Comments from Proposed Rule

Commenters expressed numerous concerns about the HCPCS add-on code G2211, including concerns about code descriptors, program integrity issues and documentation, the necessity of the code, and utilization assumptions.

Concerns about code descriptors. Many commenters were supportive of HCPCS add-on code G2211 and believed that the code descriptor fit its intended purpose, is well-defined, and did not allude to specific specialties. Others disagreed maintaining that the code descriptor was unclear and requested that CMS provided clinical examples. In its reply, CMS provides an example, of 68-year old woman with progressive congestive heart failure, diabetes, and gout, on multiple medications, who presents to her physician for an established visit. CMS goes on to argue that the add-on code could be appropriate in this instance as the physician is addressing the broad scope of the patient's health care needs. It also provides an example where HCPCS add-on code G2211 would not be appropriately reported, such as for a discrete, routine, or time-limited nature, such as a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, among other reasons cited. CMS states that it also does not expect that this code would be reported when the office/outpatient E/M is reported with a payment modifier, as visits reported with payment modifiers have resources that are sufficiently distinct from stand-alone office/outpatient E/M visits. It states that it would consider this issue to inform potential future rulemaking.

Concerns about program integrity issues and documentation. Some commenters suggested that lack of clarity in the definition of the HCPCS add-on code G2211 poses program integrity challenges for CMS and it offered no information about how appropriate use will be determined or what documentation will be expected. In its reply, CMS states that it appreciates the concerns raised and that it plans to monitor utilization for appropriate use of the add-on code, which could inform additional efforts to refine the code descriptor, or provide further guidance, as appropriate. With respect to documentation, CMS states that it is considering an approach to minimize burden similar to what it finalized in the CY 2019 PFS final rule (83 FR 59560) for HCPCS add-on codes GPC1X and GCG0X. In that rule, CMS stated that supporting documentation could be information included in the medical record or in the claims history for a patient/practitioner combination, such as diagnoses, the practitioner's assessment and plan for the visit, and/or other service codes billed. It also believes that Medicare claims data could be a useful gauge of appropriate use of the code, such as patients identified in the claims as returning to the same practitioner for routine preventive services would indicate that the practitioner has taken responsibility for ongoing medical needs. In contrast, CMS indicates that an annual visit for ophthalmologic care, or a single episode of dermatologic care – even when several services are billed over a few months – would not suggest ongoing care provided with consistency and continuity over time and would suggest an inappropriate use of the code, were it to be billed with such visits. Additionally, to provide evidence of the ongoing relationship between the patient and practitioner, it is possible that use of patient relationship codes that were established under MACRA and finalized in the CY 2018 PFS (82 FR 53234) could be further example of evidence in the claims record to support the use of HCPCS add-on code G2211.

Concerns about its necessity. Other commenters expressed continued concern regarding the necessity of the HCPCS add-on G2211 entirely and recommended that CMS withdraw the code. Others noted that it may be duplicative to care management services, such as TCM or CCM. CMS states its belief that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that results in comprehensive, longitudinal, and continuous relationships is not adequately described by the revised office/outpatient E/M visit code set. CMS also notes this code is inherently distinct from coding that describes care management services.

Concerns about utilization assumptions. Many commenters recommended that CMS reexamine and lower utilization assumptions for HCPCS add-on code G2211. Commenters argued that utilization trends tend to be lower than expected in the first year of implementation and cited the low utilization of the TCM and CCM codes. Other reasons for slow adoption included the necessity for medical specialty societies to educate their members about appropriate use, electronic health records integration, and the persistence of the COVID-19 pandemic in many parts of the country. They recommended that utilization could be as low as 10 percent of reported office/outpatient E/M visits and could range as high as 25 percent of reported office/outpatient E/M visits. Other commenters recommended that CMS delay the implementation of this add-on code, citing the expected budget neutrality offset. In response, CMS agrees that practitioners that rely on office/outpatient E/M visits may not report HCPCS add-on code G2211 with every office visit. It disagreed that utilization will be as low as the 10 percent to 25 percent as recommended by these commenters. CMS modifies, however, its utilization assumptions and now will assume this will be 90 percent of office/outpatient E/M visits instead of the 100 percent it assumed in the proposed rule for certain specialties.

d. Prolonged Office/Outpatient E/M Visits (CPT code 99417/HCPCS code G2212)

CMS reviewed its final policy for 2021 regarding the reporting of prolonged office/outpatient E/M visits finalized in the 2020 PFS final rule. CPT code 99417 (referred to in previous rules as temporary CPT code 99XXX) is only reported when time is used to select the visit level, and only the time of the physician or qualified healthcare professional is counted. After reviewing its policy finalized last year, CMS believes that allowing reporting of CPT code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. CMS provides an illustrative example. The time range for CPT code 99215 is 40-54 minutes and if the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99417 and prolonged services should not be reportable as it finalized last year.

CMS finalizes its proposal that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99417 could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. For example, the maximum time for 99205 is 74 minutes, and thus 99417 could be billed once 89 minutes have been used. CMS provides examples in Tables 26 and 27 in the final rule.

Several commenters agreed with CMS' concerns about the lack of clarity in the code descriptor and the potential for double-counting time. Others disagreed with its proposal and recommended that CMS adopt the CPT code descriptors. To resolve the lack of clarity, CMS finalizes its proposal regarding the time that may be counted for prolonged office/outpatient E/M visits; and to resolve the potential inconsistency of its policy with CPT code 99417, it creates a new HCPCS code G2212 to be used when billing Medicare for this service instead of CPT code 99417, starting in 2021. HCPCS code G2212 is as follows, "Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) "(Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes))." The valuation for HCPCS code G2212 will be the same as for CPT code 99417.

G. Scope of Practice and Related Issues

1. Teaching Physician and Resident Moonlighting Policies

In the March 31st COVID-19 IFC and the May 8th COVID-19 IFC, CMS implemented several policies related to PFS payment for the services of teaching physicians involving residents and resident moonlighting during the PHE. In the PFS proposed rule, CMS indicated it would address comments received on both IFCs for these policies and for associated proposals in the proposed rule in the PFS final rule.

a. Finalization of IFC with Comment Period Provisions Related to Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID-19 PHE

Commenters were appreciative and supportive of the policies implemented for the COVID-19 PHE. After consideration of comments, CMS finalizes these policies for the duration of the PHE.

b. Summary of Proposed Rule Provisions and Public Comment

In the proposed rule, CMS solicited comments on whether the policies implemented on an interim basis during the PHE should be extended on a temporary basis or be made permanent. Assuming the PHE for COVID-19 ends in 2021, a temporary basis would extend these policies to December 31, 2021 to allow for a transition period before reverting to status quo policy. These policies provide additional flexibilities under the teaching physician regulations. Section 1842(b)(7)(A)(i)(I) of the Act specifies that for physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for 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. Regulations regarding PFS payment for reaching physicians and services of moonlighting residents are codified in 42 CFR 415.

(i) Supervision of Residents in Teaching Settings through Audio/Video Real-Time Communications Technology

In the proposed rule, CMS proposed to allow direct supervision to be provided using real-time, interactive audio/video real-time communications technology (excluding audio only) through the later of the end of the calendar year in which the PHE ends or December 31, 2021. CMS had several concerns about continuing these policies after the PHE including patient safety and program integrity concerns. CMS also noted that this flexibility could result in increased access to practitioners in certain communities as COVID-19 cases could continue or increase in certain communities. CMS sought comments to better understand how this flexibility would support patient safety (especially for at-risk patients) and reduce burdens without creating risks to patient care or increase fraud.

Comments/Responses: Commenters were generally supporting of the policies implemented during the PHE. Several commenters thought they should become permanent to promote patient access to physician services, particularly in rural area. Other commenters thought that a permanent policy would provide for additional training opportunities to care for underserved populations or increase specialty training opportunities for rural training programs. Some commenters were supportive of the flexibilities provided on an interim basis and through they should be extending through the end of the PHE for resurgences in COVID-19 infections. These commenters cited a need to gather data about patient safety and impact on resident training before permanent implementation of the policies. Commenters broadly supported the exclusion of surgical, high risk, interventional, endoscopic, or other complex procedures, including anesthesia, from the virtual presence policy.

CMS remains concerned that absent the circumstances of the PHE, virtual presence may not be sufficient to warrant payment to the teaching physician. CMS believes physical, in-person presence may be necessary for the teaching physician to provide adequate oversight and to ensure the teaching physician furnishes sufficient personal services to exercise full, personal control of the key portion of the case. CMS appreciates commenters' statements that the virtual presence policy has increased access to Medicare-covered services and the impact in rural areas. CMS has a longstanding interest in increasing beneficiary access to care to rural areas and believes this need to improve rural access for patients and training for residents overshadows its concerns about the ability of the teaching physician to render sufficient personal and identifiable physicians' services through virtual presence. CMS agrees with commenters' that additional data should be obtained before expanding this flexibility to non-rural settings and it may obtain that information through a commissioned study, analysis of claims data or other mechanisms.

CMS appreciates commenters' suggestion that the Accreditation Council for Graduate Medical Education (ACGME) and other accrediting organizations have standards and systems to ensure patients safety and oversight of results during virtual supervision by a teaching physician. CMS notes, however, the commenters provided no specific description of any policies and cannot opine on the sufficiency of these organizations to provide guardrails. CMS will continue to rely on the clinical judgement of teaching physicians and residents to their care ensures patient safety.

Final Decision: CMS finalizes a permanent policy to permit teaching physicians to meet the requirements to bill for their services involving residents through virtual presence, but only for services furnished in residency training sites that are located outside of an OMB-defined metropolitan statistical area (MSA).[23] For all other settings, CMS is not permanently finalizing its teaching virtual presence polices. CMS finalizes these policies will remain in place for the duration of the PHE; this will provide flexibilities to communities that may experience resurgences in COVID infections.

CMS clarifies its existing documentation requirement to ensure that the teaching physician is compliant with section 1842(b)(7)(A)(i)(l) of the Act. CMS specifies at §415.172(b) that when a teaching physician, through virtual presence, furnishes services involving residents in a residency training site outside of a MSA, the patient's medical record must clearly reflect how and when the teaching physician was present for the service in accordance with CMS' regulations. CMS adds the same requirement for all teaching settings for the duration of the PHE. An example offered is that in the medical record, the teaching physician could document their physical or virtual presence at the training site during the key portion of a service, along with a notation describing the specific portion(s) of the service for which the teaching physician was virtually present, and/or that the teaching physician reviewed the service with the resident during or immediately after the service in accordance with the primary care exception under §415.174. CMS notes it expects that is there is a disruption to the virtual connection between the teaching physician and the resident who is with the patient, the encounter would be paused until the connection resumes or the appointment would be rescheduled.

CMS amends its regulations to reflect these final policies.

- Under §415.172, adds language allowing the requirement for the presence of the teaching physician during the key portion of the service furnished involving a resident to be met using audio/visual real-time communications technology. The teaching physician must be observing real time and the use of audio-only technology is not permitted.
- Under §415.174(b), CMS adds language clarifying the documentation requirements for residency training sites located outside a MSA and for all teaching settings for the duration of the PHE.
- Under §415.174(c), adds language that for all teaching settings for the duration of the PFE, teaching physicians may remotely direct primary care furnished by residents, and remotely review resident-provided services during or after the visit, using audio/visual real-time communications technology.
- Under §415.174(d), adds language that for residency training sites that are located outside a MSA, teaching physicians may remotely direct primary care furnished by residents, and remotely review resident-provided services during or after the visit, using audio/visual real-time communications technology.
- Under §415.180, adds language that for residency training sites that are located outside of the MSA, the requirement for the presence of the teaching physician during the interpretation of diagnostic radiology by a resident may be met using audio/visual real-

[23] Revised Delineations of MSA, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas: https://www.whitehouse.gov/wp=content/uploads/2020/03/Bulletin-20-01.pdf.

time communications technology. CMS add the same requirement for all teaching settings for the duration of the PHE. A physician (other than the resident) must review the resident's interpretation and the medical record must document the extent of the teaching physician's participation in the interpretation of the review.

- Under §415.184, adds language that for residency sites that are outside of the MSA, the requirement for the presence of the teaching physician during a psychiatric service involving a resident may be met by the teaching physician's direct supervision using audio/visual real-time communications technology. CMS add the same requirement for all teaching settings for the duration of the PHE.

(ii). Virtual Teaching Physician Presence during Medicare Telehealth Services

In the proposed rule, CMS proposed to permit the use of audio/visual real-time communications technology to establish the presence of a teaching physician when a resident furnishes telehealth services to beneficiaries in order to make payment for teaching physician services through the later of the end of the calendar year in which the PHE ends or December 31, 2021

In considering whether to extend or make this policy permanent, CMS has the same concerns and considerations noted above. Additionally, CMS worries that the different distant sites for the resident and teaching physician may prevent the teaching physician from being able to render sufficient personal and identifiable physicians' services to exercise full, personal control over the service to warrant a separate payment under the PFS.

Comments/Responses: Commenters were generally supporting of this interim policy; several commenters thought they should become permanent to promote patient access to physician services, particularly in rural area, and others recommended temporarily extending the policy through the end of the PHE. Comments and CMS' responses are similar to those discussed above for supervision of residents through audio/video real-time communications technology. CMS appreciates commenters' statements that the virtual presence policy has increased access to Medicare-covered services and the impact in rural areas. CMS believes it would be appropriate to continue this policy in rural areas; this will also facilitate needed training opportunities consistent with the primary care exception (§415.174).

Final Decision: CMS finalizes a permanent policy to allow Medicare payments under the PFS for teaching physicians when a resident furnishes Medicare telehealth services in a residency training located outside of a MSA to a beneficiary who is in a separate location outside the same MSA as the residency training site or is within a rural area outside of a different MSA, while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only), in a third location, either within the same rural training site as the resident or outside of that rural training site. CMS also finalizes the same documentation requirements as finalized for the supervision of residents through audio/video real-time communications technology.

For all other settings, CMS is not permanently finalizing this policy; CMS finalize this policy only for the duration of the PHE. CMS also finalizes the same documentation requirements as

finalized for the supervision of residents through audio/video real-time communications technology.

CMS amends its regulations at §§415.172(a) and 415.172(b) to reflect these final policies.

(iii) Resident Moonlighting in the Inpatient Setting

In the proposed rule, CMS proposed to continue the moonlighting policy for services furnished to inpatients if the services (i) are identifiable physicians' services, (ii) can be separately identified from services that are required as part of the approved GME training program, and (iii) meet relevant conditions for payment and state license requirements through the later of the end of the calendar year in which the PHE ends or December 31, 2021 In considering whether to extend or make this policy permanent, CMS had program integrity concerns, such as duplicate payments under the IPPS for GME and under the PFS if the services are not adequately separately identified from services required as part of the GME program.

Comments/Responses: Commenters were generally supporting of this interim policy; several commenters thought they should become permanent to promote patient access to physician services and others recommended temporarily extending the policy through the end of the PHE because of the need to maintain surge capacity. A few commenters suggested CMS educate providers about the need for sufficient documents to demonstrate that moonlighting services are separate from those services required as part of an approved GME program. CMS appreciates comments and agrees with the need for proper documentation.

Final Decision: CMS finalizes permanent expansion of the settings in which residents may moonlight. Specifically, CMS amends its regulations at §415.208(b)(2) to include the services of residents that are not related to their approved GME program and are performed in the outpatient department, emergency department, or inpatient setting of a hospital in which they have their training program are separately billable services provided they meet the conditions of payment of physician to beneficiaries in providers in 415.102(a); that the resident if fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and that the services are not performed as part of the approved GME program.

CMS also amends §415.208(b)(2) to clarify that regardless of whether the resident's services are performed in the outpatient department, emergency department, or inpatient setting of a hospital in which they have their training program, the medical record must clearly document that the resident furnished identifiable physician services that meet the conditions of payment of physician to beneficiaries in providers in 415.102(a); that the resident if fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and that the services are not performed as part of the approved GME program. An example offered is that in the medical record, the resident could state that they are licensed to practice in the State the service was performed, document that the service was performed outside of their approved GME program, and include a notation describing the specific physician service furnished.

(iv) Primary Care Exception Policies

Under section §415.174, PFS payment may be made 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; this is referred to as the primary care exception. The teaching physician must provide direct supervision; must review with each resident the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies during or immediately after each visit; must have no other responsibilities at the time; must assume management responsibility for the beneficiaries seen by the residents; and must ensure that the services furnished are appropriate. Codes for services of lower and mid-level complexity that may be furnished under the primary care exception are specified in section 100 of chapter 12 of the Medicare Claims Processing Manual.[24]

In the March 31st IFC, CMS amended §415.174 to permit all levels of office/outpatient E/M visits to be furnished by a resident and billed by the teaching physician during the PHE. In the May 8th IFC, CMS further expanded the list of services and allowed PFS payment to the teaching physician for services furnished by residents via telehealth (if the services were also included on the list of Medicare telehealth services).

In the proposed rule, CMS considered whether to temporarily extend or make permanent all, or some, of these PHE policies, including whether the services added by both IFCs should remain part of the primary care exception. CMS notes the expanded services were intended to be responsive to critical needs during the PHE for patients quarantined at home or otherwise isolated to minimize risk of exposure for COVID-19. However, CMS is concerned that many of the added service codes require decision-making of moderate to higher complexity. This may result in a teaching physician not being able to directly supervise other residents which could compromise patient safety.

Comments/Responses: Commenters were generally supporting of the policy adopted on an interim basis to allow payment to the teaching physician for additional services under the primary care exception, including all levels of office and out-patient E/M codes, audio-only telephone E/M services, transitional care management (TCM), and communication-technology-based services (CTBS). Commenters were also generally support of the interim policy to allow payment to teaching physicians for services furnished by residents via telehealth under the primary care exception if the services are on the Medicare telehealth list. Several commenters supported making these policies permanent; several other comments supported only making certain services permanent such as CTBS that require low to moderate complexity medical-decision making. Some commenters also supported the permanent inclusion of inter-professional consults (CPT code 99452). Commenters did not agree about the permanent inclusion of level 4 and level 5 office/outpatient E/M codes and TCM services. Several commenters recommended temporarily extending the primary care exception through the end of the PHE.

[24] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.

In response, CMS reiterates its concerns about permanently adding all of the proposed services to the primary care exception especially for services requiring at least a moderate level of decision making, consistent with the original intent of the primary care exception. CMS agrees with the comments regarding the advantages of expanding services under the primary care exception in rural areas.

Final Decision: CMS finalizes for residency training sites located outside of a MSA, a policy to allow Medicare payments to the teaching physician when the resident furnishes an expanded list of services under the primary care exception. CMS limits the permanent array of services under the primary care exception to include CTBS and interpersonal consults (CPT codes 99421-99423 and 99452, and HCPCS codes G2010 and G2012). CMS also adds to the primary care exception for residency training sites located outside of an MSA, Medicare telehealth services that are furnished by residents, including E/M services of low-to-mid-level complexity.

For all other settings, CMS is not permanently finalizing this policy; CMS finalize this policy for the duration of the PHE, including services furnished under Medicare telehealth. At the end of the PHE CMS will exclude E/ M services of moderate and high complexity and TCM services from the primary care exception for all settings (CPT codes 99204, 99214, 99205, 992215, 99495 and 99496).

CMS amends its regulations at §§415.174 to reflect these final policies. CMS adds a new paragraph (d) to include that residency training sites located outside of an MSA meet the requirement of the primary care exception and that the teaching physician can meet the requirements to direct the care and review the services furnished by each resident during or immediately after each visit through interactive, audio/video real-time communications technology (excluding audio only) under the primary care exception associated with these sites.

2. Supervision of Diagnostic Tests by Certain NPPs

CMS finalizes its proposal to amend its regulations at §410.32(b)(1) to permit NPs, CNSs, PAs and CNMs to supervise diagnostic tests consistent with state law and scope of practice requirements. CMS will establish similar permanent policies for these NPPs to supervise diagnostic and neuropsychological testing at §410.32(b)(2)(iii)(B).

With respect to physician assistants, CMS finalizes its proposal to specify that diagnostic tests performed by PAs do not require a specified level of supervision assigned to individual tests.

CMS received many comments supporting the proposed flexibilities. Some commenters opposed changes to allow NPPs to supervise the performance of psychological and neuropsychological tests. CMS responds that its intent is to allow NPPs to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic test, only to the extent that the scope of practice and State laws authorize them to do so.

3. Pharmacists Providing Services Incident To Physicians' Services

In the proposed rule, CMS discussed stakeholders request for clarification that pharmacists may provide "incident to" services similar to other clinical staff. CMS reiterated the clarification it made in the May 8th IFC (85 FR 27550 through 27629) that pharmacists are captured by the regulatory definition of auxiliary personnel at §410.26. Thus, pharmacists may provide incident to services (such as medication management services) under the appropriate level of supervision of the billing physician or NPP, consistent with state scope of practice and applicable state law. However, if payment is made for those services under Part D, the services may not be reported or paid under Part B.

Commenters requested additional clarification to explain why pharmacists are specifically excluded from directly billing office/outpatient E/M codes. CMS agrees that under the general CPT framework pharmacists could be considered qualified health care providers (QHP) or clinical staff. CMS explains that Medicare law does not allow payment for services that are furnished and billed directly by pharmacists. Regarding the E/M codes, because CPT does not define these codes as clinical staff codes and instead designed them to be directly furnished and reported by physicians and other QHPs, they cannot be used to bill the PFS for services performed by a pharmacist on an "incident to" basis. CMS appreciates the role that pharmacists have in the health care delivery system and suggests that new coding may be needed.

4. Provision of Maintenance Therapy by Therapy Assistants

In the May 8th IFC, CMS allowed physical therapists and occupational therapists who establish a maintenance program to assign duties to a physical therapy assistant (PTA) or occupational therapy assistant (OTA) to perform maintenance therapy services in Part B settings. CMS finalizes its proposal to make this policy permanent effective January 1, 2021.

Commenters supported this proposal and indicated that having Part B policy align with Part A policy for Home Health and SNF settings will promote consistency and continuity of care across programs.

5. Medical Record Documentation

CMS has previously explained that any individual authorized to furnish and bill for their professional services may review and verify (sign and date) the medical record for the services they bill; they are not required to re-document notes in the medical record made by other care team members.

CMS clarifies that this principle also applies to therapists who bill for therapy services. CMS emphasizes that this medical record documentation only applies to the clinician who is billing for their professional service.

6. Regulatory Impact

CMS expects that its finalized policies on scope of practice would result in increased administrative and clinical flexibility for the professionals involved. However, it cannot determine the specific impact the policies would have on practice business plans and demand for certain types of clinicians.

H. Valuation of Specific Codes

The final work RVUs, work time and other payment information for all the final payable codes in 2021 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 final 2021 valuation of specific codes:

Table 28	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 29	Direct PE Refinements
Table 30	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 31	Invoices Received for Existing Direct PE Inputs
Table 32	New Invoices
Table 33	No PE Refinements

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

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

2. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.[25] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values. [26]

[25]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[26]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.

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

CMS discusses its concern that many codes reviewed by the RUC have recommended work RVUs that do not appear to account for significant changes in the reduction in time. In addition to using its standard methodologies such as survey data, crosswalk to key reference or similar codes, CMS uses the relationship between the old-time values and the new time values to help identify alternative work RVUs based on changes in time components. CMS states that a decrease in time does not always equate to a one-to-one linear decrease in work RVUs but absent a rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs.

In the 2019 PFS final rule (83 FR 59515), CMS clarified that terms "reference services", "key reference services" and "crosswalk" are part of the RUC's process for code valuation and not defined by CMS. To minimize confusion and provide clearer language, CMS tries to limit the use of "crosswalk" to those cases where it makes a comparison to a CPT code with the identical work RVU.

Table 28 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2020.

Comments/Responses: CMS responds to the comments it received about its methodology for work valuation. CMS agrees with comments about the importance of using the current data available for work times. CMS disagrees with comments that it is not appropriate to compare available work times and work RVUs to newly surveyed work time and RUC recommended work RVUs. CMS believes that its operating assumptions about the validity of the existing values as points of comparison is critical to the integrity of the relative value scale and any other assumption would undermine the validity of the allocation of indirect PE to physician specialties.

CMS also disagrees with comments that the use of time ratios is not a valid methodology. CMS believes that the use of time ratios is important for identifying potential work RVUs, especially when the values recommended by the RUC and other commenters do not account for survey information suggesting that the time for furnishing a service has significantly changed. CMS reiterates that consistent with the statute, it is required to value the work RVU based on the relative resources involved in furnishing the service, including time and intensity. CMS does not think it is appropriate to develop work RVUS solely based on time ratios and provides examples of codes with identical work times but different work RVUs.

In response to comments discouraging the use of RVU increments, CMS notes that the RUC also uses this methodology when it lacks valid survey data for a service. As for commenters' concerns that CMS seems to not consider compelling evidence[27] that a service has changed, CMS states that the compelling evidence concept was developed for the RUC for its own review process and is not part of the statutory framework based on time and intensity. CMS notes that is does consider changes in technology, patient population and other factors as they affect the time and intensity of the service.

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 29 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 30 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)[28];
- Clinical labor time in the facility setting (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap.

CMS received invoices for several existing and new supply and equipment items (see Tables 31and 32). CMS encourages stakeholders to review these prices and if prices appear inaccurate

[27] The RUC's compelling evidence criteria includes documented changes 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 service.

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

it encourages stakeholders to submit invoices or other information to improve the pricing. CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations).

4. Valuation for Specific Codes

This section discusses proposed RVUs for 58 code groups (listed in the table below). Highlights of CMS' discussions, are summarized; the numbering is consistent with the preamble format. **This includes discussion of the Interim Final Rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (CPT code 99072).** The reader is referred to the final rule for more specific details

Code Group Number and Name		**Codes (CPT and HCPCS Codes)**	**CMS Proposals Agree with RUC RUV Recommendations**		**CMS Final RVUs Agree With Proposed RVUs**	
			Work	**PE**	**Work**	**PE**
1	Fine Needle Aspiration	11021 and 10004 - 10012	No	No	Yes	Yes
2	Tissue Expander Other Than Breast	11960	No	Yes	Yes	Yes
3	Breast Implant-Expander Placement	11970, 19325, 19340, 19342, and 19357	No	Yes	Yes	Yes
4	Breast Implant-Expander Removal	11971, 19328, and 19330	No	Yes	No**	Yes
5	Modified Radical Mastectomy	19307	Yes	Yes	Yes	Yes
6	Breast Lift-Reduction	19316 and 19318	Yes	Yes	Yes	Yes
7	Secondary Breast Mound Procedure	19370, 19371, and 19380	No	Yes	Yes	Yes
8	Hip-Knee Arthroplasty	27130 and 27447	Yes	Yes	Yes	Yes
9	Toe Amputation	28820 and 28825	No	No	Yes	Yes
10	Shoulder Debridement	29822 and 29823	Yes	Yes	Yes	Yes
11	Absorbable Nasal Implant Repair	30468	Yes	Yes	Yes	Yes
12	Lung Biopsy-CT Guidance Bundle	32408	No	Yes	Yes	Yes
13	Atrial Septostomy	33741, 33745, 33746	No	NA	Yes	NA
14	Percutaneous Ventricular Assist Device Insertion	339995, 33990-33992, 33997, and 33993	Yes	NA	Yes	NA
15	Esophagogastroduodenoscopy (EGD) with Biopsy	43239	Yes	Yes	Yes	Yes
16	Colonoscopy	45385	Yes	Yes	Yes	Yes
17	Transrectal High Intensity Focused US Prostate Ablation	55880	No	Yes	Yes	Yes
18	Computer-Aided Mapping of Cervix Uteri	57465	Yes	Yes	Yes	Yes
19	Colpopexy	57282 and 57283	No	Yes	Yes	Yes
20	Laparoscopic Colpopexy	57425	No	Yes	Yes	Yes
21	Intravitreal Injection	67028	Yes	No	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposals Agree with RUC RUV Recommendations		CMS Final RVUs Agree With Proposed RVUs	
			Work	PE	Work	PE
22	Dilation of Eustachian Tube	69705 and 69706	Yes	Yes	Yes	Yes
23	X-Ray of Eye	70030	Yes	Yes	Yes	Yes
24	CT Head-Brain	70450, 70460, and 70470	Yes	Yes	Yes	Yes
25	Screening CT of Thorax	71250, 71260, 71270, and 71271	No	No	Yes	Yes
26	X-Ray Bile Ducts	74300 and 74328-74330	No	NA	Yes	NA
27	Venography	75820 and 75822	Yes	NA	Yes	NA
28	Introduction of Catheter or Stent	75984	Yes	Yes	Yes	Yes
29	Medical Physics Dose Evaluation	76145	NA	Yes	NA	Yes
30	Ophthalmic Ultrasound Anterior Segment	76513	No	No	No**	Yes
31	Dual-energy X-ray absorptiometry (DXA)	77080	NA	NA	NA	NA
32	Radiation Treatment Delivery	77401	NA	No	NA	No
33	Photon Beam Treatment Delivery	77520, 77522, 77523, and 77525	NA	NA*	NA	NA*
34	Immunization Administration	90460, 90462, 90471-90474 and G0008-G0010	No	No	No**	No**
35	Liver Elastography	91200	Yes	Yes	Yes	Yes
36	Remote Retinal Imaging	92227, 92229, and 92229*	Yes	No	Yes	Yes
37	Auditory Evoked Potentials	92584 and 92650-92653	Yes	Yes	Yes	Yes
38	Vestibular Evoked Myogenic Potential Testing	92517-92519	Yes	Yes	Yes	Yes
39	Complete Electrocardiogram	93000, 93005, and 93010	Yes	Yes	Yes	Yes
40	External Extended ECG Monitoring	93242-93247, 93242, 93244, 93246, and 93248	Yes	No	Yes	Yes
		93241, 93243, 93245, and 93247	Yes	No	Yes	No*
41	Complete Transthoracic Echocardiography (TTE) with Doppler	93306	Yes	Yes	Yes	Yes
42	Pacing Heart Stimulation	93623	No	NA	Yes	NA
43	Intracardiac Echocardiography (ECG)	93622	No	NA	Yes	NA
44	Ventricular Assist Device (VAD) Interrogation	93750	No	Yes	Yes	Yes
45	Spirometry	94010 and 94060	Yes	Yes	Yes	Yes

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposals Agree with RUC RUV Recommendations		CMS Final RVUs Agree With Proposed RVUs	
			Work	PE	Work	PE
46	Exercise Test for Bronchospasm	94619, 94617, 94618, and 94621	Yes	Yes	Yes	Yes
47	Evaluation of Wheezing	94640 and 94667-94669	NA	Yes	NA	Yes
48	Exhaled Nitric Oxide Measurement	95012	NA	Yes	NA	Yes
49	Acupuncture Service	97810, 97811, 97813, and 97814	No	NA	No**	NA
50	Personal Protective Equipment (PPE)	99072	NA	NA	NA	NA
51	Chronic Care Management	99439 and G2058	Yes	Yes	Yes	Yes
52	External Counterpulsation	G0166	NA	No	Yes	Yes
53	Molecular Pathology Interpretation	G0452	Yes	Yes	Yes	Yes
54	E/M, Observation, and Provision of Self-Administered Esketamine	G2082 and G2083	NA	NA	NA	NA
55	Bundled Payments for Substance Use Disorders	G2086-G2088	NA	NA	NA	NA
56	Initiation of Medication Assisted Treatment (MAT)	G2213	NA	NA	NA	NA
57	Percutaneous Creation of an Arteriovenous Fistula (AVF)	G2170 and G2171	NA*	NA*	NA*	NA*
58	Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System	0446T – 0448T	NA	NA	NA	NA

*Contractor Priced Codes
**CMS does not finalize proposed values and instead finalizes the RUC-recommended value.

(8) Hip-Knee Arthroplasty (CPT codes 27130 and 27447)
In the final rule, CMS sought comment from the medical community about how to consider and/or include pre-optimization time (pre-service work and other activities that improve surgical outcomes). Commenters' appreciated CMS' consideration of pre-optimization time and some recommended creating a new G code that includes patient screening and education, as well as coordinating with other health care providers to help manage the entire episode of care. CMS continues to be interested in stakeholders' thoughts about the issue and how to capture pre-optimization activities when they are not captured in a specific code.

(12)Lung Biopsy-CT Guidance Bundle (CPT code 32408)
CMS did not propose the RUC recommended work RUV of 4.00 (the survey median) because it believes this value overstates the increase in the intensity of this service and did not account for the time decrease for performing this service. A commenter stated that CMS inappropriately relies on time-based ratios and overlooks the compelling evidence for why this service is

misvalued. The commenter discussed cancer treatment protocols which require more definitive tissue diagnosis including biomolecular marker profiles. CMS disagrees and continues to believe that the use of time ratios is appropriate and consistent with the statute. Although CMS does consider changes in technology and patient population as they affect the time and intensity of the service, it does not use the RUC's compelling evidence criteria.

(14) Percutaneous Ventricular Assist Device Insertion (CPT codes 33995, 33990-33992, 33997, and 33993)
CMS acknowledges the comment explaining the increase in intra-procedure time associated with the SmartAssist technology which was not included in the RUC recommendations. The commenter also discussed the impact of inappropriate reimbursement on physician adoption of new technologies and patient access. CMS acknowledges that new technology can sometimes make services more complex and difficult to perform, but it can also introduce greater efficiencies in the procedure and finalizes its proposal which is based on the RUC recommendations.

(*29) Medial Physics Dose Evaluation (CPT code 76145)*
Commenters recommended that CMS remove the DRA cap designation for CPT code 76145 because this service is a patient-specific organ dose assessment and evaluation and is not an imaging service. CMS agrees and removes CPT code 76145 from the DRA cap.

(31) Dual-energy X-ray absorptiometry (DXA) (CPT code 77080)
In response to the proposed rule, a stakeholder contacted CMS and stated that the Medicare payment for this code has declined in the nonfacility setting from $140 in 2006 to approximately $40 in 2020. CMS explains that the decreases were due to the adoption of the current PE methodology during 2007-2010 and the fact that the code's last RUC review was in 2014. CMS notes that it proposed a modest increase in totals RVUs for CPT code 77080, but the decrease in the CF results in the decrease in the payment for this code. If there is continued stakeholder concern about the valuation of this service, CMS may consider considering this code as a misvalued code.

(32) Proton Beam Treatment Delivery (CPT codes 77520, 77522, 77523, and 77525)
Although the specialty society thought this family of codes should remain contractor priced, the RUC determined that these services should be surveyed because their Medicare utilization was over 10,000 services. CMS discussed the concerns it has with the recommended direct PE inputs and proposed to maintain contractor pricing for these codes. CMS was concerned about what it describes as "extraordinary high prices" on invoices for the two new equipment items, the Proton Treatment Vault (ER115) and the Proton Treatment Delivery System (ER116). CMS stated that the invoices contained building construction cost and that expenses associated with constructing new office facilities are not part of direct PE and would be more appropriately classified as a form of building maintenance or office rent under indirect PE. If CMS were to propose pricing for these codes, it would remove building construction costs which would substantially lower the equipment prices and would refine the equipment times to the standard formula for highly technical equipment by reducing the time by 3 minutes. After consideration of comments, CMS finalizes its proposal to maintain contractor pricing for these codes.

(34) Immunization Administration (CPT codes 90460, 90461, 90471-90474, and HCPCS codes G0008-G0010)
After considering comments, CMS does not finalize its proposal to crosswalk the valuation of the codes for immunization administration to CPT code 36000 (introduction of needle or intracatheter, vein). Instead, CMS finalizes maintaining the 2019 payment for all services in this family, including the add-on codes. CMS continues to seek additional information that specifically reflects the resource costs and inputs that it should consider to establish payment for these services.

(40) External Extended ECG Monitoring (CPT codes 93224-93227 and 93241-93248)
CMS discussed its concerns with the direct PE inputs. One of the issues is related to the new supply item, the "extended external ECG patch, medical magnetic tape recorder" (SD339). CMS notes it did not receive a traditional invoice to establish a price, instead it received two separate calculated prices of $440 and $416.85 and invoices from the clinical study marketplace of $595. CMS stated it requires an invoice representative of commercial market pricing to establish a national price. CMS proposed to crosswalk the supply to the "kit, percutaneous neuro test stimulation" supply (SA022) at a price of $413.24.

In response to CMS' request for invoices or other information related to pricing SD339, it received conflicting information. CMS finalizes its proposals for CPT codes 93242-93247, 93242, 93244, 93246, and 93248. Based on the conflicting price information for SD339, CMS finalizes its proposal with modifications for CPT codes 93241, 93243, 93245, and 93247 and finalizes contractor pricing for these codes. CMS welcomes the submission of additional invoices or other pricing information to accurately value these services.

(50) Interim Final Rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (CPT code 99072)
In September 2020, the CPT Editorial Panel approved the creation of CPT code 99072 (*Additional supplies, materials, and clinical staff time and above those usually included in an office visit or other non-facility services, when performed during a PHE, as defined by law, due to respiratory-transmitted infectious disease*.) Stakeholders recommended direct PE inputs for CPT code 99072 and requested CMS immediately implement and develop payment for this code.

Interim Final Policy: After reviewing the information provided by stakeholders, CMS finalizes CPT code 99072 as a bundled service on an interim basis. CMS agrees that there have been additional costs for providers as part of the PHE but payment for the services described under CPT code 99072 are always bundled into payment for other services. In recognition of the increased market-based costs for certain types of PPE, CMS finalizes, on an interim basis, several supply pricing increases based on the invoices submitted. CMS did not previously include the N95 mask in its supply database and finalizes, on an interim basis, its addition under supply code SD344 at the median price of $2.36 (based on 94 submitted invoices. CMS also finalizes, on an interim basis, an increase in the price of the surgical mask (SB033) supply to the median price of $0.43 and an increase in the price of the surgical mask with face shield (SB034) supply to the median price of $3.40. The increased cost associated with these forms of PPE will be reflected in payment for services that include these supply inputs. CMS does not finalize any changes in the prices of non-sterile gloves (SB022), nitrile gloves (SB032), patient gowns

(SB026), and sterile surgical gown (SB028) because of concerns it has with the data on the submitted invoices, including median prices lower than their 2021 prices. CMS notes it will consider the market costs for these supplies during the PHE, as appropriate.

CMS determines there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the September 2020 creation of CPT code 99072 which did not allow for its inclusion in the proposed rule. **CMS is providing a 60-day comment period seeking comments about its general approach to CPT code 99072,** as well as how to identify services that may not include these specific PPE items but have incurred costs related to the PHE.

(54) Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS codes G2082 and G2083)
CMS does not agree with a comment that it should issue a J-code specifically for esketamine treatment and a HCPCS code that separates the clinical work of the service from the medication. Given that the product is only available through a restricted distribution under a REMS which requires at least 2 hours of patient monitoring post administration, CMS continues to believe the building block methodology is appropriate for determining the reimbursement of G2082 and G2083. CMS notes that other reasonable and necessary E/M services may be furnished and billed for a patient such as services furnished and billed for a patient on dates before and after HCPCS codes G2082 and G2083, including services for the treatment and diagnosis of treatment-resistant depression.

(58) Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (CPT codes 0446T, 0447T, and 0448T)
These Category III CPT codes describe services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from a subcutaneous pocket, CPT codes 0446T, 0447T, and 0448T, respectively.

CMS proposed work and PE inputs based on a crosswalk of these codes to the CPT codes for insertion, removal, removal and reinsertion of non-biodegradable drug delivery implant, CPT codes 11981, 11982, and 11983, respectively. CMS proposed work RVUs of 1.14 for code 0446T, 1.34 for code 0447T and 1.91 for code 0448T. For PE inputs, CMS proposed to add a new "implantable interstitial glucose sensor (supply code SD334) priced at $1,500.00. CMS proposed to price the smart transmitter by using a similar item as a proxy, the "heart failure patient physiologic monitoring equipment package (EQ392) with a price of $1,000.00. CMS assigned a time of 25,920 minutes for EQ392 in codes 0446T and 0448T (based on 1 minute of equipment use out of every 5 minutes of time every day per a 90-day billing quarter).

Commenters agreed with CMS' proposal for the inclusion of the "implantable interstitial glucose sensor" supply (SD334) for CPT codes 0446T and 0448T but stated that the cost of the smart transmitter equipment (EQ392) associated with the use of the implantable interstitial glucose sensor should only be included as part of the costs for CPT code 0446T. CMS appreciated the additional information and finalizes the removal of the heart failure physiologic monitoring equipment package (EQ392) from CPT code 0448T.

I. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

CMS describes section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, which established a new Part B benefit for OUD treatment services furnished by OTPs beginning January 1, 2020. The 2020 PFS final rule implemented the coverage requirements for OUD treatment services and established payment codes for bundled episodes of OUD care furnished by OTPs. For 2021, CMS proposed several refinements and clarifications and requested feedback on several policies.

2. Definition of OUD Treatment Services (§410.67(b))

Opioid Antagonist Medications. Under prior rules, OUD treatment services did not include opioid antagonist medications such as naloxone. CMS had considered including those medications in the definition established in the 2020 PFS final rule but declined to do so at the time. For 2021, CMS finalizes its proposal to extend the definition of OUD treatment services at §410.67(b) to include opioid antagonist medications that are approved by the FDA for the emergency treatment of known or suspected opioid overdose. Commenters overwhelmingly supported this change.

Final adjustments to the bundled payments for OUD treatment services. As proposed, the final rule will reimburse for naloxone through the use of add-on codes to the bundled payment on an as needed basis. The proposed HCPCS add-on G codes and payments are specified in Table 34 (and duplicated below).

TABLE 34: OTP Code Descriptors and Payment Amounts*

HCPCS	Descriptor	Total Payment
G2215	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$92.13
G2216	Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	Contractor-priced

* Nasal naloxone drug costs are calculated using ASP data plus a payment of $2.53 for overdose education. HCPCS code G2216 will be contractor-priced and will also include a payment of $2.53 for overdose education.

- The final payment for nasal naloxone was based on the same methodology previously used for pricing the drug component of an episode of care that includes implantable or injectable medications except the payment amounts would not include any add-on percentages to the ASP therefore setting it equal to ASP +0. A payment for the non-drug component of this code will be determined using a crosswalk to the Medicare payment rate for CPT code 96161 of $2.53. The non-drug component is described further below under "opioid overdose education."

- CMS had proposed to price the add-on code for the take-home supply of injectable naloxone using the lowest price available (the lower of ASP + 0, Wholesale Acquisition Cost (WAC) + 0, or national average drug acquisition cost.) In the final rule, CMS states that because the information it has is not based on a typical dose, it is contractor pricing the code for CY 2021. After it obtains more information on the typical dosage, it will establish national pricing for injectable naloxone in future rulemaking. The payment for the non-drug component of this code will be the same as for HCPCS G2215.

CMS had requested feedback from stakeholders about whether it should also create a code and establish an add-on payment for a take-home supply of auto-injector naloxone. Since the publication of the proposed rule, however, both the brand and authorized generic formulation of the auto-injector naloxone have been discontinued so it does not finalize an add-on code for auto-injector naloxone.

Opioid Overdose Education. Some commenters recommended that treatment services also include overdose education that could be either added to the currently established bundled payment or could be a separate add-on code. After consideration of comments, CMS finalizes the definition of OUD treatment services to include overdose education and states that overdose education includes educating patients and caregivers on how to recognize respiratory depression, the signs and symptoms of overdose, how to administer naloxone, and the importance of calling for emergency medical help.

CMS will crosswalk to the CY 2020 Medicare payment rate for CPT code 96161 [*Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*], which is assigned a non-facility payment rate under the PFS of $2.53. CMS believes this reference code describes a similar level of service intensity and amount of clinical staff time involved in furnishing overdose education and that a separate add-on code for overdose education billed in 15-minute increments, as suggested by some commenters, could result in overpayment.

Frequency limit. CMS finalizes its proposal to limit OTPs to one add-on code for naloxone every 30 days to the extent it is medically reasonable and necessary. It reviews the frequency limits applicable to naloxone under the Part D and TRICARE as well as utilization data on naloxone use.

In response to commenters who opposed any frequency limit, CMS agrees that access to naloxone should not be limited when it is a medically reasonable and necessary part of treatment for OUD and so in the final rule, it establishes an exception to the frequency limit where the beneficiary overdoses and uses the initial supply and where it is medically necessary to furnish additional naloxone. If additional naloxone is furnished, the OTP must document in the medical record the reason(s) for the exception.

Duplicative Payment. As naloxone is available under Medicare Part D, CMS reminds readers that any payment to an OTP for naloxone would be duplicative if the same medication is separately paid under Medicare Part B and Part D for the same beneficiary on the same date of service. If this were to happen, CMS would recoup any duplicative payment.

Similarly, if a community pharmacy supplies Medication Assisted Treatment (MAT)-related medications, CMS expects an OTP to take measures to ensure that there is no claim for payment other than as part of the OTP bundled payment.

Regulatory Impact. CMS estimates that the impact of adding naloxone to the definition of OUD treatment services will be approximately $0.5 million in 2021 and estimates 10-year costs of $5.6 million. The estimate incorporates the assumption that between 20,000 and 25,000 beneficiaries would use the OTP benefit in the first year and assumes that each patient receiving naloxone will receive the maximum permitted number of doses.

Periodic Assessments (§410.67(b)(7)). In the 2020 PFS final rule, OUD treatment services were defined to include intake activities and periodic assessments. CMS defined an add-on G code to describe these services (HCPCS code G2077). Such activities are required to be medically reasonable and necessary, and OTPs must document the reason for billing the add-on code in the patient's medical record.

During the COVID-19 PHE period, the definition of such assessments was revised on an interim final basis to permit such assessment to be furnished via audio-only telephone calls for a beneficiary that does not have access to tow-way audio-video communications technologies. CMS does not believe, however, that this flexibility should be continued beyond the conclusion of the PHE. CMS states that, based on the expected acuity of patients seeking OUD services and the likelihood of co-morbidities, a face-to-face medical exam or biopsychosocial assessment should be performed.

CMS finalizes as proposed, that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment must be performed including through two-way interactive audio-video communication technology.

Commenters supported CMS' proposal to allow OTPs to utilize two-way interactive audio-video communication to satisfy the proposed requirement that periodic assessments include a face-to-face encounter. In response to commenters who supported permitting audio-only assessments for individuals who don't have access to video, CMS notes that while it permits audio-only assessments during the COVID-19 PHE, it does not support continuing to permit those assessments permanently. It believes that the effectiveness and quality of care is reduced when practitioners can't observe visual cues. As such, CMS finalizes its proposal to provide that periodic assessments must be furnished during a face-to-face encounter but may also be furnished via two-way interactive audio-video communication technology.

3. WAC Pricing

CMS finalizes its proposal to limit WAC-based payments for injectable or implantable medications included in the drug component of an episode of care if used. Although currently none of the drugs that are included in the drug component of an episode of care are paid based on WAC, CMS notes that it is possible that it may use WAC in the future and so proposed to establish the methodology that would apply in advance. Consistent with its decision to limit

payment amounts to 100 percent of ASP, it finalizes its proposal to limit WAC-based payments to 100 percent of WAC when WAC pricing is used for payment for an implantable or injectable medication included in the drug component of an episode of care.

A commenter expressed concern about deviating from the standard methodology under Medicare Part B of paying for drugs at the current rate of ASP plus 6 percent and by limiting payment to 100 percent of WAC, when used, would impede OTPs' ability to treat Medicare beneficiaries. CMS declines to make any changes to the policy and states that closely tailoring payment to providers' acquisition costs reduces the likelihood that a drug will be chosen for reasons other than clinical need.

4. Billing and Payment Policies

Institutional Claim Forms. CMS continues to explore how to provide flexibility in claims processing such as by permitting OTPs to bill for services on institutional claim forms (as opposed to professional claim forms) as requested by some providers. It states that any future relevant changes related to claims processing including the use of institutional claims forms will be described in guidance.

Date of Service. In response to inquiries from OTPs who use a standard billing cycle in which all episodes of care for all patients begin on the same day of the week, CMS clarifies that its definition of an episode of care is not inconsistent with that approach. In a case in which the OTP uses a standard billing cycle, the date of service would be the first day of the OTP's billing cycle. If a beneficiary starts treatment at the OTP on a day that is in the middle of the OTP's standard weekly billing cycle, the OTP can still bill the applicable code for that episode of care provided that the threshold to bill for the code has been met. For OTPs that choose to adopt weekly billing cycles that vary across patients, the initial date of service will depend upon the day of the week when the patient was first admitted to the program or when Medicare billing began. Under this approach, when a patient is beginning treatment or re-starting treatment after a break in treatment, the date of service would reflect the first day the patient was seen, and the date of service for subsequent consecutive episodes of care would be the first day after the previous 7-day period ends.

For the codes describing add-on services (HCPCS codes G2076-G2080), the date of service should reflect the date that service was furnished; however, if the OTP has chosen to apply a standard weekly billing cycle, the date of service for codes describing add-on services may be the same as the first day in the weekly billing cycle. CMS notes that this approach is consistent with guidance in the OTP Billing and Payment Fact sheet (https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf).

Coding. In the 2020 PFS final rule, CMS finalized an add-on code (HCPCS code G2080) to adjust the bundled payment when additional counseling or therapy services are furnished that substantially exceed the amount described in the patient's individualized treatment plan. CMS has since received feedback describing a large range of different care and service intensities that are needed. Differences between the induction phase and the maintenance phase of treatment as well as differences in patients' needs over time are described. CMS sought comments on how it

might better account for differences in resource costs among patients over the course of treatment. Commenters generally supported continuing the coding and payment policies established in the 2020 PFS and CMS plans to continue that coding structure for 2021 and may consider refinements in future rulemaking.

5. Annual Updates

The current payment rates, as finalized in the CY 2020 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP webpage under Billing and Payment at https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/Opioid-Treatment-Program/billing-payment. The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2021, is available in the file called CY 2021 PFS final rule OTP Payment Rates on the CMS Web site under downloads for the CY 2021 PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.

Some commenters noted that using the Medicare Economic Index (MEI) to update payments rates for non-drug components of the bundled payment will not permit those rates to keep pace with growing practice costs. They recommended alternative updates. CMS replies that it did not propose any changes to the annual update process but may consider this feedback for future rulemaking.

J. Technical Correction to the Definition of Public Health Emergency

CMS corrects an error in the March 31st COVID-19 IFC (85 FR 19285) where it referred in the regulations at §400.200 by referring to the authority for the PHE as the "Public Health Security Act" rather than the "Public Health Service Act". CMS corrects this error in this final rule.

III. Other Provisions

A. Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment Reductions; Comment Solicitation on Payment for Specimen Collection for Covid-19 Tests

1. Conforming CLFS Regulations to Statutory Changes

Section 1834A of the Act requires "applicable laboratories" to report private payer prices and volumes to CMS. CMS uses that information to determine CLFS payment amounts for each test based on the weighted median of the private payer prices reported by applicable laboratories.

The first data collection occurred in 2016. The data was reported to CMS in 2017 and used for payment beginning in 2018. The next data collection period was January 1, 2019 through June 30, 2019. That data was scheduled to be reported to CMS from January 1, 2020 through March 31, 2020 and used for payment beginning January 1, 2021. However, the Further Consolidated Appropriations Act (FCAA) of 2020 delayed the reporting period to January 1, 2021 through

March 31, 2021. Under the FCAA, the 2019 data would be used for payment beginning January 1, 2022. The Coronavirus Aid, Relief, and Economic Security (CARES) Act later delayed the reporting period to January 1, 2022 through March 31, 2022.

The FCAA and the CARES Act did not change the 2019 data collection period. Under current law, data reported from January 1, 2019 through June 30, 2019 will be used to determine CLFS payment beginning January 1, 2023. The law new requires that data be reported to CMS every three years beginning January 1, 2022.

The law further limits the reduction in payment annually under the CLFS. The limits were originally 10 percent for 2017 through 2019 and 15 percent for 2020 through 2022. (CMS implemented the provision one year after its statutory deadline of January 1, 2017.) Under the FCAA, the limits were changed to 10 percent per year from 2018 through 2020 and 15 percent per year from 2021 through 2022. The CARES Act limited the reduction to 0 percent in 2021 and 15 percent from 2022 through 2024.

CMS proposed to revise the regulations to conform with the changes made by the FCAA and the CARES Act. Commenters supported the conforming changes to the regulations while one comment asked CMS to further delay phase-in of payment reductions under the CLFS. CMS is finalizing the changes as proposed.

2. Comment Solicitation on Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests

As result of the COVID-19 public health emergency (PHE), CMS established the following codes for COVID-19 specimen collection from homebound and non-hospital inpatients.

- G2023 (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source); and
- G2024 (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) (Coronavirus disease [COVID19]), from an individual in a SNF or by a laboratory on behalf of an HHA, any specimen source).

CMS established a higher fee for these codes than normally paid for specimen collection from homebound or non-hospital inpatients. The higher payment provides independent laboratories with additional resources to provide COVID-19 testing and helps with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home.

In the proposed rule, CMS requested comments on whether it should delete these codes and revert to using the normal specimen collection codes and fees once the PHE is over. CMS asked for comments on why increased payment for specimen collection specifically for COVID-19 tests, in contrast to other tests, might be needed following the end of the PHE.

Comments/Responses: Several commenters expressed support for permanently extending payment for specimen collection for COVID-19 tests after the PHE citing heightened safety precautions, the need for personal protective equipment, and the requirement for special training

for specimen collection will persist beyond the immediate PHE. Other comments asked CMS to expand use of these codes and higher payment amounts to specimen collection for all other tests. There were also comments asking CMS to clarify that these codes can be used other than when the patient is homebound or a non-hospital inpatient. CMS will take these comments into consideration in developing future policy.

B. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

1. Modifications to OTP Enrollment Process

Under prior rules (§424.310) a provider or supplier must complete, sign, and submit to its MAC, Form CMS-855 to enroll in the Medicare program and obtain Medicare billing privileges. Existing §424.67 requires OTPs to complete the Form CMS-855B application for clinics, group practices and other suppliers to enroll in Medicare.

CMS finalizes without change, proposals to revise §424.67 (enrollment requirements for OTPs) to permit OTPs to enroll as a Medicare provider using Form CMS-855A (Medicare Enrollment application for institutional providers).

Under the final rule (italics indicate the final additions):

- §424.67(b)(1) is amended to state that a newly enrolling OTP must complete and submit *Form CMS-855A or* Form CMS-855B application (or their successor applications). Existing §424.67 requires the completion of Form CMS-855B, only.
- §424.67(b)(1)(ii) is revised to require an OTP to certify compliance with applicable requirements and standards via *Form CMS-855A or* Form CMS-855B (instead of Form CMS-855B, only).
- §424.67(b)(5) is amended to require an OTP to report on the *Form CMS-855A or* Form CMS-855B all OTP staff who meet the definition of "managing employee" (instead of on Form CMS-855B, only).

In the November 15, 2019 final rule (84 FR 62568) CMS estimated the information collection burden associated with completing Form CMS-855B: about 1,700 OTPs were eligible for Medicare enrollment and 67 OTPs would become certified by the Substance Abuse and Mental Health Services Administration (SAMSHA) per year over the next 3 years. The cost for such enrollment was estimated to be $244,146 for 1,767 entities in the first year and just over $9,257 in each of years two and three. Forms were expected to take about 2.5 hours to complete.

Under this final rule, CMS expects roughly one-half of the new enrollments in years 2 and 3 would elect to complete a Form CMS-855A rather than a Form CMS-855B and 300 currently enrolled OTPs would change their enrollment from a Form CMS-855B to a Form-855A. At a later date, CMS estimates that 10 OTPs may change their enrollment from the Form CMS-855-A to Form CMS-855-B. CMS estimates that the Form CMS-855-A would take 3.5 hours to complete plus an additional 30 minutes to review and sign the form. The resulting net increase in annual burden for those groups of OTPs would be $17,743 for each of 3 years for those filing Form CMS-855-As and a burden reduction of $4,091 for those switching to CMS-855-B.

2. Screening Activities Associated with Risk Designation

Section 424.518 outlines provider enrollment screening requirements and categories based on the degree of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type presents, the greater the degree of scrutiny applied when reviewing and screening enrollment applications. There are three levels of screening described in §424.518: limited; moderate; and high. CMS describes the circumstances that result in an OTP provider being assigned to each of those levels and the types of screening applied to providers in each of those categories.

Recognizing that some currently enrolled OTPs may want to enroll as an institutional provider, CMS seeks to minimize any unnecessary duplicative screening. To minimize the burden of currently enrolled OTPs re-enrolling as an institutional provider, CMS proposed to amend §424.67(b)(3), which describes the requirement to complete the applicable categorical risk level screening, to provide for an exception from existing screening requirements for OTPs changing their OTP enrollment. CMS finalizes the amendments as proposed including re-designating the paragraph as (b)(3)(i).

New paragraph (b)(3)(ii) states that currently enrolled OTPs that are changing their OTP enrollment from a Form CMS-855B to a Form CMS-855A, or vice versa, must successfully complete the limited level of categorical screening if the OTP has already completed the moderate or high level of categorical screening. CMS notes that this would prevent OTPs from needing a second site visit (currently required for OTPs assigned to a medium level of risk) and fingerprinting (currently required for OTPs assigned to a high level of risk) if fingerprinting was done with their original Form CMS-855B enrollment.

In addition, a conforming change to §424.518(a)(1) adds OTPs changing their OTP enrollment to a list of provider and supplier types subject to limited risk categorical screening.

3. Additional OTP Enrollment Clarifications (§§424.67)

CMS finalizes without change three additional clarifications to the enrollment provisions for OTPs:

- *Single Enrollment.* CMS explicitly states that an OTP may be enrolled via either Form CMS-855A or Form CMS-855B but not both.
- *Effective Date of Billing.* For OTPs that change from a Form CMS-855B enrollment to a Form CMS-855A enrollment, the effective date of billing that was established for the OTP's prior enrollment applies to the OTP's new enrollment. CMS notes that the time limits for filing claims in existing §424.44 would continue to apply (within 1 calendar year of the date of service with certain exceptions. Switching enrollment does not qualify as an exception).
- *Application Fee.* To clarify the application of enrollment fees, which are required under existing rules for institutional providers, CMS states that compliance with the application fee requirements in §424.514 also apply to currently enrolled OTPs changing enrollment

from a Form CMS-855B to a Form CMS-855A or vice versa. In the regulatory impact statement, CMS estimates that projected fees would total $179,700 in 2021. That amount assumes 300 OTPs would change to a Form CMS-855A enrollment, requiring each to pay $599 for the application fee. CMS projects a fee of $605 for 2022 and $611 for CY 2023. This results in a total application fee cost of $3,025 ($605 x 5 OTPs) in 2022 and $3,055 in 2023 ($611 x 5 OTPs).

C. Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

In the 2018 PFS final rule, CMS finalized policies to permit RHCs and FQHCs to furnish and bill for care management services using HCPCS codes G0511 and G0512. Payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491; it is updated annually based on the PFS amounts.

2. Requirements for PCM Services in RHCs and FQHCs

In the 2020 PFS final rule, CMS established separate payment for PCM services using HCPCS codes G2064 and G2065.

- G2064: Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities
- G2065: Comprehensive care management for a single high-risk disease services, e.g. principal care management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities

CMS finalizes its proposal to permit RHCs and FQHCs to furnish and bill for PCM services. It adds HCPCS codes G2064 and G2065 to G0511 as a comprehensive care management service for RHCs and FQHCs beginning January 1, 2021. HCPCS codes G2064 and G2065 will be used in calculating the average of the national non-facility PFS payment rates for HCPCS code G0511. RHCs and FQHCs will be able to bill for PCM services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim.

CMS considered creating a separate G code for PCM services but decided against this approach because PCM and CCM are similar services; it believes that grouping them together is consistent with an integrated approach to care with reduced reporting requirements. Commenters were all in support of adding the PCM HCPCS codes to the general care management HCPCS code G0511.

3. Regulatory Impact

CMS estimates that the addition of HCPCS codes G2064 and G2065 to G0511 would have a negligible impact on Medicare spending.

D. Changes to the FQHC PPS for 2021: Rebasing and Revising of the FQHC Market Basket

1. 2021 Productivity-adjusted Market Basket Update for FQHCs

The annual update to the FQHC PPS is equal to 1.7 percent. CMS rebases and revises the 2013-based FQHC market basket to reflect a 2017 base year. Thus, CMS finalizes for 2021 an update equal to the 2017-based FQHC market basket of 2.4 percent less 0.7 percentage points for a productivity adjustment.

The 2.4 percent update is based on the most recent historical data available at the time of publication of the final rule; the final update is based on the four-quarter moving-average percentage change of the 2017-based FQHC market basket through the second quarter of 2020.

CMS continues to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP) which is the same measure of MFP applied to other Medicare market basket updates. Using IGI's third quarter 2020 forecast of MFP, CMS projects a reduction of 0.7 percent for productivity.

2. Rebasing the FQHC Market Basket

CMS finalizes its proposal to rebase and revise the FQHC market basket; the current FQHC market basket is from a 2013 base year. CMS bases the FQHC market basket on data from cost reports beginning in FY 2017. CMS makes some modifications to its technical approach, as discussed in more detail below. Rebasing and revising the market basket may result in changes in the cost weights and price proxies used to develop the price index value that is used to update the rates for FQHC services.

a. Development of 2017-Based FQHC Market Basket Cost Categories and Weights

CMS finalizes, with modifications, a 2017-based FQHC market basket that consists of 11 major cost categories plus a residual "all other" category to determine allowable costs for freestanding FQHCs. In response to public comments, CMS will use net costs rather than total costs to derive the FQHC market basket cost weights. This changes the derived weights from the proposed rule and the lines on the cost report used to make these calculations. CMS notes that the 2013-based FQHC market basket used six cost categories; the new categories separate costs that were previously combined into a single category which CMS notes is a technical improvement. CMS

defines allowable costs for freestanding FQHCs as the total expenses reported on Worksheet A, column 7, for lines 1 through 7, lines 9 through 12, and lines 23 through 36. CMS continues to exclude Professional Liability Insurance (PLI) costs because FQHCs that receive grant funds under section 330 of the Public Health Service Act (PHSA) are also are eligible to apply for medical malpractice coverage under section 224 of the PHSA.

CMS excludes those FQHCs with cost weights that are less than or equal to zero for a category as well as those cost weights that are in the top and bottom 5 percent for all cost categories. The residual "All Other" cost category reflects all remaining costs not captured in the 11 major cost categories.

Table 35 in the final rule (reproduced below) shows the proposed and final 2017-based FQHC cost report weights compared to the corresponding 2013-based FQHC market basket cost weights. The preamble to the final rule provides details on the specific worksheets, parts, columns, and lines used to derive costs for each cost category.

Table 35: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Final 2017-Based FQHC Cost Report Weights (Percent)	Proposed 2017-Based FQHC Cost Report Weights (Percent)	2013-Based FQHC Market Basket (Percent)
FQHC Practitioner Compensation*	*28.4*	*30.0*	31.7
FQHC Practitioner Wages & Salaries	19.4	20.5	-
FQHC Practitioner Employee Benefits	4.5	4.5	-
FQHC Practitioner Contract Labor	4.6	4.9	-
Clinical Staff Compensation*	*16.8*	*16.2*	9.5
Clinical Staff Wages & Salaries	12.9	12.4	-
Clinical Staff Employee Benefits	3.1	3.0	-
Clinical Staff Contract Labor	0.8	0.8	-
Non-Health Staff Compensation*	27.2	25.4	27.4
Pharmaceuticals	2.4	3.9	5.1
Medical Supplies	2.2	2.4	-
Fixed Capital	4.4	4.7	4.5
Moveable Capital	2.0	1.9	1.7
All Other (Residual)	16.5	15.5	20.1

*Employee Benefits weight from the 2013-based FQHC Market Basket (10.7 percent), which was derived from the Medicare Cost Reports (81 FR 80395) and distributed across the three compensation categories: FQHC Practitioner, Clinical Staff, and Non-Health Staff based on the relative shares of each category. Note: Totals may not sum to 100.0 due to rounding

The above table does not separately show contract labor. As it did for the 2013-based FQHC market basket, CMS is allocating contract labor to wages and salaries and employee benefits based on its share of costs attributable to each of these categories (81 percent to wages and salaries and 19 percent to employee benefits). CMS provides further detail in the final rule on the data sources used to derive weights within the capital cost category and all other categories.

Commenters generally supported the use of the Medicare cost report data to derive the eleven major cost categories in the 2017-based FQHC market basket (an increase from 6 cost categories used in the 2013-based FQHC market basket). These commenters disagreed, however, with the use of columns 1 and 2 from Worksheet A to capture a health center's expenses and suggested that the net expenses as listed in Worksheet A, column 7 of the Medicare cost report most accurately reflects the Medicare allowable cost for a community health center. CMS reexamined its data and found that a large percentage of providers had reclassifications and adjustments and these had an impact on the distribution of total expenses among major cost weight categories. Thus, CMS modifies its methodology from the proposed rule to reflect the use of net expenses as listed in Worksheet A, column 7 of the Medicare cost report.

b. 2017-based FQHC Market Basket Cost Categories and Weights

Table 37 of the final rule (reproduced below) shows the cost categories and weights for the final 2017-based FQHC market basket compared to the proposed 2017-based FQHC market basket and the 2013-based FQHC market basket.

Table 37: Final 2017-Based FQHC Market Basket Cost Weights Compared to Proposed 2017-Based FQHC Market Basket, and the 2013-Based FQHC Market Basket Cost Weights

Cost Category	Final 2017-based FQHC Market Basket Cost Weight	Proposed 2017-based FQHC Market Basket Cost Weight	2013-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**	**100.0**
Compensation	**72.5**	**71.6**	**68.7**
FQHC Practitioner Compensation	**28.4**	**30.0**	**31.7**
FQHC Practitioner Wages and Salaries	23.1	24.6	-
FQHC Practitioner Employee Benefits	5.4	5.4	-
Clinical Staff Compensation	**16.8**	**16.2**	**9.5**
Clinical Staff Wages and Salaries	13.6	13.0	-
Clinical Staff Employee Benefits	3.3	3.2	-
Non-Health Staff Compensation	**27.2**	**25.4**	**27.4**
All Other Products	**8.5**	**10.0**	**16.1**
Pharmaceuticals	2.4	3.9	5.1
Utilities	0.6	0.5	1.4
Telephone	-	-	1.7
Postage	-	-	1.0
Medical Equipment	1.2	1.1	2.2
Medical Supplies	2.2	2.4	2.0
Miscellaneous Products	2.2	2.1	2.8
All Other Services	**12.6**	**11.8**	**9.0**
Professional, Scientific, and Technical Services	6.4	6.0	2.9
Administrative and Facilities Support Services	1.7	1.6	3.4
All Other Services	4.5	4.2	2.7

Capital-Related Costs	6.4	6.6	6.1
Fixed Assets	4.4	4.7	4.5
Movable Equipment	2.0	1.9	1.7

Note: Totals may not sum due to rounding.

CMS did not receive any comments on its proposed derivation of the detailed operating cost weights. Thus, it finalizes its methodology, as proposed.

c. Selection of Price Proxies

After developing the cost weights, CMS selects what it believes is the most appropriate price proxy currently available to represent the rate of price change for each cost category. CMS mostly bases price proxies on BLS data and groups them into employment cost indexes (ECIs), producer price indexes (PPIs), or consumer price indexes (CPIs). Table 38 in the final rule lists all the cost categories and associated price proxies that CMS used for the 2017-based FQHC market basket; the preamble includes a detailed discussion of the price proxy used for each cost category.

CMS did not receive any comments on its proposed price proxies, and thus is finalizing them without modification.

3. Regulatory Impact

CMS estimates that the economic impact of finalizing the FQHC market basket rebasing and revising for CY 2021 is approximately $1 million, which it considers to be negligible impact.

E. Comprehensive Screenings for Seniors: Section 2002 of the SUPPORT Act

Section 2002 of the SUPPORT Act amended Medicare provisions defining the required elements of the initial preventive physical exam and the annual wellness visit to include (1) Screening for potential substance use disorders and (2) A review of any current opioid prescriptions. Under the final rule, CMS finalizes as proposed incorporation of the required elements for an initial preventive physical exam in §410.15 and the annual wellness visit in §410.16.

CMS provides background on the need for vigilance in identifying opioid risks in Medicare beneficiaries as well as the existing elements for coverage of an initial preventive physical exam and the annual wellness visit.

As proposed, CMS amends each of §410.15 and §410.16 to:

- Add “Screening for Potential Substance Use Disorders” as a required element for coverage of an initial preventive physical exam and an annual wellness visit, including for a first annual wellness visit and a subsequent annual wellness visit.
- Add “a review of any current opioid prescriptions” as a required element for coverage of an initial preventive physical exam and an annual wellness visit, including for a first annual wellness visit and a subsequent annual wellness visit.

- In each of those sections, the screening is described as a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.
- In each of those sections, the review of current opioid prescriptions is defined to include a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and a referral to a specialist, as appropriate.

CMS does not adopt a commenter's recommendation to only pay for these services as a separate encounter and notes that there are other opportunities throughout a year (in addition to the annual wellness visit or initial preventive physical exam) to evaluate the patient's pain. In response to a request for additional detail about what is required of practitioners to meet the new required elements of the annual wellness visit and initial preventive physical exam, CMS states that it has not been prescriptive in the regulatory language in order to minimize burden and maximize flexibility.

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

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid EPs[29] can receive incentive payments for the adoption, implementation, upgrade, and meaningful use of Certified Electronic Health Record Technology (CEHRT). To demonstrate meaningful use of electronic health records (EHR) technology, the EHR user is required to report clinical quality measures selected by CMS or a state and submit them in the form and manner specified by CMS or the state. In selecting electronic clinical quality measures (eCQMs) for EPs to report, the Secretary is required to avoid redundant or duplicative reporting. All state Medicaid Promoting Interoperability Program incentive payments must be issued by the statutory deadline of December 31, 2021.

For 2020, Medicaid EPs are required to report on any six eCQMs relevant to the EPs' scope of practice, regardless of whether they report via attestation or electronically. CMS also adopted the MIPS requirement that EPs report on at least one outcome measure or, if an applicable outcome measure is not available or relevant, one other high priority measure.

2. eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2021

CMS finalizes for 2021 an alignment of the eCQMs available for Medicaid EPs under this program with the list of quality measures available under the eCQM collection type on the final list of quality measures established for the MIPS 2021 performance period. CMS believes that allowing clinicians to report the same eCQMs for both programs might encourage participation

[29] CMS has previously determined that no hospitals are eligible to receive Medicaid Promoting Interoperability Program payments in 2021 (84 FR 42592).

in the Medicaid Promoting Interoperability Program and will help ensure uniform application of the most current clinical standards and guidelines possible. Further, CMS believes that the alignment will reduce reporting burden on clinicians with only minor adjustments required by states. (Appendix 1 of the final rule includes changes to the list of available eCQMs for the MIPS 2021 performance period.)

Reporting Requirements. The 2020 reporting requirements are continued for 2021. That is, EPs must report on any six eCQMs relevant to the EPs' scope of practice, regardless of whether they report via attestation or electronically, and report on at least one outcome measure or, if an applicable outcome measure is not available or relevant, one other high priority measure. The three methods for identifying high priority measures for EPs that were established in the 2019 PFS final rule (83 FR 59702) are continued. These pertain to the MIPS high priority measures under the quality performance category, the Core Sets for Medicaid and CHIP, and eCQMs identified by the state and approved by CMS.

CMS notes that the eCQMs that would be available for Medicaid EPs to report in 2021, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under the proposal are: CMS2, "Preventive Care and Screening: Screening for Depression and Follow-Up Plan"; CMS122, "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)"; CMS125, "Breast Cancer Screening"; CMS128, "Anti-depressant Medication Management"; CMS136, "Follow-Up Care for Children Prescribed ADHD Medication (ADD)"; CMS137, "Initiation and Engagement of Alcohol and Other Drug Dependence Treatment"; CMS153, "Chlamydia Screening for Women"; CMS155, "Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents"; and CMS165, "Controlling High Blood Pressure."

Reporting Period. The previously established eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program is a minimum of any continuous 90-day period within 2021, provided that the end date for this period falls before October 31, 2021, or falls before a state-specific alternative date prior to October 31, 2021 that is specified in the state's Medicaid health IT plan. This 2021 eCQM reporting period is designed to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before the December 31, 2021 end date for these payments.

Responding to comments, CMS notes that none of the EHR vendors who submitted comments indicated any problem with issuing system updates in time for EPs to attest to meaningful use and states to provide incentive payments by the statutory deadline.

G. Medicare Shared Savings Program (MSSP)

CMS reviews in detail the legislative and regulatory history of the Medicare Shared Savings Program (MSSP). Prior key actions include the following:

- Section 3022 of the Affordable Care Act (Pub. L. 111-148) added Section 1899 of the Act, which created the program's Accountable Care Organizations (ACOs).
- The Bipartisan Budget Act of 2018 (Pub. L. 115-123) added flexibility to the beneficiary assignment rules and allowed ACOs to add beneficiary incentive programs.

- CMS finalized a major program redesign in a December 2018 final rule referred to as "Pathways to Success" (CMS-1701-F, 83 FR 67816) that emphasizes the adoption of two-sided risk by ACOs.
- CMS extended the applicability of the MSSP's Extreme and Uncontrollable Circumstances policy to the COVID-19 PHE in the March 31st COVID-19 IFC.
- In the May 8th COVID-19 IFC, CMS acted to:
    - Allow ACOs whose participation agreements were to expire on December 31, 2020 to extend their agreements at the same participation level for one year;
    - Adjust program calculations to remove episodes of care for COVID-19; and
    - Expand the definition of primary care services used for beneficiary assignment to ACOs to add telehealth and other communications-based technology services.

This final rule addresses changes to the MSSP brought forth in the Medicare PFS proposed rule for 2021 (CMS-1734-P, 85 FR 50074) dealing with the following:

- Modifying the approach to measuring ACO quality performance;
- Revising the MSSP Quality Performance Standard and the methodology for using the standard to determine the shared savings and losses of ACOs;
- Updating the quality provisions of the Extreme and Uncontrollable Circumstances policy;
- Updating the definition of primary care services and its impact on ACO benchmarks; and
- Revising the MSSP's repayment mechanism arrangement policy.

1. Quality Reporting Requirements

a. Background

For performance year 2020, MSSP ACOs are scored on a set of 23 quality measures, arrayed into 4 domains, with data collected on a CMS-selected sample of beneficiaries assigned to the ACO. Ten measures are submitted by the ACO through the CMS Web Interface, 10 are derived from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey as fielded on behalf of each ACO, and 3 are calculated directly by CMS from ACO claims data. Each ACO's quality score is used within the MSSP to determine whether the ACO meets the MSSP quality standard; that standard then is used in determining shared savings and shared losses.[30] The ACO's quality score is further used to assess compliance with the quality-related provisions of its participation agreement with CMS.

Additionally, the ACO's quality score is used within CMS' Quality Payment Program (QPP) when scoring ACO clinicians subject to the Merit-based Incentive Payment System (MIPS) pathway of the QPP (see section IV of this final rule and of this summary for more about the QPP). Many ACO clinicians are scored using the MIPS alternative payment model (APM) scoring standard.[31] Under that standard, MIPS Quality performance category scores of ACO clinicians are based on their ACO's quality scores.

[30] Shared losses apply only to MSSP two-sided risk tracks: Track 1+, Track 2, BASIC track Levels C, D, and E, and the ENHANCED track.

[31] The APM scoring standard applies to clinicians whose ACO tracks 1) are not Advanced APMs (e.g., BASIC track Level A) or 2) are Advanced APMs but the clinician does not reach Qualifying APM Participant (QP) status.

In the 2020 Medicare PFS proposed rule (84 FR 40709 through 40713), CMS requested comments on more closely aligning MSSP quality requirements with those of MIPS. Most comments were negative, and CMS did not proceed with any alignment proposals for performance year 2020.

b. Application of the APM Performance Pathway to MSSP ACOs

(1) Required Reporting

(a) Replacing the MSSP CMS Web Interface Quality Measure Set with the APP Measure Set

In the proposed rule, CMS restated its interest in more closely aligning MSSP and MIPS quality provisions and proposed to do so by requiring MSSP ACOs to utilize the Alternative Payment Model (APM) Performance Pathway (APP) for quality reporting and scoring beginning with performance year 2021.[32] The APP-based quality score would be used both for quality scoring of ACO overall performance by CMS and for quality category scoring of ACO clinicians under the MIPS APM scoring standard. As proposed, the APP contains 6 measures for which data would be collected from all patients treated by the ACO: 3 reported by ACOs, 2 claims-based, and one summative CAHPS measure. CMS proposed that required reporting through the APP would begin with performance year 2021. Relatedly, the CMS Web Interface would be terminated and the APM scoring standard would sunset, beginning with performance year 2021.[33]

Some commenters supported the burden reduction offered by a smaller measure set, but most commenters voiced concerns about the proposal to totally replace the current MSSP ACO quality measure with the APP measure set. The most common objections offered were related to the time, effort, and cost entailed in transitioning to new measures and reporting processes, particularly in the context of the ongoing COVID-19 PHE. Commenters also questioned the rationale for altering the quality policies of a total cost-of-care program (MSSP) to more closely align with those of a FFS program (MIPS), if CMS is committed to incenting value-based rather than volume-based care delivery within Medicare. Others worried that a small measure set is more easily adversely impacted by random variation in a single measure. Many commenters requested CMS delay implementation and gather more stakeholder input.

CMS responds that the measures chosen are broadly applicable to the primary care focus of the MSSP and goes on to conclude that commenters were most concerned about the 2021 start date for required APP-based reporting. To address timeline concerns, CMS finalizes with modifications the proposed replacement of the MSSP Web Interface measure set with the APP measure set beginning with performance year 2021, as described below:

- *For performance year 2021*, the ACO must choose to report either the 10 CMS Web Interface measures or the 3 APP-specified measures, and
    - Fields the CAHPS for MIPS survey (scored as 1 measure); and
    - Is assessed on 2 administrative claims-based measures, as calculated by CMS.

[32] The APP would also be available, but optional, for use by all MIPS APMs other than the MSSP.
[33] These two proposals are discussed with the QPP in section IV of the rule and of this summary.

- *For performance year 2022 and subsequent performance years*, ACOs must report the 3 APP-specified measures, and
    - Field the CAHPS for MIPS survey (scored as 1 measure); and
    - Be assessed on 2 administrative claims-based measures, as calculated by CMS.

(b) APP Measure Set Design Issues

Measure Mix. The proposed APP quality measure set includes 3 clinical care measures, 2 utilization measures, and a patient experience of care survey (CAHPS for MIPS). Multiple commenters questioned whether this distribution of measure type appropriately assesses MSSP ACOs; specific concerns included overweighting of utilization measures and imbalance of outcome and preventive measures. CMS responds that the APP measure mix samples areas on which ACO attention should be focused but it is not intended to do so exhaustively.

Technical Issues. Commenters asked whether the measures and collection types adequately accommodate care delivered via telehealth. CMS responds that nearly all of the CMS Web Interface and APP measure sets capture telehealth encounters. Commenters noted that CMS does not make publicly available detailed measure specifications for CAHPS and for some claims-based measures, to which CMS gives no response. Concerns were voiced about the narrow performance ranges of the APP clinical care measures; CMS notes that the same is true of some CMS Web Interface measures. Commenters suggested that risk adjustment of the APP measures is inadequate and that the hospital readmission measure is too volatile, but CMS disagrees.

Patient Population and Sampling. Multiple commenters raised concerns related to moving from the Web Interface measure patient sample drawn from beneficiaries actually assigned to the ACO, to data collection and scoring of APP measures based on the entire universe of patients treated by the ACO. They stated that the unlimited APP measure patient sample would not fairly reflect ACO quality improvement efforts; legal barriers could affect ACO access to needed data for non-assigned patients; and disparities in reporting could be exacerbated. Other commenters cited increased burden by the required reporting of data on many more patients under the APP and asked that CMS instead require reporting on a sample of the ACO's patients. CMS responds that ACO-wide data reporting is appropriate since ACOs should improve care for all of their patients not simply assigned beneficiaries. Commenters further note that capturing data for all ACO patients will require retooling of their IT systems that will take time and be costly. CMS responds with some suggestions about data export file creation.

Individual Measure Issues. Commenters cited differences in the methodology for the CAHPS for ACOs survey and the CAHPS for MIPS survey and were concerned about the suitability of replacing the former with the latter under the APP. CMS responds that the survey instruments are the same and reports their analysis of 2019 CAHPS results when the CAHPS for MIPS was used to score ACO quality. The ACO quality point distribution was similar to that for MIPS groups who also were scored under CAHPS for MIPS, while the ACO point range was wider than that under CAHPS for ACOs. CMS regards this finding positively, stating that the wider range will expose smaller performance differences between ACOs than does CAHPS for ACOs.

Several commenters opposed inclusion of the Hospital-Wide, 30-day, All-Cause Unplanned Readmission Rate for MIPS Eligible Clinician Groups measure in the APP for reasons including the measure's narrow range, excess sensitivity to risk-adjustment, and large quality score differences resulting from small performance differences. CMS states a belief that the measure will provide a meaningful assessment of ACO quality performance and retains the measure in the APP and states a plan to monitor ACO performance on this measure and adjust if indicated.

ACOs with Atypical Populations. CMS sought comment on an alternative proposal for allowing ACOs that find the APP measures not applicable to their patient populations to opt out of reporting under the APP and report instead directly to MIPS as an APM Entity. CMS received relatively few comments, support for the alternative varied, and CMS takes no related actions.

The finalized APP quality measure set for use by ACOs is shown below.

Final APM Performance Pathway Quality Measure Set for MSSP ACOs*					
Measure #	**Measure Title**	**Collection Type**	**Submitter Type**	**2021 Only[1]**	**Begin 2022[1]**
Quality ID: 321	CAHPS for MIPS	CAHPS Survey	Survey vendor	X	X
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	CMS Claims	N/A (CMS Calculated)	X	X
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	CMS Claims	N/A (CMS Calculated)	X	X
Quality ID: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 318	Falls: Screening for Future Fall Risk	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 110	Preventive Care and Screening: Influenza Immunization	Web Interface	ACO/Third Party Intermediary	B	N/A

Final APM Performance Pathway Quality Measure Set for MSSP ACOs*					
Measure #	**Measure Title**	**Collection Type**	**Submitter Type**	**2021 Only[1]**	**Begin 2022[1]**
Quality ID: 226	Preventive Care and Screening Tobacco Use: Screening and Cessation Intervention	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 113	Colorectal Cancer Screening	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 112	Breast Cancer Screening	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 370	Depression Remission at Twelve Months	Web Interface	ACO/Third Party Intermediary	B	N/A
* Table created by HPA from the preamble Tables 39 and 40 and section G.1.b(1) narrative					
[1] Legend for reporting requirements by performance year: X: Required for reporting along with A measures or A+B measures for performance year 2021 Required for reporting with A measures for performance year 2022 and subsequent years A: May be reported together with X measures as one option for performance year 2021 B: May be reported together with X measures and A measures for performance year 2021 N/A: No longer available for satisfying MSSP ACO required reporting					

(2) Quality Scoring under the APP

Pay-for-Reporting (P4R). Currently, all required quality measures are scored as P4R for MSSP ACOs within the first performance year of their first participation agreement period (first-year ACO transition year). As a result, first-year ACOs receive a quality score of 100 percent if they report fully and completely on all measures. Also, new and substantially revised measures are designated as P4R during a two-year phase-in period, after which they move to pay-for-performance (P4P) scoring. Finally, CMS retains the right to revert any measure to P4R status for reasons such as unexpected measure performance or potential patient harm by its use.

CMS proposed to terminate the new ACO transition year P4R scoring since the APP framework aligns MSSP with MIPS scoring and there is no comparable P4R transition provision in MIPS. Commenters objected, citing time needed for new ACOs to build out their quality improvement processes and the potential deterrent to ACO participation of eliminating the transition year. CMS is persuaded by commenters and finalizes a modified proposal beginning with January 1, 2022. MIPS scoring policies would be applicable to all ACOs for the APP's 3 clinical measures, but first-year ACOs would be required only to meet MIPS data completeness and case minimum

requirements on those measures (and field the CAHPS for MIPS survey) to meet the ACO quality standard.

CMS also proposed to terminate the P4R phase-in period for new measures as part of aligning MSSP and MIPS quality policies. Commenters cited the phase-in period benefits of time for large-scale real-world testing of new measures for unanticipated issues and time for workflow and operations adjustments. CMS is not persuaded and finalizes terminating the P4R phase-in period as proposed effective with the implementation of APP reporting by MSSP ACOs.

Pay-for-Performance (P4P). Currently, all required quality measures reported by MSSP ACOs are scored as P4P other than as described above. During P4P scoring, ACO performance is compared to a historical MSSP benchmark, converted to a percent or percentile rating, from which performance points and quality improvement points are derived. P4P scoring is done first within each quality domain, after which the (equally-weighted) domain total scores are summed to the final ACO Quality Score. Incomplete reporting on any measure will result in zero points being awarded to the ACO for all CMS Web Interface measures (all-or-nothing scoring).

Under the proposed APP framework for MSSP ACOs, all quality measures are scored as P4P using MIPS policies and methodology. Measures are not grouped into domains. Each measure that meets data completeness and case minimum requirements receives 3-10 points after comparison to a MIPS-based benchmark, and MIPS policies for improvement and bonus points would be applicable. Measures not reported would receive zero points (i.e., all-or-nothing scoring is eliminated). However, an ACO that fails to report any of the APP's 3 clinical measures and does not field a CAHPS for MIPS survey would not meet the MSSP quality performance standard. CMS received no comments and finalizes the policy that the quality standard is not met if the ACO does not report APP clinical measures and field a survey.

ACO Clinician Reporting Outside the ACO. The MSSP ACO normally reports quality data to the QPP on behalf of its clinicians. CMS discusses available options should the ACO fail to report. ACO participants could report for their clinicians outside of the ACO (e.g., at the TIN level); if they do so using the APP framework, the reweighting of the MIPS cost category to zero percent and full credit given for the Improvement Activities category would apply. If the ACO participant reports for its clinicians other than under the APP, the cost reweighting and improvement activities credit would not apply. CMS refers readers to Section IV.A.3.c.5 of the rule for a detailed discussion of generally applicable policies for reporting outside of the APP.

c. Shared Savings Program Quality Performance Standard

The MSSP Quality Performance Standard establishes for ACOs the minimum performance level necessary at which they may share in any savings earned, have shared losses mitigated, and avoid quality-related compliance actions. The standard currently requires first that for all performance years, all ACOs must completely and accurately report all quality data used to calculate and assess their quality performance (P4R and P4P). Second, the standard requires that for shared savings eligibility, ACOs must meet minimum attainment for P4P measures, defined as 30 percent or the 30th percentile of the performance benchmark on at least one measure in each domain.

In concert with requiring ACOs to report under the APP, CMS proposed to raise the quality standard from the current 30th percentile on at least one measure in each domain to the 40th percentile across all MIPS Quality performance category scores.[34] Support varied, with many opposed, and alternate specific standards were suggested. Many commenters urged delayed implementation of any changes. CMS clarifies that the QP status of ACO clinicians and any associated APM incentive payments would not be affected by the higher standard. CMS also cites its internal analysis of 2019 data showing nearly 99 percent of ACOs met the current standard as evidence for the propriety taking the quality standard to a higher level. CMS also clarifies that the ACO would not be required to meet the 40th percentile for each APP measure but across the APP measures in aggregate; aggregation details are not provided.

CMS acknowledges the potential challenges of implementation for performance year 2021, especially given the ongoing COVID-19 PHE, and finalizes their proposal with a modified timeline. An MSSP ACO will meet the quality performance standard if:

- *For performance years 2021 and 2022*, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and
- *For performance year 2023 and subsequent performance years*, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

CMS further finalizes that:

- For performance year 2021. If an ACO does not report any of the ten CMS Web Interface measures or any of the three APP clinical measures and does not field a CAHPS for MIPS survey, the ACO will not meet the quality performance standard
- For performance year 2022. If an ACO does not report any of the three clinical measures via the APP and does not field a CAHPS for MIPS survey, the ACO will not meet the quality performance standard.
- For performance years 2023 and subsequently. If an ACO does not report any of the three APP clinical measures and does not field a CAHPS for MIPS survey, the ACO will not meet the quality performance standard.

As previously described above (section G.1.b.(2) of this summary), CMS finalized that ACOs in their first performance year of their first performance agreements would be required only to meet MIPS data completeness and case minimum requirements on the APP clinical measures and field the CAHPS for MIPS survey to meet the ACO quality standard for that year (see §425.512(a)(2)).

Finally, CMS proposed to add a provision for performance year 2021 and subsequent years, to require that ACOs must submit quality data via the APP (i.e., instead of the CMS Web Interface) to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO

[34] Providers eligible for facility-based scoring are excluded and scored under specific MIPS policies (see §414.1305).

participant for purposes of the MIPS Quality performance category. CMS received no comments and finalizes this addition.

The Quality Performance standard and timeline for changes is shown below.

MSSP Final Policy Quality Reporting Standard with Timeline by Performance Year (PY)			
	PY 2021	**PY 2022**	**PY 2023 and subsequent**
Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th percentile** across all MIPS Quality performance category scores	Same as PY 2021	A quality performance score that is equivalent to or higher than the **40th percentile** across all MIPS Quality performance category scores
Quality Performance Standard Standard Met	ACOs are eligible to share in savings at maximum sharing rate; on two-sided tracks losses, if any, are reduced per track policy	Shared savings and loss determinations same as PY 2021	Shared savings and loss determinations same as PY 2021

Table 39 in the rule as modified by HPA

d. Shared Savings and Shared Loss Determinations

Currently, to be eligible to receive shared savings, MSSP ACOs on all tracks must meet the ACO quality performance standard, with amounts determined by the terms of its track (or level within the track). For ACOs bearing two-sided risk (Track 1+, Track 2, the ENHANCED Track, and BASIC Track Levels C, D, and E), their shared loss amounts are determined by the terms of their tracks and the amount owed may be mitigated by their quality scores.

In keeping with the proposed changes to the MSSP ACO Quality Standard, CMS also proposed changes to the policies governing shared savings and loss determinations to begin January 1, 2021. First, to receive shared savings an ACO must:

- Meet the minimum savings rate requirements for its track;
- Satisfy the terms of the new quality performance standard; and
- Maintain its eligibility to participate in the MSSP.

CMS received no comments on this proposal and finalizes it without modifications.

Second, CMS also proposed to revise the final sharing rate provisions for all ACO tracks to state that if an ACO meets the MSSP quality performance standard, ACO would share in savings at the maximum rate allowed under their track. An ACO failing to meet the quality standard would not be eligible to share in savings.

Support from commenters about the shared savings proposals was variable. Some viewed the enhanced potential for larger rewards while others opposed the all-or-nothing nature of the proposal for applying the maximum shared savings rate whenever an ACO meets the quality performance standard. Supporters of sliding scale shared savings rates believe the latter reduces risk of missing out on shared savings upon which some ACOs count to underwrite the ACO's care coordination activities and infrastructure, particularly if the new 40th percentile standard must be met for each reported measure. Others recommended bonuses for high performers or for substantial improvement by an ACO over time.

CMS responds that the shared savings provisions would reduce burden by their simplicity and increase the number of ACOs that earn the maximum shared savings rate. CMS notes that improvement would be factored into APP measure scoring and that the new quality performance standard as finalized will be phased in over 3 years. CMS proceeds to finalize the shared shavings proposals

Third, CMS proposed to modify the shared loss determination methodology applicable to Track 2 and ENHANCED track ACOs to reflect the changes to the quality performance standard. The shared loss rate for an ACO meeting the new quality standard would be determined as follows:

- **Step 1**: Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- **Step 2**: Calculate the product of the quotient described in step 1 and the sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.
- **Step 3**: Calculate the shared loss rate as 1 minus the product determined in step 2. Shared losses rates may not exceed 60 percent nor be less than 40 percent for Track 2 ACOs and may not exceed 75 percent nor be less than 40 percent for ENHANCED track ACOs.

CMS further proposed that for Track 2 and ENHANCED track ACOs that fail to meet the quality standard, the maximum loss rate would apply: 60 percent for Track 2 and 75 percent for the ENHANCED track, respectively. Finally, technical and conforming changes were proposed for clarity and to maintain the current shared loss policy for these ACO tracks for performance years 2020 and earlier.

Few comments were received about the proposed shared loss policy changes and they were generally supportive. CMS, therefore, finalizes the proposals without modification.

e. Compliance with the Quality Performance Standard

A Shared Savings Program that fails to meet the quality performance standard may be subject to adverse actions, including a warning letter, a corrective action plan, and termination from the program. Beginning with 2021, CMS proposed to identify ACOs that may be subject to termination for noncompliance with the quality according to the following:

- The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

- The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.
- A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period, and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.
- A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

CMS notes that a warning letter may precede termination along with requiring the ACO t submit a corrective action plan. CMS further notes that a terminated ACO on a two-sided risk track would become liable for a prorated share of any shared losses accrued during the year of termination. Termination also would have consequences for ACO clinicians, who could lose their QP status. The few comments received were split between support and opposition of the proposed changes. CMS disagrees that a "gross negligence" standard should be used when assessing failure to meet the quality standard. CMS finalizes the compliance policy changes as proposed without modifications.

f. Updating the Process Used to Validate ACO Quality Data Reporting

The current audit process used by CMS to validate MSSP ACO quality data is conducted in a single phase. An ACO selected for audit must provide relevant beneficiary medical records data as reported to CMS by the ACO. CMS calculates an overall match rate, defined as: Total number audited records with information matching that submitted by the ACO via the CMS Web Interface / Total number of records audited. The match rate is linked to CMS actions as follows:

- Match rate 90 percent or above – the ACO passes the audit, no action taken by CMS;
- Match rate above 80 percent and below 90 percent – CMS may request a corrective action plan (CAP) be submitted by the ACO to CMS;
- Match rate less than 80 percent – CMS adjusts the ACO's quality score proportional to the match rate, which may affect the ACO's reconciliation and shared savings and losses.

As part of aligning MSSP and MIPS quality-related policies, CMS proposed to replace the current ACO audit process with the MIPS Data Validation and Audit (DVA) process, since ACOs will be required to report the three clinical APP measures, which are MIPS measures. The single audit process would satisfy both MSSP and MIPS audit purposes for ACOs and be implemented January 1, 2021.

The few comments received were supportive. CMS finalizes its proposal as part of new section §425.510, such that CMS retains the right to audit and validate ACO quality data reporting according to the MIPS DVA process at §414.1390.

g. Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2021

CMS finalizes its proposal, with modification, to update the extreme and uncontrollable circumstances policy under the MSSP consistent with its proposal to align the quality reporting requirements for MSSP with the APP. CMS modified its proposal to allow for a gradual phase-in of the threshold for quality performance standard. Specifically, for performance year 2021 and 2022, CMS will set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year to equal the 30th percentile MIPS Quality performance category score. CMS will use the higher of the ACO's MIPS Quality performance category score or the 30th percentile MIPS Quality performance category score. For performance year 2023 and subsequent years, CMS will set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year to equal the 40th percentile MIPS Quality performance category score. CMS will use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score.

CMS also finalizes its proposal to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries rather than the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. Under the revisions to the quality reporting requirements, CMS will no longer generate a CMS Web Interface quality reporting sample.

CMS also sought comment on a potential alternative extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years that it did not adopt in the final rule. Under this alternative approach, CMS would have determined shared savings for an affected ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track (or payment model within a track) by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

Commenters had mixed reactions to CMS' proposal to modify the extreme and uncontrollable circumstances policy. While some favored the new approach, others expressed concern about the number of changes that have occurred on this policy in recent years making it more difficult for health care providers to adjust to these policy changes. Some suggested that CMS allow more time to examine the impacts of the PHE for COVID-19 before proceeding with any changes to this policy for performance year 2021 and subsequent years. In response, CMS notes that it is modifying its proposal and will align the extreme and uncontrollable circumstances policy with the gradual phase-in of the quality performance standard, which should offer more protection for ACOs, while still incentivizing reporting. CMS states that it will continue to consider feedback as it plans for future updates and changes to the extreme and uncontrollable circumstances policy.

h. Technical Changes to Incorporate References to Revised Quality Performance Standard

CMS makes certain technical, conforming changes to the following provisions to reflect its finalized proposals to add new sections of the regulations at §425.510 on the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021, and §425.512 on determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. These are discussed in detail in the final rule.

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

a. HCPCS and CPT Codes Used in Assignment

(1) Background

CMS reviews the history of how beneficiary assignment has evolved since the November 2011 rule (76 FR 67853), which established the initial list of primary care services used for assignment. For performance years beginning on January 1, 2019, and subsequent performance years, CMS defined primary care services in §425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under §425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

- 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).
- 99304 through 99318 (codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded).
- 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).
- 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).
- 99487, 99489 and 99490 (codes for chronic care management).
- 99495 and 99496 (codes for transitional care management services).
- 99497 and 99498 (codes for advance care planning).
- 96160 and 96161 (codes for administration of health risk assessment).
- 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).
- 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

HCPCS codes:

- G0402 (the code for the Welcome to Medicare visit).
- G0438 and G0439 (codes for the annual wellness visits).
- G0463 for services furnished in ETA hospitals.
- G0506 (code for chronic care management).
- G0444 (codes for annual depression screening service).

- G0442 (code for alcohol misuse screening service).
- G0443 (code for alcohol misuse counseling service).

CMS notes that in the May 8th COVID-19 IFC (85 FR 27582 through 27586), it revised the regulations to add §425.400(c)(2) to add specified codes for remote evaluations, virtual check-ins, e-visits, and telephone evaluation and management services.

(2) Revisions

Based on feedback from ACOs and further review, CMS now believes that changes are needed to the definition of primary care services used in MSSP assignment. CMS finalizes its proposal, to revise the definition of primary care services in its regulations with modification to include G2010 and G2012 in the definition of primary care services used in assignment. CMS finalizes this definition in a new provision of the regulations at §425.400(c)(1)(v), which includes the HCPCS and CPT codes specified in § 425.400(c)(1)(iv), as well as the following additional codes, and limitations on the use of certain codes:

- Online digital E/M CPT codes 99421, 99422, and 99423;
- Assessment of and care planning for patients with cognitive impairment CPT code
- 99483;
- Chronic care management code CPT code 99491;
- Exclusion of advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting;
- Remote evaluation of patient video/images HCPCS codes G2010;
- Virtual check-in HCPCS code G2012;
- Non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439 as finalized elsewhere in this final rule;
- Principal care management HCPCS codes G2064 and G2065; and
- Psychiatric collaborative care model HCPCS code GCOL1, which is being finalized as HCPCS code G2214, as discussed elsewhere in this final rule.

This revised definition would apply beginning with the performance year starting on January 1, 2021 and apply in subsequent performance years. CMS notes that it did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at §425.400(c) on a permanent basis because these are non-covered services when not provided during the PHE for the COVID-19 pandemic.

Most commenters were generally supportive of CMS' proposals regarding the expansion of the definition of primary care services for purposes of assignment in the Shared Savings Program regulations. Comments indicated, for example, that the PHE for COVID-19 has led healthcare providers to expand their provision of services via telehealth. CMS also received comments in favor of the permanent addition of the remote evaluation of patient video/images (G2010) and virtual check-in (G2012) HCPCS codes to the MSSP definition of primary care services used for assignment, beginning with performance years 2021 and CMS' proposal to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient setting. In its

reply, CMS stated that it was persuaded that healthcare providers will continue to provide the services identified by G2010 and G2012 and that there will continue to be an uptake of services identified by these codes in lieu of an in-person primary care visit by the beneficiary even after the end of the PHE. CMS also agrees with commenters that advance care planning codes when used in an inpatient setting should not be used in assignment.

b. Exclusion from Assignment of Certain Services Reported by FQHCs or RHCs When Furnished in SNFs.

Concerns were raised by ACOs that CMS' methodology for excluding primary care services billed under CPT codes 99304 through 99318 from use in beneficiary assignment when provided during a beneficiary's stay in a SNF does not apply to these services when billed by FQHCs. CMS agrees with commenters that this policy will allow for more accurate assignment of beneficiaries. Thus, CMS finalizes its proposal to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. Operationally, the exclusion will occur when the following conditions are met:

(1) Either a professional service is billed under CPT codes 99304 through 99318, or an FQHC/RHC submits a claim including a qualifier CPT code 99304 through 99318; and
(2) A SNF facility claim is in its claims files with dates of service that overlap with the date of service for the professional service or FQHC/RHC service.

3. Reducing the Amount of Repayment Mechanisms for Eligible AOCs.

a. Background

An ACO that will participate 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 §25.204(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).

b. Revisions

CMS finalizes its proposal to establish two policies that would allow certain ACOs to benefit from a lower repayment mechanism amount than would otherwise be required under the current regulations. The first policy applies prospectively to any renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program to use an existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in its new agreement period. The second policy permits certain ACOs whose agreement periods began July 1, 2019 or January 1, 2020 to elect to reduce the amount of their repayment mechanisms.

Under this approach, a renewing ACO and a re-entering ACO that is the same legal entity as an ACO that previously participated in the program that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period will be required to have a repayment mechanism amount equal to the lesser of the following: (1) 1 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) 2 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. As specified in the May 8th COVID-19 IFC, CMS is forgoing the application cycle for the January 1, 2021 start date. Therefore, this policy for determining the repayment mechanism amount for renewing ACOs will apply with the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

CMS believes that there is minimal risk to the agency with such a policy. Based on its experience, nearly all ACOs fully repay shared losses without use of their repayment mechanisms. CMS considered, but did not adopt a policy that would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available.

CMS also finalizes its proposed policy at §425.204(f)(4)(iv)(B), which grants a one-time opportunity for an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO’s new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount.

CMS also finalizes in §425.204(f)(4)(iv)(B) that CMS will notify an eligible ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism. The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with its requirements. CMS is not finalizing a 30-day deadline in regulation text, though its states it may revisit this issue.

CMS also amends §425.04(f)(5) regarding the replenishment of funds available through the repayment mechanism) to specify that the resulting amount available through the repayment mechanism after replenishment must be at least the amount specified by CMS in accordance with §425.04(f)(4).

CMS finalizes technical changes to §425.04(f)(3)(iv) and its proposal to revise §425.04(f)(3)(i) through (iii) to ensure that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

Many commenters expressed support for CMS' proposal to eliminate the requirement that renewing ACOs that wish to continue use of their existing mechanism maintain the higher repayment mechanism amount in their subsequent agreement period, when a lower amount is calculated at the time of renewal application. Commenters were also supportive of CMS' proposed approach that provides a one-time opportunity for eligible ACOs whose agreement periods began July 1, 2019 or January 1, 2020 to elect to reduce the amount of their repayment mechanisms. Some commenters supported a policy that would allow more frequent/annual repayment mechanism decreases, if applicable. Commenters also expressed concerns that securing a repayment mechanism is a regulatory burden and urged CMS to take additional steps to minimize burdens on ACOs associated with repayment mechanism requirements. In response, CMS agrees with the commenters support of its proposed policies. It does not favor commenters' suggestions to establish a policy to allow for annual repayment mechanism decreases by all two-sided model ACOs, as this goes beyond the scope of the modifications proposed. CMS notes that it will continue to examine these issues and may revisit in future notice and comment rulemaking.

4. Applicability of Policies to Track 1+ Model ACOs

CMS states that unless specified otherwise, the changes to the MSSP regulations in this final rule that are applicable to MSSP ACOs within a current agreement period would apply to ACOs in the Track 1+ Model (unless the requirement has been waived). Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model Participation Agreement, any changes to those regulations would also apply to Track 1+ Model ACOs. CMS list these changes and how they apply to Track 1+ Model ACOs in the final rule.

H. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

Effective January 1, 2021, Medicare will cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment. Prior to furnishing home infusion therapy, the physician who establishes the plan of care is required to notify the beneficiary of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy.

CMS solicited comments on the notification requirement in the 2020 PFS and home health (HH) proposed rules. Comments were summarized in each respective final rule and taken into consideration in developing the policies being announced in this rule and the 2021 HH rule. Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning in 2021, CMS indicates that physicians are to continue with the current practice of discussing options available for furnishing infusion therapy

under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. Public comments supported CMS' policy that it is continuing without change.

I. Modifications to Quality Reporting Requirements and Comment Solicitation on the Extreme and Uncontrollable Circumstances Policy for Performance Year (PY) 2020

1. Changes to Extreme and Uncontrollable Circumstances Policy for ACOs in PY 2020.

Under the current extreme and uncontrollable circumstances policy, as modified in the March 31st COVID-19 IFC, ACOs physically located in an area affected by an extreme and uncontrollable circumstance and which has 20 percent of its assigned beneficiaries residing in an area affected by an extreme and uncontrollable circumstance will have their quality performance score set equal to the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year. However, if the ACO completely and accurately reports all quality measures, CMS uses the higher of the ACO's quality performance score or the mean quality performance score.

In the March 31st COVID IFC, CMS made changes to the Part C and Part D Star Rating system out of concern that the COVID-19 pandemic would pose significant challenges and safety concerns in completing the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. The quality measure set for the Shared Savings Program 2020 PY includes 10 measures collected through the CAHPS for ACOs survey. The PY 2020 CAHPS for ACOs sample frame will be constructed based on primary care visits among assigned beneficiaries from July 2019 through July 2020.

CMS is now concerned that the primary care experience of beneficiaries during the July 2019 through July 2020 period will be impacted by the COVID-19 PHE. Fewer beneficiaries are seeking primary care, and among those using primary care there may be shifts in the types of care provided because of the PHE. These shifts could introduce non-random differences in the patient pool in 2020 as compared to prior years.

In response to these potential negative effects on the size and generalizability of the survey sample, CMS finalizes its proposal to waive the CAHPS for ACOs reporting requirement for PY 2020 and to assign all ACOs automatic credit for each of the CAHPS survey measures within the patient/caregiver experience domain. CMS adopts the proposed amendments at §425.500(d) without modification. Most commenters supported CMS' proposal citing inadequate sample size, an inability to generalize results of the survey due to safety measure implemented during the PHE for COVID-19, reduction of burden on Medicare ACO beneficiaries, and concerns that paper surveys were not a sanitary choice for gathering feedback.

2. Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for PY 2020

CMS sought feedback on a potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for PY 2020. Instead of providing full points credit for the CAHPS for ACOs measures, CMS could, for ACOs that completely report quality data, use the higher of the ACO's 2020 quality performance score or its 2019 quality performance score.

In the proposed rule, CMS cited the potential advantages of such an approach. It could help to mitigate the impact of the PHE for COVID-19 on ACOs that report and could incentivize reporting by new ACOs that would receive 100 percent if they were to complete quality reporting. CMS also cited data on the high percentage of ACOs reporting quality data for PY 2019 despite having been impacted by the PHE for COVID-19 during the 2019 reporting period.

Specifically, CMS sought feedback on the following potential approaches for PY 2020:

(1) If an ACO in a second or subsequent performance year completely and accurately reports the CMS Web Interface measures for performance year 2020, the ACO would receive the higher of its performance year 2020 ACO quality performance score that would include automatic full credit for the CAHPS for ACOs survey measures, or the score used in 2019 for purposes of financial reconciliation. For re-entering ACOs that terminated in their second or subsequent agreement period, the ACO would receive the higher of its most recent prior ACO quality performance score or its 2020 quality performance score.

(2) If an ACO in a second or subsequent performance year or a re-entering ACO that terminated in its second or subsequent agreement period does not completely and accurately report the CMS Web Interface measures for performance year 2020, the ACO would receive the 2020 ACO mean quality performance score.

(3) If an ACO in its first performance year in the program or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period completely and accurately reports the CMS Web Interface measures, it would receive a quality performance score of 100 percent that reflects automatic full credit for the CAHPS for ACO survey measures.

(4) If an ACO in its first performance year or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period, does not completely and accurately report the CMS Web Interface measures for performance year 2020, it would receive the 2020 mean ACO quality performance score.

Many commenters urged CMS to make all ACO quality measures pay-for-reporting in PY 2020 stating, among other reasons, that the current extreme and uncontrollable circumstances policy was better suited for local disasters, such as hurricanes or floods. In addition, while many commenters supported the alternative approach of assigning the higher of the ACO's 2019 or 2020 quality scores for ACOs that report quality, they explained that they consider this a

"fallback option" and that they would prefer CMS to convert all measures to pay-for-reporting for PY 2020 due to the impact of the PHE for COVD-19.

In its reply, CMS states that it believes that its current extreme and uncontrollable circumstances policy, in addition to giving ACOs automatic full credit for the CAHPS for ACOs survey measures, will mitigate the negative effects of the PHE for COVID-19 on quality performance for performance year 2020. It does not believe that it is necessary to make PY 2020 a pay-for-reporting year. Accordingly, pursuant to the current regulation at §425.502(f)(2), ACOs will have their quality performance score set to equal the mean quality performance score for all Shared Savings Program ACOs for performance year 2020. However, if an ACO completely and accurately reports all CMS Web Interface measures during the quality reporting period, CMS will use the higher of the ACO's quality performance score for performance year 2020 or the mean quality performance score for performance year 2020 for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

3. Changes to Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy Provision adopted in the March 31st COVID-19 IFC

As discussed above, in the March 31st COVID-19 IFC, CMS modified the Shared Savings Program extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended (85 FR 19267 through 19268).

Commenters believed that this was a thoughtful approach to addressing the quality submission challenges resulting from the PHE for COVID-19 and welcomed this change. CMS finalizes, without modification, the revisions that were made to the regulation at §425.502(f) in the March 31st COVID-19 IFC to remove the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended.

J. Removal of Selected National Coverage Determinations

In 2013, CMS established procedures for requesting a National Coverage Determination (NCD) or reconsideration of an existing NCD (78 FR 48164). CMS also established an expedited administrative process, using specific criteria, to remove NCDs older than 10 years. CMS may consider an older NCD for removal if, among other things, any of these circumstances apply:

- CMS believes that allowing local contractor discretion to make a coverage decision better services the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.

- The national policy does not meet the definition of an "NCD" as defined in sections 1862(l)[35] or 1869(f)[36] of the Act.
- The benefit category determination is no longer consistent with a category in the Act.

CMS notes that the process of removal does not result in an NCD as defined in sections 1869(f) and 1862(l) of the Act because there would not be any uniform national decision about whether or not a particular item or service is covered. Instead, the initial coverage decision would be made by the local contractors.

CMS previously removed NCDs in 2013 and 2015. Because of the Supreme Court's decision in Azar v. Allina Health Services[37], CMS decided to use the notice and comment rulemaking procedures described in section 1871(a)(2) of the Act to remove outdated or unnecessary NCDs.

Table 41, reproduced below, list the nine NCD's CMS proposed to review. This list is based on CMS' review, request 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.[38]

Table 37: Proposed NCDs for Removal	
NCD Manual Citation	**Name of NCD**
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatability Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

Comments/Responses: Many commenters generally supported CMS' proposal to periodically identify and remove outdated NCDs and thought that rulemaking was a transparent way to gather input from stakeholders. CMS clarifies that it is not required nor did it propose to use rulemaking to establish or change a particular NCD. CMS also clarifies that Medicare Advantage (MA)[39] plans are required to comply with LCD in the geographic area where the MA plan provides coverage. MA plans have the option to comply with the LCD that provides the most beneficial

[35]Section 1862(l) of the Act describes the national and local coverage determination process.
[36] 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.''
[37] Azar v. Allina Health Services, 587 U.S. ——, 139 S. Ct. 1804 (2019)
[38] The manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items?CMS014961.
[39] MA program regulation at 42 CFR 422.101(b)

coverage to the plan's enrollees in cases where the MA plan service area includes more than one LCD area.[40]

In response to CMS' request for other reasons for supporting the removal of an NCD, a number of commenters supported the continued use of the factors CMS uses. Other commenters identified other factors for CMS to consider, including evidence-based professional society guidelines. CMS appreciates the comments it received and will consider these comments as it considers removal of additional NCDs. CMS does not intend to establish an exclusive list of criteria as decisions may depend on the particular changes in medical practice over time.

CMS discusses the comments received about the 10 year time-threshold for identifying older NCDs for evaluation for potential removal. A number of commenters stated that a specific time threshold is arbitrary and does not reflect the rapid evolution of medical care. Other commenters suggesting time frames ranging from annual review, 3 years. 5 years, 7 years to 10 years. CMS appreciates these suggestions and will consider these as it evaluates whether existing NCDs should be removed.

CMS received several comments supporting removal of the following NCDs: NCD 30.4, NCD 100.9, NCD 220.21, NCD 20.5, and NCD 220.616. CMS did not receive any comments about NCD 110.19. CMS will also consider the recommendations for corresponding changes to the claims processing instructions as it implements the removal of these NCDs. CMS notes that implementing the change for NCD 20.5 Extracorporeal Immunoadsorption (ECI) using Protein A Columns requires changes to national coding systems and requires a Change Request (CR) to ensure claims are adjudicated appropriately retroactive back to January 1, 2021.

As recommended by commenters', CMS will modify the NCD manual to ensure that contractors have the authority to make a coverage determination when claims are submitted for PET for Inflammation and Infection. Specifically, CMS will revise the NCD manual section at 2206.16 to remove the current NCD language and replace it with language stating that the MAC has local contractor discretion for coverage determinations for FDG PET for Inflammation and Infection, effective January 1, 2021. In response to request to revise NCD 220.6 to remove the non-coverage language and expand availability of PET for non-oncologic indications at MAC discretion, CMS states that revision requires a reconsideration of the NCD that is beyond the scope of this rulemaking.

CMS received conflicting comments, some supporting and some opposing, each of the following NCDs: NCD 110.14, NCD 190.1, and NCD190.3. Since commenters have contrasting viewpoints on each of these NCDs, CMS needs more time to consider the specific issues raised by commenters and will it decided not to finalize its proposal to remove these NCDs.

Commenters recommended additional NCDs for removal including: NCD 10.5 Autologous Epidural Blood Graft; NCD 90.1 Pharmacogenomic Testing for Warfarin Response; NCD 150.10 Lumbar Artificial Disc Replacement (LADR); NCD 160.22 Ambulatory EEG

[40] Section 1852(a)(1)(C) of the Act with additional guidance in the Medicare Managed Care Manual, Chapter 4, Section 90.

Monitoring, NCD 210.3 Screening Computed Tomography Colonography (CTC) for Colorectal Cancer, and NCD 240.6 Transvenous (Catheter) Pulmonary Embolectomy. In addition, a commenter requested that CMS revise NCD 210.12 Intensive Behavioral Therapy for Obesity to expand the eligible providers able to offer this therapy. CMS will take these suggestions under advisement for future review. Stakeholders can also submit formal requests for reconsideration as outlined on the Medicare Coverage page at https://www.cms.gov/Medicare/Coverage/Determination/Process/howtorequestanNCD.

Final Decision:
CMS finalizes its proposal to remove the following NCD's:

- NCD 30.4 Electrosleep Therapy;
- NCD100.9 Implantation of Gastroesophageal Reflux Device;
- NCD 220.21 Magnetic Resonance Spectroscopy;
- NCD 20.5 Extracorporeal Immunoadsorption (ECI) using Protein A Columns;
- NCD 110.19 Abarelix for the Treatment of Prostate Cancer; and
- NCD 220.616 FDG PET for Inflammation and Infection.

The changes in these finalized policy will be effective on January 1, 2021 (the effective date of this final rule). CMS notes that it typically takes a number of months to implement a change in coverage, and the implementing CR will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the final rule.

CMS does not finalize its proposal to remove the following policies:

- NCD 110.14 Apheresis (Therapeutic Pheresis);
- NCD190.1 Histocompatibility Testing; and
- NCD190.3 Cytogenetic Studies.

K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

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 using the NCPDP SCRIPT 2017071 standard, with certain exceptions specified in the SUPPORT Act as well as any additional exceptions as specified by HHS.

CMS had proposed to amend the timeline for electronic prescribing using the NCPDP SCRIPT 2017071 standard so that instead of beginning January 1, 2021, it would be required as of January 1, 2022. CMS described this delay as necessary to recognize the unique challenges that prescribers are facing during the COVID-19 PHE. Instead of finalizing its proposal, however, CMS instead finalizes requiring that prescribers use the NCPPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances *beginning January 1, 2021*, but finalizes a compliance date of January 1, 2022. Prescribers who do not implement the new standard for electronic prescribing will have until January 1, 2022 before being considered non-compliant.

Background is provided on electronic prescribing including the circumstances under which the Secretary is permitted to waive the electronic prescribing requirement, the increase in electronic prescribing for controlled substances during the COVID-19 PHE, existing Drug Enforcement Agency regulations, the advantages and efficiencies of using electronic prescribing for providers and patients, the current electronic prescribing environment including major differences in access and use of electronic technologies between practices of different sizes and in urban versus rural environments, and the challenges associated with incorporating electronic prescribing.

Most commenters supported requiring the NCPDP SCRIPT 2017071 standard although a few worried that requiring electronic prescribing would worsen the opioid epidemic because physicians could write prescriptions without seeing the patient. CMS states that implementing electronic prescribing standards should not impact the appropriateness of a prescription.

While many prescribers indicated that implementation of the standards by 2021 would not be feasible especially in light of the PHE, CMS points out that nearly 98% of all pharmacies in the US are ready to accept electronic prescribing for controlled substances and that once implemented, it believes electronic prescribing will reduce the burden on prescribers as compared with coordinating and managing paper prescriptions. CMS intends to monitor PDE data to identify any concerning prescribing patterns that may come to light as prescribers come into compliance.

In response to a question about whether the electronic prescribing requirement will apply to the inpatient setting, CMS points out that the requirement applies to all providers who prescribe medications that are Schedule II, III, IV, or V controlled substances that are Part D covered drugs. This generally includes medications dispensed in outpatient pharmacies but may also include medications dispensed to a patient who is being discharged to home from an inpatient or emergency room setting, a long-term care setting, or a Medicare hospice or who is receiving care in the patient's home.

Information Collection Requirements. CMS provides its estimates of the net cost of implementing electronic prescribing requirements in section 2003 of the SUPPORT Act. It expects a net cost of $24.9 million which is comprised of a one-time cost of $27.2 million for providers to implement their initial set-up, establish policies and procedures and train staff. That amount would be reduced by annual savings of $2.3 million reflecting the lower cost of e-prescribing relative to manual prescribing.

L. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

1. Background

The section 505(b)(2) pathway is an FDA abbreviated approval pathway for a new drug application (NDA); it is distinguishable from an abbreviated new drug application (ANDA) used for new generic drugs. A section 505(b)(2) application is an NDA that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for

approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use.

CMS notes that the number of drugs approved using the section 502(b)(2) pathway has increased significantly in recent years. With respect to payment under section 1847A of the Act for Part B drugs that are approved using the 505(b)(2) pathway, CMS considers whether the drug should be assigned to an existing multiple source drug code or to a single source drug code. It believes that the definitions of multiple source drug and single source drug in sections 1847A(c)(6)(C) and (D) of the Act as well as the discretion given to CMS under sections 1847A(b)(3) and (6) of the Act to assign additional drug products to a multiple source drug code provide ample legal authority for its policy to make determinations on whether the drug should be assigned to a multiple source or single source drug code.

In determining whether to assign drugs approved by the FDA using the section 502(b)(2) pathway to an existing multiple source drug billing and payment code, CMS considers several factors, including the active ingredient(s), drug name, and drug description; information in drug labeling; and prescribing and clinical use of the drug.

2. Codify Existing Policy for Section 5050(b)(2) Drug Products

CMS is not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulations text changes for 2021. CMS had proposed to codify what it says has been its approach on this issue for at least 12 years. Specifically, it proposed to add a new paragraph (k) to §414.904 (relating to ASP as the basis for payment of Part B drugs) to specify in regulation both the policy and the factors it uses in making determinations to assign section 505(b)(2) approved drugs to single source drug or multiple source drug billing and payment codes. Additionally, CMS proposed to amend its regulatory definition of a multiple source drug to include a reference to drugs approved through the section 505(b)(2) pathway. CMS noted that it was concerned by higher payments (and higher associated beneficiary copayments) for section 505(b)(2) drugs if they are assigned to unique HCPCS codes despite being described by existing multiple source drug codes.

The agency noted that where a section 505(b)(2) product is not itself therapeutically equivalent, pharmaceutically equivalent, or bioequivalent, as determined by the FDA, to another drug product, CMS would nonetheless consider it to meet the definition of a multiple source drug if, based on an assessment of its active ingredient, labeling, compendia, and other information, the product is described by the code descriptor for an existing multiple source drug code. CMS proposed to assess the section 505(b)(2) drug product's active ingredient(s), drug name, and description, whether its labeling (particularly the prescribing information) includes information from other drug products that are paid under the multiple source drug code; and whether the drug product is used and prescribed in a manner similar to other products in the multiple source drug code. CMS also said it would reevaluate and potentially revise previous payment (and coding) decisions to maintain consistency with its proposed policy.

Commenters, mostly manufacturers, were generally opposed to CMS' section 505(b)(2) drug product proposals and corresponding regulation text changes. They stated that the proposal was contrary to the statute, conflicted with FDA's therapeutic equivalence ratings, would impair access for patients, underpay providers, and dampen innovation. Some commenters wanted CMS

to provide more detail about the framework and the determination process and requested that it delay finalizing the proposal. Other commenters requested additional details, such as how differences in the active ingredient and labeling might be interpreted and which drug products might be affected. CMS is emphatic that it has authority to assign certain section 505(b)(2) drug products to existing multiple source drug codes based on an interpretation of section 1847A of the Act and that its approach does not conflict with previously published program instruction or the FDA's therapeutic equivalency ratings. CMS states, however, that in response to commenters requesting more detail about its proposed approach and requests to delay finalizing a decision, it is not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. CMS states that this will provide time for it to further consider this issue.

3. Regulatory Impact

CMS is not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. There are no impacts for 2021.

M. Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

1. Background

Since 2019, for the QPP and the Promoting Interoperability Programs CMS has required the use of certified EHR technology (CEHRT) certified under the Office of the National Coordinator (ONC) Health Information Technology Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition. Similarly, under the Hospital Inpatient Quality Reporting (IQR) Program hospitals are required to use only the 2015 Edition CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination (83 FR 41607).

The ONC published a final rule modifying the 2015 Edition criteria on May 1, 2020 (85 FR 25642 through 25961). The "21st Century Cures Act final rule" makes revisions to existing criteria and adds new certification criteria that establish the capabilities and related standards and implementation specifications for the certification of health IT (the "2015 Edition Cures Update"). These changes involve technical standards, including an e-prescribing standard required for alignment with other CMS programs, and other technical updates to existing 2015 Edition functionality. For example, 2015 Edition certification criteria that referenced the Common Clinical Data Set (CCDS) regulatory definition were updated to reference instead the United States Core Data for Interoperability (USCDI) standard. (HPA prepared a detailed summary of that final rule.)

The timelines under the 21st Century Cures Act final rule varied; removal of some criteria from the base definition of the 2015 Edition were effective on June 30, 2020. Where the 21st Century Cures Act final rule updated or added new 2015 Edition criteria, developers were generally given until May 2, 2022 (24 months from the publication date of the rule) to make technology available that is certified to the updated or new criteria. Until the specified compliance date, health IT

developers are expected to continue supporting technology certified to the prior version of the certification criteria, and healthcare providers participating in the Promoting Interoperability Programs and QPP may use such technology for the purposes of these programs while working with health IT developers to implement updates in a manner that best meets their needs.

However, ONC subsequently took steps to provide additional flexibility for health IT developers subject to the policies in the 21st Century Cures Act final rule in response to the COVID-19 public health emergency.[41] On November 4, 2020, it published an IFC, which extended compliance dates for certain 2015 Edition certification criteria (85 FR 70064). Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make available technology certified to new or updated criteria (i.e., May 2, 2022), the ONC IFC extended the timeline until December 31, 2022 (and until December 31, 2023 for §170.315(b)(10), "EHI export"). In order to reduce confusion, ONC aligned these dates to the calendar year cycle which also aligns them to the CMS program annual cycle. During this transition period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates.

In this final rule, CMS discusses in detail the specific changes made by the 21st Century Cures Act final rule and the timelines for enforcement. Among them, CMS notes that removal of certain criteria were delayed until January 2022 because they are needed for measures under the Medicaid Promoting Interoperability program, which ends in 2021. Health IT developers are encouraged to retain these criteria through 2021 even as they move forward with other updates.

2. Updates to Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Program, and Quality Payment Program due to the 21st Century Cures Act Final Rule

With respect to the QPP and the Promoting Interoperability Program, CMS finalizes that healthcare providers must use technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the Cures Act final rule as modified by the ONC IFC. That is, for updated and new certification criteria included in the CEHRT definitions in §§495.4 and 414.1305, until December 31, 2022, program participants may use technology certified to either the current 2015 Edition certification criteria or the 2015 Edition Cures Update; that health IT will be considered certified under the ONC Health IT Certification Program. After that date, technology must be certified to the 2015 Edition Cures Update. CMS notes this policy is consistent with prior transitions, such as the period during which providers could use technology certified to either the 2014 Edition or the 2015 Edition, after which certification only to the 2015 Edition was required.

[41] For more information including timeline graphics, see https://www.healthit.gov/curesrule/download and https://www.healthit.gov/curesrule/resources/fact-sheets. Note that the 2021 PFS proposed rule discussed the April 2020 ONC announcement that it would exercise enforcement discretion regarding the 21st Century Cures Act final rule. That announcement was superseded by the new compliance dates finalized in the IFC discussed here.

CMS believes that the December 31, 2022 deadline for use of the 2015 Edition Cures Update provides sufficient time for heath information technology developers to make products available that allow providers to demonstrate meaningful use. It notes that the updates to the eCQM and e-prescribing criteria are already being implemented under existing CMS programs. In addition, CMS believes the required updates to CEHRT for the USCDI standard and Application Programming Interfaces (APIs) will not require substantial redesign of existing clinical and administrative workflows for health IT users. Instead, the ONC final rule impact analysis anticipates that the majority of the burden associated with these updates falls on health IT developers of certified health IT (85 FR 25912).

In addition, CMS believes the transition period allows providers to manage the financial impacts of the PHE for COVID-19 with respect to when they implement and begin using technology updated to the 2015 Edition Cures Update. In many cases, CMS anticipates that the Cures Updates will be implemented by health IT developers as part of routine cyclical updates. Providers are encouraged to refer to the Certified Health IT Product List (CHPL) to identify the specific certification status of a product (https://chpl.healthit.gov/).

CMS discusses how providers can transition to implementing CEHRT that meets the 2015 Edition Cures Update within the 90-day reporting requirement[42] for the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. One transition example offered is using a phased approach that uses a combination of updated and non-updated certified health IT for the 90-day reporting period that ends prior to December 21, 2022 and using only updated health IT modules in 2023. Alternatively, a provider could update everything at once and complete a 90-day reporting period for 2022 using nonupdated health IT, and then use only updated health IT modules in 2023. A provider may also fully move to updated certified health IT for reporting periods prior to December 31, 2022.

CMS emphasizes that a MIPS-eligible clinician need not demonstrate use of updated technology on January 1, 2023; they may choose any 90-day period for 2023, including the last 90 days of the year. Further, readers are reminded that clinicians must report on how many times they used certified technology for the completion of the action defined by each measure, not on their possession of certified technology for the 90-day performance period they have selected.

The availability of hardship exemptions under the Promoting Interoperability Programs for extreme and uncontrollable circumstances, which may include vendor issues or decertified EHR technology, is discussed. Readers are referred to https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship. Providers are encouraged to participate in developing future requirements for CEHRT and are welcome to submit suggestions via the Promoting Interoperability Call for Measures.

Table 42 in the final rule, reproduced below, details the measures for the Promoting Interoperability Program for eligible hospitals and CAHs and the MIPS Promoting

[42] CMS notes that it has not adopted an HER reporting period for the Promoting Interoperability Program for 2023, but says it may consider considering use of a 90-day reporting period in future rulemaking. In the final rule is reiterates that providers do not have to demonstrate use of Cures Update CEHRT on January 1, 2023.

Interoperability performance category along with the 2015 Edition certification criteria that support each measure. (CMS notes that the table only addresses the measures and does not include all the updated certification criteria included in the CEHRT definition and refers readers to the Cures Act final rule for more information (85 FR 25667)). The table has been updated from the proposed rule to reflect addition of the Health Information Exchange (HIE)(alternative) Bi-Directional Exchange measure for the MIPS Promoting Interoperability performance category, as finalized elsewhere in this rule. (See QPP section of this summary.)

CMS notes two provisions for which updates in the 21st Century Cures Act final rule affect information it has provided in past rulemaking regarding the certification criteria which support specific Promoting Interoperability objectives and measures. First, the 21st Century Cures Act final rule is retiring the "drug-formulary and preferred drug list checks" criterion at §170.315(a)(10), which is currently identified as supporting measures under the e-prescribing objective. ONC has finalized that health IT may be certified to this criterion only until January 1, 2022. CMS believe the removal of this criterion from the Certification Program will have negligible impact on healthcare providers because in prior rulemaking providers have noted that the utility of the specific functionality that is certified is not consistently applicable for all prescriptions (80 FR 62833). This certification criterion is no longer associated with the measures under the e-prescribing objective for the Promoting Interoperability Programs and MIPS, beginning with the 2021 reporting and performance periods.

Second, the new API certification criterion, "standardized API for patient and population services" at §170.315(g)(10) requires the use of FHIR Release 4. After December 31, 2022 ONC will retire the current "application access – data category request" at §170.315(g)(8), which is currently identified as supporting the "Provide Patients Electronic Access to Their Health Information" measure. Table 42 shows that either the existing criterion at §170.315(g)(8), or the newly finalized criterion at §170.315(g)(10), may be used by healthcare providers to complete the actions of the "Provide Patients Electronic Access to Their Health Information" measure for the Promoting Interoperability Programs and MIPS during the transition period.

TABLE 42: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§170.315(b)(1) Transitions of care §170.315(b)(2) Clinical information reconciliation and incorporation

TABLE 42: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria		
Objective	**Measure**	**2015 Edition**
Health Information Exchange (alternative)[3]	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§170.315(e)(1) View, download, and transmit to 3rd party §170.315(g)(7) Application access — patient selection §170.315(g)(8) Application access — data category request §170.315(g)(9) Application access — all data request §170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§170.315(f)(4)[1] Transmission to cancer registries §170.315(f)(6)[2] Transmission to public health agencies — antimicrobial use and resistance reporting §170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting[2]	§170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible clinicians, and eligible hospitals and CAHs	§170.315(c)(1) §170.315(c)(2) §170.315(c)(3)(i) and (ii) §170.315(c)(4) (optional)

1 = Specific to Eligible Clinicians (MIPS Promoting Interoperability performance category)
2 = Specific to Eligible Hospitals and CAHs (Promoting Interoperability Programs)
3 = Specific to Eligible Clinicians, finalized in section IV.A.3.c.(4)(c)(ii)(B) of this final rule (MIPS Promoting Interoperability performance category)

CMS also makes technical changes to two definitions under §414.1305 to reflect the previously adopted change in the MIPS performance category name. References to the "Advancing Care Information" performance category would be replaced by the "Promoting Interoperability" performance category in the definitions of CEHRT and Meaningful EHR user for MIPS.

3. Changes to Certification Requirements under the Hospital IQR Program due to the 21st Century Cures Act

For the Hospital IQR Program, beginning with the CY 2020 reporting period/FY 2023 payment determination and for subsequent years, CMS finalizes that hospitals may use either: (1) technology certified to the 2015 Edition criteria for CEHRT as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537-41608), or (2) technology certified to the 2015 Edition Cures Update standards as adopted in the 21st Century Cures Act final rule.

CMS notes that of particular relevance to hospitals that participate in the Hospital IQR Program, the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at §170.315(c)(3) to refer to CMS QRDA Implementation Guides and removes the Health Level 7 (HL7®) QRDA standard requirements. CMS notes that it has in the past encouraged health IT developers to annually test any updates (including any updates to the eCQMs and eCQM reporting requirements for the Hospital IQR Program) based on the CMS QRDA I Implementation Guide for Hospital Quality Reporting, and reports that its data indicate that most Hospital IQR Program participants already use it for submission of eCQMs to the Hospital IQR Program.

Responding to concerns of commenters about the requirement to adopt the 2015 Edition Cures Update, CMS emphasizes the December 31, 2022 compliance date as extended in the ONC IFC, and recommends that readers review the scope of the updates and how this scope was considered in establishing the timelines. The extraordinary circumstances exception (ECE) request process is discussed, and CMS notes that infrastructure challenges or vendor issues outside the control of the hospital are possible qualifying hardships.

N. Establishing New Code Categories

In response to stakeholder's concerns about the variability in bioequivalence between buprenorphine/naloxone products (J0572-J0575), CMS proposed an expanded series of 15 codes to identify these products. Table 43 in the final rule lists the 15 new HCPCS code categories CMS proposed for reporting all currently marketed buprenorphine/naloxone products, based on strength and therapeutic equivalence. CMS also proposed to discontinue four existing codes (Table 44). CMS noted these coding proposals do not change Medicare coverage or payment policies for oral or sublingual buprenorphine codes. The drug products described by these codes are not separately payable under Part B.

Some commenters supported CMS' proposal and other commenters suggested retaining the existing four codes and not finalize the expanded list.

After consideration of this comments, CMS will further consider the appropriate level of coding granularity for buprenorphine/naloxone products and has decided not to finalize its proposal for new code categories. The existing four codes in Table 44 will remain in effect on January 1, 2021.

O. Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

CMS finalizes changes to clarify and add flexibility to MDPP policies applicable during emergency periods.

1. Revisions to §410.79(e).

The March 31st COVID-19 IFC established certain flexibilities for MDPPs applicable during the PHE period, as defined in 42 CFR 400.200. Those flexibilities generally permit MDPPs to use virtual visits and to allow individuals participating in those programs the ability to waive the once per lifetime limit on MDPP services and the weight loss requirement as specified in §410.79(e). MDPP suppliers are also permitted to pause or delay the delivery of services and subsequently resume them.

CMS finalizes its proposal to revise the period during which the flexibilities are available. In addition to being available during the current PHE period, CMS expands them to be available during future emergency periods, and in emergency areas where the Secretary has authorized 1135 waivers where such a waiver event may cause a disruption to in-person MDPP services as determined by CMS.

Under its revised policy, services will be considered to be disrupted when MDPP suppliers are unable to conduct classes in-person or MDPP beneficiaries are unable to attend in-person classes for reasons of health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, avoiding transmission of contagious diseases, complying with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and coaches. CMS will be required to communicate its determination to all impacted MDPP suppliers. CMS states that such notice will include the effective date and the end date which will be either at the end of the emergency period or when in-person services are no longer disrupted.

CMS notes that while the emergency policy permits services to be furnished entirely on a virtual basis, it only permits such services if the supplier had already been authorized to furnish service in person by Center for Disease Control and Prevention's Diabetes Prevention Recognition Program.

CMS also revises the following new emergency policies:

- MDPP suppliers will be permitted to begin new cohorts during the emergency period so long as a baseline weight measurement could be obtained either in person, via digital technology, self-reported using video that documents the weight as it appears on a digital scale, or self-reported via a photograph of their digital scale (added in response to comments).
- In response to comments to provide beneficiaries with additional choices, the final rule includes modifications that support the provision of virtual MDPP services and permit new cohorts to start. Under its revised rules, CMS adds clarifications and identifies four separate sets of choices for beneficiaries based on when they began their MDPP services. (1) Beneficiaries receiving MDPP services as of March 31, 2020 may elect to restart the

set of MDPP services at the beginning or resume with the most recent attendance session of record. (2) Beneficiaries who begin on or after January 1, 2021 and who are in the first 12 months and whose sessions are suspended due to an applicable 1135 waiver event, may elect to restart the set of MDPP services at the beginning, or may resume with the most recent attendance session of record. (3) Beneficiaries who begin on or after January 1, 2021 and who are in the second year and whose sessions are suspended due to an applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the ongoing maintenance interval in which they were participating at the start of the applicable 1135 waiver event, or may resume with the most recent attendance session of record. (4) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record. If services are suspended and subsequently resumed, they may begin again either upon the end date of the 1135 waiver event or upon an effective date specified by CMS.

- Based on comments received in the final rule to allow beneficiaries more choices, CMS modifies its once per lifetime requirement as it will now allow beneficiaries to restart the set of MDPP services at the beginning if the beneficiaries are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event. They may also resume with the most recent attendance session of record. MDPP beneficiaries in the second year of the set of MDPP services as of the start of the applicable 1135 waiver, are not allowed to restart the set of MDPP services at the beginning but would have the option of restarting the ongoing maintenance session interval or resume the set of MDPP services at the most recent attendance session of record.

- Existing rules limit the number of virtual make-up sessions that can be offered during the PHE. (No more than 15 virtual make-up sessions may be offered weekly during months 1 through 6 of the MDPP services period; no more than 6 virtual make-up sessions during months 7 through 12; and no more than 12 virtual make-up sessions monthly during the ongoing maintenance session or months 13 through 24.) CMS eliminates the term "make-up" from the description of those sessions to clarify that all sessions may be offered virtually – they do not need to be "make-up" sessions. The limitations on those virtual visits would also be increased. Under its finalized policy, no more than 16 virtual sessions may be offered weekly during months 1 through 6, no more than 6 virtual sessions offered monthly during months 7 through 12, and no more than 12 virtual sessions offered monthly during the ongoing maintenance session or months 13 through 24.

- CMS eliminates, effective January 1, 2021, the permitted waiver of minimum weight loss requirements during the PHE since CMS finalized its policy that weights could be reported via alternative virtual approaches (described above).

2. Revisions to §424.210

CMS proposed, but does not finalize, adding certain definitions to §424.210. This would have included a section addressing certain definitions such as the engagement period or the time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to an MDPP beneficiary.

The following definitions were proposed but not finalized.

1135 waiver event would be defined as an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized waivers under section 1135 of the Act.

COVID-19 Public Health Emergency is the emergency period and emergency area, as such terms are defined in section 1135(g)(1)(B) of the Social Security Act, related to the COVID-19 pandemic and declared by the Secretary on January 27, 2020.

Engagement incentive period would be defined as the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to an MDPP beneficiary. It begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary, and ends when one of the following occurs, whichever occurs first:

- The MDPP beneficiary's MDPP services period ends,
- The MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier, or
- The MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

After consideration of comments, CMS did not finalize the definition of the engagement incentive period. That provision will continue to specify that the engagement incentive period will end if the MDPP supplier has not had direct contact with the MDPP beneficiary, whether in person, by telephone, or via other telecommunications technology, for more than 90 consecutive calendar days during the MDPP service period. It also believes that the usability requirement is not necessary in light of other requirements set forth at §424.210(b) that requires that the in-kind beneficiary engagement incentive must be reasonably connected to the CDC-approved curriculum furnished to the MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session. Thus, CMS does not finalize the proposed usability requirement nor the proposed definitions of "COVID-19 Public Health Emergency" and "1135 waiver event" proposed at §424.210(b).

Regulatory Impact. CMS updates its estimates of the impact of the MDPP flexibilities established in the March 31st COVID-19 IFC. Under its revisions, MDPP suppliers can continue providing services virtually, pause and restart virtually, or pause and restart after the emergency event ends. It now expects that 20 percent of MDPP suppliers and 20 percent of MDPP beneficiaries will want to restart MDPP services after the emergency period ends. In addition,

2,500 beneficiaries will be impacted in areas where there are future emergencies. The cost per impacted geographic area of the removal of the once-per-lifetime limit is estimated to be $209,000.

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

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless the financial relationship satisfies all requirements of an applicable exception. Section 1877 of the Act also prohibits the entity from submitting claims to Medicare or billing the beneficiary or any other individual or entity for designated health services that are furnished as a result of a prohibited referral.

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

In response to the COVID-19 outbreak, the AMA has established and published new CPT codes on its website to identify currently available SARS-CoV-2 tests (see https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-guidance). As of January 1, 2021, tests for COVID-19 are designated health services.

The AMA has also established and published two new CPT codes to identify each of two COVID-19 vaccines under development, both are included on the Code List as qualifying for the exception at §411.355(h). CMS anticipates new CPT or HCPCS codes will be established to identify additional COVID-19 vaccines as they become available. In order to ensure that any COVID-19 vaccine to which a CPT or HCPCS code applies prior to the publication of the 2022 Code List qualifies for the exception at §411.355(h), CMS is including language in the 2021 Code List to address such vaccines. Specifically, CMS finalizes that the physician self-referral prohibitions does not apply to CPT code 90749 (unlisted vaccine/toxoid) when it used to identify a COVID-19 vaccine or to any future CPT or HCPCS code designated for a COVID-19 vaccine. CMS notes this 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. Coding and billing guidance will be developed as COVID-19 vaccines become available.

The updated comprehensive Code List effective January 1, 2021 is available on the CMS website:
http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

Additions and deletions to the Code List conform to the most recent publications of CPT and HCPCS Level II codes and to changes in Medicare coverage policy and payment status. Tables 67 and 68 in the rule identify additions and deletions to the Physician Self-Referral List. These tables also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in §411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in §411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

VI. Waiver of Delay in Effective Date for this Final Rule

Normally, CMS publishes a final rule at least 60 days prior to its effective date, in accordance with the Congressional Review Act (CRA). In the case of the 2021 PFS final rule, CMS is using its authority under the CRA to waive this requirement because of its work on COVID-19. CMS believes it would be contrary to the public interest to do otherwise. CMS notes that it is providing a 30-day delay in accordance with the Administrative Procedures Act (5 U.S.C. 553(d)) and section 1871(e)(1)(B)(i) of the Social Security Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

VII. Regulatory Impact Analysis

A. RVU Impacts

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

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2020 with payment rates for 2021 using 2019 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 2021, before applying any other adjustments. In addition to the update factor, the CF calculation for 2021 takes into account an RVU budget neutrality adjustment.

The CF for 2021 is $32.4085, which reflects the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act and a budget neutrality (BN) adjustment of -10.20 percent (2020 conversion factor of $36.0896*1.00*0.898). The unusually large BN adjustment results from the revaluing of E/M codes (policies finalized in 2020 and implemented in 2021) and revaluing of certain codes analogous to E/M codes in this year's final rule. Increases to work RVUs also results in increases to PE and MP values for these codes, holding all other factors constant. This BN adjustment is necessarily large because office/outpatient E/M visits comprise nearly 20 percent of PFS allowed charges. See Table 104 from the final rule, reproduced below.

Table 104: Calculation of the 2021 PFS Conversion Factor

Conversion Factor in effect in 2020		**$36.0896**
Statutory Update Factor	0.00 percent (1.0000)	
2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
2021 Conversion Factor		**$32.4085**

The 2021 anesthesia conversion factor is $20.0547, which reflect the same adjustments and an additional adjustment due to an update to the practice expense and malpractice risk factor for anesthesia specialty. See Table 105 from the final rule, which is reproduced below.

Table 105: Calculation of the 2021 Anesthesia Conversion Factor

2020 National Average Anesthesia Conversion Factor		**$22.2016**
Statutory Update Factor	0.00 percent (1.000)	
2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
2021 Practice Expense and Malpractice Adjustment	0.59 percent (1.0059)	
2021 Conversion Factor		**$20.0547**

Table 106 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

2021 PFS Impact Discussion

The large redistributive effects in RVU changes and payments among specialties can largely be attributed to previously finalized policies for increases in valuation for office/outpatient E/M visits. Increases are also due to increases in RVUs for services that are analogous to office/outpatient E/M visits, such as transitional care management services, certain ESRD services, ED visits, and others. Other changes that have smaller effects but may affect certain specialties more than others include continued implementation of the adjustment to indirect PE allocation for some office-based services and updates to supply and equipment pricing.

Specialty-specific payment impacts largely vary based on use and mix of E/M services. Specialties where E/M services represent a greater share of total allowed charges, such as endocrinology (+16%), rheumatology (+15%), hematology/oncology (+14%), and family practice (+13%) would receive the largest increases relative to other specialties. In contrast, specialties that have a low use of E/M services based on the nature of their specialty, such as radiology (-10%), nurse anesthetists (-10%), chiropractor (-10%), pathology (-9%), and physical/occupational therapy (-9%) would receive the largest decreases relative to other specialties. The impact of the E/M changes were dampened for certain specialties such as emergency medicine practitioners based on other changes. For emergency medicine practitioners, estimated impacts of -6 percent account for a 3 percent gain because of increased valuations to ED visits, but the increase was dampened by the magnitude of the office/outpatient E/M visit valuations. For nephrology, CMS' policy to increase the valuations of the ESRD monthly capitation payments that have office/outpatient E/M visits explicitly included in their valuations largely resulted in the estimated impacts of +6 percent.

Of significance, these impacts do not take into account CMS' November 20, 2020 Interim Final Rule (85 FR 76180) that creates a Most Favored Nation (MNF) model for Part B drugs. The MFN Model prices Medicare Part B drugs based on international prices in all states and U.S. territories for 7 performance years—from January 1, 2021 to December 30, 2027 for 50 single source drugs and biologicals that encompass a high percentage of Medicare Part B drug spending. Participation is mandatory. Some of the specialties that are expected to receive large net increase from changes in the PFS final rule are expected to receive large decreases in revenue from implementation of the MFN Model. This includes specialties such as hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecology/oncology, infectious disease, hematopoietic cell transplantation & cellular therapy, and dermatology. The net combined impact is unclear.

Column F of Table 106 shows the estimated 2021 combined impact on total allowed charges by specialty of all the final RVU and other changes.

TABLE 106: 2021 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$247	5%	4%	0%	9%
Anesthesiology	$2,020	-6%	-1%	0%	-8%
Audiologist	$75	-4%	-2%	0%	-6%
Cardiac Surgery	$266	-5%	-2%	0%	-8%
Cardiology	$6,871	1%	0%	0%	1%
Chiropractor	$765	-7%	-3%	0%	-10%
Clinical Psychologist	$832	0%	0%	0%	0%
Clinical Social Worker	$857	0%	1%	0%	1%
Colon and Rectal Surgery	$168	-4%	-1%	0%	-5%
Critical Care	$378	-6%	-1%	0%	-7%
Dermatology	$3,767	-1%	0%	0%	-1%
Diagnostic Testing Facility	$748	-1%	-2%	0%	-3%
Emergency Medicine	$3,077	-5%	-1%	0%	-6%

(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
Endocrinology	$508	10%	5%	1%	16%
Family Practice	$6,020	8%	4%	0%	13%
Gastroenterology	$1,757	-3%	-1%	0%	-4%
General Practice	$412	5%	2%	0%	7%
General Surgery	$2,057	-4%	-2%	0%	-6%
Geriatrics	$192	1%	1%	0%	3%
Hand Surgery	$246	-2%	-1%	0%	-3%
Hematology/Oncology	$1,707	8%	5%	1%	14%
Independent Laboratory	$645	-3%	-2%	0%	-5%
Infectious Disease	$656	-4%	-1%	0%	-4%
Internal Medicine	$10,730	2%	1%	0%	4%
Interventional Pain Mgmt	$936	3%	3%	0%	7%
Interventional Radiology	$499	-3%	-5%	0%	-8%
Multispecialty Clinic/Other Phys	$153	-3%	-1%	0%	-3%
Nephrology	$2,225	4%	2%	0%	6%
Neurology	$1,522	3%	2%	0%	6%
Neurosurgery	$811	-4%	-2%	-1%	-6%
Nuclear Medicine	$56	-5%	-3%	0%	-8%
Nurse Anes / Anes Asst	$1,321	-9%	-1%	0%	-10%
Nurse Practitioner	$5,100	5%	3%	0%	7%
Obstetrics/Gynecology	$636	4%	3%	0%	7%
Ophthalmology	$5,343	-4%	-2%	0%	-6%
Optometry	$1,359	-2%	-2%	0%	-4%
Oral/Maxillofacial Surgery	$79	-2%	-2%	0%	-4%
Orthopedic Surgery	$3,812	-3%	-1%	0%	-4%
Other	$48	-3%	-2%	0%	-5%
Otolaryngology	$1,271	4%	3%	0%	7%
Pathology	$1,265	-5%	-4%	0%	-9%
Pediatrics	$67	4%	2%	0%	6%
Physical Medicine	$1,164	-3%	0%	0%	-3%
Physical/Occupational Therapy	$4,973	-4%	-4%	0%	-9%
Physician Assistant	$2,901	5%	2%	0%	8%
Plastic Surgery	$382	-4%	-3%	0%	-7%
Podiatry	$2,133	-1%	0%	0%	-1%
Portable X-Ray Supplier	$95	-2%	-4%	0%	-6%
Psychiatry	$1,112	4%	3%	0%	7%
Pulmonary Disease	$1,654	0%	0%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,809	-3%	-3%	0%	-5%
Radiology	$5,275	-6%	-4%	0%	-10%
Rheumatology	$548	10%	5%	1%	15%
Thoracic Surgery	$352	-5%	-2%	0%	-8%
Urology	$1,810	4%	4%	0%	8%
Vascular Surgery	$1,293	-2%	-4%	0%	-6%
TOTAL	**$97,008**	**0%**	**0%**	**0%**	**0%**

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

The following is an explanation of the information for Table 106:

- 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 2019 utilization and 2020 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 2021 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 2021 impact on total allowed charges of the changes in the PE RVUs.

- Column E (Impact of MP RVU Changes): This column shows the estimated 2021 impact on total allowed charges of the changes in the MP RVUs.

- Column F (Combined Impact): This column shows the estimated 2021 combined impact on total allowed charges of all the changes in the previous columns

B. Impacts of Other Policy Changes

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 telehealth services, scopes of practice, bundled payments of substance use disorders, CLFS provisions, payment for PCM services in RHCs, and FQHCs, modifications to the MSSP quality reporting requirements, among others.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 55 percent of the nearly 1.6 million clinicians billing to Part B (890,742) will be assigned a MIPS score for 2023 because others will be ineligible for or excluded from MIPS. Table 108, reproduced below, provides the details of clinicians' MIPS eligibility status for 2023 MIPS payment year (2021 MIPS performance year). CMS notes that actual opt-in participation data became available with the transition to the use of CY 2019 performance period data. CMS estimates that an additional 2,346 clinicians would be eligible through this "opt-in" policy.

TABLE 108: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the 2021 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	200,372	$48,461
	Do not participate in MIPS	27,115	$6,345
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	660,909	$17,061
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	2,346	$51
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**890,742***	**$71,918**
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	381,771	$9,979
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	83,039	$460
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	269,905	$10,225
Total Number of Clinicians Not MIPS Eligible		734,715	20,664
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,457	92,582

*Estimated MIPS Eligible Clinician Population

** Table 108 does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 5,000 clinicians and $530 million in PFS allowed charges).

*** Allowed charges estimated using 2018 and 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 2023 payment year, it would redistribute about $458 million in payment adjustments on a budget neutral basis and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The mean final score is 79.80 and the median is 85.27. The maximum positive payment adjustments are 5.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 93 percent of eligible clinicians are expected to have a positive or neutral payment adjustment and 7 percent will have a negative payment adjustment.

Table 109, reproduced below, shows the impact of payments by practice size, and based on whether clinicians are expected to submit data to MIPS. CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would not perform as well as larger sized practices. For example, almost one-fifth of clinicians in small practices (1-15 clinicians) are expected to receive a negative payment adjustment compared with about 3 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. It also does not consider potential clinicians who might elect to apply for the extreme and uncontrollable circumstances policies.

Table 109: MIPS Estimated Payment Year 2023 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	123,536	81.7%	46.9%	18.3%	1.0%
2) 16-24	40,688	87.5%	46.6%	12.5%	1.3%
3) 25-99	189,346	90.5%	50.6%	9.5%	1.5%
4) 100+	510,057	97.0%	55.6%	3.0%	1.7%
Overall	**863,627**	**93.0%**	**52.9%**	**7.0%**	**1.4%**
Among those not submitting data					
1) 1-15	22,956	0.0%	0.0%	100.0%	-8.6%
2) 16-24	1,225	0.0%	0.0%	100.0%	-8.7%
3) 25-99	2,212	0.0%	0.0%	100.0%	-8.7%
4) 100+	722	0.0%	0.0%	100.0%	-8.8%
Overall	**27,115**	**0.0%**	**0.0%**	**100.0%**	**-8.6%**

Note: Results of this model may change significantly if more clinicians apply for the application-based extreme and uncontrollable circumstances policy exception in CY 2021 because of the PHE for COVID-19.

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

** 2019 data used to estimate 2021 performance period adjustments. Payments are trended to 2023.

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

CMS estimates that approximately 196,000 to 252,000 eligible clinicians will become QPs for the 2023 and a total of $700-$900 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 2023 MIPS payment year that it was not able to model with its historic data sources. The scoring model results assume that 2019 submissions and performance are representative of 2021 QPP data submissions and performance. Results could vary from predictions, for example, if clinicians 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. Impact on Beneficiaries

CMS does not believe that its policies will have a negative impact on beneficiaries given overall PFS budget neutrality. CMS believes that many of its changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact on improve the quality and value of care provided to Medicare beneficiaries. It also cites the changes to the MDPP as having a positive impact on affected beneficiaries as it would allow them to maintain eligibility for the program, and request virtual sessions if needed for successful completion of attendance and weight loss milestones.

Most of the policy changes could result in a change in beneficiary liability as relates to coinsurance. For example, the 2020 national payment amount in the nonfacility setting for CPT code 99215 (Office/outpatient visit, established) is $148.33 which means in 2020 a beneficiary is responsible for 20 percent of this amount, or $29.67. Based on this final rule, using the 2021 CF, the 2021 national payment amount in the nonfacility setting for CPT code 99215 is $172.74 which means that in 2021, the beneficiary coinsurance is $34.55.

E. 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 final 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 $110.74 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $885.92 (8.0 hours x $110.74) and the total cost of reviewing this regulation is about $35.6 million ($885.92 x 40,227 reviewers on this year's proposed rule).

SUMMARY OF PHYSICIAN FEE SCHEDULE 2021 FINAL RULE Part II

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IV. Quality Payment Program

A. Overview

The Quality Payment Program (QPP) was established as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) as a mechanism to link updates to the Physician Fee Schedule (PFS) to the quality and costs of care provided to beneficiaries. The key structural features of the QPP remain as follows:

- Two participant tracks: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs);
- Two-year lag between a performance year and its corresponding payment year;
- Payment adjustments (two-sided risk) for MIPS-eligible clinicians based on their reported data for four performance categories: Quality, Cost, Improvement Activities (IA) and Promoting Interoperability (PI)
    - Adjustments increasing in size over time per statute, stabilizing at a maximum value of ± 9 percent in payment year 2022 (performance year 2020);
    - An additional positive adjustment for exceptional performance through payment year 2024 (based on a sliding scale)
- Through payment year 2024, lump sum ("bonus") APM incentive payments to clinicians whose participation in Advanced APMs exceeds pre-set thresholds that increase over time per statute ("APM Qualifying Participants" or QPs)
    - The final, maximum QP thresholds will be reached in performance year 2021 (payment year 2023)
- Per statute, the bonus will be replaced in payment year 2026 by a higher annual PFS update for QPs than non-QPs (0.75 vs. 0.25 percent, respectively); and
- QPP annual updates are implemented as part of the PFS rulemaking process.

CMS estimates that there will be nearly 900,000 MIPS eligible clinicians and that between 196,000 and 252,000 eligible clinicians will become QPs for the 2021 performance period.

Calendar year 2021 is the QPP's third payment year: MIPS payment adjustments are being applied, and APM incentive payments are being made, to eligible clinicians based upon their

2019 performance data. MIPS adjustments range from -7 to +7 percent, made to payments for covered Part B professional services furnished during 2021. The 2021 APM incentive payment is set at 5 percent of a QP's covered Part B professional services furnished during 2020. The 2021 performance year corresponds to the 2023 payment year, during which MIPS adjustments will range from -9 to +9 percent. CMS estimates that the positive and negative adjustments will each total $458 million (the program is budget neutral) and that the maximum possible positive payment adjustment attainable for payment year 2023 will be 5.9 percent, combining the MIPS base adjustment with the adjustment for exceptional performance.[1]

B. Summary of Major Proposals for 2021 (QPP Year 5)

Finalized changes to the QPP for 2021 will become effective January 1, 2021, unless otherwise noted. CMS states a purposeful intent to limit the volume of QPP changes in 2021 to promote QPP stability during the ongoing COVID-19 PHE. CMS emphasizes the singular importance of changes finalized to the MIPS Value Pathways (MVPs), viewing MVPs as the desired future state of MIPS. CMS reiterates that an initial set of MVPs and policies for their implementation will be proposed during 2022 rulemaking and will be designed to align with the National Quality Roadmap,[2] the finalized interoperability rules released by HHS in May 2020,[3] and the goals of the Health Care Payment Learning & Action Network for APM adoption.[4]
Other finalized changes in this rule highlighted by CMS include:

- Establishing the APM Performance Pathway (APP) for reporting by MIPS APM clinicians;
- Including services provided via telehealth in measurements of quality and cost;
- Changing the MIPS Cost and Quality category weights for payment year 2023 as shown in the table below; and
- Finalizing QPP-related changes made during 2020 in response to the COVID-19 PHE through IFCs issued on March 31 April 30, August 25, and October 28.

MIPS Performance Category Weights (%)			
Performance Category	**Performance Year 2020 *Final***	**Performance Year 2021 *Proposed***	**Performance Year 2021 *Final***
Quality	45%	40%	40%
Cost	15%	20%	20%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

[1] The full regulatory impact analysis for the QPP is found in section VIII.H.15 of the rule.
[2] The Roadmap, published by the Department of Health and Human Services on May 15, 2020, in response to Executive Order 13877, is available at https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.
[3] From the Office of the National Coordinator for Health Information Technology (85 FR 25642 through 25961) and CMS (85 FR 25510 through 25640), respectively.
[4] https://hcp-lan.org

C. MIPS Value Pathways

In the 2020 PFS final rule, CMS finalized the definition of a MIPS Value Pathway (MVP) as "a subset of measures and activities established through rulemaking" (§414.1305) and adopted a set of guiding principles for the MVP framework (84 FR 40734). The MVP framework is intended to be "the future state of MIPS" through improving value, reducing burden, enabling patients to compare clinician performances, and reducing barriers to risk-bearing APM participation by clinicians.

1. Guiding Principles

CMS proposed to update the guiding principles for the MVP framework. Additions addressed the contribution of clinician subgroup reporting to comprehensively reflect the services provided by multispecialty groups and thereby enhance information available to beneficiaries when making healthcare choices; and stated an explicit commitment to transitioning to digital quality measures (DQMs).

The updated principles were generally supported by many commenters. The addition of subgroup reporting also received support, although some commenters were concerned about the potential to add complexity and burden through implementation policies or operational details. CMS states a commitment to working with stakeholders to mitigate their concerns and notes that policies will go through the PFS rulemaking process. Conceptual support was expressed for DQMs but commenters sought clarification as to the definition and scope of DQMs. CMS responds that DQMs originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems, and offered examples of sources including clinical registries and wearable devices.

FINAL ACTION: CMS finalizes the updated guiding principles for the MVP framework as proposed, listed below.

1. MVPs should consist of limited, connected, complementary sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, align scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.
3. MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.
5. MVPs should support the transition to digital quality measures.

2. MVP Development Criteria

a. Criteria in General

CMS emphasizes the need to establish criteria that will standardize what is expected of candidate MVPs and will guide their selection for implementation. CMS, therefore, proposed to develop and select MVPs using the following criteria, beginning with the 2022 performance period:

- Utilization of Measures and Activities across Performance Categories,
- Intent of Measurement,
- Measure and Activity Linkages with the MVP,
- Appropriateness,
- Comprehensibility,
- Incorporation of the Patient Voice, and
- Measures and Improvement Activities Considerations (specific to each MIPS performance category).

Commenters expressed conceptual support for establishing MVP development criteria. Others sought details of how specific criteria might be applied in assessing candidate MVPs. CMS responds that MVP development has not reached the stage to allow definitive responses to operational questions, but emphasizes the agency's commitment to transparency and dialogue with stakeholders, while retaining ultimate authority to determine when a candidate MVP is ready for implementation, subject to notice-and-comment rulemaking.

FINAL ACTION: CMS finalizes the proposed criteria for developing and selecting candidate MVPs as listed above. CMS calls attention to an MVP Town Hall meeting that the agency is hosting on January 7, 2021 for stakeholders to provide feedback about MVP topics.[5]

b. Selected Specific Criteria

Patient Voice. While discussing the MVP guiding principles and development criteria, CMS repeatedly states the importance of including the patient voice as candidate MVPs evolve. CMS underlined this point by explicitly proposing that MVP developers include patients during their candidate MVP development processes and encouraged the use of several approaches to engaging patients for each MVP. Some commenters were supportive. Others were concerned that patient inclusion would delay MVP development and some voiced a concern that the criterion of MVP comprehensibility to patients required evaluation through a Technical Expert Panel before being finalized.

FINAL ACTION: CMS disagrees with both concerns and proceeds to finalize its proposal without modification.

Population Health Measures. While discussing the MVP guiding principles and development criteria, CMS also repeatedly states the importance of including population health measures

[5] Further information about the meeting is available at 85 FR 74729 through 74730 published November 23, 2020.

calculated from administrative claims data. Commenters were divided between support and opposition. CMS maintains the necessity for population health measures in MVPs, and offers a detailed discussion of the *Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups* measure, proposed (and finalized later in this rule) for addition to the MIPS quality measure inventory beginning with performance year 2021. Relatedly CMS proposed that to satisfy the MVP criteria, each MVP would be required to include the full MIPS Promoting Interoperability (PI) category measure set. That requirement is included as part of the now finalized MVP criterion *Measures and Improvement Activities Considerations (specific to each MIPS performance category*.

FINAL ACTION: CMS finalizes that the full PI category measure set must be included in every MVP.

3. Candidate MVP Consideration Process

CMS proposed a process for candidate MVP consideration, to begin in performance year 2022:

1. The developer formally submits the candidate MVP utilizing a standard template from CMS (to be published in the QPP Resource Library https://qpp.cms.gov/about/resource-library). Information showing how the selection criteria have been met and why certain measures were chosen must be included.
2. On a rolling basis, CMS (and its contractors) will review submissions using the selection criteria and will evaluate certain technical features of the included quality and cost measures (e.g., cost measure uses codes appropriate to the included clinician types). During this step, CMS may contact the MVP developer to answer questions.
3. CMS will reach out to developers whose MVPs have been judged during the agency's internal review as potentially feasible for implementation, to arrange a "feedback loop meeting" at which CMS may suggest modifications and next steps. To protect the rulemaking process, there will be no further communication between CMS and the developer prior to publication of the next PFS proposed rule that addresses MVP selection decisions.
4. A public webinar hosted annually by CMS will review candidate MVP development criteria, submission process, and associated timelines.

Commenters were relatively few but mostly supportive, although concern was raised about the prohibition on communication between CMS and the candidate MVP developer prior to publication of the next PFS proposed rule. CMS responds that the rulemaking process must be protected and that the agency will ultimately determine if and when a candidate MVP is ready for implementation. CMS states an intent to host an MVP development webinar that will provide additional clarity on expectations, the assessment process, and communication between CMS and developers.

FINAL ACTION: CMS finalizes the MVP consideration process as proposed as described above, without modifications.

4. Other MVP Elements

a. Qualified Clinical Data Registry (QCDR) Measures

CMS states a belief that measures developed by QCDRs are relevant, meaningful for clinicians, and address MIPS measure inventory gaps. CMS notes that stakeholders previously supported QCDR measure inclusion in MVPs as long as new costs and burden could be avoided. CMS proposed that QCDR measures included within a candidate MVP must meet all current QCDR measure requirements (§ 414.1400(b)(3)), and emphasized that the measure must have been fully tested at the clinician level. CMS also points out that the timelines for QCDR measure development and for MVP-related rulemaking could overlap and potentially pose logistical challenges. Therefore, beginning with the 2022 performance period, CMS proposed that only QCDR measures already approved in the previous year may be considered for inclusion within a candidate MVP. CMS notes that QCDR measures included in candidate MVPs that are adopted during PFS rulemaking would be eligible for 2-year measure approval (§ 414.1400(b)(3)(vi)).

Commenters generally supported the potential for including QCDR measures within MVPs. Multiple concerns were voiced about the requirement for such measures to have been approved in the year before they are considered within a candidate MVP. CMS declines to accept commenter suggestions of ways to allow not-yet-approved QCDR measures to be included provisionally in candidate MVPs.

FINAL ACTION: CMS finalizes the proposals to limit MVP inclusion of QCDR measures to those approved in the prior year and that the measures meet established criteria for their use within MIPS.

b. Reporting of MVPs through Third Party Intermediaries

CMS states a belief that third party intermediaries (QCDRs, qualified registries, and Health IT vendors) that already report MIPS performance category data to CMS on behalf of clinicians will be able to support reporting through MVPs, providing clinicians with another method for MVP reporting. CMS states a plan to develop a process to allow QCDRs and qualified registries to identify and select which MVPs they can support following publication of the PFS final rule each year.

Commenters were divided in their support for MVP data submission through third party intermediaries. Concerns were voiced about the associated financial burden; CMS responds that clinicians would not be required to utilize intermediaries for MVP data submission. No details of or a timeline for release is provided by CMS about the process to allow QCDRs and qualified registries to identify and select which MVPs they can support.

FINAL ACTION: No action is required of CMS as no proposal was made.

5. MVP Implementation Timeline

CMS had previously intended to begin a gradual transition from the current MIPS participation options[6] (now termed "traditional MIPS") to MVP reporting by proposing an initial set of MVPs for adoption for performance year 2021. To allow clinicians to focus their attention on patient care during the COVID-19 PHE, CMS instead chose to defer proposing any MVPs until at least performance year 2022. Commenters agreed, with some asking for further delay. CMS disagrees that delay beyond 2022 is necessary since the agency has committed to a gradual, incremental transition for clinicians to MVP reporting.

FINAL ACTION: CMS defers proposing any candidate MVPs until 2022 rulemaking.

CMS estimates the burden per respondent to nominate an MVP to be 12 hours and $1818.[7]

D. APM Performance Pathway (APP) (§414.1367)

1. General Considerations

The APM scoring standard was designed to reduce burden and increase meaningful measurement for MIPS eligible clinicians participating in MIPS APMs who do not reach QP status and thus remain subject to MIPS reporting for a performance year.[8] CMS proposed to terminate the APM scoring standard due to associated persistent operational difficulties for CMS and clinicians, and developed the APM Performance Pathway as a new option for MIPS reporting and scoring for MIPS APM clinicians beginning with performance year 2021.[9] CMS proposed that MIPS APM clinicians would be able to report through or outside of the APP and at the individual or group level.

FINAL ACTION: After receiving supportive comments, CMS finalizes reporting flexibility for MIPS APM clinicians as proposed.

2. Alignment of MIPS APMs and the APP

CMS makes several proposals that would align current MIPS APM regulations with those proposed for the APP.

- Create and designate § 414.1367 as "APM performance pathway".
- Retain but renumber two existing criteria for MIPS APMs:
    - § 414.1370(b)(1) "APM Entities participate in the APM under an agreement with CMS or through a law or regulation" would become § 414.1367(b)(1); and
    - §414.1370(b)(3) "APM bases payment on quality measures and cost/utilization" would become § 414.1367(b)(2).
- Expand the MIPS APM definition by removing § 414.1370(b)(2) and (b)(4); this allows inclusion of APMs that are facility-based and/or have only an Affiliated Practitioner List.

[6] MIPS eligible clinicians may participate as individuals or through a group, virtual group, or MIPS APM Entity.
[7] Details of the burden analysis are found in Table 93, section VII.B.5.k of the rule.
[8] Most CMS-sponsored Advanced APMs are also MIPS APMs.
[9] CMS also proposed to apply the APP framework to MSSP ACOs (discussed earlier in the rule and this summary).

FINAL ACTION: Absent comments, CMS finalizes the above proposals without modifications.

3. MIPS Performance Category Scoring in the APP (§414.1367(c))

CMS describes reporting and scoring provisions applicable only to those MIPS APM clinicians reporting through the APP for 2021 and subsequent performance years.

a. Quality

CMS proposed 3 clinical, 2 claims-based, and a single CAHPS for MIPS survey measure as the basis for APP Quality category scoring. CMS proposed to remove a measure from scoring for a submitter who cannot meet the minimum case threshold. Were a measure in the APP set found to be topped out, CMS also proposed not to apply the topped out measure scoring cap requirement to that measure (§ 414.1380(b)(1)(iv)). The Multiple Chronic Conditions for ACOs measure (ACO MCC) would be applicable only to those Medicare ACOs who choose or who are required to participate through the APP (e.g., MSSP). CMS discussed in detail the changes made to align the MCC ACO measure version with the version currently used in MIPS that similarly utilizes administrative claims data (MIPS MCC).

Some commenters were supportive of the proposed measure set. Others raised concerns including the following:

- The measure set does not represent the full scope of clinical practice.
- The mix of measures is overweighted towards claims-based measures.
- Not all of the measures in the set are National Quality Forum (NQF) -endorsed.
- Not all of the measures in the set are outcome measures.
- Better measures are available than the ACO MCC measure.
- There is insufficient time before performance 2021 year starts for transitioning existing reporting systems to APP measure reporting.

CMS responds that the measures are targeted to the goals of the APP; the 3 clinical measures have high reliability; and that the small measure set reduces reporting burden. CMS also finalizes adding the CMS Web Interface measure set to the APP for performance year 2021 only; this allows ACOs who currently report via that method to do so for 2021 while preparing to report through the APP for 2022.

FINAL ACTION: CMS finalizes the APP quality measure set as proposed with the modification of adding 7 clinical measures for reporting by ACOs through the CMS Web Interface for the 2021 performance year. The final measure set is shown below.

Final APM Performance Pathway Quality Measure Set					
Measure #	**Measure Title**	**Collection Type**	**Submitter Type**	**2021 Only[1]**	**Begin 2022[1]**

Final APM Performance Pathway Quality Measure Set					
Quality ID: 321	CAHPS for MIPS	CAHPS Survey	Survey vendor	X	X
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	CMS Claims	N/A (CMS Calculated)	X	X
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	CMS Claims	N/A (CMS Calculated)	X	X
Quality ID: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM; Web Interface	ACO/Third Party Intermediary	A	X
Quality ID: 318	Falls: Screening for Future Fall Risk	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 110	Preventive Care and Screening: Influenza Immunization	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 226	Preventive Care and Screening Tobacco Use: Screening and Cessation Intervention	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 113	Colorectal Cancer Screening	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 112	Breast Cancer Screening	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Web Interface	ACO/Third Party Intermediary	B	N/A
Quality ID: 370	Depression Remission at Twelve Months	Web Interface	ACO/Third Party Intermediary	B	N/A

Table created by HPA from Tables 39, 40, and 47 and narrative from sections III. G.1.b(1) and IV.A.3.b(3)(a) of the rule

[1] Legend for reporting requirements by performance year:

X: Required for reporting along with A measures or A+B measures for performance year 2021
Required for reporting with A measures for performance year 2022 and subsequent years

A: May be reported together with X measures as one option for performance year 2021

B: May be reported together with X measures and A measures as one option for performance year 2021

N/A: No longer available for satisfying MSSP ACO required reporting

b. Cost

CMS has used its authority under section 1115A(d)(1) of the Act to waive the Cost performance category for CMS Innovation Center APMs (§414.1370(g)(2)). CMS proposed to continue this waiver for MIPS APMs, and thereby for APP cost category scoring. Commenters were supportive, noting that MIPS APMs mandate cost performance assessments in their model designs.

FINAL ACTION: CMS finalizes the APP Cost category scoring proposal without modification.

c. Improvement Activities

Per statute, all MIPS APM clinicians automatically receive at least one-half of the maximum IA score. For the APP, CMS proposed to assign a specific IA performance score to each MIPS APM. As is done currently for MIPS APMs, CMS would calculate IA scores based upon the activities required by each APM's design and their associated scores in the general MIPS structure. Should a MIPS APM's IA score be less than the general MIPS IA category maximum, clinicians who report through the APP could submit additional IA data to raise their scores. CMS would publish the assigned IA scores on the CMS website annually. CMS clarifies that a MIPS APM clinician must complete all of the activities required by the terms of the APM to qualify for the IA category automatic scoring credit.

FINAL ACTION: CMS finalizes the proposal for APP IA scoring as proposed.

d. Promoting Interoperability

CMS proposed that PI performance category scoring under the APP would be the same as is done under the general MIPS structure currently. CMS received a request to enable PI category repotting at the APM Entity level, which is not possible under MIPS at present. CMS responds that APM Entity-level PI reporting is not operationally feasible for ACOs comprised of two or more TINs at this time.

FINAL ACTION: CMS finalizes PI category scoring under the APP as proposed.

e. Category Weights and Reweighting under the APP

CMS proposed using waiver authority[10] to set the following MIPS performance category weights for clinicians reporting through the APP: Quality 50 percent; Cost 0 percent; IA 20 percent; and PI 30 percent. CMS also proposes category reweighting as follows, if MIPS APM clinicians choosing to report through the APP be unable to complete their reporting (e.g., extreme and uncontrollable circumstances, hardship, lack of applicable measures):

- When PI is reweighted to zero percent, Quality is set at 75 percent and IA at 25 percent.

[10] Waivers are based on sections 1115A(d)(1) and 1899(f) of the Act for CMS Innovation Center APMs and the Shared Savings Program, respectively.

- When Quality is reweighted to zero percent, PI is set at 75 percent and IA at 25 percent.

FINAL ACTION: No comments were received and CMS finalizes the proposal without changes.

f. Final Scoring for MIPS APM Participants Reporting through the APP

CMS proposed that the final score method calculation used in the general MIPS structure would be applied to MIPS APM clinicians selecting the APP.

Final score = (Quality score x Quality weight) + (Cost score x Cost weight) + (IA score x IA weight) + (PI score x PI weight)

FINAL ACTION: No comments were received and CMS finalizes the proposal without changes.

g. Performance Feedback

CMS proposed to provide performance feedback to clinicians who select the APP in the same manner as is done for all MIPS eligible clinicians.

FINAL ACTION: No comments were received and CMS finalizes the proposal without changes.

E. Merit-Based Incentive Payment System (MIPS): Performance Category Reporting and Scoring Updates

1. Quality Performance Category (§§414.1330 through 414.1340)

a. Quality Category Weight

CMS proposed to reset the MIPS Quality performance category weight from 45 percent for performance year 2020 to 40 percent for performance year 2021 and 30 percent for performance year 2022 and each subsequent year. CMS notes that by statute the Quality and Cost category weights total 60 percent, so that changes to their weights move in tandem, and are directed in statute to reach 30 percent each for performance year 2022 and subsequent years.

Commenters largely opposed reducing the Quality category weight from 45 percent in performance year 2020 to 40 percent for performance year 2021 and further to 30 percent for performance year 2022 and all future years. They stated that the reduction was inappropriate during the ongoing COVID-19 PHE given the added demands being placed on physicians by the pandemic. Some commenters urged CMS to maintain the Quality category weight at 45 percent until the PHE ends. They added that a transfer of weight to the Cost category was ill-advised, citing a paucity of well-developed cost measures, especially for some specialists.

CMS reminds stakeholder that statute requires that the Quality category weight to be set at 30 percent for performance year 2022. The agency notes that 18 episode-based cost measures are available along with the broadly-based Total Per Capita Cost and Medicare Spending per Beneficiary (Clinician).

FINAL ACTION: CMS finalizes the Quality category weight at 40 percent as proposed.

b. CMS Web Interface Reporting (§414.1330(c))

The CMS Web Interface is an application supporting quality measure data collection and submission, open for use by groups (or virtual groups) with 25 or more eligible clinicians and required for quality reporting by MSSP ACO participants. CMS proposed to sunset the Web Interface beginning with the 2021 performance year after conducting an internal analysis showing steadily declining use other than by required users. CMS notes that the Web Interface is the most stringent of the existing collection/submission types, as it involves more measures, larger minimum patient samples, a higher data submission completeness threshold, and does not award credit for partial reporting. Concomitantly, CMS proposed to revise the MSSP quality performance standard and transition those ACOs to reporting through the proposed APP.

Most commenters opposed sunsetting the Web Interface, stating that CMS had not given users adequate notice to transition to another reporting platform and citing the time and resources that would be required for that transition. Some noted that the application has been particularly cost-effective for ACOs comprised of TINs who do not share a common electronic health record. Commenters recommended a delay of a year or more, given the substantial burden of transition, because clinicians are preoccupied with the COVID-19 pandemic, or creating a new hardship exception from quality reporting.

CMS concludes that commenters were objecting primarily to the short timeline for migrating from the Web Interface to the APP or another platform, rather than to the loss of a superior reporting mechanism. CMS, therefore, finalizes the proposal to sunset the Web Interface for quality reporting but delays the implementation until performance year 2022. During performance year 2021, required users may choose to report under the APP or the Web Interface. CMS also finalizes conforming changes to the definitions of collection type and submission type to reflect the termination of the Web Interface.

FINAL ACTION: CMS finalizes the proposal to sunset the Web Interface, with modification to delay implementation to performance year 2022, and with related conforming changes.

c. Quality Measure Inventory Changes

Changes proposed to MIPS quality measures by CMS were provided in the tables of Appendix 1 of the proposed rule (85 FR 50413 through 50665), and would result in an inventory of 206 measures for performance year 2021 and future years. The proposed changes comprised 2 new administrative claims-based outcome measures, modifications made to 43 existing specialty measure sets, 14 deletions, and 112 previously finalized measures with substantive changes.

FINAL ACTION: CMS finalizes an inventory of 209 measures presented in Table Groups A through D of Appendix 1 of this rule. Three proposed measure deletions were not finalized based on input from commenters.[11]

d. Administrative Claims Measures Performance Periods (§414.1320(d)(1))

Currently, the MIPS Quality category performance period is one year -- the full calendar year that is 2 years prior to the associated MIPS payment year. CMS proposed to create an exception for claims-based quality measures to have extended performance periods, beginning with performance year 2021, and the exception would be applicable to the proposed new measure *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for MIPS*, for which the performance period would be 3 years.

Commenters raised concerns about confusion arising from non-uniform performance periods and time periods whose length degrades the quality of feedback to physicians. CMS disagrees, noting that variable performance periods are used in other CMS programs (e.g., hospital value-based purchasing program).

FINAL ACTION: CMS finalizes, as proposed, that performance periods for administrative claims-based measures may be other than one full calendar year.

e. CAHPS for MIPS Survey

New Survey Items. The CAHPS for MIPS Survey is a key instrument used in assessing patient experience of care for services provided by MIPS eligible clinicians. CMS proposed to integrate one telehealth item and update the cover page to refer to care received in telehealth settings, starting with the 2021 CAHPS for MIPS Survey administration, in recognition of the greatly increased use of such services during the COVID-19 PHE. The proposed changes were supported by most commenters. CMS clarifies that the new telehealth item would be for informational purposes only and not for quality scoring or payment purposes.

FINAL ACTION: CMS finalizes the proposed changes to the CAHPS for MIPS survey for the 2021 survey administration without modification.

CMS also proposed a technical change to the instructions for the CAHPS for MIPS survey section *Your Care From Specialists in the Last 6 Months*. No public comments were received. However, qualitative testing of the revised instructions was performed with beneficiaries; based on test results, CMS does not finalize the proposed technical change.

2021 Survey Beneficiary Assignment. CMS generally maintains alignment of the primary care services as defined for purposes of CMS Web Interface and CAHPS for MIPS survey beneficiary

[11] Retained measures address post-fracture care, urinary incontinence, and psoriatic and rheumatoid arthritis (quality # 024, 048, and 337, respectively).

assignment with those defined for beneficiary assignment to MSSP ACOs. As the COVID-19 PHE has evolved, CMS has made changes (through IFCs) to the ACO assignment definition to accommodate an expanded list of telehealth services and communications technology-based services (CTBS). To continue that alignment, in the proposed rule CMS proposed to codify the definition of primary care services for CMS Web Interface and CAHPS for MIPS survey beneficiary assignment for performance year 2021 and subsequent years at §414.1305 by adding additional CTBS codes (e.g., online digital E/M services). The resulting code list is shown below.

FINAL ACTION: Absent comments, CMS finalizes the expanded definition as proposed.

> *CPT codes already included:* 99201-99215 (office/outpatient); 99304-99318 (nursing facility); 99319-99340 (domiciliary); 99341-99350 (home); 99487/99489/99490 (chronic care management); 99495-99496 (transitional care management)
>
> *CPT codes new for performance year 2021 and subsequent years:* 99421-99423 (online digital E/M); 99441-99443 (telephone E/M); 96160-96161 (Health Risk Assessment)
>
> *HCPCS codes already included:* G0402 (Welcome to Medicare); G0438-G0439 (Annual Wellness Visit)
>
> *HCPCS codes new for performance year 2021 and subsequent years:* G2010 (remote eval images; G2012 (virtual check-in)

2020 Survey Beneficiary Assignment. In the September 2nd COVID-19 IFC, CMS proposed to similarly expand the primary care services used for assigning beneficiaries for the 2020 CMS Web Interface and CAHPS for MIPS survey. This expansion represents a retroactive policy change for which the Secretary has determined that applying this change is in the public interest, and as such is allowed through section 1872(e)(1)(A)(ii) of the Act. Commenters were supportive.

FINAL ACTION: CMS finalizes the interim final provisions of the IFC without modifications. The finalized list of services for 2020 is the same as that provided above for 2021.

CMS estimates the total burden imposed by the MIPS program for performance period 2021 at approximately 1,500,000 hours and $145 million, most of which is attributable to the Quality performance category, an increase of 1,163 hours and $120,391 from 2020.[12]

2. Cost Performance Category (§414.1305)

a. Cost Category Weight

[12] The complete, detailed burden analysis for the MIPS program is found at section VII.B.5 of the rule.

The weights of the Quality and Cost performance categories must total 60 percent and move in tandem, with a statutory requirement that each be weighted at 30 percent of the MIPS total score for performance year 2022. CMS has consistently stated a plan for gradual increases to the Cost weight to meet the statutory requirement, thereby allowing time for clinicians to gain experience with the cost measures. CMS was persuaded by stakeholder input, particularly concerns about performance feedback to clinicians, to make no increase in the Cost weight from 2019 (15 percent) to 2020.

To propose a Cost category weight for performance year 2021, CMS considered leaving the weight at 15 percent for 2021 followed by the required increase to 30 percent for 2022. The agency also considered increasing the weight to 20 percent for performance year 2021 then to 30 percent for 2022 and thereafter. CMS viewed this 2-step increase approach as more gradual and formally proposed this approach.

Comments were numerous and some were supportive of the proposed Cost category weights for performance years 2021 and 2022. Most commenters opposed the increasing weights, based on:

- The impact of the COVID-19 PHE on patterns of healthcare delivery and case mix;
- The impact of the COVID-19 PHE on costs of care for all patients and disproportionate cost impacts on clinicians in COVID-19 hotspots;
- Data anomalies during and for some time after the COVID-19 PHE, confounding analysis of the data by CMS;
- Insufficient number of cost measures to fairly evaluate clinicians of many specialties;
- Concerns about the brief experience of clinicians and CMS with many of the available cost measures; and
- Concerns about the validity and accuracy of existing cost measures (e.g., cost attribution at a group rather than individual level, measure reliability).

CMS reiterates the statutory requirement to reach a Cost category weight of 30 percent by performance year 2022. CMS notes the availability of 16 episode-based cost measures and two broad-based measures (Total Per Capita Cost, TPCC, focused on primary care, and Medicare Spending Per Beneficiary – Clinician (MSPB-clinician, targeting inpatient hospitalizations), and that additional episode-based measures are under development. CMS states a belief that the agency can accurately assess clinician Cost category performances with the available measures. CMS also states that the 2-step increase approach allows time for clinicians to gain familiarity with cost measures and reports during the ongoing PHE. Technical concerns about existing measures cannot be addressed within the current (2021) rulemaking cycle. The agency notes that the episode-based cost measures (e.g., joint replacement) are designed to exclude unrelated services, and that the TPCC and MSPB are risk-adjusted, mitigating COVID-19 PHE impacts. Also, the standardized payments used in measure calculation will remove the 20 percent COVID-19 increase in hospital payments and regional payment variations, improving measurement accuracy.

FINAL ACTION: CMS proceeds to finalize the proposed Cost category weights for performance years 2021 (20 percent) and 2022 (30 percent) without modifications.

b. Adding Telehealth Services to Episode Cost Measures

CMS notes that clinicians are being assessed on 18 episode cost measures for performance year 2020 along with TPCC and MSPB-clinician.[13] Some telehealth service costs have already been assigned to specific episodes, but CMS proposes to assign codes that have been newly added to the Medicare telehealth list during the PHE and codes that were being commonly used at the time of episode construction.[14] Comments were generally supportive with some concerns raised about quantifying the impact of the code additions so that clinicians could understand the cost implications of telehealth service use. CMS responds that the telehealth costs are anticipated not to cause large or disproportionate cost impacts and that their addition is not a substantive change that requires specific testing of their effects.

FINAL ACTION: CMS finalizes the proposal for adding telehealth services without changes.

3. Improvement Activities Category (§414.1355)

a. Call for Activities Exceptions

CMS notes that requests to add new or modify IAs should be submitted during the annual Call for Activities on a standardized nomination form. The nomination period currently runs from February 1 through June 30; nominations received are reviewed for potential action during the following year's rulemaking cycle. CMS proposed two exceptions to the Call for Activities process. First, beginning with performance year 2021, CMS would accept IA nominations all year round for the duration of any declared PHE. Second, CMS also would accept nominations all year round from within HHS, without requiring an ongoing PHE.

Commenters were supportive of allowing IA nominations year-round during any declared PHE. In response to suggestions for additional changes, CMS clarifies that no other aspect of the Annual Call for Activities process would be altered. Commenters also supported the proposal for CMS to accept IA nominations all year round from within HHS as a permanent policy change.

FINAL ACTION: CMS finalizes the two changes to the new IA measure nomination process as proposed.

b. Improvement Activity Nomination Criteria

Requestors of new or revised IAs must link their candidate IAs to a set of criteria that are considered by CMS in IA selection (82 FR 53660). CMS proposed two new criteria: 1) the activity is linked to existing quality and cost measures, as applicable and feasible; and 2) a new HHS-nominated activity is aligned with at least one of the HHS goals, when feasible and

[13] The performance year 2021 cost measures are listed in Table 47 of the CY 2020 PFS final rule (84 FR 62979).
[14] The updated specifications and cost measure information forms for the 2021 episode measures are available for download at https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback

appropriate. The first new criterion would facilitate the addition of IAs that could be incorporated into candidate MVPs, as the latter are each required to connect quality and cost measures with IAs relevant to a condition or patient population. The second criterion would facilitate the adoption of IAs from within HHS that would support achieving broad healthcare goals, such as the IA for participation in COVID-19 clinical trials that was added for performance year 2020 through the March 31st COVID-19 IFC.

Most commenters were supportive of both new criteria.[15] CMS clarifies that the criterion for MVP linkage of IAs is not a standalone criterion and that the existing criteria remain applicable as well. CMS also notes that the new criterion is additive to the requirements adopted during 2020 rulemaking for MIPS quality stewards and QCDRs to link their quality measures to existing cost and IAs as applicable and feasible.

FINAL ACTION: CMS finalized both new IA criteria as proposed.

c. Improvement Activity Category Inventory Changes

CMS proposes revisions to two existing IAs, to take effect for performance year 2021 and subsequently:

- IA_BE_4 *Engagement of patient through implementation of improvements in patient portal*
    - Updated to include patients' caregivers and bidirectional information exchange.
- IA_AHE_7 *Comprehensive Eye Exams*
    - Updated denominator criteria and exclusions.

FINAL ACTION: Commenters were supportive and the proposed IA revisions are finalized without changes.

CMS notes that an IA measure *COVID-19 Clinical Trials* was established in the March 31st COVID-19 IFC. The measure was modified in the September 2nd COVID-19 IFC, retitled *COVID-19 Clinical Data Reporting with or without Clinical Trial*, and extended through the 2021 performance period. Commenters to the IFCs were supportive of the interim changes.

FINAL ACTION: CMS finalizes this IA's interim addition and subsequent modification and continuation through performance year 2021.

4. Promoting Interoperability Category (§414.1375)

a. Future Performance Periods

[15] The discussion of comments and responses regarding the new criterion for HHS-nominated activities is found with the measure specifications in Table C of Appendix 2 in the rule rather than in the body of the preamble. Comments about the revised IAs appear in Table A. Deletion of obsolete IA_CC_5 is discussed in Table B.

The PI performance period has been established annually for QPP Years 1-5. For payment year 2023 the period was finalized as a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021. CMS proposes to continue this approach for payment year 2024 and thereafter at new §414.1320(g)(1). CMS notes that this proposal aligns with the finalized CY 2022 EHR reporting period for eligible hospitals and CAHs under their Medicare PI programs. Commenters were strongly supportive.

FINAL ACTION: CMS finalizes setting the PI performance period in perpetuity as proposed.

b. Promoting Interoperability Measure Changes

CMS proposed one change under the Electronic Prescribing objective and two changes under the Health Information Exchange objective.

Query of Prescription Drug Monitoring Programs (PDMP) Measure.

For the 2020 PI performance period, reporting of the Query of PDMP measure is optional and eligible for 5 bonus points. CMS agreed with stakeholders that the Query of PDMP measure is not ready for required reporting due to multiple operational challenges, and proposed to continue the measure as optional for the 2021 performance period. CMS further proposed to increase the available bonus points for reporting the measure during that period from 5 points to 10 as an incentive to clinicians to perform PDMP queries as a routine part of patient care.

While acknowledging the great potential utility of the Query PDMP measure in responding to the opioid use pandemic, nearly all commenters supported maintaining reporting of this measure as optional and increasing the associated bonus points. A few urged CMS to move more quickly to required reporting. CMS agrees with the former group.

FINAL ACTION: CMS finalizes maintaining the Query of PDMP measure as optional and assigning 10 bonus points for reporting in performance period 2021.

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

CMS proposed to replace "incorporating" with "reconciling" in the name of this measure because "incorporating" of health information received is not always required, but information received must always be "reconciled" into the Medication, Medication Allergy, and Current Problem List sections when using CEHRT. Commenters agreed with the clarity added by revising the measure name but also asked that this name be maintained going forward, as this proposal represents the third name change in 5 years.

FINAL ACTION: CMS finalizes the name change as proposed *Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure*.

Health Information Exchange (HIE) Bi-Directional Exchange Measure.

CMS uses the term "bi-directional exchange" to indicate that a clinician's EHR can support querying and sharing data (sending, receiving, incorporating) for every patient via an HIE. CMS reviews the status of HIEs available nationally including their distribution (e.g., by health service area and by hospital) and their capabilities (e.g., EHR notes and lab data). While HIEs are widely distributed, gaps remain and provider engagement with HIEs varies. To emphasize the importance of bi-directional exchange, CMS proposed to add a new measure beginning with the 2021 performance period *Health Information Exchange (HIE) Bi-Directional Exchange.* Clinicians would be able to optionally attest to this measure in lieu of reporting the two existing measures *Support Electronic Referral Loops by Sending Health Information* and *Support Electronic Referral Loops by Receiving and Incorporating Health Information.*

The new measure would be worth 40 points, the maximum allowed under the Health Information Exchange Objective of the PI category, to incent clinicians to engage in bi-directional exchange via HIEs and to recognize that the measure requires a broader standard of performance on information exchange than is required to satisfy the two existing measures. The new measure would apply to all patient encounters and all patient records (i.e., no partial credit would be available). CMS notes that actions required to satisfy the new measure would not affect the applicability of any HIPAA Privacy Rule provisions.

The measure would be satisfied through attestation and the proposed attestation language is shown below:

> ++ I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.
>
> ++ The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.
>
> ++ I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).

Comments were numerous and were generally supportive of the measure, its optional use as an alternative to two existing measures, and its 40-point value. Some commenters were concerned that the measure is premature given variable access by clinicians to bidirectional exchange at this time. Others requested that CMS provide examples or a list of HIEs having the attributes specified in this measure. Delayed implementation was recommended to allow alignment of the measure with the Medicare PI Program for hospitals and critical access hospitals. Concern was raised about the significant expenses for clinicians related to reporting the new measure, and it was suggested that the measure be phased-in with an allowance for partial credit.

Requests also were received to revise the language of the 2nd attestation statement to specifically include exchange frameworks or other organizations focused on bidirectional exchange, or to remove the statement. Others asserted that clinicians should not have to attest to the capabilities of their HIE as these may not be made known to clinicians by their institutions or their HIEs.

CMS emphasizes that the measure is optional and should incent expansion of access to bidirectional exchange. CMS clarifies that enabling bi-directional exchange does not mean that an eligible clinician would be required to conduct information transactions that are not clinically necessary, but instead that eligible clinician has established the capabilities necessary to complete exchanges of information for their patients at the appropriate time. CMS declines to delay implementation to align with hospital programs. CMS also rejects phased-in adoption with a partial credit allowance for this measure since it is optional and attestation-based.

CMS clarifies that the measure requires connection to an HIE to receive the assigned 40 points, not simply that the clinician is ready and able to participate in bidirectional change and is awaiting vendor support. CMS further clarifies that if a clinician meets the exclusion criteria for the electronic prescribing measures, the latter measure's 10 points would be additive to the new measure's 40 points. CMS declines to provide examples or a list of HIEs with the capabilities necessary to satisfy this measure to avoid appearing to endorse specific HIEs and because the HIE space is rapidly changing. CMS encourages HIEs who satisfy the terms of this measure to publicly announce their availability and that institutions supplying HIE access to clinicians make their clinicians aware of their HIE's capabilities.

CMS further clarifies that clinicians practicing near a state border are not required to connect to multiple HIEs. CMS also clarifies that clinicians reporting this measure must use CEHRT to engage in bidirectional exchange but that content outside their CEHRT would not be included for reporting (e.g., patient portal messages).

CMS emphasizes that this measure does not override applicable privacy or electronic health record access policies at the state, tribal, or federal level. CMS revises the first attestation statement to explicitly state that bidirectional exchange is conducted in accordance with applicable law and policy, shown below. CMS indicates that the 2nd attestation statement is already worded such that arrangements denoted as exchange frameworks and networks or similar terms are included. CMS revises the third attestation statement to make clear that flexibility is being provided for clinicians to use different functions of Certified Electronic Health Record Technology (CEHRT) as appropriate to enable bidirectional exchange with any HIE that otherwise meets this measure's requirements, shown below.

FINAL ACTION: CMS finalizes the proposals for adding a new bidirectional exchange measure as proposed with modifications to the first and third attestation statements. The finalized complete statement is shown below:

++ I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.

++ The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.

++ I use the functions of CEHRT to support bidirectional exchange with an HIE.

c. Promoting Interoperability Scoring Methodology

CMS proposed that for the 2021 PI performance period, clinicians would be scored as described in Table 48 of the rule. Commenters were supportive.

FINAL ACTION: CMS finalizes PI scoring as proposed, shown below.

TABLE 48: Scoring Methodology for the Performance Period in CY 2021		
Objective	**Measure**	**Maximum Points**
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)
Health Information Exchange OR	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information *	20 points
Health Information Exchange	HIE Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	10 Points

Note: The Security Risk Analysis measure is required, but will not be scored.
*Measure with a proposed name change in this proposed rule.

d. Other Promoting Interoperability Category Considerations

PI Reporting by Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

CMS previously established a policy for the 2017 through 2020 performance periods to assign a weight of zero to the PI performance category if CMS determines that there are insufficient measures applicable and available to these clinician types. Were such a clinician to report data, however, that clinician would instead be scored for the PI category using their data under the general MIPS PI scoring policies currently in effect.

CMS analyzed PI data submitted for the 2017 through 2019 performance periods to assess whether reweighting in fact remains appropriate. While individual submission of PI category data by these clinician types has increased somewhat over time, the most recent participation rate of 30 percent actually represents a slight decline. CMS proposed to maintain the established policy of reweighting the PI category to zero for these clinician types for the 2021 performance period but scoring any clinician who submits PI data during that period.

FINAL ACTION: Commenters were supportive, and CMS finalizes the proposal without modifications.

PI Reporting by Physical Therapists, Occupational Therapists, Qualified Speech-language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

For the 2020 PI performance period, CMS finalized a policy to treat physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals in the same manner as the previously discussed group (nurse practitioners, etc.). Having no new, specific PI reporting data for these clinician types and given the likely impacts of the COVID-19 PHE, CMS proposed for the 2021 performance period to maintain the established policy of reweighting the PI category to zero but scoring any clinician who submits PI data during that period.

FINAL ACTION: The sole comment received was supportive, and CMS finalizes the proposal without changes.

5. APM Scoring Standard and APM Entity Groups

a. APM Scoring Standard Termination (§414.1370)

The APM scoring standard was designed to encourage APM participation by clinicians delivering care through APMs but failing to reach QP status and its associated MIPS reporting exemption. CMS has concluded that the standard is not feasible to fully implement, and proposed to eliminate the APM scoring standard effective January 1, 2021, allowing MIPS APM clinicians to report at the individual and group level rather than only through their APM entities. CMS also proposed to redesignate in part the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and to title that section "APM Entity Groups." (Also, as finalized earlier in this rule, CMS has added the APM Performance Pathway as an option for MIPS reporting and scoring, available for MIPS APM clinicians starting January 1, 2021.) Comments were few but supportive.

FINAL ACTION: CMS eliminates the APM Scoring Standard effective January 1, 2021, as proposed and consolidates regulations for APM Entity group determinations at § 414.1317.

b. APM Entity Groups: Eligibility

CMS groups and assesses eligible clinicians through their collective participation in an APM Entity group that is in an Advanced APM for the purpose of QP determinations. Determinations are made for clinicians appearing on APM Participation Lists or Affiliated Practitioner Lists on QP status snapshot dates (March 31, June 30, and August 31), and on December 31 for clinicians

in certain APMS, termed "full-TIN APMs".[16] Concomitant with terminating the APM scoring standard, CMS proposed to:

- End the full-TIN policy (expanding eligibility for December 31 QP determinations);
- Delete the defined term "full-TIN APM"; and
- Allow MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any snapshot date (March 31, June 30, August 31, or December 31) to be considered participants in an APM Entity group, beginning in the 2021 MIPS performance period.

FINAL ACTION: Absent comments, CMS finalizes the above proposal without modifications.

c. APM Entity Groups: Low-volume Threshold

CMS states that termination of the APM scoring standard ends the need to conduct MIPS low-volume exception threshold assessments at the APM Entity level. CMS, therefore, proposed to no longer make low-volume assessments at the APM Entity level effective January 1, 2021 and to modify the definition of low-volume threshold accordingly at §414.1305.

FINAL ACTION: Absent comments, CMS finalizes the above proposal without modifications.

d. APM Entity Groups: Scoring and Score Reweighting (§414.1317)

CMS proposed to adapt some policies that were first created in association with the APM scoring standard for continued application to APM Entity groups and move those adapted policies from § 414.1370 to § 414.1317, shown below, effective beginning January 1, 2021.

- When performance category data are not reported by an APM Entity, CMS would use the highest available score for each clinician in the group.
- Available scores could be a group score reported by a TIN to which the clinician belongs or an individual score using data reported by the clinician.
- When a MIPS eligible clinician in an APM Entity is excepted from otherwise applicable reporting requirements, CMS would use a null score for that clinician when calculating the entity's performance category score.
- When scoring is available from the preceding performance period, CMS would calculate an improvement score for each performance category having prior scores.

FINAL ACTION: Absent comments, CMS finalizes the above proposal without modifications.

e. APM Entity Groups: Score Reweighting (§414.1317)

CMS also addressed performance category reweighting for APM Entity groups during extreme and uncontrollable circumstances through the proposals below, beginning with the 2020 performance year.

[16] A full TIN APM is an APM where participation is determined at the TIN level, and all eligible clinicians who have assigned their billing rights to a participating TIN are therefore participating in the APM.

- An APM Entity group may apply for MIPS performance category reweighting due to extreme and uncontrollable circumstances.
    - The request would apply for all 4 categories and all MIPS eligible clinicians in the group, and would be approved or denied in its entirety.
    - In its application, the entity must demonstrate that over 75 percent of its participant MIPS eligible clinicians would be eligible for PI reweighting.[17]
- If CMS approves the request, the group's clinicians would be excepted from MIPS for the applicable performance period and the APM Entity's final score would be set equal to the applicable year's MIPS performance threshold. Any group data submitted during the applicable performance period would not override the reweighting to trigger scoring of the group on the data submitted.

These proposed reweighting policies could be considered changes to the scoring methodology and payment after the associated performance year has begun. However, CMS states that it would be contrary to the public interest not to establish these policies for the 2020 performance year. Absent these policies, reporting requirements specific to the Shared Savings Program would preclude its participants from taking advantage of extreme and uncontrollable circumstances that are available to other MIPS eligible clinicians.

FINAL ACTION: After receiving only supportive comments, CMS finalizes the reweighting provisions described above as proposed.

F. Merit-Based Incentive Payment System (MIPS): Final Scoring Methodology and Payment Adjustments

1. Final Scoring Methodology: Quality Performance Category Scoring

a. Existing Policy Extensions

CMS states that proposals for performance year 2021 are limited to those necessary to maintain MIPs program stability and are confined to the Quality performance category. No scoring policy changes were proposed for the Cost, IA, and PI categories. CMS proposed to continue several quality-scoring policies without change other than extending their applicability through performance year 2021 (payment year 2023):

- Assignment of achievement points, including maintaining a 3-point floor for all quality measures for which data are properly submitted, can reliably be scored against its benchmark, and meet the requirements for case minimums and data completeness.
- Scoring of measures that fail case minimums or data completeness, or that lack a benchmark, as described in Table 43 of the proposed rule. (The proposed scoring policies are identical to those shown below in Table 49 of this final rule.)
- Awarding bonus points for reporting high priority measures and to cap those points at no greater than 10 percent of the total available measure achievement points.

[17] This 75 percent criterion is consistent with policies for PI reweighting for hospital-based and non-patient-facing clinician groups.

- During improvement scoring calculations, substitute a 30 percent Quality category achievement score for the preceding year (base year for comparison) for clinicians who earned a score equal to or less than 30 percent.

Most commenters supported continuation of the existing policies listed above through performance year 2021. CMS declines a request to raise the 3-point floor to 5 points to mitigate PHE effects. A few commenters opposed continuing to assign 3 achievement points to measures without a benchmark; CMS notes the potential for changing this via future rulemaking.

FINAL ACTION: CMS extends the applicability through performance year 2021 of the existing policies listed above. Table 49 in the rule summarizes the 2021 scoring policies, shown below.

TABLE 43: Quality Performance Category: Proposed Scoring Policies for the CY 2021 MIPS Performance Period*

Measure type	Description	Scoring rule for Traditional MIPS
Class 1	Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2021.)	For the 2021 MIPS performance period: 3 to 10 measure achievement points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark; and (2) Meets case minimum.	For the 2021 MIPS performance period: 3 measure achievement points.
Class 3	Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero points for these measures. Small practices will continue to receive 3 points.

*Administrative claims-based measures and CMS Web Interface measures are not subject to the Class 2 and Class 3 scoring policies.

b. Scoring Flexibility: Truncation and Suppression

CMS also proposed to provide scoring flexibility for use when a measure's specifications, coding, or clinical guidelines change during a performance year and the change(s) would impair data submission or could produce potentially misleading results. Beginning with the 2021 performance period, in such circumstances CMS would attempt scoring based on data from 9 consecutive months of the affected performance period (truncation).[18] Absent such data, the

[18] CMS has previously applied this approach to measures affected by ICD diagnostic codes updates, which occur annually in October.

measure would be excluded from scoring and CMS would remove its potential 10 achievement points from the clinician's total available achievement points (suppression).

Some commenters were supportive; some were opposed viewing the proposed policy as confusing and introducing additional complexity to the already complex MIPS program. Others queried implementation details, such as whether clinicians could select the 9 months of their data that would be scored when CMS truncates a measure. (CMS clarifies that the agency determines the 9-month period.) Several commenters asked about the expected impact of the proposed policy, i.e., the number of measures affected in a performance year. CMS responds that truncation and suppression have been rare events to date, but also that the future total impact is unpredictable, particularly in the context of the COVID-19 PHE. CMS clarifies that it will monitor the impact of the markedly increased use of telehealth services on data available for MIPS quality reporting and apply truncation or suppression as needed.

FINAL ACTION: CMS finalizes the policy for truncation and suppression as proposed other than wording changes to clarify that the finalized policy applies to all measure collection types including administrative claims measures. The finalized provisions appear at § 414.1380(b)(1)(vii)(A), having been consolidated from existing §§ 414.1380(b)(1)(vii)(A) and (b)(1)(viii).

c. Measure Benchmark Baselines

Based on concerns that data for 2019, the historical performance year for 2021 performance period benchmarking, would not be sufficiently representative for benchmark derivation due to COVID-19 PHE impacts, CMS proposed to use its established regulatory flexibility to set benchmarks based on actual data from the 2021 performance period. CMS also considered an alternative to use 2018 performance data to set 2021 benchmarks. The alternative would allow clinicians to know their benchmarks in advance, as is usually the case, whereas the proposed policy would not.

Many commenters supported the use of actual concurrent performance year data for benchmark-setting for performance year 2021. Others voiced concerns about the inability to know benchmarks in advance particular in the uncertain background of the ongoing pandemic. A suggestion was offered that CMS calculate two sets of benchmarks, one historical and one concurrent, and apply whichever was most favorable to clinicians for each measure.

CMS responds with the results of the agency's analysis of the actual 2019 data that have become available since the publication of the proposed rule: the data are sufficient, reliable and complete (or at least representative) to calculate historical benchmarks as is usually done. CMS notes slight increases in reporting of electronic quality measures and group reporting and also only a slight increase in the number of clinicians not reporting to MIPS in 2019 compared to 2018.

FINAL ACTION: Based on its analysis of 2019 actual data, CMS does not finalize the proposal to derive measure benchmarks for 2019 from concurrent performance year data. Historical benchmarks will be calculated and applied.

d. Topped Out Measures

Because setting benchmarks using concurrent performance year data for 2021 would interfere with the established process for topped out measures, CMS proposed to modify the policy for topped out measures as follows: a measure would be considered topped out were it to be identified as such in the historical baseline-based benchmarks for the 2020 MIPS performance period and in the performance period-based benchmarks proposed for use in the 2021 performance period. CMS stated that the established 7-point scoring cap, however, would be retained for topped out measures for performance year 2021 (and subsequent years).

Comments were focused on opposition to retention of the 7-point scoring cap. CMS disagrees, stating that the topped out measures should not be eligible to receive the same maximum 10 points as for measures that demonstrate variations in performance and room for improvement (i.e., measures that are not topped out). CMS concludes by noting that benchmarks for 2021 will in fact be derived from historical data as usual, so that the proposed policy modification as described above is unnecessary.

FINAL ACTION: CMS does not finalize its proposal to modify how topped out measures are identified for the 2021 performance year. CMS affirms that the established 7-point scoring cap will continue to apply to topped out measures.

e. Case Minimums

CMS has previously established a case minimum of 20 cases for quality measure scoring, except for the all-cause hospital readmission measure, an administrative claims-based measure, for which the minimum is set at 200 cases. CMS notes having proposed beginning in performance year 2021 to replace the all-cause hospital readmission measure with a new hospital-wide readmission measure for group reporting, also claims-based and with a 200-case minimum (see Table Group A in Appendix 1 of the rule). CMS further notes having proposed for 2021 a second new administrative claims-based measure *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for MIPS* for which the case minimum is set at 25 and the measure is applicable to individuals and groups. CMS proposed to amend the existing case minimum policy, retaining the default minimum for MIPS quality measures at 20, but to set minimums for administrative claims-based measures individually for each measure and communicate that information through the annual MIPS final list of quality measures.

A commenter objected to the 25-case minimum for the new arthroplasty complication measure as insufficient to produce meaningful data. CMS disagrees, stating that the measure's reliability is acceptable and that the minimum as set allows more clinicians to be able to be scored. Another commenter did not support the proposal to set minimums for claims-based measures on a case-by-case basis. CMS disagrees, noting that the proposal allows case minimums to be tailored to the design of each measure.

FINAL ACTION: CMS finalizes the case minimum requirements as proposed: a default minimum of 20 cases for MIPS quality measures and to set minimums for claims-based measures on a case-by-case basis.

f. High-Priority Measure Reporting Incentives

CMS restates its intent to consider removal of the bonus for reporting multiple high-priority measures (the total bonus points cannot exceed 10 percent of the total available measure achievement points) in future rulemaking. In consideration of potential COVID-19 impacts, however, for performance year 2021, CMS proposed to extend the bonus for this year. Commenters supported extending the policy for 2021 and opposed future removal of the bonus.

FINAL ACTION: CMS finalizes its proposal to continue to apply the high-priority bonus measure scoring policy without change through performance year 2021.

g. Incentive for End-to-end Reporting Using CEHRT

CMS restates their intent to consider removal of the bonus for end-to-end measure reporting using CEHRT (the total bonus points cannot exceed 10 percent of the total available measure achievement points) in future rulemaking. In consideration of potential COVID-19 impacts, however, for performance year 2021, CMS proposed to extend the bonus for this year. Commenters supported extending the policy for 2021 and its continuation in future years.

FINAL ACTION: CMS finalizes its proposal to continue to apply the end-to-end CEHRT reporting bonus measure scoring policy without change through performance year 2021.

2. Final Scoring Methodology

a. Complex Patient Bonus

The complex patient bonus was established for performance year 2018 to satisfy the statutory mandate to consider risk adjustment in the MIPS program (Section 1848(q)(1)(G) of the Act). The bonus is a maximum of 5 points added to a clinician's MIPS total score and is determined based on beneficiary HCC scores and dual eligibility status. After extensively reviewing the potential increases in complexity of caring for patients in performance year 2020 due to the COVID-19 PHE, CMS proposed to double the bonus points awarded to ensure care access and quality for vulnerable beneficiaries. CMS stated that this retrospective MIPS payment change was justified as failure to increase the bonus for 2020 to adjust for COVID-19 effects on patient complexity that could not have been anticipated during the 2020 rulemaking cycle would be contrary to the public interest. The bonus would be calculated as usual based on beneficiary Hierarchical Category Condition (HCC) risk scores and the presence of dual Medicare-Medicaid eligibility. That number would then be doubled, with a possible maximum total of 10 points added to clinicians' MIPS final scores. CMS considered alternatives including maintaining the bonus unchanged, tripling the bonus, and adding a new complexity factor specific to patients with COVID-19.

Most commenters supported doubling the bonus and its retrospective application to performance year 2020. Some requested continuation of a higher bonus for 2020 and continuing a higher bonus for the 2021 performance period or permanently. Others voiced concerns about inadvertently inflating MIPS final scores, masking poor performance by clinicians, rewarding clinicians who did not treat significant numbers of COVID-19 patients, incenting upcoding by clinicians, and duplicating increased payments already put in place through Part A and Part B reimbursement.

CMS states its assessment that continuation of the increased bonus beyond performance year 2020 should not be necessary but will reassess when more data become available. CMS further states that the benefit of the bonus in supporting care for vulnerable patients outweighs the potential for inflating MIPS final scores or masking poor performance. CMS also states that the care of all vulnerable beneficiaries has been rendered more complex by the pandemic regardless of COVID-19 patient numbers treated and that upcoding intended to boost beneficiary HCC scores is not feasible since the scores for 2020 are based on 2019, pre-COVID-19, data. CMS concludes by noting that the complex patient bonus is designed to capture care complexity as it relates to MIPS scoring not care costs and is unrelated to COVID-19-related Part A and Part B reimbursement adjustments.

FINAL ACTION: CMS finalizes doubling of the complex patient bonus for performance year 2020 as proposed. Bonus calculation will first follow existing formulas then be doubled up to a maximum of 10 points added to the final MIPS performance score.

b. Performance Category Weights

CMS proposed category weights for performance periods 2021, 2022, and future years as shown in Table 44 of the proposed rule. Those weights were discussed then finalized as proposed in earlier category-specific sections of this rule. The finalized weights are shown in the table below (modified from Table 50 in this final rule).

Performance Category	**Performance Year 2021 (Proposed and Final)**	**Performance Year 2022 and Future MIPS Years (Proposed and Final)**
	Payment Year 2023	**Payment Year 2024 and Future MIPS Years**
Quality	40%	30%
Cost	20%	30%
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

CMS notes its authority for category score reweighting (Section 1848(q)(5)(F) of the Act) and reviews its approaches to category reweighting for previous performance years. In general, CMS has avoided increasing the Cost category weight, believing that this category is the most challenging and least familiar to clinicians. CMS has seldom increased the IA category weight,

regarding it as less rigorous since IA measures most often are satisfied by attestation than by data submission. CMS proposes reweighting policies for performance year 2021 and for 2022 and future years in tables 45 and 46 of the rule, respectively (recreated below). With the statutory rise of the Cost category weight to 30 percent for performance year 2022, CMS expects clinician familiarity with cost measures to increase and proposes Cost category weight increases in certain circumstances.

c. Redistributing Performance Category Weights

CMS proposed reweighting policies for performance year 2021 and for 2022 and future years in tables 45 and 46 of the proposed rule. The agency continues to generally follow the principle of not redistributing weight to the Cost performance category given clinicians'' relative lack of experience with this category. Proposed changes to redistributing policies for performance years 2021 and 2022 are required by CMS' decision, finalized earlier in this rule, to increase the Cost category weight to 20 percent and decrease the Quality category weight to 30 percent.

Commenters generally supported the principle not to redistribute weight to the Cost category. Some suggested changes to decrease the weights of the IA and PI category weights, as they consider those categories to be of less importance to clinical care than the Quality category. CMS disagrees and particularly emphasizes its commitment to advancing interoperability.

FINAL ACTION: CMS finalizes the proposals for category reweighting for performance years 2023 and 2024 without modifications as shown below in Tables 51 and 52, respectively, from the final rule.

TABLE 51: Performance Category Redistribution Policies Finalized for the 2023 MIPS Payment Year (2021 Performance Year)

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	40%	20%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	65%	20%	15%	0%
-No Quality	0%	20%	15%	65%
-No Improvement Activities	55%	20%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
-No Quality and no Improvement Activities	0%	20%	0%	80%

TABLE 52: Performance Category Redistribution Policies Finalized for the 2024 MIPS Payment Year (2022 Performance Year)

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

d. MIPS Applications for Reweighting for Payment Year 2021 Based on Extreme and Uncontrollable Circumstances

CMS reprises interim policies adopted in the March 31st COVID-19 IFC to provide MIPS burden relief and added flexibility for clinicians for whom MIPS participation is impaired by the pandemic: 1) extending the deadline for submitting an application for performance category reweighting; and 2) creating a policy exception for the 2019 performance period only, such that data submitted by a clinician(s) already approved for reweighting for one or more MIPS performance categories will not override the approved application and the clinician(s) will not be scored on the data submitted.

Commenters were generally supportive. Others sought to broaden the policies by, for example, not requiring clinicians to demonstrate that they have been impacted to be granted reweighting. CMS responds that the suggestions for broadening the interim policies are inconsistent with statute or would create undue burden.

FINAL ACTION: CMS adopts the interim final policies as final

e. MIPS Applications for Reweighting for Payment Years 2023 Based on Extreme and Uncontrollable Circumstances

CMS states an expectation that the COVID-19 PHE will continue into and through performance year 2021 (payment year 2023). CMS through this final rule reminds clinicians that they may submit applications for category score reweighting under the MIPS extreme and uncontrollable policy if they find themselves to be significantly impacted by the pandemic. Reweighting may be requested by an individual MIPS eligible clinician, group, or virtual group for one or more MIPS

performance categories. CMS notes that any reweighting application will be overridden were the applicant to submit 2021 performance period data and the applicant will be scored using the data submitted.

FINAL ACTION: This informational item from CMS does not require any action by the agency.

3. MIPS Payment Adjustments

a. Final MIPS Score Hierarchy

CMS proposed to update the hierarchy by which a final score is assigned to a clinician (as represented by a TIN/NPI combination) who has more than one MIPS final score within a given performance period. The simplified hierarchy would prioritize a virtual group final score over all others while currently an APM Entity final score takes precedence. Most commenters were supportive of the new hierarchy, but a few stated that it devalued ACO participation. CMS disagrees.

FINAL ACTION: CMS finalizes the revised hierarchy for assigning a final MIPS score to a clinician who has two or more MIPS final scores for use beginning with performance year 2021, as shown in Table 54 of the rule, recreated below.

TABLE 54: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

b. Establishing the Performance Threshold

Payment adjustments for clinicians subject to MIPS are determined by comparing their final MIPS scores to a threshold score set annually by the Secretary within statutory parameters. For performance year 2021/payment year 2023, the performance threshold was set in the 2020 PFS final rule at 60 points, an increase of 15 points from the prior year. At that same time, the threshold score for performance year 2022 was estimated to be 74.01 points.

In the 2021 PFS proposed rule, due to concerns about the disruptive effects of the COVID-19 PHE on healthcare delivery and on the ability of clinicians to collect and submit their MIPS data, CMS proposed to 1) lower the MIPS threshold to 50 points for the 2021 performance year; 2) leave the estimated threshold score for performance year 2022 unchanged at 74.01 points; and 3)

revisit and perhaps revise the estimated score of 74.01 points for performance year 2023 if new data were available.

CMS notes that for performance year 2022/payment year 2024, statute requires that 1) the Secretary set the performance thresholds at the mean or median of the final scores for all MIPS clinicians for a prior period specified by the Secretary; and 2) the threshold scores for performance years 2019 through 2021 increase in a way that ensures a gradual and incremental transition leading up to performance year 2022. CMS also notes that in the interval since publication of the 2021 proposed rule, actual clinician scores from performance year 2019 have become available, demonstrating a mean of 79.8 points and a median of 85.27 points.[19] Finally, CMS notes that the 2019 data were submitted by clinicians or their agents (e.g., third party intermediaries) during the early months of the COVID-19 PHE (January through March, 2021).

Several commenters did not support decreasing the MIPS performance threshold for performance year 2021 to 50 points from the previously finalized 60 points. These commenters argued the proposal woul lessen the incentive for clinicians to participate and score well in the MIPS program. Others argued for a threshold even lower than 50 (e.g., 45 points) to further reduce burden for clinicians who continue to care for COVID-19 patients as the pandemic continues. CMS responds that the newly available 2019 data support the ability of clinicians to satisfy MIPS requirements and to submit their performance data despite the ongoing COVID-19 PHE. CMS also agrees with commenters that a threshold score of 50 points does not incent clinicians to perform at their best in the MIPS program.

Commenters voiced concerns about revising the projected performance threshold of 74.01 points for performance year 2022, based on continued uncertainty about potential further effects of the COVID-19 PHE. Others agreed, suggesting that the incremental increase from 2021 to 2022 should not exceed 10 percent. Some urged CMS to work with the Congress to alter the statutory requirements for the 2022 performance year threshold to be set at the mean or median of all clinician scores. CMS agrees that the future impacts on clinician performance of the COVID-19 PHE remain unknown but stated that legislative change is premature at this time.

FINAL ACTION: CMS does not finalize its proposal to decrease the previously finalized MIPS threshold score for performance year 2021 to 50 point from 60 points. CMS also does not finalize its proposal to revise the estimated threshold score of 74.01 points for performance year 2022. Table 56 of the rule shows the resulting finalized threshold score progression over time, and is reproduced below in part.

Table 56: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year						
Payment Year	**2019**	**2020**	**2021**	***2022**	**2023**	**2024**

[19] Because targeted score reviews are still ongoing, these estimates are not yet final.

Table 56: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year						
Performance Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Performance Threshold	**3 points**	**15 points**	**30 points**	**45 points**	**60 points**	**74.01 Points**

*Some clinicians were excepted from MIPS reporting based on qualifying for the MIPS extreme and unusual circumstances policy.

c. Example of Adjustment Factors

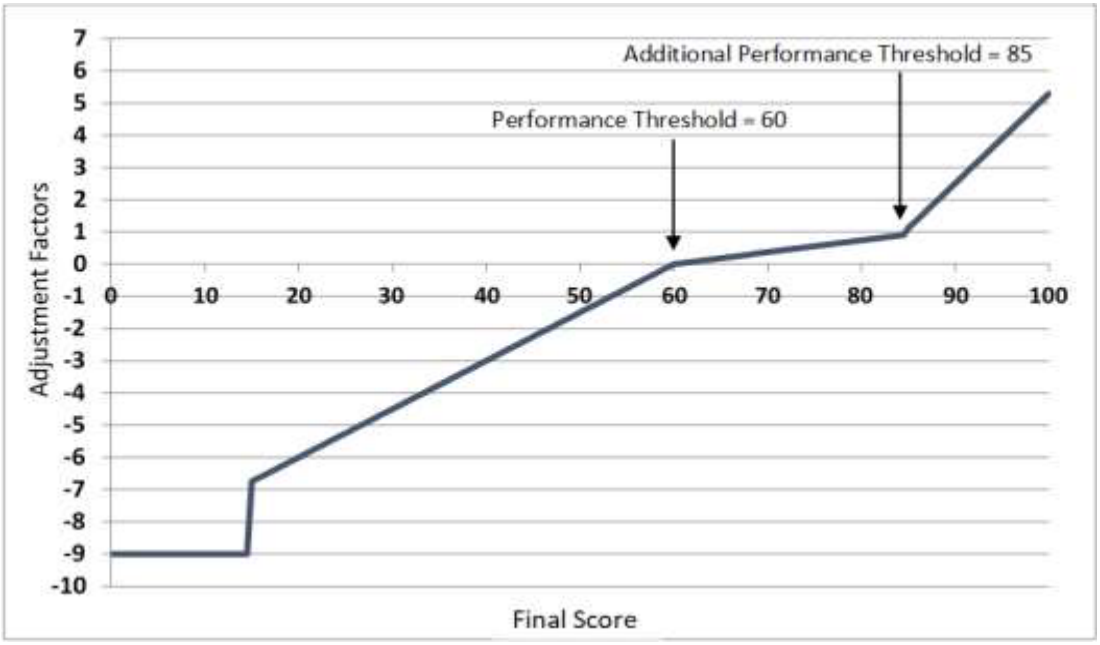
Each year CMS provides a figure to illustrate how MIPS final performance scores are converted into payment adjustment factors. Figure A, the finalized example figure for payment year 2023, which is based on performance year 2021, is reproduced at the end of this section. The example takes into account the finalized MIPS performance threshold of 60 points and the threshold for exceptional performance of 85 points, as set for performance year 2021, along with the statutory MIPS adjustment percentage of ± 9 percent for payment year 2023.[20]

CMS also annually provides a table illustrating the MIPS final point score intervals and their corresponding adjustment percentages. Table 57 from the rule, excerpted at the end of this section, reflects the finalized performance thresholds, 2023 MIPS payment adjustment range, and finalized MIPS policies for performance year 2021.

FINAL ACTION: Finalized policies and thresholds and their payment adjustment correlations are demonstrated in Figure A and Table 57 from the rule, shown below.

[20] A scaling factor to ensure budget neutrality of MIPS payment adjustments is also applied. The additional payment adjuster for exceptional performance ranges from 0.5 to 10 percent and is also scaled to guide distribution of the $500 million funding pool available for this adjustment.

Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2023 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 85 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 57 Relationship of MIPS final performance score to MIPS payment adjustment for Performance Year 2021 (as modified by HPA from Table 57 of the final rule)	
Final Score Points	**MIPS Adjustment**
0.0 – 15.0	Negative 9%
15.01 – 59.99	Negative MIPS payment adjustment > negative 9% and less than 0% on a linear sliding scale
60.0	0 % adjustment
60.01 – 84.99	Positive MIPS payment adjustment > 0% on a linear sliding scale; the sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor > 0 but not exceeding 3.0 to preserve budget neutrality.
85 - 100	Positive MIPS payment adjustment > 0% on a linear sliding scale; the sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor > 0 but not exceeding 3.0 to preserve budget neutrality. **PLUS** An additional MIPS payment adjustment factor for exceptional performance that starts at 0.5% and increases on a linear sliding scale. The sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not > 1.0 in order to proportionately distribute the funds available for exceptional performance.

d. Feedback and Performance Improvement

CMS is required to provide clinicians with confidential, timely feedback on their Quality and Cost category performances and has previously established a policy to provide feedback annually.[21] CMS targets distributing feedback on or around July 1 of each year. In the proposed rule, CMS informed stakeholders that disruptions caused by the COVID-19 PHE would delay performance year 2019 feedback report release.[22] Through this rule, CMS indicates that the feedback report was released on August 5, 2020.

A commenter found the online portal for accessing reports confusing and difficult to navigate, and requested additional scoring information. CMS refers readers to the 2019 MIPS Performance Feedback Resources user guide that provides detailed information on portal access and additional scoring information.

FINAL ACTION: None required. CMS has satisfied its statutory requirement for giving feedback to MIPS clinicians about their 2019 performances.

[21] Provision of IA and PI performance category data is at CMS' discretion and is provided when technically feasible.
[22] Clinicians can now access reports by logging in at https://qpp.cms.gov/#:~:text=Performance%20Year%202019&text=Final%20performance%20feedback%20is%20available,or%20request%20a%20targeted%20review.

G. Third Party Intermediaries

1. MIPS Data Submission Requirements

CMS proposed to clarify requirements for MIPS data submission applicable to several types of third party intermediaries – Qualified Clinical Data Registries (QCDRs), Qualified Clinical Registries, and Health IT Vendors (HIT vendors) – particularly for those who might in the future decide to become involved with data submission related to MVPs. CMS proposed changes to §414.1400(a)(2) that would require all three types of intermediaries to be able to submit data for:

- The MIPS Quality performance category, except for the CAHPS for MIPS survey
  - Qualified registries and health IT vendors would not be required to support data submission for QCDR quality measures;
- The IA category; and
- The PI category, if the clinician (or group or virtual group) is using CEHRT
  - An intermediary may be excepted if the clinician (or group or virtual group) falls under a performance category reweighting policy.

Further, Health IT vendors who do not support MVPs must be able to submit data for at least one MIPS performance category other than the Cost category. CMS notes that data submission under the APP would also be subject to the proposed requirements and would entail reporting three quality measures as CQMs and eCQMs, beginning with performance year 2021.

FINAL ACTION: Commenters were supportive; CMS finalizes the proposals without changes.

2. Third Party Intermediary Approval Criteria

CMS notes having discovered failures of some third party intermediaries to meet existing requirements, behaviors that raise program integrity concerns, and interactions with their clinicians that encourage the latter to submit data that are not truly representative of their practices ("cherry picking"). CMS proposed to add language at §414.1400(a)(4)(ii) to strengthen the approval criteria for all types of intermediaries by explicitly adding failure to meet existing requirements and encouraging inaccurate data submission as factors to be used by CMS when making approval decisions.

FINAL ACTION: CMS finalizes the proposed language and clarifies that an entity subject to a Corrective Action Plan is not automatically disqualified as a third party intermediary.

3. Third Party Training and Support

Currently, QCDRs and qualified registries already are expected to participate in CMS' ongoing support conference calls for intermediaries and an annual in-person meeting at CMS headquarters. CMS proposed to broaden requirements for participation in training and support activities from QCDRs and qualified registries to include HIT and survey vendors beginning with the MIPS 2021 performance year, to be codified at §414.1400(a)(4)(iii).

FINAL ACTION: After receiving a few comments both of support and opposition, CMS finalizes the requirement as proposed that all third party intermediaries including HIT and survey vendors participate in CMS' third party training and support activities.

4. Future Safeguards

Having become aware of potential program integrity concerns involving HIT vendors, CMS stated an intent to consider data validation and audit safeguards applicable to those vendors.[23] CMS also stated a belief that established requirements for survey vendors to have quality assurance plans in place prior to approval as vendors are sufficient to mitigate data accuracy concerns. CMS invited comment about potential requirements for HIT and survey vendors.

Commenters were divided regarding the establishment of data validation and audit processes for HIT vendors. Several noted that HIT vendors are now subject to "Real World Testing" of their certification criteria through the Office of the National Coordinator for HIT (ONC) and that added requirements for data validation and audit would be duplicative and burdensome.

FINAL ACTION: CMS opts to work with ONC to coordinate oversight requirements for HIT vendors rather than move forward with data validation or audit regulations through future rulemaking. CMS further concludes that current quality assurance requirements for CMS-approved survey vendors are sufficient.

5. QCDR Data Validation and Targeted Audits

a. Data Validation Audit

In prior rules and guidance, CMS has set expectations that QCDRs and qualified registries would 1) validate their data prior to submission; 2) provide CMS with a data validation execution report by May 31st of the year following the performance period (shortly after the submission period closes on March 31); and 3) correct, prior to data submission to CMS, any data found by the QCDR to be inaccurate, incomplete, or otherwise compromised. Uncorrected flawed data could lead to remedial action or termination of QCDR approval. CMS proposed to codify data validation and targeted audit requirements to be part of QCDR approval criteria for performance year 2021 at §414.1400(b)(2)(iv) and (v)), listed below.

- Data validation audits must be conducted annually, before data are submitted to MIPS.
- Validation must be conducted for each performance category and for each submitter type under which data will be submitted by the QCDR;[24]

[23] CMS notes that not all HIT developers also act as HIT vendor intermediaries under MIPS and the safeguards would be relevant to those who fill both roles. HIT developers must comply with requirements set by the office of the National Coordinator (ONC) for HIT when seeking CEHRT certification for their health IT modules.
[24] Submitter types would include MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants, as applicable. CMS notes that voluntary participant data may be publicly posted (Physician Compare).

- Validation that an action was performed or an outcome was measured must be obtained by the QCDR (i.e., clinical documentation provided by the reporting clinicians);
- Sampling methodology for a validation audit must –
    - Use a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data, unless a 3 percent sample would capture fewer than 10 TIN/NPIs;
    - Use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample would capture more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs; and
    - Use a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample; the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.[25]
- The audit must include –
    - Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant;
    - Verification of the accuracy of TINs and National Provider Identifiers;
    - Calculation of reporting and performance rates according to the quality measure's specifications; and
    - Verification before submission that only MIPS quality measures and QCDR measures that are valid for the performance period being reported have been used.

The QCDR must report the validation results, including the overall deficiency or data error rate; types of deficiencies or errors discovered; the percentage of clinicians impacted by any error or deficiency; and how and when each deficiency or data error type was corrected. The report must be produced in a form and manner specified by CMS and by a CMS-specified deadline.

CMS received numerous comments and discusses them at length.[26] The most prominent objections are listed below with CMS' responses:

- the heavy burden that data validation would impose upon the QCDRs --
    - CMS disagrees that the level of effort required to conduct data validation causes undue burden for QCDRs;
- the limited ability of QCDRs to ascertain whether data provided to them by clinicians are true and accurate –
    - when a clinician(s) fails to produce documentation, and/or to correct what appear to be data errors, upon request of the QCDR, the QCDR should advise the clinician(s) that the QCDR will not submit upon their behalf;
- requesting that CMS provide tools to assist with the audit, including an API to verify eligibility of clinicians as Medicare providers --
    - CMS notes that information helpful to eligibility determinations is available at https://cmsgov.github.io/qpp-eligibility-docs;
- the excess compliance risk posed to the QCDR by transmitting protected health information (PHI) during a data validation audit –

[25] CMS notes that similar methods were used for the Physician Quality Reporting System that preceded MIPS.
[26] The full discussion can be read at pp. 1345-1361 of the display copy.

    - CMS disagrees that the audit requirements improperly increase risk to the confidentiality of PHI beyond that of other QCDR functions; and
- the complexity and extent of the sampling requirements --
    - the sampling methodology is familiar to many QCDRs since it was used in predecessor CMS programs (e.g., Physician Quality Reporting System)
    - CMS provides examples of sample size calculation to clarify the meaning of TIN/NPI.

CMS emphasizes that all data submitted to CMS by a third party intermediary on behalf of a clinician or clinician group must be certified by the intermediary as true, accurate, and complete to the best of its knowledge.

FINAL ACTION: CMS finalizes the data validation audit requirements as proposed (i.e., as listed above).

b. Targeted Audit

CMS proposed that when a data validation audit detects one or more deficiency or data error, a targeted audit must follow, during which the QCDR must investigate the impact and root cause for each deficiency or data error. For performance year 2021 and future years, CMS proposed the following requirements for targeted audits, to be codified at §414.1400(b)(2)(v):

- Targeted audits must be conducted, and all deficiencies and data errors discovered must be corrected, before data are submitted to MIPS for the relevant performance year;
- Targeted audits must follow the sampling methodology described above for data validation audits; and
- The samples for a data validation audit and its linked target audit may not overlap.

The QCDR must report results to CMS in a form and manner and by a deadline specified by CMS, to include the overall deficiency or data error rate; types of deficiencies or errors discovered; the percentage of clinicians impacted by any error or deficiency; and how and when each deficiency or data error type was corrected.

Comments specific to the targeted audit review were few. One suggested that the size of the target audit sample be left to the QCDR's discretion based on the nature of the error, with which CMS disagrees. CMS clarifies that random human error (e.g., coding error) requires a targeted audit just as does an error due to any other root cause.

FINAL ACTION: CMS finalizes the target audit requirements as proposed (i.e., as listed above).

c. Renaming the QCDR Section (§414.1400(b))

Finally, given the addition of requirements for data validation and targeted audits, CMS proposes to rename §414.1400(b) as "QCDRs" rather than "QCDR approval criteria" to reflect a broader content.

FINAL ACTION: Absent comments on the new section title, CMS finalizes it as proposed.

6. Revised Requirements for QCDR Measures

a. Requirements for Face Validity and Full Testing

During PFS rulemaking for 2021, CMS finalized a requirement for full development and testing of QCDR measures prior to their submission to CMS during the annual self-nomination period, beginning with performance year 2021. However, the May 8th COVID-19 IFC-2 delayed the effective date for full measure testing by one year, to performance year 2022, due to PHE-associated healthcare disruptions. Subsequently, in the 2021 PFS proposed rule, CMS further modified the full testing requirement, creating a final proposal that:

- QCDR measures previously approved for performance year 2020 would be required to have *face validity* prior to being self-nominated for performance year 2022;
    - Face validity would be defined as described by the CMS Blueprint: the extent to which a test appears to cover the concept it purports to measure "at face value". [27]
- Those approved measures having face validity would be required to be fully tested before self-nomination for any subsequent performance periods (i.e., 2023 and beyond);
    - Full testing would utilize the Blueprint's definition of beta-testing (also known as field testing): beta-testing serves as the primary means to assess scientific acceptability and usability of a measure.
- A new QCDR measure would be required to be face valid to be approved for the 2022 performance year; and
    - For approval in performance year 2023 and future years, the recently approved new measure would also need to be fully tested.

Most commenters supported the delayed implementation of full testing, and some asked for further delay. Others opposed any requirement for full testing as imposing added burden and cost on QCDRs and discouraging their further participation in the APP. CMS declines to consider further delay. CMS retains the requirement for full testing to ensure measures are reliable and valid. In response to queries about further details of testing, CMS directs commenters to the CMS Blueprint.

FINAL ACTION: CMS finalizes the requirements for QCDR testing as described above.

b. Measure Testing Requirements for Inclusion in MVPs

CMS proposed that a QCDR measure must be fully tested in order to be included within any candidate MVP submitted to CMS. Commenters were divided about this proposal. CMS responds that only fully tested measures are appropriate for inclusion in a national P4P program.

[27] The CMS Measures Management System (the Blueprint) is available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.

FINAL ACTION: CMS finalizes the proposal without modifications.[28]

c. Duplicative Measures and Measure Harmonization

CMS begins by restating the current meaning of *measure harmonization* to be "measures for which previously identified areas of duplication with other approved QCDR measures or MIPS quality measure have been addressed". To reflect the current terminology, CMS had proposed to revise previously codified policies that refer to measure harmonization such that:

- Beginning with performance year 2020, CMS could provisionally approve a QCDR measure for one year contingent upon the QCDR resolving certain areas of duplication with other measures (MIPS or QCDR approved);
  - if duplication is not resolved, the measure may be rejected;
- Beginning with performance year 2021, a QCDR measure could be approved for two years (rather than the usual one year) at CMS' discretion;
  - However, approval for the second year may be revoked if the measure is duplicative of a more robust measure, is topped out, contains an outdated clinical guideline, or if the measure's self-nominating QCDR is no longer in good standing; and
- Technical corrections would be made to remove two policies (at §§414.1400(b)(3)(vii)(H) and (L)), that would become redundant if the above two changes are finalized and to renumber the paragraphs remaining in §414.1400(b)(3)(vii).

FINAL ACTION: The majority of commenters were supportive of the changes, which CMS finalizes as proposed without modifications.

d. Data Collection Implementation Delayed by May 8th COVID-19 IFC

During 2020 PFS rulemaking, CMS had finalized that beginning with performance year 2021, QCDRs must collect data appropriate to the measure type before submitting that measure to CMS during the self-nomination period. Subsequently, in the May 8th COVID-19 IFC, CMS delayed implementing this requirement to begin with performance year 2022.

FINAL ACTION: CMS received supportive comments and finalizes the delay as provided for in the May 8th COVID-19 IFC without changes.

7. Qualified Registries

In prior rules, CMS set expectations for qualified registries that parallel the agency's expectations for qualified clinical data registries (QCDRs), such that qualified registries would 1) validate their data prior to submission; 2) provide CMS with a data validation execution report by May 31st of the year following the performance period (shortly after the submission period closes on March 31); and 3) correct, prior to data submission to CMS, any data found by the

[28] CMS has delayed proposing any MVPs for adoption until the 2022 PFS rulemaking cycle.

qualified registry to be inaccurate, incomplete, or otherwise compromised. Uncorrected flawed data could lead to remedial action or termination of the qualified registry's approval.

a. Data validation audit

CMS proposed to codify data validation and targeted audit requirements to be part of the criteria for approval applicable to qualified registries for performance year 2021. The requirements would remain at §414.1400(c), but the section would be retitled "qualified registries" rather than "qualified registry criteria" to align the title with the content of the regulation more closely. The data validation audit requirements proposed by CMS for qualified registries parallel those for QCDRs as listed above in section IV.F.5.a of this summary, other than referring to qualified registries rather than QCDRs.

The comments received by CMS about the proposed data validation audit requirements for qualified registries 1) noted the heavy burden that would be imposed on the registries by the audit requirements; and 2) asserted that any errors discovered by the registries would be attributable to the clinician(s) and not to the registry. CMS responds that beginning with performance year 2021, qualified registry approval requires the registry to satisfy data validation audit requirements. CMS also states that having discovered any error attributable to a clinician(s), a qualified registry shares responsibility with the clinician(s) to ensure that the inaccurate data are not included in the registry's submissions to CMS on behalf of the clinician(s).

FINAL ACTION: CMS finalizes the data validation audit requirements for qualified registries as proposed.

b. Targeted audit

CMS proposed that a targeted audit must follow the identification of any error by a qualified registry during a data validation audit. The requirements proposed by CMS for the targeted audit by a qualified registry parallel those proposed for targeted audits conducted by a QCDR as listed above in section IV.F.5.b of this summary, other than containing references to qualified registries rather than to QCDRs.

Commenters invoked concerns about the burden imposed on qualified registries by the targeted audit requirements. CMS responds that beginning with performance year 2021, qualified registry approval requires the registry to satisfy data targeted review requirements.

FINAL ACTION: CMS finalizes the targeted audit requirements for qualified registries as proposed.

8. Corrective Action Plans

CMS' options for remedial action against a third party intermediary include requiring the intermediary to submit a corrective action plan (CAP), and CMS specifies the timeline for plan

submission. CMS made several proposals designed to set expectations about and consistency of plan content by revising §414.1400(f)(1)(i). In addition to providing any intermediary-specific information requested by CMS, a CAP would be required to address all of the following:

1. All issues that contributed to the non-compliance;
2. The impact to individual clinicians, groups, or virtual groups, regardless of their MIPS participation status (i.e., MIPS eligible, voluntary participants, or opting in);
3. Corrective actions that the intermediary will take to resolve the non-compliance and prevent future recurrence; and
4. A timeline detailing when the intermediary will become compliant with all applicable requirements.

A single commenter sought guidance on the scope of required reporting for clinician impact and/or harms and how the intermediary could approach quantifying the impart and/or harms. CMS directs the commenter to regulation text at §414.1400(f)(1)(i) specifying that information about the volume and identity of clinicians that have been negatively impacted by the intermediary's non-compliance must be provided, and states that the how the impact is quantified should be tailored based on the nature of the non-compliance.

FINAL ACTION: CMS finalizes the revised CAP policy as proposed.

H. Public Reporting on Physician Compare

CMS notes that the definitions of "Physician Compare" in the Affordable Care Act and in MACRA are not in agreement. CMS proposes to codify the definition that appears in MACRA at §414.1305: *Physician Compare Internet Web site of the Centers for Medicare & Medicaid Services* (or a successor Web site).

FINAL ACTION: Having received no comments, CMS finalizes the definition as proposed.

I. APM Incentive Payment §414.1450

1. Basis for Payment

APM incentive ("bonus") payments are made to clinicians who meet or exceed statutory thresholds for the amount of care they deliver through APMs sponsored by Medicare or other payers. The bonus payment also is set in statute (section 1833(z)(1)(A) of the Act) at 5 percent of the estimated aggregate payments for covered professional services provided in the incentive payment base period – the calendar year following the applicable performance year.[29]

CMS proposed to add clarifying language (at §414.1450(b)(1)) to state that the payment amount is calculated using paid amounts on claims submitted from January 1 through December 31 of the incentive base period, thereby excluding amounts that were allowed but not paid. In

[29] Covered professional services are defined in section 1848(k)(3) of the Act.

response to comments, CMS notes that using the paid amounts, rather than the allowed amounts, is set in statute.

FINAL ACTION: CMS finalizes the proposed clarification without change.

2. Payment Recipient Identification

CMS notes that the APM incentive payment is made to the TIN through which the clinician participated (through an APM Entity in an Advanced APM) to reach QP status. When the clinician has left that TIN, CMS seeks to disburse the payment to the TIN listed on the clinician's CMS electronic funds transfer form as of the day of payment (CMS-588 EFT). CMS adds that when a clinician achieves QP status by participating in multiple APMs, the bonus is apportioned according to the covered professional service payments made to each of the APMs for the clinician and those payments are disbursed to the TINs in which the clinician participated, respectively.

For some clinicians receiving bonuses in 2019, CMS encountered difficulties in identifying the TINs to be paid. CMS attributes the challenges to the lag time from service provision by the clinician to incentive payment disbursement to the TIN, during which clinician affiliations may change, new TINs may be created, and other similar events discussed by CMS in the rule. Most of these events should trigger changes in PECOS or on APM provider lists at CMS, but CMS has found delays in changes being made. To improve the bonus disbursement process, CMS makes several proposals.

First, CMS proposed a cutoff date, after which CMS will no longer accept new helpdesk requests from QPs or their representatives who have not received their payments; the cutoff would occur on November 1 of each payment year or 60 days from the day on which CMS disburses the initial round of APM Incentive Payments, whichever is later.

Second, CMS proposed a hierarchy of TINs to be followed for payment disbursement (at §414.1450(c). Because the hierarchy takes into account all TINs having relationships with the clinician and the nature of those relationships (e.g., the TIN associated with an APM Entity through which the clinician achieved QP status), the 8-step hierarchy is complex and detailed and is best appreciated by reading its full description in the rule (pp 1403-1404 of the display copy).

Third, as part of the hierarchy's eighth and final step, CMS addressed the scenario in which no appropriate TIN has been identified to receive the incentive payment. CMS proposed to attempt to contact the QP directly through a public notice requesting Medicare payment information. The QP would have until November 1 of the payment year to respond as directed in the notice, or 60 days after CMS announces having made initial bonus payments for the year, whichever comes later. A QP who fails to respond by the deadline would forfeit any claim to an APM incentive payment for that payment year.

Commenters objected to the complexity of the hierarchy. They also noted that the date by which CMS announces having made initial bonus payments for the year has not been clearly set in perpetuity, resulting in a policy that is not transparent. CMS responds that the complexity of the hierarchy is necessitated by statutory provisions and that the proposed cutoff date is clearly described in the proposal.

FINAL ACTION: CMS finalizes all three proposals for APM payment disbursement without modifications.

3. Payments in the Absence of Covered Services

CMS' payment year 2019 experience uncovered a cohort of clinicians for whom an APM Entity is paid under the terms of the APM for supplemental services on behalf of an eligible clinician who is on their Participation List (e.g., care coordination payments made under some primary care advanced payment models), yet who did not bill for any part B services during the incentive base period. CMS believes this situation is most often due to clerical errors or failure to update a clinician's Medicare payment information (e.g., PECOS). The absence of claims confounds attempts to identify a TIN to receive payment, and CMS proposed to use step 8 of the TIN identification hierarchy for such cases.

FINAL ACTION: Having received no comments, CMS finalizes the proposal without changes.

4. QP and Partial QP Determinations

a. Attribution of Prospectively Attributed Beneficiaries (§414.1435)

QP determinations are most often made at the APM Entity level and generally apply to all of the clinicians who are on the Advanced APM's Participation List. Payments and patient counts for care delivered by those clinicians through the APM are aggregated for comparison to the payment year's QP thresholds. For patient count comparisons, the denominator of the comparison ratios is defined as those beneficiaries who could potentially be attributed to the Entity's clinicians based on the attribution rules of the payment model. CMS has found that when beneficiaries are prospectively attributed to an APM (e.g., Next Generation ACO model), they may still be counted as attribution-eligible in some APM Entities for which attribution is retrospective, even though their prospective assignment effectively precludes them from attribution to the retrospective-attribution model's entity. As a result, the denominator for the retrospective-attribution entity would be artificially inflated and increase the difficulty for the Entity's clinicians to meet QP thresholds and receive bonus payments.

CMS proposed to resolve this problem by changes to §414.1435(c), the result of which would be to remove prospectively-attributed beneficiaries from the denominators of threshold score calculations made for entities aligning beneficiaries retrospectively. Comments were supportive.

FINAL ACTION: CMS finalizes the proposal without modifications; prospectively-attributed beneficiaries will be removed from the denominator of QP threshold score calculations when performed for APM entities that align beneficiaries retrospectively.

b. Targeted Review of QP Determinations §414.1455

CMS refers to statutory and regulatory provisions that preclude administrative or judicial review of determinations of QP and Partial QP status, Advanced APM status determinations, and APM incentive payment amounts. However, CMS proposed to create a targeted review process through which clinicians could present potential clerical errors made by CMS for review and correction when appropriate. The proposed process was designed to align with the established MIPS targeted review process (§414.1385)

Commenters supported the targeted review concept. CMS declines a request to lengthen the targeted reviewer request submission period beyond 60 days.

FINAL ACTION: CMS finalizes the policy for targeted review as proposed; the review will be conducted according to the following process:

- A review request may be submitted by either a clinician or APM Entity.
- All review requests must be submitted during the targeted review request submission period -- a 60-day period starting on the day when CMS makes the MIPS payment adjustment factors for the payment year available.
- CMS may deny a review when the request is duplicative; the request is not submitted during the submission period; or the request is outside the scope of such review. After denial, no changes would be made to the QP status of the involved clinician.
- CMS must respond to review requests that are submitted timely.
- Supporting information may be submitted by the requester at the time of review request.
- Requests for additional information made by CMS to the requester must be responded to within 30 days; absent a response, CMS may proceed to review completion and final decision-making using the information available at that time.
- CMS' decisions on targeted review requests are final.
- Should a review disclose a pattern of CMS errors that impacts clinicians or entities other than the requesters, CMS may adjust the QP status of those other clinicians without review requests from the former group, awarding them the most favorable QP status.

c. Advanced APM and QP Determinations During the COVID-19 Public Health Emergency

CMS reaffirms that the agency is exercising enforcement discretion when determining whether an APM meets criteria to be considered an Advanced APM. CMS will not reconsider APM determinations for those previously judged to meet criteria for CY 2020, even though subsequent changes to the terms of an APM would have led to loss of Advanced APM status at the time those changes were made.

Also, CMS provides the finalized list of Advanced APMs for 2020:

- Bundled Payments for Care Improvement Advanced Model (BPCI-Advanced);

- Comprehensive Care for Joint Replacement (CJR);
- Comprehensive Primary Care Plus (CPC+);
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (MSSP Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model
- Oncology Care Model (Two-Sided Risk Arrangements); and the
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).