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Physician Fee Schedule Proposed Rule for 2021
Summary

Medicare Program: 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirements for Electronic Prescribing for Controlled Substance for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy
Proposed Rule
[CMS-1734-P]

On August 4, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2021[1] and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the August 17, 2020 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2021. **The 60-day comment period ends at close of business on October 5, 2020.**

The final rule would normally be published by November 2, 2020 to allow for a 60-day delay in the effective date in accord with the Congressional Review Act. CMS is waiving the 60-day delay because of the COVID-19 public health emergency (PHE). CMS expects to provide a 30-day delay which means that the final rule would likely be published no later than December 2, 2020.

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

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I. Introduction

The proposed rule would update the PFS payment policies that apply to services furnished in all sites by physicians and other practitioners. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities (IDTFs). The

proposed rule includes proposals for refining the E/M coding and documentation policies finalized in 2020 for implementation January 1, 2021 including proposals to revalue code sets that rely upon 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 to make proposals to expand the use of care management services and remote physiologic monitoring services. The rule also contains proposals designed to address the expansion of telehealth services covered during the COVID-19 PHE.

To promote stability during the COVID-19 PHE, CMS limits the number of proposals in 2021 for the Quality Payment Program (QPP). CMS continues to develop the MIPS Value Pathways (MVPs) but defers proposing an initial set of MVPs and policies for their implementation. CMS proposes eliminating the Alternate Payment Model (APM) scoring standard and establishing the APM Performance Pathway (APP).

The proposed conversion factor for 2021 is $32.2605, which reflects a 0.00 percent update adjustment factor and a budget neutrality adjustment of -10.61 percent (2020 conversion factor of $36.0896*1.000*0.8939). 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 (+17%), rheumatology (+16%), 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 (-11%), nurse anesthetists (-11%), chiropractor (-10%), pathology (-9%) and physical/occupational therapy (-9%) would receive the largest decrease.

II. Provisions of the Proposed Rule for PFS

A. Background

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

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

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

1. Practice Expense Methodology

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

For 2021, CMS makes note of 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 seeks comments regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. It also welcomes information on any additional costs associated with these services not currently reflected in its assigned crosswalk.**

With respect to the formula for calculating equipment cost per minute, CMS proposes 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. In rare situations where items are replaced every few months, CMS believes it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. This issue arose because the RUC, specialty societies, and other commenters suggested a useful life of less than 1 year for several of the new equipment items for 2021 and as low as three months in one case. CMS notes that only 4 out of its 777 equipment codes have a useful life duration of less than 3 years. Moreover, 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.[2] **CMS seeks suggestions on alternative ways to incorporate these items into its methodology or potential changes to the equipment cost per minute formula more broadly.**

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

[2] 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.

2. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

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

CMS notes, as in previous years, that it will continue to display two versions of the Labor Task Detail public use file to facilitate rulemaking for 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 (these are listed in Table 5 in the proposed rule). There are seven scope equipment codes that continue to lack invoices and pricing.

For 2021, CMS did not receive any further recommendations from the RUC Scope Equipment Reorganization Workgroup. 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 proposes 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 proposes to update 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.

CMS states it remains open to further comments regarding the pricing of the seven scope equipment codes that lack invoices, as well as additional data regarding the pricing of the scope equipment codes that currently share the same price.

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

For 2021, CMS proposes to correct an inconsistency in the direct PE input database. CMS proposes 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.

d. Updates to Prices for Existing Direct PE Inputs

For 2021, CMS proposes to update the prices of one supply and four equipment items in response to public submission of invoices. Because these pricing updates were each part of the formal review for a code family, CMS proposes that the new pricing take effect for 2021 instead of being phased in. See Table 27 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.

CMS notes that to be included in a given year's proposed rule, it generally needs to receive invoices by February (February 10th deadline in 2021). 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 also discusses four additional issues: (1) market-based supply and equipment pricing update, (2) updated supply pricing for venous and arterial stenting services, (3) myocardial PET equipment inputs, and (4) adjustment to allocation of indirect PE for some office-based services (fourth and final year of the adjustment)

(1) Market-Based Supply and Equipment Pricing Update
In 2019, CMS initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs for supply and equipment pricing.[3] These supply and equipment inputs had not been systematically examined since 2004-2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. CMS finalized these pricing recommendations with changes to about 70 supply and equipment codes based on comments and feedback.

Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, CMS finalized a policy to phase in its use of the new direct PE input pricing over a 4-year period. CMS implemented this pricing transition such that

[3]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.

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 6 in this rule (reproduced below).

Table 6: 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 proposes to phase-in any new or updated pricing over the remaining years of the proposed 4-year transition period. This includes (1) existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which its establishes prices based on invoices submitted by the public, and (2) any updated pricing on very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. CMS notes that it continues to welcome feedback from stakeholders, including the submission of additional invoices for consideration.

For 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 the review of the invoices, CMS proposes to update the prices of the supply and equipment items listed in Table 7 in the proposed rule. In those cases, CMS averages the prices from the previous market research and the newly submitted invoices. CMS chose not to update the price of certain supply and equipment items for which invoices were submitted as it received a single invoice for each item and the invoice prices were significantly higher than those reviewed by StrategyGen just two years prior – this included supplies commonly used in cytopathology procedures.

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period is available on the CMS website: https://www.cms.gov/files/zip/cy-2021-pfs-proposed-rule-market-based-supply-and-equipment-pricing-update.zip

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

Stakeholders contacted CMS and presented additional information regarding supply pricing for certain venous and arterial stenting services. Based on this feedback, CMS proposes 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 proposes 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

CMS also received additional information regarding the direct PE inputs for several codes associated with Myocardial PET services. Based on this new information, CMS proposes 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 proposes to update 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) 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 proposes 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.[4]

[4] See https://www.cms.gov/files/zip/cy-2021-pfs-proposed-rule-codes-affected-alternative-methodology-indirect-pe.zip

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.[5] 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 and 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.[6]

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 hat 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 solicits 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 indicates 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. **CMS indicates it is not making proposals based on this report at this time but seeks feedback regarding RAND's report. Comments can be submitted as public comments or, if outside the public comment process, via email at PE_Price_Input_Update@cms.hhs.gov.**

C. Potentially Misvalued Services under the PFS

CY 2021 Identification and Review 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

[5] See https://www.rand.org/pubs/research_reports/RR2166.html
[6] See https://www.rand.org/pubs/research_reports/RR3248.html.

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 proposes to nominate CPT code 22867 as a potentially misvalued code.

D. Telehealth and Other Services Involving Communications Technology

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. For 2021, requests must have been received by February 10, 2020.

The Medicare telehealth services list is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html. Information about submitting a request to add services to the Medicare telehealth services list is also available on this website.

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.[7] 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

[7] 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.

Service Type	CPT codes
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 8 in the proposed rule) lists the services CMS proposes 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 Basis	
HCPCS Code	**Code Description**
GPC1X	Visit complexity inherent to E/M (Add-on code)
90853	Group psychotherapy
96121	Neurobehavioral status exam (List in addition to primary procedure)
99XXX	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)
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.[8]	

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 9). 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.

[8] 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.

b. Proposed 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 proposes to create a third category of criteria for adding services to the Medicare telehealth list on a temporary basis. CMS would include 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.

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

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

CMS proposes 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.

The table below (based on Table 10 in the proposed rule) list the 13 services CMS proposes to continue on the telehealth list on a Category 3 basis.

Service Type	CPT Codes	Code Description
Domiciliary, Rest Home or Custodial Care Services, Established patients*	99336	Domiciliary or rest home E/M visit for an established patient (40 minutes)
	99337	Domiciliary or rest home E/M visit for an established patient (60 minutes)
Home Visits, Established patients*	99349	Home visit for E/M of an established patient (40 minutes)
	99350	Home visit for E/M of an established patient (60 minutes)

Service Type	CPT Codes	Code Description
Emergency Department (ED) Visits	99281	ED visit for E/M for a self-limited or minor problem
	99282	ED visit for E/M for a low of moderately severe problem
	99283	ED visit for E/M for a moderately severe problem
Nursing Facilities Discharge Day Management	99315	Nursing facility discharge, 30 minutes or less
	99317	Nursing facility discharge, more than 30 minutes
Psychological and Neuropsychological Testing	96130	Psychological testing evaluation, first hour
	96131	Psychological testing evaluation, additional hour
	96132	Neuropsychological testing evaluation, first hour
	96133	Neuropsychological testing evaluation, additional hour
*These services can be billed when furnished as a telehealth service only for treatment of a substance use disorder or occurring mental health disorder.		

CMS requests comments on the services identified for temporary addition to the Medicare telehealth list on a Category 3 basis and identification of other services it should consider on a Category 3 basis. CMS also requests information that would supplement its clinical assessment of any proposal for the addition of a telehealth service through the Category 3 criteria. CMS provides the following examples of information that would be helpful when proposing additional services:

- By whom and for whom are the services being delivered via telehealth during the PHE;
- What practical safeguards are employed to maintain safety and effectiveness of the telehealth service and how are practices quickly and efficiently transitioning patients from telehealth to in-person care;
- What specific health outcomes are being or are capable of being gathered to demonstrate clinical benefit;
- How is technology being used to facilitate collection of clinical information that would be otherwise obtained by a hands-on physical examination;
- Whether patient outcomes are improved;
- Whether furnishing the service via telehealth promotes prudent use of resources;
- Whether the addition of the service to the telehealth list supports a quick response to the spread of infectious diseases or other emergent circumstances; and
- What is the impact on the health care workforce of the inclusion of the service on the telehealth list.

CMS also requests that commenters consider its goals to ensure high quality of care; ensure protection for vulnerable beneficiary populations with high risk of adverse outcomes; support emergency preparedness and maintain surge capacity for potential COVID-19 resurgence or other health care issues; and ensure appropriate resource utilization and cost efficiency.

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

Table 11 in the proposed rule lists the 60 services that CMS is not proposing to retain on the telehealth list after the PHE ends. (Table 12, reproduced at the end of this section, includes similar information.) CMS seeks additional information from commenters, similar to the request outlined above for proposing services to the telehealth list on a Category 3 basis, on whether these services should also be added to the telehealth list on a Category 3 basis. These services

include Discharge interactions; higher level ED visits; hospital, intensive care, emergency care, and observation stays; and therapy services.

CMS summarizes its previous decisions for not including physical therapy, occupational therapy, and speech-language pathology services on the telehealth list. Physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs) are not among the practitioners who may furnish and bill for Medicare telehealth services (as identified in section 1842(b)(18)(C) of the Act). Since the majority of the therapy service codes are billed by therapy professionals who cannot bill telehealth, CMS believes adding these services to the telehealth list would cause confusion about who is authorized to furnish and bill these services via telehealth.

CMS seeks comments on the following issues related to therapy services and telehealth:

- Should these services be added to the telehealth list so that an eligible practitioner can furnish these services?
- Can all aspects of these services be fully and effectively furnished via two-way, audio/video telecommunications technology?

CMS notes that given its clarification about telehealth services furnished incident to the professional services of a physician or practitioner (83 FR 27562), if these services were added to the telehealth list, they could be furnished by a therapist and billed by a physician or practitioner who can furnish and bill for telehealth services provided that all of the "incident to" requirements are met.

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 seeks comments on the following issues related to critical care services and telehealth:

- Whether additional codes are needed to describe models of critical care delivery that utilize a remote monitoring and clinical staff at the location of the beneficiary to allow for a practitioner at a distant site to monitor vital signs and direct in-person care when an onsite practitioner is not available?
- How to distinguish the technical component of the remote monitoring of the service from the DRG payment to the hospital?
- How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, including patients that are not Medicare beneficiaries?
- How this service intersects with both the critical care consult G codes and the in-person critical care CPT codes?

Table 12, reproduced below, summarizes CMS' 2021 proposals for services on the telehealth list.

TABLE 12: Summary of CY 2021 Proposals for Addition of Services to the Medicare 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 code 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334-99335) • Home Visits, Established Patient (CPT codes 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT code 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X) • Prolonged Services (CPT code 99XXX) • Psychological and Neuropsychological Testing (CPT code 96121)
2. Services we are proposing as Category 3, temporary additions to the Medicare telehealth services list.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99336-99337) • Home Visits, Established Patient (CPT codes 99349-99350) • Emergency Department Visits, Levels 1-3 (CPT codes 99281-99283) • Nursing facilities discharge day management (CPT codes 99315-99316) • Psychological and Neuropsychological Testing (CPT codes 96130- 96133)
3. Services we are not proposing to add to the Medicare telehealth services list but are seeking comment on whether they should be added on either a Category 3 basis or permanently.	• Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Psychological and Neuropsychological Testing (CPT codes 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) • Initial hospital care and hospital discharge day management (CPT 99221- 99223; CPT 99238- 99239) • Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT 99468- 99472; CPT 99475- 99476) • Initial and 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) • Radiation Treatment Management Services (CPT 77427) • Emergency Department Visits, Levels 4-5 (CPT 99284-99285) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324- 99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Initial and Subsequent Observation and Observation Discharge Day Management (CPT 99217- 99220; CPT 99224- 99226; CPT 99234- 99236)

2. Technical Refinement to the Medicare Telehealth Services List to Reflect Coding Consultations

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 proposes to delete the old CPT codes and replace them with the new successor CPT codes on the telehealth list.

CMS proposes 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.

3. 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).[9] **CMS seeks comment 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.

Stakeholders requested that CMS revise its frequency limitations for telehealth nursing facility visits from once every 30 days to once every 3 days. Stakeholders stated that CMS should allow clinicians the discretion to decide the frequency of a telehealth visit for an individual patient and that telehealth maintains a continuum of care in the nursing facility setting. CMS agrees and proposes to revise the telehealth frequency limitation to one visit every three days.

Stakeholders also requested that CMS revise its frequency limitations which allow telehealth subsequent inpatient visits once every 3 days. CMS disagrees and reiterates 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 and maintains its current policy.

CMS seeks 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.

4. Proposed Technical Amendment to Remove References to Specific Technology

CMS' regulation at §410.78(a)(3) states 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.

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

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 proposes to adopt this change on a permanent basis.

5. 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 proposes to adopt this policy on a permanent basis. **CMS seeks comments on other appropriate benefit categories for these services**.

CMS also proposes two additional HCPCS G codes for CTBS services for billing by practitioners who cannot independently bill for E/M services:

- G20X0: 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.
- G20X2: 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 proposes 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 seeks comments on the value for these codes, including potentially increasing the value for G2010 and G2020**.

CMS also proposes the following policies for CTBS:

- Designate G20X0, G20X2, 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.

6. Comment Solicitation on 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[10] 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 is not proposing 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 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**.

7. 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.

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

CMS seeks 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. Specifically, CMS requests comments on the following:

- Should CMS clarify that non-face-to-face services do not need to be on the Medicare telehealth list in order to be billed and paid when furnished using telecommunications technology rather than in-person?
- Are there additional physician services using evolving technologies that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services?
- Are there impediments that contribute to healthcare provider burden and reluctance to bill for CTBS?

8. Proposed Clarification of Existing PFS Policies for Telehealth Services

CMS proposes the following clarifications:

- Services that may be billed incident to may be provided via telehealth incident to a physicians' 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 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.

9. 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 proposes 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 notes that if it finalizes this policy and the PHE ends before the effective date of the 2021 final rule, the interim policy would not be in effect during the period between the expiration of the PHE and the effective date of the final rule.

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.

CMS seeks 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. Specifically, CMS requests comments on the following:

- What risks the policy might introduce to beneficiaries receiving care from practitioners that are supervising care virtually?
- How to address concerns around induced utilization and fraud, waste, and abuse?
- What experience providers have with virtual direct supervision during the PHE?
- What training is required for effective use of audio/video communications technology?

10. 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. **For COVID-19 testing, CMS seeks comments on whether it should extend this policy for a limited period of time or make this policy permanent**.

11. Regulatory Impact

CMS expects that its proposed policies to add services on a provisional Category 3 basis will increase access to care in rural areas. Based on telehealth utilization of services already on the list, CMS estimates there will be only a negligible impact on PFS expenditures from these additions.

E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

In this proposed rule, CMS continues to improve payment for care management services. Table 13 (reproduced below) summarizes the care management codes.

Table 13: 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
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

Remote Physiologic Monitoring Codes	
CPT Code*	**Description**
99453	Remote monitoring of physiologic parameter, initial
99454	Remote monitoring of physiologic parameter, each 30 days
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.[11] 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.

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

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 practice and Medicare benefit category includes the service and who is authorized to independently bill Medicare for the service.[12,13]

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.[14] CMS interprets time in the code descriptor to mean the time spent in direct, real-time interactive communication with the patient.

RPM and COVID-19. CMS proposes to make permanent two of the interim changes in response to the COVID-19 PHE.[15] CMS proposes to allow consent for RPM services to be obtained at the time the services are furnished. For CPT codes 99453 and 99454, CMS also proposes allowing auxiliary staff (which include clinical staff and other individuals who are employees, or leased or contracted employees) to furnish services under the general supervision of the billing physician or practitioner.

After the PHE ends, CMS will again require that RPM servicers 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.

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[12] Additional discussion of this issue is included in the 2016 PFS final rule at 80 FR 70957.
[13] 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)).
[14] 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).
[15] See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications to RPM services during the PHE.

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. **CMS requests comments, including any additional information about how RPM services are used in clinical practice, and how they might be coded, billed and valued**.

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 proposes 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 14 in the proposed rule, CMS proposes that 14 End-Stage Renal Disease Service codes and the Complex Chronic Care Management Code G2058 could be billed concurrently with TCM.

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

4. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS code GCOL1)

In response to stakeholder's request for additional coding to capture shorter time increments, CMS proposes to establish a G-code to describe 30 minutes of behavioral health care manager time. The proposed code is:

> GCOL1: 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 proposes that the required elements listed for CPT code 99493, including the CPT time rules, would also be required for billing GCOL1. CMS also proposes 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 would be required for each service. Consistent with other codes in this family, CMS proposes to add GCOL1 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.[16] 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:

- 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 (CPT code 99XXX) and discontinued the use of CPT codes 99358 and 99359 (prolonged E/M visit without direct patient contact).

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

- Finalized separate payment for HCPCS code GPC1X 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 99XXX, as well as the new HCPCS code GPC1X. These valuations were finalized with an effective date of January 1, 2021. These are described in Table 16 below from the proposed 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 16: 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
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
99XXX	N/A	N/A	15	0.61
GPC1X	N/A	N/A	11	0.33

c. Continuing Stakeholder Feedback

Since publication of the 2020 PFS final rule, CMS has 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 seeks 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 GPC1X.

2. Proposals 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 proposes 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 17 in the proposal rule (shaded below to illustrate what times have been proposed).

Table 17: 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

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 proposes 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) ESRD Monthly Capitation Payment (MCP) services

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; and that the specified number of visits in the code descriptor must be furnished in order to bill for the service.

CMS proposes 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 19 and 20 in the proposed rule and shown below in a combined table. **CMS believes the majority of the visits included in the ESRD MCP bundles are being furnished, but seeks comment on whether there are instances where the number and level of visits being furnished are not consistent with the number and level of visits built into the valuation of the code.**

Extract from Tables 19 & 20: 2020 ESRD MCP Work RVUs, Physician and Clinical Time Compared with Proposed 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Proposed 2021 Work RVUs**	**2020 Phys. Time**	**Proposed 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Proposed 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	8.04	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	0.27	2.5	3.2	2	1.8

Notes: Time is in minutes; NF – Nonfacility; Facility clinical staff time for 2020/proposed 2021 is the same for these codes: 60 minutes for 90951-90966, and 2 minutes for 90968-90970.

(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 proposes 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 19 and 20 in the proposed rule and show below in a combined table.

Extract from Tables 19 & 20: 2020 TCM Work RVUs, Physician and Clinical Time Compared with Proposed 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Proposed 2021 Work RVUs**	**2020 Phys. Time**	**Proposed 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Proposed 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 proposes 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 19 and 20 in the proposed rule and show below in a combined table.

Extract from Tables 19 & 20: 2020 Maternity Work RVUs, Physician and Clinical Time Compared with Proposed 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Proposed 2021 Work RVUs**	**2020 Phys. Time**	**Proposed 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Proposed 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

Extract from Tables 19 & 20: 2020 Maternity Work RVUs, Physician and Clinical Time Compared with Proposed 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Proposed 2021 Work RVUs**	**2020 Phys. Time**	**Proposed 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Proposed 2021 NF Clinical Staff Time**
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/proposed 2021 is the same for these codes: 59400, 59410, 59510, 59515, 59610, 59614, 59617, 59622, and no time listed for the remained.

(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 proposes 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.

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

CMS proposes 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 show below.

Extract from Tables 19 & 20: 2020 IPPE and AWV Work RVUs, Physician and Clinical Time Compared with Proposed 2021 Values							
HCPCS	**Short Descriptor**	**2020 Work RVUs**	**Proposed 2021 Work RVUs**	**2020 Phys. Time**	**Proposed 2021 Phys. Time**	**2020 NF Clinical Staff Time**	**Proposed 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/proposed 2021 is not applicable for these codes. * Updated these times based on work times in published tables. Values were incorrect in proposed rule.

(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 proposes the values recommended by ACEP (shown in table 21 in the proposed rule). The work RVU values would increase from 1.42 to 1.60 for 99283; 2.60 to 2.74 for 99284; and 3.80 to 4.00 for 99285.

(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 proposes 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 proposes to apply 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 21 and reproduced below.

Extract of Table 21: Current and Proposed Work RVUs for Therapy and Psychotherapy Services			
HCPCS Code	**Short Descriptor**	**Current Work RVU**	**Proposed 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
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

CMS recognizes that this is not the methodology typically used to value services under the PFS. **It seeks comment on potential alternative methodologies or specific values for these services, particularly about whether commenters believe it would be better to develop values using comparator codes from the office/outpatient E/M visit code set, and if so, why.**

(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 proposes 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 and reproduced below.

Extract of Table 21: Current and Proposed Work RVUs for Therapy and Psychotherapy Services			
HCPCS Code	**Short Descriptor**	**Current Work RVU**	**Proposed 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

(9) Ophthalmological services

CMS also received a request to revalue four ophthalmological services (CPT codes 92002, 92004, 92012, 92014). which it is not proposing to revalue. 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. **CMS seeks comment on whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation.**

c. Comment Solicitation on the Definition of HCPCS code GPC1X

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 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 GPC1X, 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 solicits comments that would provide additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how it might address those concerns, and how it might refine its utilization assumptions for the code.**

d. Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)

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 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 99XXX 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 99XXX and prolonged services should not be reportable as it finalized last year.

CMS proposes that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX 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 99XXX could be billed once 89 minutes have been used. CMS provides examples in Tables 22 and 23 in the proposed rule.

G. Scope of Practice and Related Issues

In December 2019, CMS sought feedback on Medicare regulations that stakeholders believe have more restrictive supervision requirements than existing state scope of practice laws or which limit professionals from practicing to the full extent of their licenses. CMS proposes policies to provide greater flexibility for supervision and other requirements under its regulations to address the issue. The proposed policies are still subject to state- and facility-specific policies that limit the ability of professionals to perform certain services. **CMS seeks comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities and if so, to what extent.**

1. Teaching Physician and Resident Moonlighting Policies

a. Background

For the COVID-19 PHE, CMS implemented several policies on an interim, final basis in the March 31st and the May 1st IFCs related to PFS payment for the services of teaching physicians involving residents and resident moonlighting regulations. **CMS seeks comment on whether the policies should be made permanent or whether they should be temporarily extended after the conclusion of the PHE to provide for a transition back to the previous policies.** For example, if the PHE ends in 2021, the policies could be extended through the end of that year. In commenting, stakeholders should include data and other information on their experiences implementing the policies during the PHE.

b. Supervision of Residents in Teaching Settings through Audio/Video Real-Time Communications Technology

Among the policies adopted for the PHE, CMS permitted the use of audio/visual real-time communications technology to satisfy presence or direction requirements under its regulations.

- Under §415.172, the requirement for the presence of the teaching physician during the key portion of the service furnished involving a resident may 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(c), 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, 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-time communications technology. A physician (other than the resident) must review the resident's interpretation.
- Under §415.184, 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 solicits comment on whether to temporarily extend these policies or make them permanent. However, CMS notes several concerns. It worries that 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 also has patient safety concerns, noting that it excluded surgical, high risk, interventional, endoscopic, and other complex procedures from its virtual presence policies during the PHE. It also notes that certain patient populations require greater clinical attentiveness and skill that are not possible to provide through audio/visual interactive communications technology. Further, beneficiary cost-sharing could increase due to additional part B claims for the services of the teaching physician with the involvement of residents.

On the other hand, CMS notes that terminating this flexibility could result in reduced access to practitioners in certain communities. Additionally, notwithstanding the end of the PHE, COVID-19 cases could continue or increase in certain communities, and this flexibility provides additional safety for patients and practitioners.

CMS states that it might identify certain circumstances or procedures for which the presence of the teaching physician could be established using audio/visual real-time communications technology, such as office/outpatient evaluation and management visit codes of lower to mid-level complexity or simple procedures. **CMS seeks comment to better its understanding of how this flexibility would support patient safety (especially for at-risk patients); reduce burdens without creating risks to patient care or increase fraud; avoid duplicative payment between the PFS and the IPPS for GME programs; and support emergency preparedness.**

b. Virtual Teaching Physician Presence during Medicare Telehealth Services

For the PHE, CMS permitted 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. In considering whether to extend or make this policy permanent, CMS expresses the same concerns and considerations noted above. Additionally, the agency worries 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.

c. Resident Moonlighting in the Inpatient Setting

Generally, when a licensed resident physician furnishes services to inpatients of hospitals in which the resident has their approved GME training program, the services are not considered separately billable as physicians' services. However, subject to certain conditions, when the resident furnishes services that are not related to the approved GME training program in an outpatient or emergency department of the hospital (i.e., moonlighting), those physicians' services may be separately billed and paid for under the PFS. For the PHE, CMS extended this 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.

In considering whether to extend or make this policy permanent, CMS has 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.

d. 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.[17]

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 1st IFC, it 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).

CMS is considering whether to temporarily extend or make permanent all, or some, of these PHE policies; **it seeks comment, 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 decisionmaking 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.

With respect to extending or making permanent the primary care exception for telehealth services furnished by residents, CMS notes that both the resident and the teaching physician would be at the primary care center that serves as the distant site. CMS believes it may also make sense to allow PFS payment to the teaching physician when the resident furnishes

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

office/outpatient E/M visits via telehealth; CMS may do so even if it removes services added to the primary care exception by the PHE IFCs.

2. Supervision of Diagnostic Tests by Certain NPPs

CMS proposes 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. The May 1st IFC implemented the policy on a temporary basis which the agency now proposes to make permanent. CMS would 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 proposes to specify that diagnostic tests performed by PAs do not require a specified level of supervision assigned to individual tests.

3. Pharmacists Providing Services Incident To Physicians' Services

Stakeholders asked for clarification that pharmacists may provide "incident to" services similar to other clinical staff. CMS reiterates the clarification it made in the May 1st 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.

4. Provision of Maintenance Therapy by Therapy Assistants

In the May 1st 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 proposes to make this policy permanent effective January 1, 2021. It believes this will afford PTs and OTs more time to furnish higher skilled therapy services, such as assessment and evaluation services. The payment policy would also better align with payment for maintenance therapy services under Part A for SNF and HH settings.

CMS notes that if the PHE ends before January 1, 2021, the therapist would have to furnish maintenance therapy services until the proposed change took effect. Readers are also reminded that maintenance programs that can be carried out by the patient, or with the assistance of caregivers, are not covered.

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. It clarifies that this principle also applies to therapists who bill for therapy services.

6. Regulatory Impact

CMS expects that its proposed 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 proposed work RVUs, work time and other payment information for all the proposed payable codes in 2021 are available on the CMS website under downloads for the PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

The following tables in the proposed rule provide additional details about the proposed 2021 valuation of specific codes:

Table 24	Work RVUs for New, Revised, and Potentially Misvalued Codes
Table 25	Direct PE Refinements
Table 26	Direct PE Refinements: Equipment Refinements Conforming to Changes in Clinical Labor
Table 27	Invoices Received for Existing Direct PE Inputs
Table 28	New Invoices
Table 29	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.[18] CMS notes the importance of not only the RUC-recommended work and time values but also the accompanying rationales for setting those values. [19]

[18]Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.
[19]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

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.

Table 24 list the codes and proposed work RVUs, including all codes that CMS received recommendations from the RUC by February 10, 2020.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. Table 25 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. Table 26 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;

and pre-service packages for services typically furnished in the nonfacility setting.

- 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)[20];
- 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 27 and 28). CMS encourages stakeholders to review these prices and if prices appear inaccurate it encourages stakeholders to submit invoices or other information to improve the pricing. CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations).

4. Proposed Valuation for Specific Codes

This section discusses proposed RVUs for 56 code groups (listed in the table below). Highlights of CMS' discussions are summarized; the numbering is consistent with the preamble format. The reader is referred to the proposed rule for more specific details. **CMS seeks comments on the work values, direct PE inputs, or both, for all these code groups.**

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
1	Fine Needle Aspiration	11021 and 10004 - 10012	No	No
2	Tissue Expander Other Than Breast	11960	No	Yes
3	Breast Implant-Expander Placement	11970, 19325, 19340, 19342, and 19357	No	Yes
4	Breast Implant-Expander Removal	11971, 19328, and 19330	No	Yes
5	Modified Radical Mastectomy	19307	Yes	Yes
6	Breast Lift-Reduction	19316 and 19318	Yes	Yes
7	Secondary Breast Mound Procedure	19370, 19371, and 19380	No	Yes
8	Hip-Knee Arthroplasty	27130 and 27447	Yes	Yes
9	Toe Amputation	28820 and 28825	No	No
10	Shoulder Debridement	29822 and 29823	Yes	Yes
11	Absorbable Nasal Implant Repair	30XX0	Yes	Yes

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

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
12	Lung Biopsy-CT Guidance Bundle	324X0	No	Yes
13	Atrial Septostomy	33XX0-33XX2	No	NA
14	Percutaneous Ventricular Assist Device Insertion	339X1, 33990-33992, 339X2, and 33993	Yes	NA
15	Esophagogastroduodenoscopy (EGD) with Biopsy	43239	Yes	Yes
16	Colonoscopy	45385	Yes	Yes
17	Transrectal High Intensity Focused US Prostate Ablation	558XX	No	Yes
18	Computer-Aided Mapping of Cervix Uteri	58XX0	Yes	Yes
19	Colpopexy	57282 and 57283	No	Yes
20	Laparoscopic Colpopexy	57425	No	Yes
21	Intravitreal Injection	67028	Yes	No
22	Dilation of Eustachian Tube	697XX and 697X1	Yes	Yes
23	X-Ray of Eye	70030	Yes	Yes
24	CT Head-Brain	70450, 70460, and 70470	Yes	Yes
25	Screening CT of Thorax	71250, 71260, 71270, and 712X0	No	No
26	X-Ray Bile Ducts	74300 and 74328-74330	No	NA
27	Venography	75820 and 75822	Yes	NA
28	Introduction of Catheter or Stent	75984	Yes	Yes
29	Medical Physics Dose Evaluation	7615X	NA	Yes
30	Ophthalmic Ultrasound Anterior Segment	76513	No	No
31	Radiation Treatment Delivery	77401	NA	No
32	Photon Beam Treatment Delivery	77520, 77522, 77523, and 77525	NA	NA*
33	Immunization Administration	90460, 90462, 90471-90474 and G0008-G0010	No	No
34	Liver Elastography	91200	Yes	Yes
35	Remote Retinal Imaging	9227, 9228, and 9225X	Yes	No
36	Auditory Evoked Potentials	92584 and 92X51-92X54	Yes	Yes
37	Vestibular Evoked Myogenic Potential Testing	925X1-925X3	Yes	Yes
38	Complete Electrocardiogram	93000, 93005, and 93010	Yes	Yes
39	External Extended ECG Monitoring	93224-93227, and 93XX0-93XX7	Yes	No

Code Group Number and Name		Codes (CPT and HCPCS Codes)	CMS Proposed Work RVUs Agrees with RUC Recommendations	CMS Proposed Direct PE RVUs Agrees with RUC Recommendations
40	Complete Transthoracic Echocardiography (TTE) with Doppler	93306	Yes	Yes
41	Pacing Heart Stimulation	93623	No	NA
42	Intracardiac Echocardiography (ECG)	93622	No	NA
43	Ventricular Assist Device (VAD) Interrogation	93750	No	Yes
44	Spirometry	94010 and 94060	Yes	Yes
45	Exercise Test for Bronchospasm	946X0, 94617, 94618, and 94621	Yes	Yes
46	Evaluation of Wheezing	94640 and 94667-94669	NA	Yes
47	Exhaled Nitric Oxide Measurement	95012	NA	Yes
48	Acupuncture Service	97810, 97811, 97813, and 97814	NA	Yes
49	Chronic Care Management	994XX and G2058	Yes	Yes
50	External Counterpulsation	G0166	NA	No
51	Molecular Pathology Interpretation	G0452	Yes	Yes
52	E/M, Observation, and Provision of Self-Administered Esketamine	G2082 and G2083	NA	NA
53	Bundled Payments for Substance Use Disorders	G2086-G2088	NA	NA
54	Initiation of Medication Assisted Treatment (MAT)	GMAT1	NA	NA
55	Percutaneous Creation of an Arteriovenous Fistula (AVF)	G2170 and G2171	NA*	NA*
56	Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System	0446T – 0448T	NA	NA
*Contractor Priced Codes				

(8) Hip-Knee Arthroplasty (CPT codes 27130 and 27447)

CMS accepts the RUCs recommendations for both the work and direct PE RVUs. **CMS seeks 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). CMS is also interested in comments about what codes could be used to capture these pre-optimization activities and billed in conjunction with the surgery.**

(9) Toe Amputation (CPT codes 28820 and 28825)

Before conducting the RUC survey, the specialty societies recommended that these services should have their global period changed from a 90-day global period to a 0-day global period. CMS agrees and these codes are now 0-day global surgery codes.

(14) Percutaneous Ventricular Assist Device Insertion (CPT codes 339X1, 33990-33992, 339X2, and 33993
CMS notes that stakeholders requested that CMS maintain the current work RVUs for these codes and to crosswalk the work RVUs of the new codes to existing codes. Stakeholders stated that the RUC recommendations did not accurately reflect the work time which was increasing due to adopting new technology. 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. CMS disagrees with stakeholders that the incorporation of this new technology requires maintaining the current RVUs.

(18) Computer-Aided Mapping of Cervix Uteri (CPT code 57XX0)
CMS seeks comments on a new medical supply indicated on the PE spreadsheet submitted by the RUC, a "computer aided spectral imaging system (colposcopy) disposal speculum". CMS researched this item and cannot find any evidence it has a digital component and is proposing to change the name of this supply to the product on the invoice submitted, "disposable speculum, medium (SD337). CMS seeks clarification as to what aspect of the speculum is digital or if a cheaper, non-digital speculum would suffice.

(31) Radiation Treatment Delivery (CPT code 77401)
CMS proposes refinements to the direct PE refinements, including not proposing to include the new equipment item ER119 "Lead Room". CMS states it does not have sufficient information on what this equipment contains. **CMS requests more information to determine what this is and whether it is more accurately priced as direct or indirect PE.**

(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 discusses the concerns it has with the recommended direct PE inputs and proposes to maintain contractor pricing for these codes. CMS has concerns 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 states 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.

(39) External Extended ECG Monitoring (CPT codes 93224-93227 and 93XX0-93XX7)
CMS discusses 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 states it requires an invoice representative of commercial market pricing to establish a national price. CMS proposes to crosswalk the supply to the "kit, percutaneous neuro test

stimulation" supply (SA022) at a price of $413.24. **CMS requests invoices or other information for pricing this item.**

(52 Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS codes G2082 and G2083)
For 2020, on an interim basis, CMS established two codes and payments for E/M, observation, and the provision or self-administrated esketamine (84 FR 63102 through 63104). HCPCS code G2082 includes up to 56 mg of esketamine and HCPCS code G2083 includes greater than 56 mg of esketamine. CMS agrees with comments that it is important to ensure beneficiaries have access to new treatments for treatment-resistant depression (TRD) and proposes to maintain these codes.

In response to recommendations that esketamine should have its own J code, CMS states that the self-administered esketamine is considered a supply item and cannot be separately billed. CMS notes that in contrast to routinely updating Part B drugs paid under ASP, the supply input prices are updated periodically through rulemaking. For 2020, CMS used the most recent available quarter of WAC data for esketamine, and it plans to use either data reported for purposes of determining payments under section 1847A of the Act (such as ASP) or compendia pricing information (such as WAC). For 2021, CMS proposes to update the payment to reflect the most recent available quarter of WAC data; CMS proposes to update the supply code SH109 (56 mg esketamine) from $590.02 to $616.93 and for supply code SH1009 (84 mg esketamine)from $885.02 to $928.38. In response to comments, CMS notes that cost related to reception time, EHRs, waste management, and other requirements related to the Risk Evaluation and Mitigation Strategy (REMS) standards required by the FDA are all types of indirect costs.

CMS agrees with the recommendation to increase the valuation of clinical staff time to the clinical staff time associated with challenge tests (CPT code 95067). CMS proposes to refine the direct input of G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and 95079. Specifically, CMS proposes 150 minutes of observation time.

CMS disagrees with recommendations to increase the bundled E/M level from 99212 or to include other services, such as psychotherapy, in the bundle. CMS notes that other allowable billable services, including psychotherapy, provided on the same day as an E/M, observation and provision of self-administered esketamine service can be billed. When the health care professional supervising the self-administration and observation does not provide the esketamine product, HCPCS codes G2082 or G2083 are not appropriate; the visit and the extended observation can be reported using existing E/M codes that describe the service provided.

(53) Bundled Payments under the PFS for Substance Use Disorders (HCPCS codes G2086, G2087, and G2088)
For 2020, CMS established three new codes for bundled episodes of care for the treatment of Opioid Use Disorder (OUD). CMS agrees with stakeholders that these bundled payments should not be limited to opioids and should include all substance use disorders (SUDs). CMS proposes to revise the code descriptors for all three codes by replacing "opioid use disorder" with "a substance use disorder". The payment and billing rules would remain unchanged.

CMS notes that it would be helpful to know which specific SUDs was being treated but does not wish to add additional burden related to claims submission by requiring all the appropriate diagnosis codes for SUDs on the claim form. **CMS seeks information about what sources of data could provide this information. CMS also seeks information about the resources associated with providing services for the various SUDs and whether there is a need for additional codes**. Finally, CMS notes that the CPT Editorial Panel has created CPT codes to replace G codes and it would welcome its input on these services.

(54) Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS code GMAT1)
In the 2020 PFS proposed rule (84 FR 40545), CMS sought comment on the use of MAT in the emergency department. In the emergency department (ED), CMS thought this service would typically include medication for the treatment of OUD and referral or linkage to primary care or a hospital-based bridge clinic for continuation of medication and potentially other services, including counseling.

After consideration of comments, CMS proposes to create one add-on G code for billing with E/M visits in the ED setting:

> HCPCS code GMAT1: Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (list separately in addition to code for primary procedure).

CMS proposes to use a direct crosswalk to the work and direct PE inputs for G0397 (Alcohol/subs Inter > 30 min) which is assigned a work RVU of 1.30.

(55) Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS code G2170 and G2171)
Based on new technology applications for creation of AVFs, CMS established two HCPCS codes C9754 and C9755. These two codes are for institutional payment and do not allow for payment for the physician work related to these services. Stakeholders requested separate coding for physician payment to allow having the procedure furnished in either a physician office or an institutional setting. In response, CMS created two HCPCS G codes (G2170 and G2171) that are contractor priced and effective July 1, 2020.

CMS proposes to maintain contractor pricing for these codes and **seeks information on the resource costs for providing these services for consideration in developing payments in future rulemaking.** CMS notes that these services are assigned to APC 5193, which has a payment rate of $15,938.20 for 2020.

(56) 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. In the 2020 PFS final rule, CMS requested information to ensure proper payment for these services.

For 2021, CMS proposes 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 proposes work RVUs of 1.14 for code 0446T, 1.34 for code 0447T and 1.91 for code 0448T. For PE inputs, CMS proposes to add a new "implantable interstitial glucose sensor (supply code SD334) priced at $1,500.00. CMS proposes 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 assigns 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).

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. 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 proposes several refinements and clarifications and requests feedback on several policies.

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

Opioid Antagonist Medications. Under existing rules, OUD treatment services do 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 proposes 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.

CMS seeks comments on whether the definition should be further extended to include overdose education; whether payment for overdose education to a beneficiary and/or their family or partner should be included in the weekly bundled payments for episodes of care or whether CMS should establish an add-on payment as well as the inputs it should consider in developing the payment rate for such a service.

Proposed adjustment to the bundled payments for OUD treatment services. Under the proposed rule, reimbursement for naloxone would be through the use of an add-on code to the bundled payment on an as needed basis. The proposed HCPCS add-on G codes and payments are specified in Table 30 (duplicated below).

TABLE 30: OTP Code Descriptors and Proposed Approximate Payment Amounts*

HCPCS	Descriptor	Total Payment
GOTP1	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.	$89.63
GOTP2	Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$178

* Drug pricing subject to change pending additional data. Nasal naloxone drug costs are calculated using ASP data, auto injector naloxone drug costs are calculated using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC), the proposed price used is the WAC + 0 for the generic auto-injector naloxone. The estimated payment amounts in Table 30 are based on data files posted at the time of the drafting of this proposed rule. We will develop the final pricing for CY 2021 using the most recent data files available at the drafting of the CY 2021 PFS final rule.

- The proposed payment for nasal naloxone is 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; equal to ASP +0.
- To price the add-on code for the take-home supply of auto-injector naloxone, CMS proposes to use the lowest price available (the lower of ASP + 0, WAC + 0, or national average drug acquisition cost (NADAC)). At this time, as there is no ASP or NADAC for auto-injector naloxone, CMS will use WAC + 0 for the add-on payment for auto-injector naloxone. CMS also indicates that in most cases it believes the generic formulation of the product will be prescribed and dispensed, and so the proposed price is based on the generic formulation of the drug.

Frequency limit. CMS proposes to limit OTPs to one add-on code for naloxone every 30 days. It reviews the frequency limits applicable to naloxone under the Part D and TRICARE as well as utilization data on naloxone use. **Comments are sought on whether the proposed limit is reasonable, whether special circumstances may arise under which more frequent payment is medically reasonable and necessary, and the types of circumstances that should qualify for more frequent payment.**

CMS also seeks comments on whether it should create a code and add-on payment for injectable naloxone.

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. In this case, 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 $2.28 million in 2021. The estimate incorporates the assumption that roughly 10,600 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 two-way interactive audio-video communication technologies. However, CMS does not believe 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 their likelihood of co-morbidities, a face-to-face medical exam or biopsychosocial assessment should be performed.

CMS proposes that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to be performed. Accordingly, the definition of periodic assessment is proposed to be modified to limit such assessment to face-to-face encounters.

Feedback is sought on whether CMS should continue to make add-on payments for audio-only periodic assessments furnished by OTPs after the conclusion of the PHE for the COVID-19 pandemic, and if so, whether the payment rate for audio-only services should reflect any differences in resource costs.

3. WAC Pricing

CMS proposes to amend the OTP drug pricing methodology to limit WAC-based payments for injectable or implantable medications included in the drug component of an episode of care to 100% of the WAC consistent with its existing policy to set the payment amount at 100% of the ASP if ASP is used to determine the payment for the drug component of an episode of care.

4. Billing and Payment Policies

Institutional Claim Forms. CMS is exploring permitting flexibility in claims processing such as permitting OTPs to bill for services on institutional claim forms (as opposed to professional claim forms) as requested by providers in New York. **CMS seeks feedback on why any such flexibility would be needed.** It indicates that it may incorporate any related changes in subsequent claims processing instructions.

Readers are also referred to section III.B. of the proposed rule, OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions (summarized below), for proposed changes related to OTP enrollment and the use of institutional enrollment forms.

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 needed. Differences between the induction phase and the maintenance phase of treatment as well as differences in patients' needs over time are described. **CMS seeks feedback on how to better account for differences in resource costs among patients over the course of treatment.**

5. Annual Updates

The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for 2021, is available in the file called CY 2021 OTP Proposed Payment Rates on the CMS Web site under downloads for the 2021 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html. The current rates for 2020 can be found on the CMS OTP webpage under Billing and Payment at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/billing-payment.

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 is proposing to revise the regulations to conform with the changes made by the FCAA and the CARES Act.

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.

CMS is requesting comments on whether it should delete these codes and revert to using the normal specimen collection codes and fees once the PHE is over. The proposed rule asks 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.

B. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

1. Modifications to OTP Enrollment Process

Under existing 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 proposes 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).

The proposed rule would:

- Amend §424.67(b)(1) 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. (The italics indicate the proposed additions.)
- Revise §424.67(b)(1)(ii) 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).
- Amend §424.67(b)(5) 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 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 the proposal, 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 From 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. The resulting net increase in annual burden for those groups of OTPs would be $23,639 for those filing Form CMS-855-As and -$2,866 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 proposes 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. (The paragraph would also be re-designated as paragraph (b)(3)(i).)

Proposed new paragraph (b)(3)(ii) would state 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) would add 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(c)(1))

CMS proposes three additional clarifications to the enrollment provisions for OTPs:

- *Single Enrollment.* CMS proposes to explicitly state 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 would be applied 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 proposes to state that compliance with the application fee requirements in §424.514 would 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 $188,480 in 2021. That amount assumes 310 OTPs would change to a Form CMS-855A enrollment, requiring each to pay $608 for the application fee.

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. Proposed 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 proposes to permit RHCs and FQHCs to furnish and bill for PCM services. It would add 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 would be used in calculating the average of the national non-facility PFS payment rates for HCPCS code

G0511. RHCs and FQHCs would 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 had 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.

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 Federally Qualified Health Center Prospective Payment System (FQHC PPS) for 2021: Proposed Rebasing and Revising of the FQHC Market Basket

1. Proposed 2021 Productivity-adjusted Market Basket Update for FQHCs

The proposed annual update to the FQHC PPS is equal to 1.9 percent. CMS proposes to rebase and revise the 2013-based FQHC market basket to reflect a 2017 base year. Thus, CMS proposes for 2021 an update equal to the 2017-based FQHC market basket of 2.5 percent less 0.6 percentage points for a productivity adjustment.

The 2.5 percent update is based on the most recent historical data available at the time of publication of the proposed rule; the final update will be based on the four-quarter moving-average percent change of the 2017-based FQHC market basket through the second quarter of 2020. CMS notes the update would have been the same using the 2013-based FQHC market basket.

CMS proposes to continue 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 first quarter 2020 forecast of MFP, CMS projects a reduction of 0.6 percent for productivity.

2. Rebasing the FQHC Market Basket

CMS proposes to rebase and revise the FQHC market basket; the current FQHC market basket is from a 2013 base year. CMS proposes to base the FQHC market basket on data from cost reports beginning in FY 2017. 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 proposes 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. CMS notes that the 2013-based FQHC market basket used six cost categories; the proposed 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, Columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, Column 1, lines 23 through 36; and Worksheet S3 Part II, Columns 1 and 2, lines 2 through 14. 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 proposes to exclude 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 31 in the proposed rule (reproduced below) shows the proposed 2017-based FQHC cost report weights and the corresponding 2013-based FQHC market basket percentages. The preamble to the proposed rule provides details on the specific worksheets, parts, columns, and lines used to derive costs for each cost category.

TABLE 31: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Proposed 2017-Based FQHC Cost Report Weights (Percent)	2013-Based FQHC Market Basket (Percent)
FQHC Practitioner Compensation*	*30.0*	31.7
FQHC Practitioner Wages & Salaries	20.5	-
FQHC Practitioner Employee Benefits	4.5	-
FQHC Practitioner Contract Labor	4.9	-
Clinical Compensation*	*16.2*	9.5
Clinical Wages & Salaries	12.4	-
Clinical Employee Benefits	3.0	-
Clinical Contract Labor	0.8	-
Non-Health Staff Compensation*	25.4	27.4
Pharmaceuticals	3.9	5.1
Medical Supplies	2.4	-
Fixed Capital	4.7	4.5
Moveable Capital	1.9	1.7
All Other (Residual)	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.

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 (82 percent to wages and salaries and 18 percent to employee benefits). CMS provides further detail on the data sources used to derive weights within the capital and all other categories.

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

Table 33 of the proposed rule (reproduced below) shows the proposed cost categories and weights for the proposed 2017-based FQHC market basket compared to the 2013-based FQHC market basket.

Cost Category	Proposed 2017-based FQHC Market Basket Cost Weight	2013-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**71.6**	**68.7**
FQHC Practitioner Compensation	**30.0**	**31.7**
FQHC Practitioner Wages and Salaries	24.6	-
FQHC Practitioner Employee Benefits	5.4	-
Clinical Staff Compensation	**16.2**	**9.5**
Clinical Staff Wages and Salaries	13.0	-
Clinical Staff Employee Benefits	3.2	-
Non-Health Staff Compensation	**25.4**	**27.4**
All Other Products	**10.0**	**16.1**
Pharmaceuticals	3.9	5.1
Utilities	0.5	1.4
Telephone	-	1.7
Postage	-	1.0
Medical Equipment	1.1	2.2
Medical Supplies	2.4	2.0
Miscellaneous Products	2.1	2.8
All Other Services	**11.8**	**9.0**
Professional, Scientific, and Technical Services	6.0	2.9
Administrative and Facilities Support Services	1.6	3.4
All Other Services	4.2	2.7
Capital-Related Costs	**6.6**	**6.1**
Fixed Assets	4.7	4.5
Movable Equipment	1.9	1.7

c. Selection of Proposed 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 34 in the proposed rule lists all the cost categories and associated price proxies that CMS used for the proposed 2017-based FQHC market basket; the preamble includes a detailed discussion of the price proxy used for each cost category.

3. Regulatory Impact

Because the proposed FQHC market basket and multi-factor productivity adjustment are the same under the current 2013-based market basket and the proposed 2017-based market basket

(1.9 percent), CMS does not estimate any impact from rebasing and revising of the FQHC market basket for 2021.

E. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Section 2002 of the SUPPORT Act amended Medicare provisions defining the required elements of the initial preventive physical exam (IPPE) and the annual wellness visit (AWV) to include (1) screening for potential substance use disorders and (2) a review of any current opioid prescriptions. Under the proposed rule, CMS would modify the required elements for an IPPE in §410.15 and the AWV in §410.16 to include those new required elements.

CMS first provides background on the need for vigilance in identifying opioid risks in Medicare beneficiaries as well as the existing elements for coverage of an IPPE and AWV.

Proposed revisions would amend each of §410.15 and §410.16 to:

- Add "Screening for Potential Substance Use Disorders" as a required element for coverage of an IPPE and an AWV, 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 IPPE and an AWV, including for a first annual wellness visit and a subsequent annual wellness visit.
- In each of those sections, the screening would be 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 would be 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.

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

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid EPs[21] 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

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

Interoperability Program incentive payments must be issued by the statutory deadline of December 31, 2021.

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

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

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

Reporting Requirements. The 2020 reporting requirements would be continued for 2021. That is, EPs would have to 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) would be 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 invites comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.**

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 was 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.

G. Medicare Shared Savings Program

CMS reviews in detail the legislative history of the Medicare Shared Savings Program. CMS notes that the program was added as section 1899 of the Act by Section 3022 of the Affordable Care Act (Pub. L. 111-148), which created the program's Accountable Care Organizations (ACOs). CMS also notes that a major program redesign was finalized in a December 2018 final rule subtitled "Pathways to Success" (83 FR 67816) to emphasize the adoption of two-sided risk by ACOs. More recent provisions that address COVID-19 impacts on the program appeared in the March 31st COVID-19 IFC and the May 8th COVID-19 IFC.

1. Quality and Other Reporting Requirements: Background

CMS provides a brief history of the Shared Savings Program's quality requirements. CMS notes that beginning with performance year 2019, the ACO quality measure set was streamlined to 23 measures that emphasize outcomes and population health. ACOs currently submit data through the CMS Web Interface and by fielding the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey; CMS also directly extracts claims data for calculation of administrative claims-based measures. Clinicians who are participating in Shared Savings ACOs that do not qualify as Advanced APMs or who do not reach APM Qualifying Participant (QP) status through an Advanced APM currently are scored under the APM scoring standard of the MIPS program, unless they satisfy other MIPS exclusion criteria (e.g., low-volume threshold).

2. Application of the APM Payment Pathway to Shared Savings Program ACOs

a. Introduction

During the 2020 PFS rulemaking, CMS requested comments on aligning the Shared Savings Program quality requirements with those of the MIPS Quality performance category, including alternatives such a raising the minimum attainment level to the 40 percent; most commenters reacted negatively. CMS responds, however, by expressing a belief that the mature (now eight years old) Shared Savings Program should meet more stringent quality standards than at its inception, and cites analysis showing poor differentiation among ACO performances by the current measure set. To that end, CMS now proposes to apply the proposed APM Payment Pathway (APP; see section IV.C.2 and pp. 627-637 of the display copy) to ACO clinicians beginning with performance year 2021 as a successor to the APM scoring standard, noting that CMS is proposing termination of the CMS Web Interface elsewhere in this rule. CMS states that the APP addresses many stakeholder concerns while raising the Shared Savings Program's quality expectations for ACOs and their clinicians. The APP measure set consists of only 6 measures chosen to focus on population health and care delivered through APMs and aligns with

Medicare's program-wide Meaningful Measurement initiative.[22] The APP measure set would suffice for reporting under MIPS and under the Shared Savings Program, and the measure set also would be used to determine eligibility for shared savings under the latter.

b. Quality Scoring

The proposed APP quality measure set is shown in Tables 36 and 41 of the rule (pp 441 and 630 of the display copy) and reproduced later in this summary (section IV.C.2.c). Two of the 6 measures (Hospital All-Cause Unplanned Readmission and All-Cause Unplanned Readmission for Patients with Multiple Chronic Conditions) are claims-based and automatically scored by CMS without requiring data submission by ACOs.[23] ACOs could choose their submission mechanisms for the remaining 4 measures (e.g., through their electronic health records (EHRs) as electronic clinical quality measures (eCQMs)). Fielding the CAHPS for ACOs survey would also be required. CAHPS scoring would be done as a single measure rather than split into 10 then rolled up as is currently done, but the relative weight of the CAHPS single measure score would be fairly similar to that of the 10-measure score (17% versus the prior 25% for the 10-measure score).

APP quality measure scores would be calculated using MIPS benchmarks applicable to the data submission method used by the ACO (e.g., specific to electronic clinical quality measures, eCQM). All measures for which data are submitted would be scored on a 3-10-point scale, while measures not reported would receive zero points. CMS views this approach as less punitive than the current ACO standard under which all measures must be completely reported to generate a quality performance score above zero. Failure to report all APP quality measures under the APP would result in a score of zero and preclude the ACO from receiving shared savings. If an ACO were to fail to report via the APP, the ACO's quality score would be zero; however, the clinicians could report to MIPS outside the ACO (e.g., as individuals). Reporting outside of the ACO could also be chosen by ACOs with high proportions of patients in nursing facilities, for whom other quality measures might be more relevant.

While proposing to require ACOs to report via the APP, CMS also requests comment on an alternative approach when the APP measures are less relevant to an ACO's population. An ACO could opt out of the APP and report to MIPS via an APM Entity. CAHPS for MIPS would become optional, Improvement Activities and Promoting Interoperability data submission would be required, and the Cost category measures would be scored. In that situation, the MIPS Quality category score for the ACO would be used for determining eligibility to receive shared savings.

[22] APP measures fall into the Meaningful Measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health.
[23] CMS mentions a new claims-based measure that is under development ("Days at Home") and would consider adding it to the APP through future rulemaking.

c. Other Performance Categories under the APP

CMS discusses that ACO clinicians currently automatically receive full credit for the MIPS Improvement Activities performance category and that credit would continue under the APP unless the clinician reported to MIPS outside of the APP. The Cost performance category would remain unchanged, weighted at zero percent, since ACO clinicians already face stringent utilization and cost assessments through the Shared Savings Program. Other APP category weights are proposed as follows: Quality 50 percent, Improvement Activities 20 percent, and Promoting Interoperability 30 percent.

3. Shared Savings Program Quality Performance Standard

ACOs must meet the current Shared Savings Program quality standard, defined as the overall standard that must be met to qualify to receive shared savings, to mitigate shared losses (on some program tracks), and to avoid quality-related compliance actions. CMS proposes to increase this standard by raising the current minimum attainment level from 30 percent or the 30th percentile of a measure's benchmark to the 40th percentile for all MIPS Quality measures, excluding providers eligible for facility-based scoring for whom the Hospital Value-based Purchasing Total Performance Score is used and incorporates quality and cost. CMS describes simulating the effect of the higher attainment level on Shared Savings Program ACOs under various scenarios and finding that 95 percent (upper and lower bounds of 92 and 98 percent respectively) of providers would satisfy the higher criterion. Application of the APP to ACO clinicians would not affect their eligibility to become QPs or Partial QPs if they participate on an ACO track that meets criteria to be an Advanced APM.

For performance year 2021 and thereafter, CMS proposes to add policies on applying the APP to Shared Savings Programs as the ACO quality standard, including those below in addition to those already described above.

- ACOs must report quality data via the APP.
- CMS retains the right to audit and validate quality data reported by an ACO.
- Meeting the quality performance standard is required to be eligible to receive shared savings.
    - Minimum attainment would be set at the 40th percentile using MIPS benchmarks.

4. Shared Savings and Shared Loss Determinations

The final shared savings rate for Shared Savings Program ACOs is calculated by multiplying the quality score by the maximum sharing rate, a rate that is determined by the ACO's track: 50 percent for ACOs participating in Track 1; 60 percent for Track 2; 40 percent for ACOs at Level A or Level B of the BASIC track; 50 percent at Levels C, D, or E of the BASIC track; and 75 percent for the ENHANCED track. (The Track 1+ Model is based on Shared Savings Program Track 1 and has a maximum sharing rate of 50 percent.) CMS proposes for 2021 and subsequent years that to achieve shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the proposed quality performance standard, and otherwise maintain its eligibility to participate in the Shared Savings Program. Also

beginning with 2021, CMS proposes that an ACO that is eligible to share in savings (including meeting the proposed quality performance standard) will share in savings at the maximum sharing rate applicable to its track, up to the performance payment limit.

For some tracks requiring the assumption of two-sided risk by an ACO, quality is also used in calculating shared losses. Under Track 2 and the ENHANCED track, the shared loss rate is calculated as one minus the ACO's final shared savings rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively, and the shared loss rate may not be less than 40 percent for both tracks. ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track, are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent regardless of quality performance. Beginning with 2021, CMS proposes to use the following steps for shared loss determinations:

- 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.

Consistent with the existing structure of the financial models: under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent.

5. 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 proposes to identify ACOs that may be subject to termination for noncompliance with the quality performance standard of the Shared Savings Program 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 highlights that the above proposals would close the monitoring and action gap that otherwise could exist during the period that an ACO transitions to a new performance agreement period and emphasizes the importance of prior compliance history during the review of Shared Savings Program applications, especially for renewing and re-entering ACOs. CMS also 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 would also have consequences for ACO clinicians, who could lose their QP status. Finally, terminated ACOs on two-sided risk tracks would become liable for a prorated share of their losses accrued during the performance year in which termination occurs.

6. Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year (PY) 2021

CMS proposes 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 proposed APP. Specifically, for performance year 2021 and subsequent performance years, CMS would 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 would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score.

CMS also proposes 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 proposed revisions to the quality reporting requirements, CMS will no longer generate a CMS Web Interface quality reporting sample.

CMS seeks comment on these proposed revisions to the extreme and uncontrollable circumstances policy for the PY 2021 and subsequent PYs.

CMS also seeks comment on a potential alternative extreme and uncontrollable circumstances policy for PY 2022 and subsequent years. Under this alternative approach, CMS would determine 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. This would replace the current approach that determines ACOs are affected by an extreme and uncontrollable circumstances if 20 percent of their beneficiaries or their legal entity are located in an area impacted by an extreme and uncontrollable circumstance and determining shared savings using the higher of the ACO's own quality score and the mean ACO quality score.

CMS provides a couple of illustrative examples in the proposed rule. For example, it assumes that an ACO was impacted by an extreme and uncontrollable circumstance for nine months of

the year, had 50 percent of its assigned beneficiaries residing in the impacted area, and did report quality data but did not meet the quality performance standard of a score equivalent to a MIPS Quality performance category score at the 40th percentile. This ACO would have would have earned $100,000 in shared savings if it had met the quality performance standard; 0.75 * 0.50 * $100,000 = $37,500. Under this alternative, ACO B's shared savings would be $37,500.

CMS proposes to codify this new provision at §425.512 that would include incorporate existing policies at §425.502(f), §425.502(f)(1), §425.502(f)(2), §425.502(f)(3), and §425.502(f)(4).

7. Proposed Technical Changes to Incorporate References to Revised Quality Performance Standard

CMS proposes to make certain technical, conforming changes to the following provisions to reflect its proposal 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 proposed rule.

8. 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) Proposed 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 proposes to revise the definition of primary care services in its regulations to include the following additions:

- online digital evaluation and management 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;
- non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking;
- principal care management HCPCS codes G2064 and G2065; and
- psychiatric collaborative care model HCPCS code GCOL1, if finalized through the CY 2021 PFS rulemaking.

This revised definition would apply beginning with the PY starting on January 1, 2021 and apply in subsequent PYs.

CMS notes that it considered adding HCPCS code G2010 (remote evaluation of patient video/images) and G2012 (virtual check in). CMS decided these codes are applicable during the PHE, but that outside the context of the PHE for the COVID-19 pandemic it expects that these monitoring/check-in services for established patients will no longer replace primary care services. It also 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. **CMS seeks comment on whether to permanently include HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment.**

CMS also proposes to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting (reported with place of service code 21) for use in

determining beneficiary assignment. CMS received feedback that by not restricting place of service when using advance care planning codes in assignment, its methodology may inappropriately assign beneficiaries. **CMS seeks comment on this proposal.**

CMS also seeks comments on any other existing and new proposed codes that it should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

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

An ACO raised concerns 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 and proposes 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 would 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.

CMS solicits comment on whether additional exceptions are needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

9. 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. Proposed Revisions

CMS proposes 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 would apply prospectively to any renewing ACO that uses 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 would permit 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 proposed approach, a renewing ACO 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 would 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, if finalized, this proposed policy for determining the repayment mechanism amount for renewing ACOs would 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. Nevertheless, CMS is considering finalizing 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 would amend §425.204(f)(4)(iii) to add a provision permitting a renewing ACO to reduce the amount of its repayment mechanism if, upon renewal of its participation agreement, it chose to use its existing repayment mechanisms to demonstrate its ability to pay shared losses. It also states that it is considering finalizing provisions specifying the conditions under which a re-entering ACO may use an existing repayment mechanism arrangement to support its participation in a subsequent agreement period in the program. It is also considering specifying the same requirements for a renewing ACO, a re-entering ACO identified as the same legal entity, and an ACO whose participation agreement was terminated under §425.218 or §425.220.

Under another approach, CMS proposes to establish a policy that allows certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. Under this proposal, an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, may 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 proposes to determine eligibility for this one-time opportunity for an ACO to lower its repayment mechanism amount by comparing the recalculated amount of the ACO’s repayment mechanism based on its certified ACO participant list for performance year 2021, calculated according to §425.204(f)(4)(iii), to the ACO’s existing

repayment mechanism amount. If the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount.

CMS proposes that it would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanisms – it anticipates doing that after the start of performance year 2021. An ACO must submit its elections, together with revised repayment mechanism documentation, within 30 days of receiving written notice from CMS. It also notes that an ACO may need to provide prompt notification of its election if the ACO seeks to replenish the amount of its repayment mechanism to the permitted lower amount within the 90-day replenishment period.

These provisions discussed in this section would apply to §425.04(f)(4) and §425.04(f)(5). CMS also proposes technical changes to §425.04(f)(3)(iv) for clarity and in §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.

10. Applicability of Policies to Track 1+ Model ACOs

CMS states that unless specified otherwise, the proposed changes to the MSSP regulations in this proposed 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 proposed changes to those regulations would also apply to Track 1+ Model ACOs.

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 proposed rule and the 2021 HH proposed 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.

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 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 proposes to modify its requirement that ACOs field a CAHPS for ACOs survey for PY 2020. Instead, CMS will provide ACOs with full points for each of the CAHPS survey measures within the patient/caregiver experience domain for PY 2020. Specifically, CMS proposes to add language to §425.500(d) stating that for PY 2020 the CAHPS for ACO reporting requirement will be waived and all ACOs will receive automatic credit for the CAHPS for ACOs survey measures.

CMS is interested in feedback from ACOs and beneficiaries as to whether there are other ways to conduct the survey to avoid the concerns described above.

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

CMS is seeking 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.

CMS cites 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 cites 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 seeks 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, as proposed in this section.

(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.

J. Proposal to Remove 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)[24] or 1869(f)[25] 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[26], CMS has 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 37, reproduced below, list the nine NCD's CMS proposes 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.[27]

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)

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

[24]Section 1862(l) of the Act describes the national and local coverage determination process.
[25] 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.''
[26] Azar v. Allina Health Services, 587 U.S.____, 139 S. Ct. 1804 (2019)
[27] The manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items?CMS014961.

(1) NCD #20.5 Extracorporeal Immunoadsorption (ECI) using Protein A Columns (1/01/2001)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: ECI using Protein A columns is used to selectively remove circulating immune complexes and immunoglobulins for treating some inflammatory and autoimmune diseases. External stakeholders suggested this NCD may be outdated and coverage considerations should be left to contractor discretion.

(2) NCD #30.4 Electrosleep Therapy

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: External stakeholders suggested this NCD may be outdated. The term "Electrosleep therapy" is outdated and superseded by "cranial electrotherapy stimulators (CES). In addition, the indications for using this treatment have changed.

(3) NCD #100.9 Implantation of Gastroesophageal Reflux Device (6/22/1987)

- Circumstances/criterion; Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: External stakeholders suggested this NCD may be outdated. The Noncoverage NCD was based on the Angelchik device which was removed from the market in 1990. CMS notes that the FDA has authorized new devices for treating gastroesophageal reflux; some of these devices have limited evidence demonstrating improved long-term patient outcomes. CMS believes that local contractor discretion provides an avenue for potential coverage in appropriate candidates.

(4) NCD #110.14 Apheresis (Therapeutic Pheresis) (7/30/1992)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: Apheresis utilizes specialized equipment to remove selected blood constituents from whole blood and re-transfused the blood back into the person. CMS notes this is an old NCD that predates the current NCD public notice standards for development of an NCD.

(5) NCD #110.19 Abarelix for the Treatment of Prostate Cancer (3/15/2005)

- Circumstances/criterion: The technology is considered obsolete and is no longer marketed.
- Rationale: Abarelix is no longer marketed in the US and the NCD is no longer relevant.

(6) NCD #190.1 Histocompatability Testing (8/1/1978)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: Histocompatibility testing involves typing human leucocyte antigen (HLA) proteins. External stakeholders suggested that the NCD is outdated and burdensome because it requires submission of medical records for certain diagnosis.

(7) NCD #190.3 Cytogenetic Studies (7/16/1998)

- Circumstances/criterion: The NCD has been superseded by subsequent Medicare policy.
- Rationale: Direct DNA analysis through DNA sequencing allows providers more information to identifying abnormalities in genetic sequencing. Genetic sequencing is the focus of the NCD, Next Generation Sequencing.

(8) NCD #220.21 Magnetic Resonance Spectroscopy (MRS) (9/10/2004)

- Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: MRS determines the relative concentrations and physical properties of biochemicals and has the potential to evaluate metabolic pathways in different tissues. External stakeholders suggested this NCD may be outdated as the scientific evidence has evolved since 2004.

(9) NCD #220.16 FDG PET for Inflammation and Infection (03/19/2008)

- Circumstances/criterion: Circumstances/criterion: Local contractor discretion to make a coverage decision better serves the needs of the program.
- Rationale: CMS notes that the use of FDG PET for inflammation and infection is multifactorial and for some conditions, there is no overall consensus about the added value of using FDG PET for this indication. CMS believes that local contractors can tailor coverage decisions the pertinent facts of a patient's case.

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

CMS also solicits comments on other reasons for proposing to remove NCDs including whether the time-based threshold of more than 10 years is still appropriate or whether a shorter period of time is more appropriate.

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, with certain exceptions specified in the SUPPORT Act as well as any additional exceptions as specified by HHS. CMS proposes to amend the timeline for implementation of this requirement so that instead of beginning January 1, 2021, it would be required as of January 1, 2022. CMS describes this delay as necessary to recognize the unique challenges that prescribers are facing during the COVID-19 PHE.

CMS notes that while some prescribers who already have systems in place have been able to increase their use of electronic prescribing during the PHE period, others who needed to implement systems and upgrades are facing challenges during the PHE while key personnel are

unavailable or working offsite. CMS believes the delay strikes the appropriate balance between not providing too large a burden on providers while also leveraging the benefits of electronic prescribing as expeditiously as possible.

Background is provided on electronic prescribing including the increase in electronic prescribing for controlled substance 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.

CMS notes that the lengthened timeframe will permit it to solicit additional feedback from its prior published Request for Information on Electronic Prescribing of Controlled Substances[28], including from prescribers that are not enrolled in Medicare or Medicaid or regulated by CMS. **CMS seeks additional feedback on this proposal including the feasibility for prescribers to meet the proposed January 1, 2022 deadline, the impact of the proposal on interoperability and medical record systems; and whether the proposed change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.**

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

[28] 85 *FR* 47151: Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)

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 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 takes into account 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. Proposal to Codify Existing Policy

CMS proposes to codify what it says has been its approach on this issue for at least 12 years. Specifically, it would 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 would amend its regulatory definition of a multiple source drug to include a reference to drugs approved through the section 505(b)(2) pathway. CMS notes that it is 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 notes 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 would 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 says it would reevaluate and potentially revise previous payment (and coding) decisions to maintain consistency with its proposed policy. **CMS seeks comment on the proposal**.

3. Regulatory Impact

CMS does not provide a detailed estimate for savings it believes will accrue to the program through continuation of what it refers to as its longstanding policy for several reasons. It does not know the number of section 505(b)(2) drug products that will be approved in the coming years, and of those it cannot determine which will be payable under Part B. Additionally, it cannot estimate what share of Part B drug claims relative to similar (and potentially lower priced) multiple source drug codes the section 505(b)(2) drug products will capture, and it cannot estimate the price or payment difference between the yet to be approved section 505(b)(2) drug products and items priced in multiple source drug codes. However, CMS does provide what it calls a "very rough estimate" of the impact on spending.

Using 2018 data from the Part B Drug Spending Dashboard, and based on a 50 percent uptake of two recently approved section 505(b)(2) drug products relative to the corresponding multiple source drug code and payment allowance estimates derived from the July 2020 ASP Drug

Pricing files (or WAC from pricing compendia if ASP was not yet available), CMS estimates that payment under separate single source drug codes could result in $15 million to $33 million more spending per code each year for each section 505(b)(2) drug product that is assigned to a separate code. Assuming 5 to 10 section 505(b)(2) drug products are paid under separate codes, CMS believes it could result in $75 million to $330 million in additional spending per year absent its policies.

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 was 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 then, 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, on April 21, 2020, in response to the COVID-19 public health emergency, ONC announced additional flexibility for health IT developers subject to the policies in the 21st

Century Cures Act final rule.[29] Specifically, ONC announced that it will exercise enforcement discretion regarding new requirements in the 21st Century Cures Act final rule until three months after each initial compliance date or timeline. For example, where the 21st Century Cures Act final rule requires updates or additions to 2015 Edition by May 2, 2022, with the enforcement discretion health IT developers would have until August 2, 2022 to make the updates. During the period of enforcement discretion, healthcare providers participating in the Promoting Interoperability Programs and QPP may continue use technology certified to the 2015 Edition criteria that has not been updated yet.

In this proposed rule, CMS discusses in detail the specific changes made by the 21st Century Cures Act final rule and the timelines for enforcement. In particular, CMS notes that removal of certain criteria was 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 for that time period 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 proposes that healthcare providers would be required to use technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the Cures Act final rule. That is, taking into account the announced enforcement discretion, for updated and new certification criteria included in the CEHRT definitions in §§495.4 and 414.1305, until August 2, 2022, program participants may use technology certified to either the current 2015 Edition certification criteria or the 2015 Edition Cures Update and 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 views this proposal as 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.

CMS discusses how providers can work with their health IT developers during the transition to implementing CEHRT that meets the 2015 Edition Cures Update. One example is using a phased approach that uses a combination of updated and non-updated certified health IT for a 90-day reporting period for 2022 that ends prior to August 2, 2022, and then complete their first reporting period 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 prior to August 2 using nonupdated health IT, and then complete their first reporting period using only updated health IT modules in 2023. A provider may also move to updated certified health IT for reporting periods prior to August 2, 2022.

[29] The announcement appears at https://www.healthit.gov/curesrule/resources/enforcement-discretion and the timeline chart at https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.

Table 38 in the proposed rule, reproduced below, details the measures for the Promoting Interoperability Program for eligible hospitals and CAHs and the MIPS Promoting Interoperability performance category and the 2015 Edition certification criteria that support each measure. 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 would no longer be associated with the measures under the e-prescribing objective for the Promoting Interoperability Programs and MIPS, beginning with the 2021 performance period.

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 August 2, 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 38 shows that either the existing criterion at §170.315(g)(8), or the newly finalized criterion at §170.315(g)(10), could 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 27-month transition period.

TABLE 38: 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
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	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

TABLE 38: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria		
Objective	**Measure**	**2015 Edition**
Data Exchange	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)(3) (optional)

[1] = Specific to Eligible Clinicians (MIPS Promoting Interoperability performance category)
[2] = Specific to Eligible Hospitals and CAHs (Promoting Interoperability Program)

CMS also proposes 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. Proposed 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 proposes to allow hospitals to 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 finalized in the 21st Century Cures Act final rule. CMS will revisit this issue in future rulemaking if ONC makes additional changes (i.e., allows certification only under the 2015 Edition Cures Update).

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.

N. Proposal to Establish New Code Categories

In response to stakeholder's concerns about the variability in bioequivalence between buprenorphine/naloxone products (J0572-J0575), CMS proposes an expanded series of codes to identify these products. Table 39 in the proposed tule list the 15 new HCPCS code categories to report all currently marketed buprenorphine/naloxone products, based on strength and therapeutic equivalence. CMS also proposes to discontinue in existing codes (listed in Table 40).

CMS notes 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.

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

CMS proposes a number of changes to clarify and add flexibility to MDPP policies applicable during emergency periods. It would add certain definitions, and eliminate other policies that had been adopted in the March 31st COVID-19 IFC (85 FR 19230).

1. Proposed changes 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 proposes to revise the period during which the flexibilities are available. In addition to being available during the current PHE period, CMS would expand 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 the proposal, services would 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 would be required to communicate its determination to all impacted MDPP suppliers. CMS states that such notice would include the effective date and the end date which would be either at the end of the emergency period or when in-person services are no longer disrupted.

CMS notes that the while the proposed emergency policy permits services to be furnished entirely on a virtual basis, it only permits such services if the MDPP supplier's preliminary or

full Center for Disease Control's Diabetes Prevention Recognition Program authorizes the supplier to furnish services in person.

CMS also proposes the following new emergency policies:

- MDPP suppliers would 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, or self-reported using video that documents the weight as it appears on a digital scale.
- As under prior rules, MDPP suppliers may either deliver MDPP services virtually or suspend in-person services and resume them at a later date. Under the proposed rules, CMS adds clarifications and identifies two separate sets of choices for beneficiaries based on when they began their MDPP services. (1) Beneficiaries receiving MDPP services as of March 1, 2020 could 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, could elect to restart the set of MDPP services at the beginning, or may resume with the most recent attendance session of record. If services are suspended and subsequently resumed, they may begin again either upon the effective end date of the 1135 waiver event or upon an effective date specified by CMS. Upon resumption, the MDPP services must comply with the once per lifetime requirement. Consistent with these proposed changes, CMS would eliminate the existing provision that had permitted the once per lifetime requirement for MDPP services to be waived.
- 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 proposes to eliminate the term "make-up" from the description of those sessions to clarify that all sessions may be made virtually – they do not need to be "make-up" sessions. The limitations on those virtual visits would also be increased. Under the proposal, 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 proposes to eliminate, effective January 1, 2021, the permitted waiver of minimum weight loss requirements during the PHE since CMS is proposing that weights could be reported via alternative virtual approaches (described above).

2. Proposed Changes to §424.210

CMS proposes to add to §424.210, a section addressing beneficiary behavior incentives, a requirement that if incentives are provided during the PHE or 1135 waiver event to a beneficiary who is receiving MDPP services virtually, the incentive must be able to be used during the PHE or section 1135 waiver event. CMS provides examples of incentives that can be used during the

PHE such as vouchers for healthy food or wearable technology. Items that could not be used would include gym memberships, for example.

The following definitions are proposed to be added to this section:

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) 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 a 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.

Regulatory Impact. CMS updates its estimates of the impact of the MDPP flexibilities established in the March 31st COVID-19 IFC. Under the proposed rules, 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.

IV. Quality Payment Program

A. Background and Introduction

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) ended the Sustainable Growth Rate (SGR) formula for updates to the Physician Fee Schedule (PFS), replacing the SGR with the Quality Payment Program (QPP). The QPP is intended to move physicians from volume-driven to value-based care for Medicare beneficiaries. The evolution of Medicare's payments to physicians and the foundations of the QPP are described in the 2017 QPP proposed rule (81 FR 28167-28169). Key features of the QPP for 2020 are as follows:

- Two participant tracks: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs);[30]
- 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 increase in size over time per statute until stabilizing at a maximum value of ± 9 percent in 2022;
- Through 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)
    - Per statute, the bonus is to be replaced in 2026 by a higher annual PFS update percentage for QPs than non-QPs (0.75 vs. 0.25 percent, respectively);
- Two-year lag between each performance year and its corresponding payment year;[31] and
- QPP annual updates that are implemented as part of the PFS rulemaking process.

2020 is the QPP's second payment year: MIPS payment adjustments are being applied, and APM incentive payments are being made, to eligible clinicians based upon their 2018 performance data. MIPS adjustments range from -5 to +5 percent, made to payments for covered Part B professional services furnished during 2020. Some clinicians who met a separately-specified performance threshold are also receiving an additional positive adjustment in payment year 2020 for exceptional performance, based on a sliding scale using 2018 scores. Per statute, the exceptional performance bonus will continue through payment year 2024. The 2020 APM incentive payment is set at 5 percent of a QP's covered Part B professional services furnished during 2019, and the incentive program will continue through payment year 2024.

The 2021 performance year will correspond to the 2023 payment year, and the MIPS payment adjustments will be ± 7 percent applied to 2023 payments to physicians. CMS estimates that approximately 930,000 clinicians will be MIPS-eligible clinicians during the 2021 performance period, while another 369,000 clinicians would be potentially MIPS-eligible but not required to participate. CMS further estimates that about 300,000 clinicians will be excluded from MIPS participation because they meet all 3 low-volume threshold criteria or for other reasons, including being newly-enrolled in Medicare or having reached QP status.

Budget neutrality is required within the QPP by statute. CMS estimates that positive and negative payment adjustments distributed in payment year 2023 will each total $442 million. As in prior QPP years, an additional $500 million will be available for distribution for exceptional performance. CMS estimates that the maximum possible positive payment adjustment attainable for payment year 2023 will be 6.9 percent, combining the MIPS base adjustment with the adjustment for exceptional performance. Finally, CMS estimates that between 196,000 and 252,000 clinicians will meet thresholds to become QPs, resulting in total

[30] QPP participants currently include the following practitioner types: physician (as defined in section 1861(r) of the Act), physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, physical therapist, occupational therapist, clinical psychologist, qualified speech-language pathologist, qualified audiologist, and registered dietician and nutrition professional.

[31] 2017 was the first performance year and 2019 was the associated first payment year. CMS also uses the term "QPP Year". QPP Year 1 is the same as 2017, so that 2021 will be QPP Year 5.

lump sum APM incentive payments of $700-900 million for the 2023 payment year. The APM bonus remains at 5 percent and will be calculated using the QP's covered Part B professional services furnished during 2022.

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

Changes to the QPP for 2021 are proposed in Section IV of the PFS rule and would become effective January 1, 2021, unless otherwise noted. CMS states a purposeful intent to limit the volume of proposals for changes in 2021 to promote QPP stability in the face of the COVID-19 PHE. CMS emphasizes the singular importance of proposals related to the MIPS Value Pathways (MVPs), viewing MVPs as the desired future state of MIPS. CMS defers proposing an initial set of MVPs and policies for their implementation, but does propose for 2021 a process for MVP development with stakeholder collaboration and criteria for selecting MVPs for future implementation. CMS notes that the MVPs will align with ongoing substantive healthcare initiatives designed to transform Medicare into a value-based payment system, such as Patients Over Paperwork and the National Quality Roadmap.[32]

Other proposals in this rule highlighted by CMS include:

- Eliminating the APM scoring standard (for MIPS APMs) and establishing the APM Performance Pathway (APP),
- 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,
- Reducing the MIPS performance threshold for payment year 2023, from the previously finalized 60 points to 50 points, to mitigate the impact of the COVID-19 PHE, and
- For the 2020 performance period only, doubling the complex patient bonus to 10 points.

CMS generally invites comment on all of its QPP proposals; more detailed comment requests will be highlighted in the relevant sections of this summary.

MIPS Performance Category Weights (%)			
Performance Category	**Performance Year 2019 *Final***	**Performance Year 2020 *Final***	**Performance Year 2021 *Proposed***
Quality	45%	45%	40%
Cost	15%	15%	20%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

[32] The Roadmap was published by the Department of Health and Human Services on May 15, 2020, in response to Executive Order 13877, and is available at https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.

C. Merit-Based Incentive Payment System (MIPS): Structural Changes

1. MIPS Value Pathways

In the 2020 PFS final rule, CMS finalized the definition of an 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). Further, CMS in that rule posed multiple questions about the MVP framework; CMS states that stakeholder responses were numerous and strongly influenced proposals made in this proposed rule as noted in specific sections below.

a. Guiding Principles

The MVP framework is intended to improve value, reduce burden, enable patients to compare clinician performances, and reduce barriers to risk-bearing APM participation by clinicians. CMS proposes to update the framework's guiding principles, listed below with the revisions italicized; the fourth principle is unchanged.

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*.

CMS notes that the revised second principle responds to repeated stakeholder requests, particularly from multispecialty groups, that MIPS be changed to allow data submission by subgroups within a TIN. Subgroup reporting also could provide patients with data that more directly address clinician performance in caring for a patient's specific condition than data from a more generic set of measures from a large and diverse clinician group. Further, subgroup reporting could reduce clinician burden by requiring data submission on measures that are meaningful to the clinician and easily incorporated into everyday clinical workflow.

CMS explains that the new fifth principle was added to leverage digital innovations that reduce burden to clinicians created by MIPS requirements. CMS notes that digital quality measures (dQMs) are based on health information that can be captured and transmitted electronically via

interoperable systems.[33] Data sources for dQMs could include (but are not limited to) electronic health records (EHRs), health information exchanges (HIEs), clinical registries, and wearable devices.

b. MVP Development

Criteria. Each MVP will be designed to connect activities and measures from the four MIPS performance categories relevant to a specific patient population from which standardized clinician performance data can be extracted. CMS agrees with stakeholders that the process for developing MVPs should be collaborative and transparent, and should produce MVPs that are consistent and reliable. 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, proposes 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
- Measures and Improvement Activities Considerations (specific to each MIPS performance category)

CMS provides additional guidance for each criterion on pages 615-619 of the display copy (e.g., the MVP must include the entire set of Promoting Interoperability (PI) measures). To emphasize the importance of Incorporation of the Patient Voice, CMS specifically proposes that MVP developers should involve patients (and/or patient representatives) prior to submitting candidate MVPs to CMS and states that patient involvement would be considered a pre-requisite for consideration of an MVP by CMS. CMS encourages developers to use several approaches to engaging patients for each MVP and offers as examples technical expert panels (TEPs), advisory committees, focus groups, structured in-depth interviews, and informal listening sessions.

Process. CMS proposes 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, the MVP developer may be contacted to answer questions.

[33] Electronic clinical quality measures (eCQMs) are a subset of dQMs that use data from electronic medical records.

3. CMS will reach out to developers whose MVPs have been judged during the 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.

CMS seeks comment about balancing selection process transparency with timely addition of MVPs into MIPS by asking whether there should there be an advisory committee or TEP to review candidate MVPs, an interdisciplinary committee as used in the Call for Measures process, or a public process like the NQF-convened pre-rulemaking process?

Population Health Measures. CMS notes concerns previously expressed by stakeholders about including population health measures calculated from administrative (claims-based) data related to reliability, validity, attribution, unintended consequences, and risk adjustment. However, CMS views these measures as part of the "foundational layer" of MVPs that would increase their alignment with APMs and with performance measurement by other third-party payers. CMS currently includes one such measure in MIPS, the All-cause Hospital Readmission Measure. CMS proposes to replace this measure with a Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups, described in detail in Appendix 1 of this rule (Table Group A, page 1037 of the display copy).

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 supported QCDR measure inclusion in MVPs as long as new costs and burden could be avoided. CMS proposes that QCDR measures included within a candidate MVP must meet all current QCDR measure requirements (§414.1400(b)(3)), and emphasizes 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 proposes 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)).

c. MVP Implementation Timeline

CMS had previously intended to begin a gradual transition from the current MIPS participation options[34] (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 has chosen to defer proposing any MVPs until at least performance year 2022. CMS indicates that traditional MIPS will be maintained while a robust inventory of MVPs is built, but expects to propose thereafter that all MIPS

[34] MIPS eligible clinicians may participate as individuals or through a group, virtual group, or MIPS APM Entity.

eligible clinicians would be required to participate in MIPS via an MVP or an APM Performance Pathway (APP, discussed below). CMS will monitor MVP inventory growth along with clinician readiness to guide the timeline for transition from traditional MIPS to required MVP/APP participation.

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

a. 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, thereby encouraging their continued APM involvement.[35] CMS has found the standard infeasible to fully implement, and has heard from stakeholders that the standard's complexity and inflexibility produce confusion and add burden for clinicians to whom the standard is applicable. For those clinicians, CMS proposes to add the APM Performance Pathway as a new option for MIPS reporting and scoring, and later in this rule proposes to terminate the APM scoring standard (see Section IV.D.5.a of this summary and pages 694-698 of the display copy). The APP would become effective beginning January 1, 2021, and thus applicable to performance year 2020, for which data submission will occur during the January-March 2021 MIPS reporting period.

CMS proposes that individual MIPS eligible clinicians or groups -- if identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four QP determination snapshot dates for a given performance period (March 31, June 30, August 31, December 31) -- could choose to report and be scored through the APP. Alternatively, those clinicians could report through any other MIPS reporting option and be scored under the general MIPS standards. Individual MIPS APM participant clinicians choosing the APP would report data as individuals. Groups choosing the APP would submit data for all of their MIPS eligible clinicians, but a group's final score would apply only to clinicians who appear on their Participation or Affiliated Practitioner lists.[36]

b. MIPS APMs

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

- Create and designate §414.1367 "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).

[35] The APM scoring standard also applies to clinicians reaching Partial QP status who elect to report to MIPS.
[36] Medicare Shared Savings Program ACOs would be required to report through the APP as proposed elsewhere in this rule, but their clinicians could also choose to report outside of the APP.

- Expand the MIPS APM definition by removing §414.1370(b)(2) and (b)(4), allowing inclusion of APMs that are facility-based and/or have only an Affiliated Practitioner List.

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

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

Quality. CMS proposes the measures listed below as the basis for APP Quality category scoring. 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., Shared Savings Program). CMS discusses in detail (pp. 631-632 of the display copy) 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). The MCC ACO version received a recommendation of "conditional support for rulemaking" from the Measure Applications Partnership (MAP).[37]

APM Performance Pathway Quality Measure Set				
Measure #	**Measure Title**	**Collection Type**	**Submitter Type**	**Meaningful Measure Area**
Quality ID: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Management Chronic Conditions
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mental Health Treatment
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Management Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

Recreated from Table 41 of the proposed rule
TBD = To Be Determined

CMS proposes 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 proposes not to apply the quality measure scoring cap requirement to that measure (§414.1380(b)(1)(iv)).

[37] The MAP is convened by the National Quality Forum; CMS cites their report at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

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 proposes to continue this waiver for MIPS APMs, and thereby for APP cost category scoring, noting that : 1) MIPS APMs mandate cost performance assessments in their model designs; 2) MIPS APM cost measurement methods may differ between MIPS APMs and the general MIPS structure; and 3) attribution differences between MIPS APMs and the general MIPS structure could confound identification of beneficiaries for whom MIPS APM clinicians are responsible.

Improvement Activities. Per statute, all MIPS APM clinicians automatically receive at least one-half of the maximum IA score. For the APP, CMS proposes to assign a specific IA performance score to each MIPS APM. As is done currently for MIPS APMs, absent the APP, 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 choose to submit additional IA data to raise their scores. CMS would publish the assigned IA scores on the CMS website annually.

Promoting Interoperability. CMS proposes that PI performance category scoring under the APP would be the same as is done under the MIPS general structure.

Category Weights and Reweighting. CMS proposes using waiver authority[38] to set the following MIPS performance category weights for clinicians reporting through the APP: Quality 50 percent; Cost 0 percent; IA 30 percent; and PI 20 percent. CMS also proposes category reweighting as follows, should 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.
- When Quality is reweighted to zero percent, PI is set at 75 percent and IA at 25 percent.

Final Scoring. CMS proposes 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)

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

[38] 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.

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

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

CMS has repeatedly heard from stakeholders that they highly value policy stability in the MIPS program. CMS also acknowledges the added demands that have been placed upon clinicians by the COVID-19 PHE. CMS states, therefore, that the number of MIPS policy proposals for performance year 2021 has purposefully been limited.

a. Quality Category Weight

CMS proposes to reset the 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. CMS notes that by statute the Quality and Cost category weights total 60 percent, so that changes to their weights move in tandem. While the Secretary has been afforded some discretion to adjust these weights during QPP Years 1-5, the Quality and Cost categories must each be weighted at 30 percent for performance year 2022 (QPP Year 6), as set in statute. The changes being proposed by CMS to the Cost category weight for performance years 2021 and 2022 (see below), result in corresponding values for the Quality category weights as proposed (shown in the table found at the end of Section IV.B of this summary).

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 ACO participants in the Shared Savings Program and the Next Generation ACO. CMS proposes to sunset this application as both a collection and submission type beginning with the 2021 performance year via changes to §414.1305. CMS proposes to retire the CMS Web Interface in concert with its proposal to revise the Shared Savings Program quality performance standard and transition those ACOs to reporting through an APP for ACOs, starting with performance year 2021 (see pp. 424-463 of the display copy and Section III.G.2 of this summary).

CMS describes in detail its analysis of Web Interface use for quality reporting that disclosed that Web Interface use is heavily dominated by Shared Savings Program and Next Generation model ACO (over 80 percent) and that use by other groups has fallen annually since the MIPS program began. CMS believes that the residual small group of Web Interface users, assuming the Shared Savings Program quality standard changes are finalized, could in fact achieve higher scores by moving from the Web Interface to another data collection/submission type because the Web Interface is the most stringent of the existing collection/submission types. Web Interface reporting involves more measures, larger minimum patient samples, higher data submission completeness threshold, does not award credit for partial reporting, the measure set is heavily oriented to primary care specialty activities, and some measures are topped out. CMS notes that the benefits of moving to a less stringent collection/submission type could mitigate at least in part the burden of switching reporting mechanisms. CMS further notes that the current 10 Web

Interface measures have either equivalent eCQMs or CQMs or both that could be adopted by former Web Interface users for MIPS quality reporting, so those users would likely be able to continue many of their existing data collection processes.

c. Quality Measure Inventory Changes

Changes proposed to MIPS quality measures by CMS are provided in the tables of Appendix 1, and would result in an inventory of 206 measures (see pages 1037-1353 of the display copy). All changes are for performance year 2021 and future years unless otherwise noted. Extensive and detailed information is provided for each measure including specifications and the rationale for change(s). Measures with their proposed changes incorporated are presented as follows:

- Table Group A: New Quality Measures
    - CMS is proposing two new administrative claims-based outcome measures.
    - *Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Groups is a re-specified version of NQF #1789 Hospital-Wide All-Cause Unplanned Readmission Measure (HWR).*
    - *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for MIPS is a re-specified version of NQF #1550 Hospital-level RSCR Elective Primary THA and/or TKA.*
- Table Group B: New or Modified Specialty Measure Sets
    - Reflects responses to CMS' request for recommendations for additions and revisions announced electronically on January 6, 2020.
    - Modifications (e.g., changed clinical guidelines) are proposed for 43 existing specialty sets (all except that for Anesthesiology).
    - No new specialty sets are proposed for addition.
- Table Group C: Previously Finalized Measures Proposed for Removal
    - For 2021 and subsequent years, CMS proposes to remove 14 measures including 2 that are extremely topped out and 5 that are no longer stewarded or maintained.
- Table Group D: Previously Finalized Measures with Substantive Changes
    - All measures with substantive changes (e.g., measure specification or domain) must go through notice-and-comment rulemaking; Group D contains 112 items.
    - An "Instructions Note" has been added for codes for which telehealth encounters have been allowed for determination of denominator eligibility. Proposed, newly allowed telehealth denominator eligibility will have a notation under "Substantive Change".
    - CMS reviews in detail the rationale for inclusion in this table of *Q134 Prevention Care and Screening: Screening for Depression and Follow-Up Plan*, to recognize for 2021 and future years a substantive change made to the eCQM and Web Interface measure versions that inadvertently was not identified and included during 2019 and 2020 rulemaking.

d. Administrative Claims Measures Performance Periods

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 believes that a standardized performance period for measures requiring clinician data submission enhances reporting efficiency. CMS proposes to create an exception for administrative claims-based quality measures to have extended performance periods by modifying §414.1330(a)(1). This exception, if finalized, would be applicable to the proposed 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. CMS states that exceptions for administrative claims-based measures would not create issues for clinicians since data are extracted directly by CMS from claims and no clinician submission is required.

e. CAHPS for MIPS Survey

The CAHPS for MIPS Survey is a key instrument used in assessing patient experience of care for services provided by MIPS eligible clinicians. CMS notes the markedly increased use of telehealth and other communications technology-based services (CTBS) during the COVID-19 PHE and proposes 2 CAHPS changes to capture input from patients about their telehealth experiences during the performance year 2021 CAHPS survey administration: add a survey-based measure to assess patient-reported usage of telehealth services, and add a reference to care received by telehealth to the survey cover page to stimulate patient recall of their telehealth experiences as they begin to answer survey questions. CMS expects that high rates of telehealth and CTBS encounters will continue after the PHE ends and that the proposed changes may remain appropriate for future CAHPS surveys.

CMS further proposes to use the same set of CPT and HCPCS telehealth/CTBS codes currently used to assign beneficiaries to Shared Savings Program ACOs for the purpose of assigning beneficiaries to groups for CAHPS for MIPS survey administration for performance year 2021 and subsequent years. CMS bases this proposal on the expanded list of telehealth and CTBS services adopted in the May 1st COVID IFC for inclusion as primary care services used to assign Shared Savings Program beneficiaries to ACOs for performance year 2020 and for any subsequent performance year that starts during the COVID-19 PHE. The definition of primary care services applicable to CAHPS for MIPS beneficiary assignment for survey administration during performance year 2021 and thereafter would be codified at §414.1305 as shown below (and not limited to the PHE):

> *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)

Finally, CMS proposes a technical change to clarify the intent of a question in the CAHPS for MIPS section *Your Care From Specialists in the Last 6 Months*.

2. Cost Performance Category (§414.1305)

a. Cost Category Weight

As described above, the weights of the Quality and Cost performance categories must total 60 percent and move in tandem. CMS has consistently stated a plan for gradual increases to the Cost weight from zero percent in QPP Year 1 to meet the statutory requirement of 30 percent for performance year 2022 (payment year 2024, QPP Year 6) to allow 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.

CMS describes having considered several alternative approaches to reach the required 30 percent weight by performance year 2022 from the 2020 weight of 15 percent. One option continues the weight at 15 percent for performance year 2021, increasing to 30 percent for 2022. This approach was driven by considerations of the challenges presented by the COVID-19 PHE. However, this approach would also require a doubling of the category weight from one year to the next, an abrupt rather than gradual transition for clinicians. A second option increases the weight to 20 percent for performance year 2021 then to 30 percent for 2022 and thereafter. This approach would be more gradual and would mitigate the impact of the increased clinical costs of the PHE, and is formally proposed by CMS.

CMS requests comments on the proposed option, the alternative option considered, and any additional options, such as assigning weights of 22.5 percent and 30 percent for performance years 2021 and 2022, respectively.

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 Total Per Capita Cost of Care and Medicare Spending Per Beneficiary.[39] 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. The updated specifications and cost measure information forms for the 2020 episode measures are available for download at http://cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.

[39] The performance year 2021 cost measures are listed in Table 47 of the CY 2020 PFS final rule (84 FR 62979).

3. Improvement Activities Category (§414.1355)

a. Call for Activities Exceptions

CMS notes that requests to add new or modify existing 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 proposes 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, and this exception would not require an ongoing PHE.

CMS anticipates that the flexibility created by these two exceptions would foster prompt and ongoing engagement by clinicians in PHE-related IAs and would expedite progress towards achieving the strategic goals of HHS agency-wide initiatives (e.g., Patients Over Paperwork). Nominations made through either exception process still would be submitted using the standard form and would be subject to notice-and-comment rulemaking. For each HHS-nominated IA, CMS would routinely request stakeholder input as to whether the IA would improve clinical practice or care delivery. The existing criteria for measure nomination and selection also would continue to apply to IAs submitted under the two proposed exceptions.

b. Improvement Activity Nomination Criteria

Requestors of new or revised IAs must match their candidate IAs against a set of criteria that are considered by CMS in IA selection (82 FR 53660). CMS proposes two new criteria: 1) linked to existing quality and cost measures, as applicable and feasible; and 2) aligned with at least one of the HHS goals, when feasible and 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 in the March 31st COVID-19 IFC.

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.

The proposed revisions are presented in detail along with rationales for the changes. No IAs are proposed for removal from the current inventory.

4. Promoting Interoperability Category (§414.1375)

a. Future Performance Periods

The PI performance period has been set 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 (January 1, 2021 through December 31, 2021). CMS proposes to continue this approach for payment year 2024 and thereafter at new §414.1320(g)(1), which sets the PI performance period as a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. CMS notes that this proposal aligns with the proposed CY 2022 EHR reporting period for eligible hospitals and CAHs under their respective Medicare PI programs.

b. Promoting Interoperability Measure Changes

CMS proposes 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 describes continuing to receive stakeholder feedback that supports the potential value of this measure in addressing the opioid epidemic; the measure still is not sufficiently mature for required reporting. CMS reviews the issues identified, including the variation across states' PDMP programs, the limited capability for information exchange between them, and the poor integration of PDMPs into EHR clinical workflows. CMS also reviews in depth several provisions of the SUPPORT Act that are relevant to PDMPs, including new requirements and federal funding, as well as other federally-supported activities related to PDMPs (e.g., enhancements to the RxCheck interstate exchange hub for PDMP data). CMS concludes by agreeing with stakeholders that the Query of PDMP measure is not ready for required reporting, and proposes to continue the measure as optional for the 2021 performance period. CMS further proposes 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.

Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure.
CMS notes that "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. Therefore, CMS proposes to replace "incorporating" with "reconciling" in the name of this measure.

Health Information Exchange (HIE) Bi-Directional Exchange Measure.
CMS begins by describing the role of HIEs in facilitating interoperability and the associated aggregation of health data from multiple sources into coherent longitudinal records of patient

care. In that context, 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. CMS notes that the COVID-19 PHE has emphasized the importance and value of HIEs and bi-directional information exchange as care delivery via telehealth has rapidly expanded. CMS states a belief that care coordination across settings will be facilitated by incenting participation in HIEs that support bi-directional exchange and provides potential usage scenarios and their benefits to patients.

Based on the forgoing, CMS proposes to add a new measure beginning with the 2021 performance period *Health Information Exchange (HIE) Bi-Directional Exchange.* Clinicians would be able to 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. CMS intends for the new measure to incent clinicians to engage in bi-directional exchange via HIEs and believes that the measure's high point value is appropriate since the measure reflects 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 clinicians could interact with HIEs through certified application programming interfaces (APIs). CMS further notes that actions required to satisfy the new measure would not affect the applicability of any HIPAA Privacy Rule provisions. 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).

CMS requests comments as to whether the optional measure would incentivize eligible clinicians to participate in HIEs while establishing a high performance standard for sharing information with other clinicians. CMS also requests comment on the proposed attestation statement.

c. Promoting Interoperability Scoring Methodology

CMS proposes that for the 2021 PI performance period, clinicians would be scored as described in Table 42 of the rule, recreated below.

TABLE 42: 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 (alternative)	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, 2018, 2019, and 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, as many were ineligible to participate in the PI predecessor programs (Medicare or Medicaid EHR Incentive Programs). Were such a clinician to report data, however, that clinician would instead be scored for the PI category using their data and the general MIPS PI scoring policies currently in effect.

CMS has analyzed PI data submitted during the 2017 and 2018 performance periods to reassess whether reweighting is in fact appropriate. CMS found a paucity of data that could be definitively linked to clinicians of the types eligible for reweighting, as they most commonly report data at the group level. Further, CMS anticipates that 2019 reporting will be confounded by the effects of the COVID-19 PHE. Finally, CMS notes the absence of submissions in response to its annual request for new PI measures. CMS concludes by proposing 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.

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.), by reweighting the PI category to zero, absent data submission by such a professional. Having no new, specific PI reporting data for these clinician types and given the likely impacts of the COVID-19 PHE, CMS proposes 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.

e. Promoting Interoperability Performance Category: Future Directions

CMS states that future changes to the PI category will continue to be considered in the context of HHS strategic goals, such as burden reduction, alignment across Medicare PI programs, and interoperable health information exchange. CMS indicates that potential areas of overlap, such as the intersection of the PI category with ONC Health IT Certification Program, will be an area of focused attention.

5. APM Scoring Standard and APM Entity Groups

a. APM Scoring Standard (§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 stakeholders have repeatedly commented that the standard is complex, inflexible, confusing, and burdensome. CMS proposes to eliminate the APM scoring standard effective January 1, 2021. As described earlier, CMS is proposing to add the APM Performance Pathway as a new option for MIPS reporting and scoring applicable to MIPS APM clinicians beginning January 1, 2021.

b. APM Entity Groups: Composition

To enable CMS to make QP status determinations for a given year, eligible clinicians are grouped and assessed through their collective participation in an APM Entity group that is in an Advanced APM. 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). Determinations are also made on December 31 for clinicians in certain APMS, termed "full-TIN APMs".[40] CMS states that termination of the APM scoring standard and its reliance on quality measure reporting to an APM markedly reduces the risk of MIPS final scores being inappropriately influenced by late-year clinician list changes, the risk that the full-TIN policy was designed to target. Therefore, concomitant with terminating the APM scoring standard, CMS proposes to:

- End the full-TIN policy (limiting 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

[40] 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.

(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.

CMS states that termination of the APM scoring standard, and its reliance on reporting to MIPS through an APM Entity group, ends the need to conduct MIPS low-volume exception threshold assessments at the APM Entity level. CMS, therefore, proposes 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.

c. APM Entity Groups: Scoring and Score Reweighting (§414.1317)

CMS proposes to adapt some policies that were created in association with the APM scoring standard for continued application to APM Entity groups. The proposed revised and/or renumbered policies, effective beginning January 1, 2021, are as follows:

- When performance category data are not reported by the 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.

CMS also addresses performance category reweighting for APM Entity groups during extreme and uncontrollable circumstances through the proposals below, beginning with the 2020 performance year.

- 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 the application, the entity must demonstrate that over 75 percent of its participant MIPS eligible clinicians would be eligible for PI reweighting (consistent with policies for PI reweighting for hospital-based and non-patient-facing clinician groups).
- 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 threshold. Any group data submitted during the applicable performance period would not trigger scoring of the group.

CMS notes that the proposed reweighting policies could be considered changes to 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.

E. Merit-Based Incentive Payment System (MIPS): Final Scoring Methodology and Payment Adjustments (§ 414.1380)

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 are being proposed for the Cost, IA, and PI categories. CMS proposes to continue several policies without change other than extending their applicability through performance year 2021:

- 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 rule, recreated below.
- 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.
- 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.

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 this measure. Small practices will continue to receive 3 points.

*Administrative claims-based measures are not subject to Class 2 and Class 3 measure scoring policies. (Nor are the CMS Web Interface measures proposed for sunsetting effective January 1, 2021.)

b. Scoring Flexibility: Truncation and Suppression

CMS also proposes 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).[41] Absent such data, the measure would be excluded from scoring and CMS would remove its potential 10 achievement points from the clinician's total available achievement points (suppression).

c. Measure Benchmark Baselines

By default, MIPS quality measure benchmarks are derived from a historical baseline, the 12-month calendar year that is 2 years prior to the performance period for which the measure is being scored. However, previously finalized policies also allow CMS instead to establish a benchmark using the actual performance period data. CMS expresses concerns that data for 2019, the historical performance year for 2021 performance period benchmarking, may not be sufficiently representative for benchmark derivation due to COVID-19 PHE impacts (e.g., many physicians were offered exemption from data submission).[42] CMS plans to utilize the established flexibility and to set 2021 performance period benchmarks using actual 2021 performance year data. **While CMS does not make any proposals regarding benchmarking, it does request comments about criteria that might be used to determine whether 2019 performance data are suitable for use in benchmarking. Comments are also requested on the alternative of using the 2020 performance period benchmarks (based on 2018 data).**

d. Topped Out Measures

Per current policy, measures with benchmarks that are identified as topped out for 2 or more consecutive years receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out. CMS notes that the proposed use of performance period-based rather than historical baseline-based benchmarks for performance period 2021 would deviate from the established process for identifying topped out measures. Therefore, CMS proposes an exception for the 2021 performance period: a measure would be considered topped out were it to be identified as such in the historical baseline-based benchmarks for the

[41] CMS has previously applied this approach to measures affected by ICD diagnostic codes updates, which occur annually in October.
[42] The data submission period for performance year 2019 occurred in January through March of 2020.

2020 MIPS performance period and in the performance period-based benchmarks proposed for use in the 2021 performance period. CMS chose not to propose eliminating the 7-point cap, expecting that cap retention will incent clinicians not to select topped out measures. CMS also notes that measures found to be topped out for 2020 might not remain topped out in the 2021 period and thereby not be subject to the cap.

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). However, 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 proposes to amend the existing policy to retain the default case minimum for MIPS quality measures at 20 but to set minimums for administrative claims-based measures individually for each measure. Minimums for claims-based measures would be communicated through the annual MIPS final list of quality measures.

2. Final Scoring Methodology

a. Complex Patient Bonus

CMS notes that 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 Hierarchical Condition Category (HCC) scores and dual eligibility status. CMS has continued to apply the bonus without change for performance periods 2019 and 2020. CMS reviewed their complex bonus data and more recent relevant studies for guidance about further continuation of the bonus,[43] but concluded there was insufficient information on which to predicate changes to existing policy.

CMS also discusses in detail their concerns about the numerous potential impacts of the COVID-19 PHE on the care of Medicare beneficiaries, particularly the most vulnerable. CMS concludes that patient complexity likely will increase for performance year 2020 and proposes to increase the complex patient bonus and to raise the maximum available points to 10. The bonus would be calculated as usual for each clinician then would be doubled before being added to the clinician's final MIPS score. CMS describes alternatives considered: maintaining the bonus unchanged, tripling the bonus, and adding a new complexity factor specific to patients with COVID-19 and their rationale for proposing to double the existing bonus. CMS ends the discussion by noting

[43] The review included the March 2020 Report to the Congress on social risk in Medicare value-based purchasing programs, prepared by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE).

that increasing the complex patient bonus for the 2020 performance period is a scoring change made after the start of the period but believes it would be contrary to the public interest not to adjust for COVID-19 effects on patient complexity that could not have been anticipated during the 2020 rulemaking cycle.

CMS requests comments on doubling the bonus, alternatives considered, and additional approaches to account for patient complexity during the public health emergency that commenters believe it should consider, as well as alternative data sources for patient complexity.

b. Performance Category Weights

Consistent with related proposals elsewhere in the rule, CMS proposes category weights for performance periods 2021, 2022, and future years as shown in the table below (modified from Table 44 in the rule).

Performance Category	Performance Year 2021 (Proposed)	Performance Year 2022 and Future MIPS Performance Years (Proposed)
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.

TABLE 45: Performance Category Redistribution Policies Proposed 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 46: Performance Category Redistribution Policies Proposed 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%

3. MIPS Payment Adjustments

a. Final MIPS Score Hierarchy

It is possible for a clinician, as represented by a TIN/NPI combination, to have more than one final score associated with it for a given performance period. CMS previously established a hierarchy to determine which of those scores is assigned to that clinician. The hierarchy attempts to default to the highest available score but also emphasizes APM Entity groups over virtual groups (as shown in Table 47 of the rule on page 733 of the display copy). Having proposed termination of the APM scoring standard, modifications to APM Entity Group policies, and the addition of the APP effective beginning with the 2021 performance period, CMS proposes to update the final score hierarchy. The combination of proposed policies, if finalized, results in a streamlined hierarchy that allows full consideration of virtual group scores for 2021 and subsequent years, shown in Table 48 of the rule (recreated below). CMS states an intention to revisit the hierarchy and the associated policies and make changes as appropriate as the MVP inventory is populated.

TABLE 48: 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

The Secretary is required to annually compute a performance threshold for purposes of determining the MIPS payment adjustment factors. The threshold is either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. Additional special rules have allowed flexibility for the Secretary to establish thresholds other than the mean or median and, for QPP Years 3 through 5, require the Secretary to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold specified in statute for year QPP Year 6. The thresholds that have been finalized by prior rulemaking through 2020 have increased as shown in Table 49 of the rule; the threshold for performance year 2020 is 45 points. Not shown is the threshold for the additional adjustment for exceptional performance, set at 85 points.

CMS believes that disruptions caused by COVID-19 and their downstream effects warrant reconsideration of the performance threshold for QPP 5 (2021 performance year/2023 MIPS payment year), currently set at 60 points. At least some clinicians are likely to experience changes in their ability to participate in MIPS, particularly those who also were unable to

participate during QPP Year 4; the latter group would potentially face an abrupt and very large threshold increase from 30 to 60 points from QPP Year 3 to QPP Year 5. CMS reports using 2021 regulatory impact analysis data to model effects of varying the 50-point QPP Year 5 threshold. Reducing the threshold to 50 points from 60 would cause nearly 6 percent of clinicians to receive positive rather than negative MIPS adjustments applied to their 2023 payments. Small practices would benefit more than previously high performing clinicians. Based on their analysis, CMS proposes that the performance threshold for QPP Year 5 be set at 50 points and makes no changes to the exceptional performance payment threshold of 85 points. The table below (adapted from Table 50 in the rule) shows the resultant progression of the performance threshold over time.

CMS notes that actual performance data are not yet available for QPP Year 3 (2019 performance period/2021 payment) but anticipates finding effects from COVID-19 as the data submission period occurred during the PHE. CMS further notes that the actual 2019 data could lead to revised MIPS total score estimates for QPP Year 6 and, if so, proposes to consider corresponding performance threshold adjustments for QPP 5.

CMS requests comments on revisiting and potentially revising the QPP Year 6 performance threshold; what indicators, if any, should be used to assess the propriety of using 2019 data to revise future estimates; and whether the QPP Year 5 should be revisited.

	2019 MIPS Payment Year	**2020 MIPS Payment Year**	**2021 MIPS Payment Year**	***2022 MIPS Payment Year**	****2023 MIPS Payment Year**	**2024 MIPS Payment Year**
	Year 1	**Year 2**	**Year 3**	***Year 4**	****Year 5**	**Year 6**
Performance Threshold	3 points	15 points	30 points	*45 points *N/A for those who do not participate in year 4	**50 points	74.01 points

*Assumed affected payment year due to PHE resulting in measures not being available for reporting for MIPS participants.
** Proposed new performance threshold for the fifth year.

c. Example of Adjustment Factors

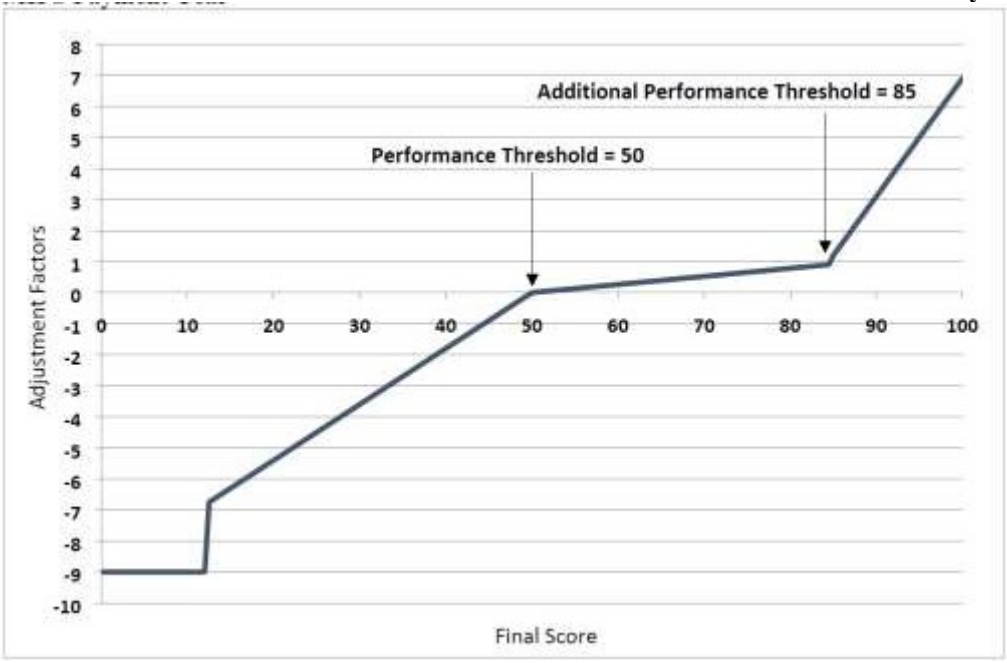
Figure A in the rule (reproduced at the end of this section) illustrates how scores would be converted into adjustment factors for 2023 payment (based on 2021 performance data). The proposed performance threshold is 50 points, and the applicable MIPS payment adjustment percentage is ± 9 percent. Clinicians with a final score of 50 points would receive a 0 percent adjustment. The scale for other scores is not completely linear because 1) all clinicians with a final score between 0 and ¼ of the performance threshold (0 and 12.5 in the example) receive the lowest negative payment adjustment of -9 percent; and 2) the slope for the positive adjustment factor is affected by the scaling factor that ensures budget neutrality. A scaling factor greater than 0 and less than or equal to 1.0 applied to a final score of 100 would result in a payment adjustment less than or equal to 9 percent. A scaling factor above 1.0, but less than or equal to

the specified limit of 3.0, applied to a final score of 100 would produce a payment adjustment above 9 percent.

The exceptional performance threshold, set at 85 points, would earn an additional adjustment factor of 0.5 percent, with a separate scaling factor applied to ensure distribution of the entire $500 million available for exceptional performance payments. The additional adjustment factor would increase to the statutory maximum of 10 percent for a perfect final score of 100.

The actual MIPS payment adjustments will be determined by the actual distribution of performance scores; the greater the number of clinicians above the threshold, the more the scaling factors will decrease, and vice versa. The point system and associated adjustments applicable to final scores, as previously finalized and newly proposed for QPP Year 5 (payment year 2023) are detailed in Table 51 in the rule (see pp. 743-4 of the display copy).

Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Thresholds for the 2023 MIPS Payment Year



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. Provision of IA and PI performance category data is at CMS' discretion and is provided when technically feasible. CMS targets distributing feedback on or around July 1 of each year. CMS through this rule is informing stakeholders that disruptions caused by the COVID-19 PHE has delayed performance year 2019 feedback report release.[44]

[44] Clinicians can now access reports by logging in at https://qpp.cms.gov/#:~:text=Performance%20Year%202019&text=Final%20performance%20feedback%20is%20a

F. Third Party Intermediaries

1. MIPS Data Submission Requirements

CMS states their intent 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 proposes clarifying 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.

Health IT vendors who do not support MVPs would be required to 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 be subject to the proposed requirements and would entail reporting three quality measures as CQMs and eCQMs, beginning with performance year 2021.[45]

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 proposes 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. **CMS requests comments on whether there are other factors that should also be considered when making approval decisions.**

3. Third Party Training and Support

CMS notes that 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. These interactions allow CMS to keep intermediaries informed, to answer their questions, and to demonstrate relevant technologies. In the context of the COVID-19 PHE, CMS believes that virtual meetings (and continued support calls) would suffice. Separately,

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vailable,or%20request%20a%20targeted%20review.

[45] The measures are: Quality ID# 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), Quality ID#: 134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, and Quality ID# 236: Controlling High Blood Pressure

CMS requires survey vendors to have successfully completed training administered by CMS. Having considered the benefits of the calls and meetings with QCDR and qualified registry staff, CMS proposes 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). **CMS requests comments about optimal methods to reach HIT vendors besides the QPP listserv.**

4. Future Safeguards

CMS notes that proposals for new MIPS program data validation and audit safeguards are being made elsewhere in this rule for QCDRs and qualified registries, and believes that similar safeguards may be applicable to all third party intermediaries.[46] CMS has become aware of potential program integrity concerns involving HIT vendors and is considering extending data validation and audit safeguards to those vendors. CMS states a belief that established requirements for survey vendors are sufficient to mitigate data accuracy concerns.

To inform future policy-making, CMS requests comments on several aspects of potential safeguards, including:

- **Adding data validation requirements to the approval process for all types of intermediaries and whether customization to entity type is needed;**
- **Capabilities of HIT vendors to engage in data validation and respond to audits;**
- **Added burden from data validation and audits, and whether that burden would discourage HIT vendors from serving as intermediaries;**
- **Overlap between the ONC certification and CMS data validation programs; and**
- **Extending data validation and audit requirements to survey vendors.**

5. QCDR Data Validation and Targeted Audits

CMS set an expectation in prior rules that QCDRs and qualified registries would validate their data prior to submission and 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). CMS also expects that data found by the QCDR to be inaccurate, incomplete, or otherwise compromised will be corrected prior to data submission to CMS; submission of such data could lead to remedial action or termination of QCDR approval. CMS, therefore, proposes to codify data validation and targeted audit requirements as part of QCDR approval criteria for performance year 2021 at §414.1400(b)(2)(iv) and (v)) and as 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;[47]

[46] 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.
[47] Submitter types would include MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in

- Validation that an action was performed or an outcome was measured must be obtain 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.[48]
- 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 must be performed 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.

If 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 proposes 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 from each targeted audit in a form and manner specified by CMS and by a CMS-specified deadline. Each report must 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. 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. **CMS requests comments about the proposed 2021 performance year timeline for**

participants, as applicable. CMS notes that voluntary participant data may be publicly posted (Physician Compare).
[48] CMS notes that similar methods were used for the Physician Quality Reporting System that preceded MIPS.

full implementation of the data validation and targeted audit proposals. Stakeholders with concerns are asked to comment on the nature of the barriers to implementation.

6. Revised Requirements for QCDR Measures

CMS notes stakeholder concerns about measure reporting complexity given the large, current inventory of QCDR measures. CMS further notes having made several changes to QCDR measure requirements during the 2020 rulemaking cycle, and proposes in this rule to build on those recent changes. CMS believes the QCDR measures requirement revisions proposed in this rule will reduce measure selection complexity by encouraging QCDRs to focus on development of measures most meaningful to clinicians. CMS anticipates that the transition to MVPs will emphasize the need for fewer but more focused measures since each MVP will contain a concise, interconnected measure set.

a. Measure Testing Requirements

CMS refers readers to their Blueprint for the CMS Measures Management System (the Blueprint) as a guide to measure construction and cites the Blueprint's support for full measure testing.[49] Last year 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 by one year due to PHE-associated healthcare disruptions.

CMS now proposes a gradual transition to full measure testing: measure approval for the 2022 performance year would require face validity demonstration and approval for performance year 2023 and future years would require face validity and full testing. CMS also proposes that measures previously approved for the 2020 performance year would be required to demonstrate face validity prior to self-nomination for approval for performance year 2022 and be fully tested prior to self-nomination for any subsequent performance period. CMS states that if a QCDR measure is not fully tested by the second year of the measure's life in MIPS, the measure would not be considered for approval for that second year. CMS clarifies that full testing of a QCDR measure would include beta testing (or field testing).[50] For measures to be considered for inclusion in an MVP for performance year 2022 and thereafter, a QCDR measure must be fully tested.

CMS also notes that implementation of the requirement for a QCDR to collect data on a measure appropriate to the measure type, prior to submitting the measure to CMS during the self-nomination period, has been delayed from performance year 2021 to performance year 2022 as provided for in the May 8th COVID-19 IFC-2.

[49] Available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.

[50] CMS refers to the Blueprint's definition of face validity; the extent to which a test appears to cover the concept it purports to measure "at face value" and discussion of beta testing.

b. Duplicative Measures

CMS begins by emphasizing a desire to eliminate duplicative measures for use in MIPS and refers to their prior suggestions for measure harmonization. In response to stakeholder requests for clarification, CMS now states that measure harmonization refers to measures for which previously identified areas of duplication with other MIPS or approved QCDR measures have been addressed. CMS proposes language changes to employ the concept of measure harmonization consistently in relevant QCDR regulations, at §414.1400(b)(3)(v)(E) and (b)(3)(vi). If finalized, these changes mean that:

- Beginning with performance year 2020, CMS may 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; and
- Beginning with performance year 2023, a QCDR measure may be approved for two years at CMS' discretion
  - approval for the second year may be revoked if the measure is duplicative of a more robust measure, or is topped out, contains an outdated clinical guideline, or the measure's self-nominating QCDR is no longer in good standing.

CMS also proposes to remove two policies that would become redundant if the above two changes are finalized: §§414.1400(b)(3)(vii)(H) and (L). Finally, CMS proposes technical changes to renumber paragraphs remaining in §414.1400(b)(3)(vii).

7. Qualified Registries

CMS begins by proposing to rename §414.1400(c) as "qualified registries" rather than "qualified registry approval criteria" to align the title with the content of the regulation more closely.

CMS set an expectation in prior rules that qualified registries would validate their data prior to submission and 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). CMS also expects that data found by the qualified registry to be inaccurate, incomplete, or otherwise compromised will be corrected prior to data submission to CMS; submission of such data could lead to remedial action or termination of qualified registry approval. CMS, therefore, proposes to codify data validation and targeted audit requirements as part of qualified registry approval criteria for performance year 2021 at §414.1400(c)(2)(iii) and (iv) and as 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 qualified registry;[51]
- Validation that an action was performed or an outcome was measured must be obtained by the qualified registry (i.e., clinical documentation obtained from clinicians);
- Sampling methodology for a validation audit must –

[51] 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).

    - Use a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry 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 qualified registry 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.[52]
- 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 must be performed according to the quality measure's specifications; and
    - Verification before submission that only MIPS quality measures and qualified registry measures that are valid for the performance period being reported have been used.

The qualified registry 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.

If a data validation audit detects one or more deficiency or data error, a targeted audit must follow, during which the qualified registry must investigate the impact and root cause for each deficiency or data error. For performance year 2021 and future years, CMS proposes the following requirements for targeted audits, to be codified at §414.1400(c)(2)(iv):

- 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 qualified registry must report results to CMS from each targeted audit in a form and manner specified by CMS and by a CMS-specified deadline. Each report must 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. **CMS requests comments about the proposed 2021 performance year timeline for full implementation of the data validation and targeted audit proposals. Stakeholders with concerns are asked to comment on the nature of the barriers to implementation.**

[52] CMS notes that similar methods were used for the Physician Quality Reporting System that preceded MIPS.

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); CMS specifies the deadline for plan submission. CMS makes several proposals designed to set expectations about and consistency of plan content by modifying §414.1400(f)(1)(i). The plan would be required to address all of the following; CMS may also specify different or additional information to be provided.

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.

G. Public Reporting on Physician Compare

CMS reports 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 as Physician Compare Internet Web site of the Centers for Medicare & Medicaid Services (or a successor Web site).

H. 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.[53] CMS first disbursed APM incentive payments in calendar year 2019 and makes several proposals based on that experience. CMS begins by proposing 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.

2. Payment Recipient

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

[53] Covered professional services are defined in section 1848(k)(3) of the Act.

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 proposes 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.

Identifying the appropriate TIN to receive the incentive payment represents a significant challenge that CMS proposes to resolve by establishing a hierarchy of TINs for payment comprising steps to followed sequentially until payment is made successfully or the final step has been completed. The hierarchy, added at §414.1450(c), 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 detail level and complexity of the 8-step hierarchy reflects the complexity of accounting for multipole TINs and multiple relationships and is best appreciated by reading its full description in the rule (pp 787-788 of the display copy). The eighth and final step indicates how CMS would proceed when no appropriate TIN has been identified to receive the incentive payment. At that time, CMS would attempt to contact the QP directly through a public notice requesting Medicare payment information, and 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.

3. Payments in the Absence of Covered Services

CMS' payment year 2019 experience also 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. CMS proposes in these cases to use step 8 of the TIN identification hierarchy as described above.

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 proposes 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 that align beneficiaries retrospectively.

b. Targeted Review of QP Determinations §414.1455

Scope. 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 proposes to create a targeted review process through which clinicians could present potential clerical errors made by CMS for review and correction when appropriate.

CMS proposes that a targeted review of a QP determination could only be requested by a clinician or APM Entity based upon a good faith belief that a CMS clerical error resulted in a clinician being omitted from the APM's Participation List upon which the QP determination was based. CMS proposes that if upon review a clerical error is confirmed, CMS would assign to the affected clinician the most favorable QP status as determined by CMS for the APM Entity on any snapshot date of the relevant performance period on which that clinician participated in that APM Entity. CMS states that the proposed approach is preferable to a recalculation of the APM Entity's QP threshold scores to include the omitted clinician's data, as the latter approach potentially would impact QP determinations for all other clinicians participating in the Entity and cause them to become subject unexpectedly to MIPS reporting.

CMS proposes that targeted reviews of potential omissions to Affiliated Practitioner Lists would not be made because 1) QP status determinations for clinicians on those lists are made at the individual level and therefore CMS would not have conducted a determination for an omitted clinician prior to a targeted review being requested; and 2) the calculations that would be required would not be operationally feasible to allow for timely APM incentive payment. CMS additionally notes that targeted reviews of omissions from Other Payer Advanced APM

Participation Lists would not be conducted since those lists are provided to CMS by the clinicians and the APM Entities themselves.

Process. CMS plans for the QP determination targeted review process to align where feasible with the established MIPS targeted review process (§414.1385). CMS makes a set of proposals for the new review process as follows:

- Place the QP determination targeted review process provisions at §414.1455(b) after redesignating the preclusions of administrative or judicial review as §414.1455(a)(1) and (2).
- Specify that a review request may be submitted by either a clinician or APM Entity.
- Require that all review requests 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; once the period closes, no further reviews would be undertaken.
- Denial of a review request may be made 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.
- Require CMS to respond to review requests that are submitted timely.
- Allow submission of supporting information by the requester at the time of review request; additional information requests from CMS to the requester must be responded to within 30 days and absent a response, CMS may proceed to review completion and final decision-making using the information available at that time.
- 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 as described previously (awarding the most favorable QP status) without review requests being made.

5. Advanced APM and QP Determinations During the COVID-19 Public Health Emergency

a. APM Determinations

CMS anticipates that the COVID-19-PHE could require it to make changes to certain features of some APMs (e.g., amending their Participation Agreements). CMS, therefore, is exercising enforcement discretion when making determinations as to 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 that would have led to loss of Advanced APM status were reconsideration to be performed would be missed. (CMS provides a list of Advanced APMs for 2020 on page 798 of the display copy)

b. QP Determinations

CMS notes that model end date changes for Advanced APMs may occur due to the COVID-19 PHE. CMS states that such changes will not be considered premature termination of an APM and will not lead to revocation of QP status for the APM Entity's clinicians. CMS also notes that the PHE could result in QP and Partial QP determinations different from what they would be

absent the PHE but declines to alter the methodology used to make those determinations. CMS believes that there are too many unknown factors to allow methodological modifications that would avoid the potential for unintended consequences and that Advanced APM participants benefit from QP determinations that are timely and predictably.

6. Partial QP Election to Report MIPS – Comment Request

MIPS eligible clinicians may reach APM Qualifying Participant (QP) status, becoming exempt from MIPS and earning a 5 percent lump sum bonus, based on the amount of care they deliver through Advanced APMs or Other Payer Advanced APMs as measured by percentages of their Part B patient payments or numbers of patients treated. CMS points out that, per statute, the thresholds required to achieve QP status will increase (and plateau thereafter) beginning with performance year 2021/payment year 2023. The corresponding thresholds for reaching Partial QP status, which confers an option for MIPS exemption but no bonus, are likewise increased. Based upon historical data, CMS expects that the increased thresholds will result in fewer clinicians achieving QP status and more reaching Partial QP compared to prior years. Threshold changes are shown in the table below.

QP and Partial QP Status Thresholds		
	Performance Year 2020 Payment Year 2022	**Performance Year 2021 Payment Year 2023***
QP		
Payment (%)	50	75
Patient Count (%)	35	50
Partial QP		
Payment (%)	40	50
Patient Count (%)	25	35

*Thresholds continue unchanged for subsequent years.

Currently, CMS contacts Partial QPs to ascertain their election to participate in MIPS, or not, by letters sent to their respective APM Entity contacts based on APM clinician lists. Rising numbers of Partial QP clinicians will require more CMS outreach, and CMS is considering other contact options. CMS suggests that it could be simpler and less burdensome to allow an APM Entity to make the election for MIPS participation, or not, on behalf of all of the Entity's clinicians. This contact method, however, could result in CMS receiving conflicting MIPS election responses. **CMS requests comment whether to allow Partial QP elections to be made in this manner and discusses several scenarios of conflicting responses for which recommendations are sought.**

V. Planned 30-day Delayed Effective Date for the 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.

VI. 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 proposed 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 proposed CF for 2021 is $32.2605, 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 -10.61 percent (2020 conversion factor of $36.0896*1.00*0.8939). The unusually large BN adjustment results from the revaluing of E/M codes (policies finalized in 2020 and implemented in 2021) and proposed revaluing of certain codes analogous to E/M codes in this year's proposed 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 88 from the proposed rule, reproduced below.

Table 88: Calculation of the Proposed 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	-10.61 percent (0.8939)	
2021 Conversion Factor		**$32.2605**

The 2021 proposed anesthesia conversion factor is $19.9631, 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 89 from the proposed rule, which is reproduced below.

Table 89: Calculation of the Proposed 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	-10.61 percent (0.8939)	
2021 Practice Expense and Malpractice Adjustment	0.59 percent (1.0059)	
2021 Conversion Factor		**$19.9631**

Table 90 (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).

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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 proposed 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 (+17%), rheumatology (+16%), 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 (-11%), nurse anesthetists (-11%), 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 proposed changes. For emergency medicine practitioners, estimated impacts of -6 percent account for a 3 percent gain as a result of proposed increase valuations to ED visits, but the increase was dampened by the magnitude of the

office/outpatient E/M visit valuations. For nephrology, CMS' proposal 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.

Column F of Table 90 shows the estimated 2021 combined impact on total allowed charges by specialty of all the proposed RVU and other changes.

TABLE 90: 2021 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$246	5%	4%	0%	9%
Anesthesiology	$2,011	-7%	-1%	0%	-8%
Audiologist	$74	-4%	-2%	0%	-7%
Cardiac Surgery	$264	-6%	-2%	-1%	-9%
Cardiology	$6,849	1%	0%	0%	1%
Chiropractor	$759	-7%	-3%	0%	-10%
Clinical Psychologist	$824	-1%	1%	0%	0%
Clinical Social Worker	$851	-1%	1%	0%	0%
Colon and Rectal Surgery	$168	-4%	-1%	0%	-5%
Critical Care	$376	-6%	-2%	0%	-8%
Dermatology	$3,758	-1%	-1%	0%	-2%
Diagnostic Testing Facility	$813	-1%	-5%	0%	-6%
Emergency Medicine	$3,065	-5%	-1%	0%	-6%
Endocrinology	$506	11%	6%	1%	17%
Family Practice	$5,982	9%	4%	1%	13%
Gastroenterology	$1,749	-3%	-1%	0%	-5%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,041	-4%	-2%	0%	-7%
Geriatrics	$190	2%	2%	0%	4%
Hand Surgery	$245	-2%	-1%	0%	-3%
Hematology/Oncology	$1,702	9%	5%	1%	14%
Independent Laboratory	$639	-3%	-2%	0%	-5%
Infectious Disease	$653	-4%	-1%	0%	-4%
Internal Medicine	$10,654	2%	2%	0%	4%
Interventional Pain Mgmt	$932	4%	3%	0%	7%
Interventional Radiology	$497	-3%	-5%	0%	-9%
Multispecialty Clinic/Other Phys	$152	-3%	-1%	0%	-4%
Nephrology	$2,213	4%	2%	0%	6%
Neurology	$1,513	3%	2%	0%	6%
Neurosurgery	$806	-4%	-2%	-1%	-7%
Nuclear Medicine	$56	-5%	-3%	0%	-8%
Nurse Anes / Anes Asst	$1,316	-9%	-1%	0%	-11%
Nurse Practitioner	$5,069	5%	3%	0%	8%
Obstetrics/Gynecology	$633	4%	3%	0%	8%
Ophthalmology	$5,328	-4%	-2%	0%	-6%
Optometry	$1,349	-2%	-2%	0%	-5%
Oral/Maxillofacial Surgery	$78	-2%	-3%	0%	-5%
Orthopedic Surgery	$3,796	-3%	-1%	0%	-5%

(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
Other	$47	-3%	-2%	0%	-5%
Otolaryngology	$1,264	4%	3%	0%	7%
Pathology	$1,257	-6%	-4%	0%	-9%
Pediatrics	$66	4%	2%	0%	6%
Physical Medicine	$1,157	-3%	0%	0%	-3%
Physical/Occupational Therapy	$4,946	-5%	-5%	0%	-9%
Physician Assistant	$2,888	5%	3%	0%	8%
Plastic Surgery	$378	-4%	-3%	0%	-7%
Podiatry	$2,111	-1%	0%	0%	-1%
Portable X-Ray Supplier	$94	-2%	-4%	0%	-6%
Psychiatry	$1,099	4%	3%	0%	8%
Pulmonary Disease	$1,647	0%	0%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,803	-3%	-3%	0%	-6%
Radiology	$5,253	-6%	-5%	0%	-11%
Rheumatology	$546	10%	6%	1%	16%
Thoracic Surgery	$350	-5%	-2%	-1%	-8%
Urology	$1,803	4%	4%	0%	8%
Vascular Surgery	$1,287	-2%	-5%	0%	-7%
TOTAL	**$96,557**	**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 90:

- 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 proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

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

- Column E (Impact of MP RVU Changes): This column shows the estimated 2021 impact on total allowed charges of the proposed 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 Proposals

The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to 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 58 percent of the nearly 1.6 million clinicians billing to Part B (931,050) will be assigned a MIPS score for 2023 because others will be ineligible for or excluded from MIPS. Table 92, reproduced below, provides the details of clinicians' MIPS eligibility status for 2023 MIPS payment year (2021 MIPS performance year). CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policy; CMS assumes 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to 2018 MIPS performance period would elect to opt-in to the MIPS program.

TABLE 92: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the 2021 PFS Proposed Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians	PFS allowed charges ($ in mil)***
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	212,973	$50,561
	Do not participate in MIPS	17,765	$3,948
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	680,253	$16,606
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low- volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	20,059	$992
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**931,050***	**72,106**
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	368,961	$8,903
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all	Not applicable	80,454	$437

TABLE 92: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the 2021 PFS Proposed Assumptions**			
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
3 low-volume threshold criteria)			
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	220,305	$7,623
Total Number of Clinicians Not MIPS Eligible		669,720	16,964
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,600,770	89,070

*Estimated MIPS Eligible Population
** Table 92 does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 20,000 clinicians and $1,643 million in PFS allowed charges).
*** Allowed charges estimated using 2017 and 2018 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

In the aggregate, CMS estimates that for the 2023 payment year, it would redistribute about $442 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 maximum positive payment adjustments are 6.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 92.5 percent of eligible clinicians are expected to have a positive or neutral payment adjustment and 7.5 percent will have a negative payment adjustment.

Table 93, 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 2018 MIPS performance period submissions data for estimation purposes and that it cannot account for at this time certain changes such as services and payment disrupted by the PHE and/or clinicians changing behavior to avoid a negative payment adjustment.

Table 93: 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	144,570	81.2%	29.9%	18.8%	1.2%
2) 16-24	43,225	86.9%	33.9%	13.1%	1.4%
3) 25-99	199,156	90.9%	36.0%	9.1%	1.4%
4) 100+	526,319	96.6%	34.4%	3.4%	1.4%
Overall	**913,270**	**92.5%**	**34.0%**	**7.5%**	**1.3%**
Among those not submitting data					
1) 1-15	15,748	0.0%	0.0%	100.0%	-8.4%
2) 16-24	644	0.0%	0.0%	100.0%	-8.5%
3) 25-99	940	0.0%	0.0%	100.0%	-8.6%
4) 100+	448	0.0%	0.0%	100.0%	-8.8%
Overall	**17,780**	**0.0%**	**0.0%**	**100.0%**	**-8.4%**

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

** 2018 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. CMS bases its analyses on the data prepared to support the 2019 performance period initial determination of clinician and special status eligibility, participant lists using the APM Participation List for the final snapshot date for the 2019 QP performance period, 2018 QPP Year 2 data, and 2018 ACO Public Use File for MSSP and Next Gen and CAHPS for ACOs. The scoring model results assume that 2018 QPP Year 2 data 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 proposals 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 proposed 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 proposed 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 proposed rule, using the estimated 2021 CF, the 2021 national payment amount in the nonfacility setting for CPT code 99215 is $172.27 which means that in 2021, the proposed beneficiary coinsurance would be $34.45.

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 proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is $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 $38.5 million ($885.92 x 43,432 reviewers on last year's proposed rule).