Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2021
Detailed Summary

The American College of Radiology (ACR) has prepared this detailed analysis of proposed changes to the Medicare Physician Fee Schedule (MPFS) in calendar year (CY) 2021. The ACR will provide detailed comments by the October 5th comment period deadline. If finalized, the rule changes will be effective Jan. 1, 2021. In the rule, due to the COVID-19 public health emergency, CMS is waiving the 60-day effective date delay for the final rule and replacing it with a 30-day effective date delay. This means the final rule will be published on or around December 1st.

Conversion Factor (Page 895*)

CMS estimates a CY 2021 conversion factor of $32.2605, which reflects a -10.61 percent budget neutrality adjustment. This is a significant decrease from the current conversion factor of $36.0896. Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in relative value units (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 must make adjustments to preserve budget neutrality. This year's budget neutrality adjustment is largely a result of increased RVUs for office/outpatient evaluation and management services (E/M). Details of these changes are described in a later section of this summary.

CMS estimates an overall impact of the MPFS proposed changes to radiology to be an 11 percent decrease, while interventional radiology would see an aggregate decrease of 9 percent, nuclear medicine an 8 percent decrease and radiation oncology and radiation therapy centers a 6 percent decrease if the provisions within the proposed rule are finalized.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

CMS did not address the appropriate use criteria (AUC)/clinical decision support (CDS) mandate for all advanced diagnostic imaging services in this rule. However, CMS did update its website on Monday, August 10th, to indicate that the current educational and operations testing period will be extended through December 31, 2021. As this decision was not included in the MPFS proposed rule, it is final and not subject to comment.

Valuation of Evaluation and Management Services (Page 144)

Background and Previous Rulemaking

In the 2021 proposed rule, CMS reiterated its decision in the 2020 final rule to move forward with adoption of a new coding structure for the office/outpatient E/M codes as recommended by the American Medical Association (AMA) and the associated increased valuations of these E/M services.

*Page numbers are from the display version of the MPFS proposed rule posted by CMS on August 4th.

In total, E/M visits billed using these CPT codes comprise approximately 40 percent of allowed charges for MPFS services; and office/outpatient E/M visits, in particular, comprise approximately 20 percent of allowed charges for MPFS services. Within the E/M visits represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed charges for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include primary care practitioners and certain other specialists such as neurologists, endocrinologists and rheumatologists.

In the CY 2020 MPFS final rule, for the office/outpatient E/M visit code set (CPT codes 99201 through 99215), CMS finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see https://www.ama-assn.org/practice-management/cpt/cptevaluation-and-management) and will be effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be used to select the level of code for office/outpatient E/M visits. Instead, an office/outpatient E/M visit will include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam will no longer apply, and the history and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate.

The changes also include deletion of CPT code 99201 *(Level 1 office/outpatient visit, new patient*), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward medical decision making (MDM) and currently largely differentiated by history and exam elements.

For levels 2 through 5 office/outpatient E/M visits, selection of the code level to report will be based on either the level of MDM or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). CMS continues to believe these policies will further its ongoing effort to reduce administrative burden, improve payment accuracy, and update the office/outpatient E/M visit code set to better reflect the current practice of medicine.

Regarding prolonged visits, CMS 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*) to report prolonged time associated with office/outpatient E/M visits. CMS also finalized separate payment for HCPCS code GPC1X, to provide payment for visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

In the CY 2020 MPFS final rule, CMS also addressed and responded to the AMA RUC recommendations. The agency 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. Table 16 below provides a summary of the codes and work RVUs finalized in the CY 2020 MPFS final rule for CY 2021.

TABLE 16: Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU	CY 2021 Total Time (mins)	CY 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

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

In the CY 2020 MPFS proposed rule, CMS sought comment on the times associated with the office/outpatient E/M visits as recommended by the AMA RUC. When surveying these services for purposes of valuation, the AMA RUC requested that survey respondents consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of 3 days prior to the visit and 7 days after, respectively. In developing its recommendations to CMS, the AMA RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The approach used by the AMA RUC to develop recommendations sometimes resulted in two conflicting sets of times: the component times as surveyed and the total time as surveyed.

Given the lack of clarity provided by commenters on the CY 2020 MPFS proposed rule about why the sum of minutes in the components would differ from the total minutes, and the agency's view and systems requirement that total time must equal the mathematical total of component times, **CMS is proposing, beginning for CY 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.**

Add-On Codes

In 2020, CMS finalized the HCPCS add-on code GPC1X describing the "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that

are part of ongoing care related to a patient's single, serious, or complex condition." CMS stated that they were not restricting billing based on specialty, but that they did assume that certain specialties furnished these types of visits more than others.

Since the publication of the CY 2020 MPFS final rule, some specialty societies have stated that CMS's 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 CMS's utilization assumptions, since the agency assumed that specialties that predominantly furnish the kind of care described by the code would bill it with every visit. Therefore, **CMS is soliciting from the public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine utilization assumptions for the code.**

CMS continues to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set.

In contrast, CMS believes HCPCS add-on code GPC1X reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time.

With regard to the prolonged visit add-on code, CMS is proposing 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.

Global Surgical Packages and Other Related Codes

In the CY 2020 MPFS final rule, CMS decided not to make changes to the valuation of 10- and 90- day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while the agency continues to collect and analyze the data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services.

CMS identified and is proposing to revalue a group of code sets that include or rely upon office/outpatient E/M visit valuation, consistent with the increases in values finalized for E/M visits for 2021. These code sets include end-stage renal disease monthly capitation payment services, transitional care management services, maternity services, cognitive impairment assessment and care planning, initial preventive physical examination and initial and subsequent annual wellness visits, emergency department visits, therapy evaluations and psychiatric diagnostic evaluations and psychotherapy services.

Practice Expense (Page 17)

Equipment Life Duration

CMS received input from stakeholders including the RUC, specialty societies, and other commenters suggesting a useful life of less than 1 year for several of the new equipment items for CY 2021, and as low as three months in one case. CMS has rarely received requests for equipment useful life of less than one year in duration and notes that these very short useful life durations are significantly lower than anything in the current equipment database, and if finalized would represent major outliers when compared to the rest of the equipment.

CMS believes that equipment items with very low useful life durations represent outlier cases that are not handled appropriately by the current equipment methodology. The current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and CMS believes that applying a multi-year depreciation in these situations would not be reflective of market pricing. Therefore, **CMS proposes to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, CMS believes that 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.**

CMS welcomes comments on this proposal.

Equipment Maintenance

CMS notes that they continue to investigate potential avenues for determining equipment maintenance costs, but the rule does not contain any proposals on this topic.

Interest Rates

CMS does not make any proposed changes to the interest rates used in developing the equipment cost per minute calculation for CY 2021.

Update on Technical Expert Panel Related to Practice Expense

CMS has contracted with the RAND Corporation to research potential improvements to CMS' Practice Expense (PE) allocation methodology and data. CMS currently uses a system for setting PE RVUs that relies on data collected in the Physician Practice Information Survey (PPIS) administered by the AMA in 2007-2008.

RAND has published its first Research Report on the topic:
https://www.rand.org/pubs/research_reports/RR2166.html

In its first report, RAND found that PPIS data are outdated and may no longer reflect the resource allocation, staffing, and cost structures that describe practitioners' requirements. For

example, the PPIS preceded widespread adoption of EHR technology, quality reporting programs, team-based billing codes, and hospital acquisition of physician practices. In their report, RAND also found that practice ownership is strongly associated with indirect PE, with physician-owned practices requiring 190% higher indirect PE compared to facility-owned practices. RAND found that aggregating specialties into broader categories resulted in small specialty-level impacts relative to the current system.

RAND recommends 1) considering ways to improve the allocation of PE RVUs by shifting more to the physician office setting, 2) establishing a new PE survey that can be repeated on an ongoing basis to ensure that PE RVUs reflect future changes, and 3) identifying codes with potentially misvalued PE using OPPS information.

RAND also convened a Technical Expert Panel (TEP) in January 2020. RAND has published a Summary of its Technical Expert Panel (TEP) on PE:
https://www.rand.org/pubs/working_papers/WR1334.html

Based on results of the TEP and RAND's research, CMS is interested in potentially refining PE methodology and updating the data used to make payments under the MPFS. CMS' goal is to obtain the data as soon as practicable and in a way that would allow stakeholders and CMS to examine.

CMS is soliciting comment on how they might update the clinical labor data (historically they used Bureau of Labor statistics). CMS is also interested in holding a Town Hall meeting for stakeholders (date TBD) to provide an open forum for discussion. CMS is not making any proposals at this time; however, stakeholders are encouraged to submit public comments during the comment period or if after comment period email to CMS at PE_Price_Input_Update@cms.hhs.gov.

Market-Based Supply and Equipment Pricing Update

For CY 2019, CMS contracted with StrategyGen to review and update the pricing for direct practice expense supply and equipment inputs. The updated prices are to be phased in over a four-year period, with the final prices to be fully implemented in CY 2022.

For CY 2021, CMS received invoices for about a dozen supply and equipment codes for consideration. Upon review, CMS is proposing updated pricing for 6 items, including 4 that pertain to radiology: guidewire, hydrophilic (SD089); vascular sheath (SD136); catheter, RF endovenous occlusion (SD155), and nuclide rod source set (ER044). The prices for these items have all decreased for CY 2022.

Equipment Recommendations for Scope Systems

For CY 2020, CMS proposed to establish 23 new equipment codes to describe scopes, scope video systems, and their associated accessories, as recommended by the RUC's Scope Equipment Reorganization Workgroup. For the eight scope equipment items that CMS received

invoices for, they proposed to replace the existing scopes with the new scope equipment. However, seven of the equipment items still lacked invoices for accurate pricing.

CMS states that the Scope Equipment Reorganization Workgroup did not submit any additional invoices for any of the equipment for CY 2021. CMS indicates that they are open to comments related to the seven scope equipment items that still do not have invoices, as well as the equipment codes that currently share the same price.

Potentially Misvalued Services Under the PFS (Page 66)

No Radiology codes were identified as potentially misvalued, either by CMS or through the public nominations process.

Proposed Valuation of Specific Codes for CY 2021 (Page 229)

Fine Needle Aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012) (Page 229)

The fine needle aspiration code family was finalized for CY 2019, with CMS accepting the RUC-recommended values for seven of the ten codes. The AMA RUC provided comment that they believed CMS had double-counted the utilization for some of the new codes, leading to the refinement of some of the code values. At the January 2020 meeting, the RUC reaffirmed the values previously recommended and resubmitted them to CMS for reconsideration. However, CMS still does not believe that utilization was erroneously double-counted for this family and states that the refined values are a result of changes in surveyed time and the relationship between the codes in the family. **CMS is proposing to maintain the values as finalized for CY2019, barring submission of any new information regarding these services.**

CMS is proposing refinements to the equipment times for CPT codes 10021, 10005, 10007, and 10009 based on the appropriate equipment formula.

Lung Biopsy-CT Guidance Bundle (CPT code 324X0) (Page 244)

CPT codes 32405 *(Biopsy, lung or mediastinum, percutaneous needle)* and 77012 *(Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation)* were identified on a screen for codes reported together 75% or more of the time. The CPT Editorial Panel then created a new code, 324X0 *((Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*)), bundling these services.

CMS disagrees with the RUC-recommended 4.00 RVU for CPT code 324X0, indicating that the value overstates the increase in intensity given the decrease in time. CMS believes there is some overlap in physician work that is not reflected in the RUC-recommended RVU. Instead, **CMS proposes 3.18 RVU for CPT code 324X0, which is the sum of the current RVUs for the component codes: 32405 at 1.68 RVU and 77012 at 1.50 RVU. CMS proposes to accept the PE inputs without refinement.**

X-Ray of Eye (CPT code 70030) (Page 256)

CPT code 70030 *(Radiologic examination, eye, for detection of foreign body)* was identified on the CMS/Other screen for codes with Medicare utilization over 20,000. **CMS proposes to accept the RUC-recommended 0.18 RVU, which is an increase over the current value. CMS also proposes to accept the PE inputs without refinement.**

CT Head-Brain (CPT codes 70450, 70460, and 70470) (Page 256)

CPT code 70450 *(Computed tomography, head or brain; without contrast material)* was publically nominated as potentially misvalued in the CY 2019 Medicare Physician Fee Schedule, citing GAO and MedPAC reports indicating that the work RVUs were overstated. The family was expanded during the survey process to include CPT codes 70460 *(Computed tomography, head or brain; with contrast material(s))* and 70470 *(Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections)*. **CMS proposes to accept the RUC-recommended 0.85 RVU for CPT code 70450, 1.13 RVU for CPT code 70460, and 1.27 RVU for CPT code 70470. These are consistent with the current values for these codes. CMS also proposes to accept the PE inputs without refinement.**

Screening CT of Thorax (CPT codes 71250, 71260, 71270, and 712X0) (Page 257)

HCPCS code G0297 *(Low dose ct scan (ldct) for lung cancer screening)* was identified on a CMS/Other screen for codes with 2017 Medicare utilization over 30,000. The RUC referred the code to the CPT Editorial Panel, which created a new CPT code for this procedure, 712X0 *(Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s))*. CT chest codes 71250 *(Computed tomography, thorax; without contrast material)*, 71260 *(Computed tomography, thorax; with contrast material(s))*, and 71270 *(Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections)*, were also addressed as part of the larger code family.

CMS disagrees with the RUC-recommended 1.16 RVU for CPT code 71250, due to a reduction in physician work time. Instead, **CMS recommends 1.08 RVU based on the ratio of current to RUC-recommended intraservice time, citing CPT code 76391 *(Magnetic resonance (eg, vibration) elastography)*, which has higher physician times and a work RVU of 1.10 as support.**

CMS disagrees with the RUC-recommended 1.24 RVU for CPT code 71260 due to a reduction in physician work time. Instead, **CMS recommends 1.16 RVU based on the ratio of current to RUC-recommended intraservice time, stating that this also maintains the appropriate intra-family relativity of 0.08 increment between 71250 and 71260.**

CMS disagrees with the RUC-recommended 1.38 RVU for CPT code 71270 due to a reduction in physician work time. Instead, **CMS recommends 1.25 RVU based on a crosswalk to CPT code 93284 *(Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed***

values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system). **CMS notes that this value is slightly higher than values suggested by the ratio of current to RUC-recommended intraservice time.**

CMS disagrees with the RUC-recommended 1.16 RVU for CPT code 712X0 and is proposing 1.08 RVU, equal to the proposed value for CPT code 71250. The current code for 712X0, G0297, was originally based on 71250, but 71250 had been recently revalued. 1.08 RVU would still be an increase over the current 1.02 RVU for G0297.

CMS is proposing to accept the direct PE inputs as recommended for CPT codes 71250, 71260, and 71270. CMS is proposing several refinements to the clinical labor inputs for 712X0 to make it more consistent with other screening codes. These refinements include reducing the RUC-recommended 3 minutes for "provide education/obtain consent" to 2 minutes and reducing the RUC-recommended 6 minutes for "Coordinate post-procedure services" to 4 minutes.

X-Ray Bile Ducts (CPT codes 74300, 74328, 74329, and 74330) (Page 259)

CPT codes 74300 *(Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation)* and 74328 *(Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation)* were identified on a CMS/Other screen for codes with 2017 Medicare utilization over 30,000. The code family was expanded to include CPT codes 74329 *(Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation)* and 74330 *(Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation)*, and all four codes were surveyed.

CMS disagrees with the RUC-recommended 0.32 RVU for CPT code 74300 and is proposing 0.27 RVU based on a crosswalk to CPT code 74021 ***(Radiologic examination, abdomen; 3 or more views),*** **which has similar intraservice time and 0.27 RVU. CMS supports their proposal with a second code, 93922, which has an identical intraservice time and is valued at 0.25 RVU.**

CMS supports the RUC-recommended 0.47 RVU for CPT code 74328.

CMS disagrees with the RUC-recommended 0.50 RVU for CPT code 74329 and is proposing 0.47 RVU, based on a crosswalk to CPT code 74328. Both codes have identical times, and CMS states that they believe "the work involved in the biliary ductal and pancreatic ductal systems is similar," justifying their equal valuation.

CMS disagrees with the RUC-recommended 0.70 RVU for CPT code 74330 and is proposing 0.56 RVU. CMS applied their time ratio methodology to CPT code 74328, resulting in their proposal of 0.56 RVU for CPT code 74330, which they are supporting with CPT code 93228 *(External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG*

data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional), which has an almost identical total time and value.

No direct PE inputs were recommended, as these codes are performed in the facility setting.

Venography (CPT codes 75820 and 75822) (Page 261)

CPT code 75820 *(Venography, extremity, unilateral, radiological supervision and interpretation)* was identified on a CMS/Other screen for codes with Medicare utilization over 20,000. CPT code 75822 *(Venography, extremity, bilateral, radiological supervision and interpretation)* was surveyed as part of the venography family**. CMS is proposing to accept the RUC-recommended 1.05 RVU for CPT code 75820 and 1.48 RVU for CPT code 75822. Both proposed values are higher than the current values for the codes. CMS is not proposing any refinements to the PE inputs.**

Introduction of Catheter or Stent (CPT code 75984) (Page 262)

CPT code 75984 *(Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation)* was reviewed by the RUC during the April 2019 meeting. **CMS is proposing to accept the RUC-recommended value of 0.83 RVU. CMS is not proposing any refinements to the PE inputs.**

Medical Physics Dose Evaluation (CPT code 7615X) (Page 262)

A practice expense (PE) survey was conducted to determine the appropriate direct inputs associated with CPT code 7615X *(Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*). This is a new CPT code and there are no analogous services for this stand-alone service. **CMS is proposing to accept the RUC-recommended PE inputs without refinement.**

Radiation Treatment Delivery (CPT code 77401) (Page 264)

CPT code 77401 *(Radiation treatment delivery, superficial and/or ortho voltage, per day)* was identified on a high-volume growth screen for services with 2017 Medicare utilization over 10,000 that has increased by at least 100 percent from 2012 through 2017. This is a PE-only code.

CMS is proposing several refinements to the clinical labor inputs for 77401. These refinements include: reducing the "clean room/equipment by clinical staff" time from 5 minutes to the standard 3 minutes and requesting additional information on the new equipment item "Lead Room", which they are proposing not to include. CMS would like more clarification on what is included in the "lead room" in order to determine accurate pricing for it as direct or indirect.

Proton Beam Treatment Delivery (CPT codes 77520, 77522, 77523, and 77525) (Page 264)

CPT codes 77522 *(Proton treatment delivery; simple, with compensation)* and 77523 *(Proton treatment delivery; intermediate)* were identified as contractor-priced Category I codes with 2017 estimated Medicare utilization over 10,000. The code family was expanded to include CPT codes 77520 *(Proton treatment delivery; simple, without compensation)* and 77525 *(Proton treatment delivery; complex),* and a PE survey was performed.

CMS indicates that they had some difficulty with the two new equipment items, specifically due to their high prices. Based on submitted invoices used to help price the items, the Proton Treatment Vault (ER115) is $19,001,914 and the Proton Treatment Delivery System (ER116) is $30,400,000, significantly higher than the current highest priced PE item in the database, which is the "SRS system, Linac" (ER082), which is $4,233,825. CMS is concerned that adding the higher priced equipment into the database could distort relativity. Another concern is that the submitted invoices reflected some costs that could be considered direct expenses, such as building construction costs.

In light of the above concerns, **CMS proposes that the code family remain contractor priced.** If CMS were to propose active pricing for this family, the construction costs would need to be removed, substantially lowering the equipment prices. CMS would also refine the equipment times to the standard formula for highly technical equipment, which would lower the times for each equipment item by 3 minutes.

Telehealth (Page 74)

Several conditions must be met for services to be added to the Medicare telehealth list. Category 1 services are services that are similar to professional consultations, office visits, and office psychiatry visits that are currently on the Medicare telehealth services list. Category 2 services are services that are not similar to those currently on the Medicare telehealth services list. For CY 2021, requests to add services to the telehealth list were due February 10, 2020.

In response to the COVID-19 public health emergency (PHE), during emergency rulemaking CMS added services to the telehealth services list on an interim final basis. Through Waiver authority in response to the COVID-19 PHE, CMS has removed the geographic and site of service originating site restrictions as well as the restrictions on the types of practitioners who may furnish telehealth services, and has allowed certain telehealth services to be furnished using audio-only technology.

At the conclusion of the PHE, these waivers and interim policies will expire, payment for Medicare telehealth services will again be limited by requirements in section 1834(m) of the Act, and CMS will return to the policies of the regular rulemaking process.

CMS is proposing to add 9 services to the Medicare telehealth services list on a Category 1 basis for 2021. These include: GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services), 99XXX (Prolonged office or other outpatient evaluation and

management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes), 90853 (Group psychotherapy (other than of a multiple-family group), 96121 (psychological and neuropsychological testing), 99483 (Cognitive Assessment and Care Planning Services), 99334 and 99335 (Domiciliary, Rest Home, or Custodial Care Services), and 99347 and 99348 (Home visits, established patients).

CMS also proposes to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis, which would include: the services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. Any service in Category 3 would remain in the telehealth services list until the end of the calendar year in which the PHE ends. CMS identified services that fit Category 3 and is proposing to include these services on the Medicare telehealth list through the calendar year of the end of the PHE. These include: domiciliary, rest home, or custodial care visits with established patients, home visits with an established patient, emergency department visits, nursing facilities discharge day management, and psychological and neuropsychological testing. CMS also invites public comment for any services added to the Medicare telehealth list during the PHE that fit these Category 3 criteria to be added to the list temporarily. CMS outlines particular services that may fit these criteria, but does not propose them (including Radiation Treatment Management services). See Table 12.

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)

CMS proposes that when new codes are issued to replace codes that describe the same clinical services that are currently on the Medicare telehealth services list, CMS will consider those new codes to be successor codes.

CMS seeks comment on whether or not to permanently waive the requirement for physician and non-physician practitioners to personally perform visits to nursing home residents, and instead allow via telehealth.

CMS seeks comment on whether frequency limitations for telehealth are burdensome and limit access to care (ex. allowing one telehealth appt. every 30 days) when services are only available through telehealth.

In the March 31st COVID-19 IFC, CMS allowed clinical social workers and clinical psychologists, occupational therapists (OTs), physical therapists (PTs), and speech language pathologists (SLPs) who bill Medicare directly for their services to bill HCPCS codes G2061 through G2063. **CMS is proposing adopt this PHE policy on a permanent basis. CMS is also proposing to allow billing of other communication technology based services (CTBS) by certain non-physician practitioners, consistent with the scope of these practitioners' benefit categories through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services.**

During the PHE, CMS established a payment for audio-only telephone E/M services. CMS is not proposing to continue this after the conclusion of the PHE, as they are unable to do so without PHE declaration. **CMS recognizes that the need for audio-only interaction could remain and is seeking comment on whether they should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. CMS is seeking input on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them.**

CMS seeks comment on whether there are additional services that fall outside the scope of telehealth services where it would be helpful to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list. CMS is also seeking comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current MPFS coding and payment, including, for example, additional or more specific coding for care management services. CMS is seeking comment on any impediments that contribute to healthcare provider burden and that may result in practitioners being reluctant to bill for CTBS.

CMS is proposing to clarify that 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.

Telehealth and Supervision

During the PHE, CMS adopted an Interim Final Policy to revise the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive technology. **CMS is proposing to extend this policy through December 31, 2021 or the end of the calendar year in which the PHE ends, whichever is later. CMS seeks comment if there should be any additional guardrails or limitations on this policy to avoid inappropriate use and potential risk. CMS is also seeking information on what risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way. Further CMS is seeking comment on potential concerns around induced utilization and fraud, waste, and abuse and how those concerns might be addressed.** Finally, the agency also invites commenters to provide data and

information about their implementation experience with direct supervision using virtual presence during the PHE, and is interested in comments on the degree of aging and disability competency training that is required for effective use of audio/video real-time communications technology.

During the PHE, CMS adopted a policy on an interim basis to allow Medicare to make payment under the MPFS for teaching physicians when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using interactive communication technology. **CMS is seeking public comment on whether they should extend or make this policy permanent.**

Scope of Practice and Related Issues (Page 181)

CMS is proposing several policies consistent with the President's Executive Order 13890 on "Protecting and Improving Medicare for Our Nation's Seniors" to modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license (84 FR 53573, October 8, 2019, Executive Order #13890). CMS believes that physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, including education and training, to the extent permitted under the Medicare statute, as long as it is not likely to result in fraud, waste or abuse. The agency believes these proposed policies may also help ensure an adequate number of clinicians, in addition to physicians are able to furnish critical services including primary care services in areas where there is a shortage of physicians. Some of the proposals may also help alleviate the opioid crisis.

Recognizing the wide variation in state laws **CMS is seeking information about the number and names of states that have licensure or scope of practice laws in place, as well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities the agency is proposing, to help assess the potential impact of, or challenges for, the proposed changes.** Information about specific services (service-level information) would be especially helpful. **CMS is seeking public comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities if CMS were to adopt the policies proposed in this section, and to what extent practitioners would be permitted to exercise these proposed flexibilities, such as for all diagnostic tests or only a subset.**

Teaching Physician and Resident Moonlighting Policies

In the March 31st COVID-19 Interim Final Rule with Comment (IFC) and the May 1st COVID-19 IFC, CMS implemented several policies on an interim final basis related to MPFS payment for the services of teaching physicians involving residents and resident moonlighting regulations. CMS accepted comments for both of the IFCs and plans to address the IFC comments for issues in which there are proposals in this proposed rule when the MPFS final rule is published. **CMS is considering whether these policies should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and is soliciting public comments on whether these policies should continue once the PHE ends.**

Under current law, payment is made under the MPFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions. If a resident participates in a service furnished in a teaching setting, MPFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The regulation states that, for the interpretation of diagnostic radiology and other diagnostic tests, MPFS payment is made if the interpretation is performed or reviewed by a physician other than a resident.

CMS adopted a policy on an interim basis during the COVID-19 PHE that the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident can be met using audio/video real-time communications technology. This policy generally requires real-time observation (not mere availability) by the teaching physician through audio and video technology, and does not include audio-only technology (for example, telephone without video). CMS also adopted a policy on an interim basis for the duration of the COVID-19 PHE to allow MPFS payment to be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. A physician other than the resident must still review the resident's interpretation. CMS is soliciting comments on the possible temporary (for a period after the end of the PHE emergency) or permanent extension of this policy.

CMS is concerned that continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant MPFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case. CMS also has concerns with patient safety when the teaching physician is only virtually present.

CMS seeks comment to help understand how the option to provide for teaching physician presence using audio/video real-time communications technology would support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability); ensure burden reduction without creating risks to patient care or increasing fraud; avoid duplicative payment between the MPFS and the IPPS for GME programs; and support emergency preparedness. CMS also invites commenters to provide data and other information on their experiences implementing this policy during the PHE.

In the March 31st COVID-19 IFC CMS adopted a policy on an interim basis to allow Medicare to make payment under the MPFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology. **CMS is considering whether this policy should be extended on a temporary basis (that is, if the PHE ends in 2021, this policy could**

be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and is soliciting public comments on whether this policy should continue once the PHE ends. CMS has concerns that the teaching physician may not be able to render sufficient personal and identifiable services to the patient to exercise full, personal control over the service to warrant separate payment and to ensure patient safety.

In the March 31st COVID-19 IFC, CMS amended its regulations to state that, during the PHE for COVID-19, the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the MPFS provided that the services are identifiable physicians' services and meet the conditions for payment of physicians' services to beneficiaries in providers, the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed, and the services can be separately identified from those services that are required as part of the approved GME program. Similar to the above, **CMS is seeking comment on the temporary or permanent extension of this policy.**

Under the so-called "primary care exception," Medicare makes MPFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. The regulation requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision) and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. There is also a requirement that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

In the March 31st COVID-19 IFC, CMS amended its regulations to allow, during the PHE for COVID-19, all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 1st COVID-19 IFC, CMS further expanded the list of services included in the primary care exception during the PHE for COVID-19. CMS also allowed MPFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services. **CMS is seeking comment on the temporary or permanent extension of these policies.**

As part of the review of public comments, CMS will weigh and make decisions based on the potential benefits and risks associated with the potential temporary or permanent continuation, in whole or in part, of these policies. The benefits of continuation may include limiting COVID-19 exposure risk for practitioners and patients, increasing workforce capacity of teaching settings to respond to continuing effects following the PHE as practitioners may be asked to assist with the response, and increasing access so the agency does not unintentionally limit the number of licensed practitioners available to furnish services to Medicare beneficiaries, which could have the unintended consequence of limiting access to services paid under the MPFS. The risks may include the potential for duplicative payment with Medicare Part A reimbursement for graduate

medical education training programs, the potential for increases to cost-sharing for Medicare beneficiaries that could result from additional Part B claims for services furnished by the teaching physician with the involvement of residents, and potential risks to patient safety.

Supervision of Diagnostic Tests by Certain Non-Physician Practitioners (NPPs)

In response to a previous request for comments, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise the performance of diagnostic tests because they are currently authorized to do so under their state scope of practice rules in many states. **In the May 1st COVID-19 IFC, CMS established on an interim basis during the COVID-19 PHE, a policy to permit these and certain other NPPs to supervise diagnostic tests.**

CMS now proposes to make those changes permanent. The agency is planning to address comments they receive on their proposals included in this proposed rule and comments received on the May 1st COVID-19 IFC simultaneously in the final rule since the comment period for the May 1, 2020 COVID-19 IFC closed on July 7, 2020.

Prior to the COVID-19 PHE, physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests.

In light of stakeholder feedback to CMS on identifying additional Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license, effective January 1, 2021, **CMS is proposing to amend the rule to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice.** These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or "incident to" their own professional services, to the extent authorized under state law and scope of practice.

CMS is also proposing to amend on a permanent basis, the regulation specifying that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians would continue to apply. CMS is also proposing to make permanent the removal of the parenthetical, previously made as part of the May 1, 2020 COVID-19 IFC that required a general level of physician supervision for diagnostic tests performed by a PA.

Medical Record Documentation

As we established in the CY 2020 PFS final rule, and expressed in the May 1st COVID-19 IFC, any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team.

Proposal to Remove Selected National Coverage Determinations (NCDs) (Page 523)

CMS is proposing to use the rulemaking process to use the criterion established in 2013 to regularly identify and remove NCDs that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. CMS is proposing this change of vehicle because removing a NCD changes a substantive legal standard related to Medicare coverage and payment for items and services under section 1871(a)(2) of the Act. Eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). On the other hand, if the previous NCD barred coverage for an item or service under title XVIII (that is, national noncoverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research that produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

Per the guidance issued in 2013, CMS may consider an older NCD for removal if, among other things, any of the following circumstances apply:

- CMS believes that allowing local contractor discretion to make a coverage decision better serves 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) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the Act.

CMS is interested in public comments that may identify other reasons for proposing to remove NCDs. The agency is also interested in whether the time-based threshold of “older” which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate.

CMS requests comment on the nine NCDs listed in Table 37 (below), as well as comments recommending other NCDs for CMS to consider for future removal.

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)

NCD #220.2.1 *Magnetic Resonance Spectroscopy*

MRS can determine the relative concentrations and physical properties of a variety of biochemicals and has the potential to probe a wide range of metabolic pathways in different human tissue. Although MRS is mostly used in assessing brain tissue, it also offers potential applicability to breast, prostate, hepatic, and other cancers. External stakeholders suggested this NCD might be outdated, noting the 2004 broad noncoverage determination for all indications was based on evidentiary review for one limited indication, the diagnosis of brain tumors. As the scientific evidence evolves and the clinical utility develops across various indications, the restrictive scope of the 2004 NCD may prohibit appropriate local coverage determinations.

NCD #220.6.16 FDG PET for Inflammation and Infection

The decision to use FDG PET for inflammation and infection is multifactorial and depends on: whether conventional diagnostics have been unsuccessful, the stage of the underlying pathophysiological condition in the affected tissues, and the sensitivity and specificity of FDG PET to inform the differential diagnosis or course of disease, among other factors. For some inflammatory and infectious conditions, there is no overall agreement in the current literature about the added value of FDG PET for this indication. Conversely, leaving such determinations to local contractor discretion builds in flexibility to tailor coverage decisions to the pertinent facts of a patient's case and considering any added benefit of FDG PET in establishing a diagnosis and treatment plan that might link the PET imaging to an improved patient outcome.

Medicare Shared Savings Program (Page 424)

Eligible groups of providers and suppliers may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Under the Medicare Shared Savings Program (MSSP), participants in an ACO continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

In the May 8th COVID-19 IFC, CMS modified MSSP policies to: 1) allow ACOs whose current agreement period ends December 31st 2020 the option to extend one year and allow ACOs on the BASIC track the option to elect to maintain their current level of participation for performance year 2021; 2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID-19; 3) expand the definition of primary care services for purposes of determining beneficiary assignment; and 4) clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the PHE beginning January 2020.

ACOs must meet a quality performance standard to qualify to share in savings, and the quality performance standard is currently based on an ACO's experience in the program rather than financial risk. The Alternative Payment Model Performance Pathway (APP) was designed for MIPS APMs, but also supports interests in aligning the Shared Savings Program with MIPS. The APP is designed to reduce burden, create new scoring opportunities for those in MIPS APMs and encourage participation in APMs. The APP requires fewer quality measures specifically intended for population health: 6 measures versus the current 23 required measures. CMS is proposing to revise the Shared Savings Program quality performance standard effective for PY 2021 and subsequent performance years to align the Shared Savings Program quality performance standard with the proposed APP under the QPP. The APP would replace the current MSSP quality measure set to streamline reporting requirements for ACOs and would be complementary to MVPs. ACOs would only need to submit one set of quality metrics that would satisfy reporting under MIPS and MSSP.

CMS seeks comment on an alternative approach for ACOs in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population. Under this approach, ACOs could opt out of the APP and report to MIPS as an APM entity. CMS is proposing to increase the level of quality performance that would be required of all ACOs to meet the Shared Savings Program quality performance standard. CMS is proposing to increase the quality performance standard for all ACOs to the 40th percentile or above across all MIPS categories.

CMS proposes to specify in regulation policies on the application of the APP to the Shared Savings Program ACOs for performance years beginning on or after January 1, 2021, and include a provision specifying that CMS establish quality performance measures to assess the quality of care furnished by the ACO. CMS also proposes to specify that the quality performance standard is the overall standard the ACO must meet to be eligible for shared savings. CMS proposes to terminate an ACO's participation agreement when the ACO fails to meet the quality performance standard for 2 consecutive performance years or any 3 performance years.

CMS is proposing to update the extreme and uncontrollable circumstances policy under MSSP consistent with the proposal to align quality reporting requirements with the APP. For performance year 2021 and subsequent years, CMS would set the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances during the performance year, to equal the 40th percentile to the MIPS quality performance score. CMS would use the higher of the ACO's MIPS quality performance category or the 40th percentile MIPS quality

performance score. If unable to report quality data and meet data completeness, CMS would use the 40th percentile MIPS quality performance score.

CMS is soliciting public comment on a potential alternative to extreme and uncontrollable circumstances starting in PY 2022. This alternative would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting. Instead of determining that ACOs are affected by extreme and uncontrollable circumstances if 20% of their beneficiaries or their legal entity are located in an area affected by extreme and uncontrollable circumstances, and using the higher of the ACOs quality score or mean ACO quality score, CMS would determine shared savings by multiplying the maximum possible shared savings the ACO would be eligible to receive by the percentage of total months impacted and percentage of beneficiaries affected.

CMS proposes two payment policies that would allow lower repayment: 1) 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 2) permit ACOs whose agreements began July 1, 2019 or January 1, 2020 to reduce the amount of their repayment mechanisms. CMS also proposes a one-time opportunity to decrease the amount of their repayment mechanism. CMS proposes that CMS would notify the ACO in writing of this opportunity.

CMS is seeking comment on a potential alternative approach to scoring ACOs under extreme and uncontrollable circumstances for PY 2020. This alternative would use the higher of an ACO's 2020 quality performance score or its 2019 quality performance score.

QUALITY PAYMENT PROGRAM

Of note, CMS is proposing to lower the weight of the quality performance category to 40 percent and raise the cost category to 20 percent of the overall performance score for performance year 2020. Several quality measures have also been proposed for removal, including *Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms*. CMS proposes to lower the performance threshold to 50 points (from the previously finalized 60 points). Small practices will still be able to claim the small practice bonus of 6 points to their quality score.

MIPS Program Details

Transforming MIPS: MIPS Value Pathways (Page 604)

The CY 2020 PFS final rule defined the framework for MIPS Value Pathways (MVPs) as "a subset of measures and activities established through rulemaking." CMS now proposes updates to the MVP guiding principles that guide MVP implementation. The proposed revisions incorporate distinct characteristics of MVPs. For instance, within each MVP, measures and activities should complement each other, and scoring practices should align among the MVPs.

Comparative performance data, valuable to patients and caregivers, should promote subgroup reporting and comprehensively reflect services provided by multispecialty groups.
MVP developers should implement CMS' Meaningful Measures framework and, when possible, include the patient voice. MVPs should transition to digital quality measures when feasible.

Although the CY 2020 PFS final rule stated that CMS would apply the MVP framework starting with the 2021 performance year, it now proposes delaying the implementation timeline to CY 2022, due to the COVID-19 pandemic national public health emergency. CMS also intends to phase in MVPs, until a comprehensive set of MVPs are available for all MIPS-eligible clinicians (ECs).

CMS explains that the MVP framework would become a vehicle for practices to participate in Advanced APMs. Further, the proposed rule states that MVP performance measures would be reported for specific populations to encourage practices to implement an infrastructure that promotes population health data analysis, an essential capability when assuming and managing risk.

MVP development criteria (Page 613)

The proposed rule explains the importance of identifying connections between the MVP-specific measures and activities and demonstrating the relevance of measures and activities to the clinicians captured within the MVP. CMS proposes criteria for MVP developers to follow when forming candidate MVPs. For instance, MVPs should include measures and activities from the four MIPS performance categories (quality, cost, improvement activities and promoting interoperability), apply to rural and small practices, capture the patient voice, specify how measures and activities in a proposed MVP drive quality care and improve value, and demonstrate how a proposed MVP is practical for phasing clinicians into APMs.

Quality measures included within a candidate MVP should meet the existing quality measure inclusion criteria. **MVP developers should confirm that the proposed quality measures contain denominators consistent across the measures and activities within the MVP** and include outcome measures (or high-priority measures).

CMS acknowledges that when relevant cost measures do not exist for specific types of care provided (e.g., conditions or procedures), the proposed MVP should include broadly applicable cost measures particular to the clinician type. Stakeholders associated with an MVP should prioritize cost measures for future development and inclusion in the proposed MVP.

The MVP Improvement Activities (IAs) should improve the quality of performance in clinical practices and confirm that the improvement activity complements and/or supplements the quality action of the MVP measures, rather than duplicate it. MVP developers should include broadly applicable IAs if specialty or sub-specialty specific IAs do not exist.

The rule also proposes that MVP developers include the full CMS-defined set of Promoting Interoperability measures.

Capturing the Patient Voice (Page 619)

CMS proposes that a pre-requisite for approving proposed MVPs is the inclusion of patients and/or patient representatives in the MVP development process.

Candidate MVP Co-Development, Solicitation Process, and Evaluation (Page 620)

Following the release of the CY 2020 PFS final rule, CMS conducted focus groups with stakeholders to understand what is preferred for MIPS participation simplification, burden reduction, and MVP intent. As a result, CMS proposes that MVP developers formally submit proposed MVPs through a standardized template, to be published in the QPP resource library. Before rulemaking, CMS would take on responsibility for approving proposed MVPs and vet quality and cost measures to validate their technical specifications. CMS anticipates engaging with MVP developers to discuss feedback on proposed MVPs potentially approved for the coming performance year.

CMS seeks comment on recommendations for a more transparent MVP approval process, including opportunities for MIPS stakeholders to participate in potential advisory committees or technical expert panels that would review MVP candidates (like that of NQF's MAP, which assesses MIPS quality measures as a part of rulemaking).

Implementing Meaningful Measures in MVPs (Page 622)

Incorporating Population Health Measures into MVPs
CMS continues the goal of implementing population health measures. In the CY 2020 PFS proposed rule, CMS expressed interest in incorporating population-health measures. These measures calculated from administrative claims-based data serve as a component of MVPs' foundation to improve patient outcomes, reduce reporting burden and costs, align clinician quality improvement efforts, and increase alignment among APMs and other payer performance measurement programs.

Incorporating QCDR measures into MVPs
CMS identifies the role of QCDR measures in MVPs, as these measures are relevant, applicable, and meaningful to a specialty or sub-specialty. In addition to meeting CMS' current standards of a QCDR measure, proposed QCDR measures should have data submitted with proposed MVPs that include empirical validity testing data at the clinician level. As such, beginning in the 2022 performance period, QCDR measures should be tested and used for more than one performance year before being included in a proposed MVP.

Reporting of MVPs through Third Party Intermediaries (Page 625)

CMS proposes that QCDRs, and other qualified registries, and Health IT vendors enable capabilities to support MIPS participation through MVPs.

Transition to MVPs (Page 626)

Timeline for MVP implementation
CMS proposes a gradual implementation of individual MVPs through the proposed development process for participation beginning as early as the CY 2022.

APM Performance Pathway

Overview (Page 627)

The proposed rule explains that there are different needs (e.g., reporting volume and measure accessibility) of MIPS-eligible clinicians (ECs) to join APMs. CMS proposes establishing the APM Performance Pathway (APP) under MIPS in the 2021 MIPS performance year. The APP would provide a predictable and consistent MIPS reporting standard to encourage APM participation.

Applicability

CMS proposes that the APP would become an optional MIPS reporting and scoring pathway for MIPS ECs. To report through the APP, ECs must appear on the Participation List, or Affiliated Practitioner List of any APM Entity participating in any MIPS APM and appear on any of the CMS-delineated "snapshot dates" (March 31, June 30, August 31, and December 31) during a performance period.

Reporting through the APM Performance Pathway

MIPS ECs participating in MIPS APMs may report through the APP at the individual level. However, groups and APM entities could report through the APP for their MIPS ECs, with the group's final score limited to those MIPS ECs appearing on a MIPS APM's Participation List or Affiliated Practitioner List on at least one snapshot date. The final score applied to each MIPS EC would be the highest available final score for that clinician (TIN/NPI).

ACOs participating in the Medicare Shared Savings Program would be required to report quality measure data through the APP, while MIPS ECs participating in ACOs retain the option to also report MIPS outside the APP at the individual or group level. CMS proposes that MIPS APM participants would be able to report through the APP or MIPS reporting mechanism.

MIPS APMs (Page 629)

CMS plans to maintain MIPS APM criteria 1) the APM Entity participate in the APM under an agreement with CMS or through law or regulation and 2) APM bases payment on quality measures and cost/utilization. **In addition,** CMS proposes to **include a third criterion - APMs in which there is only an Affiliated Practitioner List.**

MIPS Performance Category Scoring in the APM Performance Pathway (Page 629)

The following reporting and scoring rules apply to those MIPS ECs, groups, or APM entities reporting through the APP.

Quality Performance Category

CMS proposes that when reporting under the APP, MIPS ECs' quality performance category scoring would be based on the ECs' quality performance from an APP-specific measure set finalized for the particular MIPS performance period (e.g., measures for performance year 2021, *Page 630*). CMS proposes to remove specific measures from the quality performance category score denominator, if MIPS ECs, groups, or APM Entities participating in MIPS under the APP are unable to report specific quality measures. Further, when an APP quality measure becomes topped out, CMS explains that the APP quality measure set will undergo revisions through future rulemaking.

Cost

CMS plans to continue waiving the Cost performance category for those reporting in the ACO Medicare Shared Savings Plan and APM Entities in MIPS APMs. APM entities in MIPS APMs are already subject to a cost-performance assessment under their APMs. The MIPS APM criteria would include a cost-based evaluation of participants, since MIPS APMs may measure cost performance differently from MIPS. For example, basing cost on *the total* cost of care measures, demonstrates cost and resource use more broadly, than the narrower claims-based accountability standard under MIPS. Also, to measure cost, MIPS APM attribution may assign beneficiaries differently from MIPS, leading to variable overlap between the beneficiaries for whom MIPS ECs would be responsible under their APM and MIPS.

APM Entities have limited resources to improve quality and lower costs for a specified beneficiary population under the APM. Therefore, the APM Entity should be able to identify a single beneficiary population to prioritize its cost-saving efforts that are free of confounding factors. Participating through the APP, APM participants may indicate their intent to focus resources on the beneficiary population and services identified by the APM’s terms, rather than the population and services they would have been responsible for under the MIPS Cost performance category.

Improvement Activities (IAs)

CMS proposes to assign a score for the IA performance category for each MIPS APM, applicable to MIPS ECs reporting through the APP. CMS proposes to assign baseline scores for each MIPS APM based on the particular MIPS APM’s IA requirements. CMS would review the MIPS APM’s requirements regarding activities specified under the MIPS IA performance category. Each MIPS APM would be assigned an IA performance category score applicable to all MIPS ECs reporting through the APP, who are participants in the MIPS APM. To develop the

IA score for MIPS APMs, CMS would compare the APM requirements with the IAs for the applicable year and score those activities as they would be scored in MIPS.

CMS proposes to publish the assigned IA scores for each MIPS APM on the CMS website before the beginning of the MIPS performance period. If a MIPS APM does not represent the maximum IAs' score, CMS further proposes that MIPS ECs reporting through the APP may indicate additional IAs to apply to their scores.

Promoting Interoperability (PI)

Proposals to the PI performance category scoring under APP participation include that PI measures will be reported and calculated in the same manner as suggested in the PI performance category under traditional MIPS.

APP Performance Category Weights (Page 635)

CMS proposes to waive the Cost performance category for MIPS ECs reporting to MIPS through the APP. The following weights align with the performance category weights under MIPS and MVPs in cases where the cost performance category is reweighted to zero percent.

- Quality: 50 percent
- Cost: 0 percent
- PI: 30 percent
- IAs: 20 percent

Reweighting a performance category

CMS acknowledges that there are circumstances preventing MIPS ECs, groups, or APM Entities from reporting to MIPS due to extreme and uncontrollable circumstances, hardship, or the unavailability of measures. As such, CMS proposes reweighting one or more performance category. When the PI performance category is reweighted to zero percent, CMS proposes to reweight the Quality performance category to 75 percent and the IA performance category to 25 percent. Similarly, when the Quality performance category is reweighted to zero percent, CMS proposes reweighting the PI performance category to 75 percent and the IA performance category to 25 percent. **Such performance category weights contribute to an aligned performance category reweighting policy throughout MIPS in extreme and uncontrollable circumstances**.

Scoring for APM Participants Reporting through the APP (Page 637)

The proposed rule seeks comments on the final scoring of APM participants reporting to MIPS under the APP. CMS would apply appropriate adjustments after scoring each performance category, multiplying each performance category score by the applicable performance category weight, and summing each weighted performance category score.

Performance Feedback for APM Participants Reporting through the APP (Page 637)

CMS proposes to make performance feedback available to MIPS ECs reporting through the APP, like those participating under APMs.

The proposed rule acknowledges that the COVID-19 crisis and the subsequent deadline extension for 2019 MIPS reporting have created delays in finalizing performance numbers; the 2019 final scores came out on August 5th, 2020, and are available for review on the QPP website. As noted previously, CMS also proposes to delay the implementation of MVPs from 2021 to at least 2022.

2021 Performance Benchmarks (Page 709)

Due to the decreased number of MIPS submissions for the 2019 performance year, CMS acknowledges that it may not have an adequate data set to establish historical benchmarks for quality measures to be used in 2021. Therefore, CMS proposes to use 2021 performance data to establish benchmarks for the 2021 performance year rather than historical benchmarks based on the previous year's data.

2021 Performance Threshold (Page 603)

CMS also proposes to reduce the neutral payment adjustment threshold for the 2021 MIPS performance year from 60 to 50 points in recognition of the impact of COVID on clinicians. CMS had planned to raise the performance threshold based on the mean or median score of previous performance years.

Adjusted Effective Date (Page 610)

Due to delays associated with COVID-19, CMS waives the 60-day delay from publication of the final rule to the effective date of the final rule and instituting a 30-day delay instead. Meaning that the final rule will likely be published on or around December 1st, 2020.

Non-patient facing Clinicians (Page 729)

CMS will retain the previously finalized policy of reweighting the PI and IA performance categories for non-patient facing clinicians.

Non-patient facing ECs (and groups or virtual groups for whom at least 75 percent of clinicians are designated as non-patient facing) will continue to receive double credit for IAs, requiring that they submit one high-weighted or two medium-weighted IAs to receive full IA performance category credit. Non-patient-facing groups and individuals will also remain exempt from the promoting interoperability category, shifting the 25 percent PI performance category weight to the Quality performance category. In other words, the Quality performance category is worth 65 percent instead of 40 percent.

Facility-based Scoring *(Page 445)*

CMS continues to implement facility-based scoring for MIPS ECs without proposed revisions. Those selecting this MIPS participation method for performance year 2021, will use the FY 2021 measure set from the Hospital Value-Based Purchasing (VBP) program. Clinicians are eligible for facility-based measurement if they meet all of the following criteria.

- Bill at least 75 percent of covered professional services in a hospital setting.
- Bill at least one service in an inpatient hospital or emergency room.
- Attribute to a facility with a FY 2021 Hospital VBP program score.

There are no submission requirements for individual clinicians participating in facility-based measurement. However, groups must submit data for the IA or PI performance categories to be measured as a group under facility-based measurement. CMS will automatically apply facility-based measurement to MIPS ECs and groups that meet the eligibility criteria and benefit from a higher combined Quality and Cost performance category score provided by the facility. There are no proposed changes for facility-based scoring eligibility.

Low-Volume Threshold and small practice (15 or fewer eligible clinicians) considerations *(Page 978)*

Like previous MIPS performance years, the low-volume threshold allows Medicare clinicians the potential to be excluded from MIPS participation. CMS has not proposed any changes to the low-volume threshold. To avoid participating in MIPS in 2021, clinicians or groups must meet at least one of the following criteria.

- Maintain ≤ $90,000 in allowed charges for covered professional services.
- Provide covered professional services to ≤ 200 Medicare Part B-enrolled individuals.
- Provide ≤ 200 covered professional services to Medicare Part B-enrolled individuals.

CMS maintains the six-point small practice bonus included in the Quality performance category score and continues to award small practices three points for submitting quality measures that do not meet data completeness requirements. Small practices may also still report quality measures through Medicare Part B claims *(Page 985).*

MIPS Performance Threshold *(Page 732)*

The Bipartisan Budget Act of 2018 allows CMS flexibility to set performance thresholds until 2021. The statutorily required performance threshold is based on the mean or median of final scores from a prior performance period. Although, a 60-point MIPS performance threshold for the 2021 MIPS performance year was previously finalized, **CMS proposes to lower the performance threshold to 50 points for 2021,** due to the COVID-19 public health emergency. CMS is not proposing revisions to the exceptional performance threshold, set at 85 points for 2021. In the 2020 Final Rule, CMS set the payment adjustment of +/- 9 percent for performance years 2020 and beyond. No changes are proposed to the MIPS adjustment.

MIPS Category Weighting (Page 728)

For MIPS 2021, CMS proposes maintaining the Cost performance category at 20 percent, the Quality performance category weight at 40 percent, and the PI and IA performance categories at 25 percent and 15 percent. CMS intends to alleviate the stress of the COVID-19 public health emergency that is affecting many clinicians in 2020. **For the 2022 performance year, CMS proposes to lower the Quality performance category to 30 percent, increase the Cost category to 30 percent, and maintain PI and IA performance categories at 25 and 15 percent.**

The proposed rule continues to offer performance category reweighting for those unable to submit data for one or more performance categories. In most cases, the category weights will be redistributed to the Quality performance category. When a MIPS EC is scored on fewer than two performance categories, a final score equal to the performance threshold will be assigned, and the MIPS EC will receive a neutral payment adjustment.

Performance Categories and Reporting

Quality Category (Page 638)

CMS proposes to lower the weight of the Quality performance category to 40 percent for 2021 and 30 percent for 2022. (p. 728) CMS also proposes to end the CMS Web Interface measure collection type (available for groups and virtual groups with 25 or more eligible clinicians) beginning in the 2021 performance year. Removing this collection type is a result of decreased utilization of the CMS Web Interface in favor of other collection types, such as QCDRs.

Topped-out Measures (Page 715)

As mentioned previously, CMS proposes to use 2021 performance period benchmarks, rather than historical benchmarks, for the 2021 performance year out of concern that the COVID-19 public health emergency could skew benchmarking results. As a result, clinicians may not necessarily know whether a measure will continue to be considered topped out and subject to the 7-point scoring cap. Regarding their methodology for scoring topped out measures, CMS proposes that for a measure to be point-capped in the 2021 performance year, it must have been topped out for two consecutive years prior to 2021 and topped out at the conclusion of the 2021 performance year, giving clinicians an idea of whether a measure could become point-capped while allowing for the possibility that the measure may no longer be considered topped out for 2021.

Measures Proposed for Removal (Page 1223)

CMS proposes removing two measures previously reportable by radiologists or interventional radiologists.

- MIPS Quality ID 146: Inappropriate Use of ‘Probably Benign’ Assessment Category in Screening Mammograms

- MIPS Quality ID 437: Rate of Surgical Conversation from Lower Extremity Endovascular Revascularization Procedure

Since both measures have been designated as extremely topped out due to high-performance rates for two previous consecutive years, CMS proposes their removal.

CMS Data Completeness Requirements (Page 714)

CMS does not propose changes to the data completeness requirements established in the 2020 final rule, which set the data completeness requirement for quality measures at 70 percent.

Improvement Activities (Page 661)

CMS proposes to maintain the IA category 15 percent weight. There are no major changes to this performance category proposed for 2021, and no activities proposed for addition or removal.

CMS proposes flexibility when submitting new improvement activities to the Annual Call for Activities, which is currently open from February 1st through June 30th, in the event of public health emergencies (PHE) such as the COVID-19 crisis. This proposal would allow stakeholders to submit new improvement activities outside of the established 4-month timeframe in the event of a PHE.

Similarly, CMS proposes a process to allow activities nominated by the Department of Health and Human Services (HHS) to be considered year-round for addition to the improvement activities inventory.

CMS has also proposed to add a new criterion for newly submitted MIPS improvement activities beginning with the 2021 Call for Activities. This new criterion would allow newly proposed activities to be linked to existing quality and cost measures, as applicable and feasible.

Promoting Interoperability Category (Page 670)

For the 2024 MIPS payment year and each subsequent year, CMS proposes to establish a Promoting Interoperability category performance period of 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. If finalized, this proposal would establish a permanent 90-day performance period for the Promoting Interoperability category, thus addressing previous recommendations from the physician community as well as circumventing the need for CMS to continually define performance periods via the annual QPP rulemakings.

CMS proposes to add an optional, alternative measure to the "Health Information exchange" objective titled, "Health Information Exchange (HIE) Bi-Directional Exchange." This proposal would be a yes/no attestation-based measure for the full 40 points of the "Health Information Exchange" objective. To complete this measure, the clinician would need to participate in a broad HIE network of unaffiliated exchange partners to share data for every

patient encounter, transition/referral, and record stored or maintained in the EHR during the performance period. While doing so, the clinician would need to use the corresponding certified functions of certified EHR technology (CEHRT).

CMS proposes minor modifications to certain objectives and measures. The "Query of Prescription Drug Monitoring Program (PDMP)" measure would continue to be optional in CY 2021, but the bonus points would increase from 5 to 10 points. The name of the "Support Electronic Referral Loops by Receiving and Incorporating Health Information" measure under the "Health Information Exchange" objective would change from "incorporating" to "reconciling."

CMS proposes alignment of the "certified EHR technology (CEHRT)" definition with the recent 21st Century Cures Act-mandated changes to the Office of the National Coordinator for Health IT (ONC) 2015 Edition certification criteria. Per an ONC final rule promulgated earlier this year, as well as a subsequent enforcement discretion decision, health IT developers have until August 2, 2022 to get their EHR technology solutions certified to the 2015 Edition "Cures Update" criteria. CMS proposes that clinicians would be allowed to use EHR technology certified to either the prior 2015 Edition or the 2015 Edition Cures Update criteria until August 2, 2022. After August 2, 2022, clinicians participating in the Promoting Interoperability category would be required to use 2015 Edition Cures Update-certified solutions.

Cost Category (Page 656)

As stated previously, CMS proposes maintaining the 20 percent Cost performance category weight during the 2021 performance year, with plans to increase it to 30 percent for performance year 2022 and beyond. As mandated by statute, CMS will increase the Cost performance category weight to 30 percent for the 2022 performance year. However, **comments are sought on whether CMS should raise the weight to 22.5 percent for 2021 to promote a seven-and-a-half percent increase for the two consecutive years.**

For the 2021 performance period and beyond, CMS proposes to include costs associated with telehealth services in the list of cost measures. The telehealth service codes are relevant to each appropriate measure (e.g., E/M, follow-up consultation after hospital discharge). CMS does not think adding these cost codes alter the measures' intent or capture a new category of costs. Updated measure specifications with the telehealth codes are available on the MACRA Feedback website.

Groups and Virtual Groups Reporting via CMS Web Interface (Page 640)

CMS does not propose changes to the virtual group election process. Solo clinicians and those in groups of 10 or fewer have the capability to form a virtual group in order to earn a group score for MIPS performance. Virtual groups must apply with CMS during the virtual group election cycle.

CMS proposes to end the CMS Web Interface as a measure collection type for groups and

virtual groups beginning with the 2021 performance period. Removing this reporting mechanism would reduce group reporting burden.

Payment Adjustments *(Page 732)*

For clinicians submitting data in 2021, CMS estimates that 92.5 percent will receive a MIPS positive or neutral payment adjustment while remaining clinicians will receive a MIPS negative payment adjustment. This estimate is based on 2018 MIPS performance participation, which assigned MIPS participation scores based on a 15-point performance threshold.

Physician Compare *(Page 782)*

CMS proposes to revise the Physician Compare website by referring to it as the *Physician Compare Internet Website of the Centers for Medicare & Medicaid Services*. **The site hosts public reporting information, like ECs' overall MIPS final scores, individual performance category scores, and aggregate MIPS data. In 2020, CMS added a value indicator to physician profiles to designate facility-based scores.**

Advanced Alternative Payment Models (Page 781)

An Advanced APM is an APM that: 1) requires participants to use certified EHR technology (CEHRT), 2) provides payment for covered services based on quality measures comparable to MIPS, and 3) requires participating entities to bear more than nominal financial risk or participate as a Medical Home Model. For payment years 2019 through 2024, Qualifying APM Participants (QPs) receive 5 percent APM Incentive Payment. Beginning in the CY 2021 QP Performance Period, the QP payment amount threshold increases from 50 percent to 75 percent of Medicare payments, while the QP patient count threshold increases from 35 percent to 50 percent of Medicare patients.

QP Threshold Scores

Threshold scores used for QP determinations using patient count are calculated as a ratio of attributed Medicare patients whom the APM entity or eligible clinician furnished Part B services and attribution-eligible Medicare patients to whom the APM Entity or eligible clinician furnishes Medicare Part B covered professional services during the QP Performance Period. Threshold scores used for QP determinations using payment amount are calculated as a ratio of the aggregate of payments for Medicare Part B covered professional services furnished by the APM entity or eligible clinician during the QP performance period and the aggregate of payments for Medicare Part B covered professional services furnished by the APM Entity or eligible clinician to attribution-eligible beneficiaries. **CMS is proposing that in calculating the Threshold Scores used in making QP determinations, beginning in the 2021 QP Performance Period, Medicare patients who have been prospectively attributed to an APM entity during a QP Performance period will not be included as attribution-eligible Medicare patients for any APM entity that is participating in an Advanced APM that does not allow such prospectively attributed patients to be attributed again.**

This proposed policy would remove such prospectively attributed Medicare patients from the denominators when calculating QP Threshold Scores for APM Entities or individual eligible clinicians in Advanced APMs that do not allow for attribution of Medicare patients that have already been prospectively attributed elsewhere, thereby preventing dilution of the QP Threshold Score for the APM Entity or individual eligible clinician in an Advanced APM that uses retrospective alignment.

Targeted Review

CMS proposes to establish a Targeted Review process for limited circumstances surrounding QP Determinations. **CMS is proposing that starting in the 2021 QP Performance Period, CMS would accept Targeted Review requests when an eligible clinician or APM Entity believes in good faith CMS has made a clerical error such that an eligible clinician(s) was not included on a Participation List of an APM Entity participating in an Advanced APM for purposes of QP or Partial QP determinations. CMS also proposes that after the conclusion date of the targeted review, there would be no further review of QP determination with respect to an eligible clinician during the relevant performance period.**

If CMS determines an error was made, CMS proposes to assign the clinician the most favorable QP status at the APM entity level on any of the snapshot days for the relevant QP performance period.

Other Updates and Proposals

CMS proposes to clarify that the APM Incentive Payment amount is calculated based on the paid amount of the applicable claims for covered professional services that are subsequently aggregated to calculate the estimated aggregate payments. CMS proposes to establish a revised approach to identifying the TIN(s) to which they make the APM Incentive Payment: this approach would involve looking at a QP's relationship with their TIN(s) over time, as well as considering the relationship the TIN(s) have with the APM Entity or Entities through which the eligible clinician earned QP status, or other APM Entities the QP may have joined in the interim. CMS believes that this approach would allow CMS to more accurately identify TINs with which QPs are currently receiving other Medicare payments, and through which they would receive an APM incentive payment. This would also prioritize when the QP is no longer affiliated with its original TIN through which they attained QP status.

CMS proposes to introduce a cutoff date of November 1 of each payment year (or 60 days from the day on which CMS makes the initial round of APM Incentive Payments, whichever is later), as a point in time after which CMS will no longer accept new helpdesk requests from QPs or their representatives who have not received their payments. CMS believes this is necessary in order to achieve their goal of disbursing correct payments to QPs as quickly as possible.

Due to the impacts of COVID-19, CMS will not reconsider advanced APM determinations of APMs that have already met the criteria for CY 2020, even if they have undergone changes due to the Public Health Emergency. Additionally, CMS will evaluate all APMs in future years with the understanding that any provisions of the Participation Agreement or governing regulation

designed in response to the COVID-19 PHE will not be considered to the extent they would prevent the APM from meeting the Advanced APM criteria for a year. Due to the impacts of the COVID-19 PHE, certain APMs may adopt earlier end dates. CMS will not consider this to be termination from an agreement, and would not revoke QP status of eligible clinician participants. CMS clarified that they will continue to perform QP determinations at the established times for the 2020 QP performance period without modification for the PHE. CMS believes that Advanced APM participants benefit from timely and predictable QP determinations, and that making changes to the QP determination methodology would inadvertently pick winners and losers during the PHE.

CMS seeks comment on whether to allow Partial QP elections to be made by APM Entities on behalf of all eligible clinicians within the APM Entity, and how to handle potentially conflicting elections.

RO Model

The Radiation Oncology Model, as proposed, has been included in CMS' list of APMs expected to be Advanced APMs in 2021 QP Performance track. The full list of APMs expected to be Advanced APMs for the 2021 QP Performance Period include: Bundled Payments for Care Improvement Advanced (BPCI Advanced), Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Comprehensive Primary Care Plus (CPC+) Model, Direct Contracting Model, Kidney Care Choices Model, Maryland Total Cost of Care Model, Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track), Medicare ACO Track 1+ Model, Next Generation ACO Model, Oncology Care Model (two-sided risk arrangements), Primary Care First (PCF) Model, Radiation Oncology Model (if finalized) and the Vermont All-Payer ACO Model.

For questions on the Medicare Physician Fee Schedule proposed rule, please contact Katie Keysor at kkeysor@acr.org.