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Regulatory Advisory

August 4, 2021

Medicare Physician Fee Schedule: Proposed Rule for CY 2022

At A Glance

The Centers for Medicare & Medicaid Services (CMS) July 13 issued a proposed rule that would update physician fee schedule (PFS) payments for calendar year (CY) 2022. The rule also includes several proposals to implement changes to the quality payment program (QPP) created by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.

Our Take:

We are pleased that the agency proposes to delay the payment penalty phase of the Appropriate Use Criteria (AUC) program, as well as expand access to telehealth for behavioral health services. However, we continue to have concerns regarding certain aspects of the pricing methodology for drugs administered as part of the Opioid Treatment Program benefit, including limitations on take-home supplies of naloxone. Moreover, we remain concerned about the feasibility of the Merit-Based Incentive Payment System (MIPS) Value Pathways, and believe much work remains to ensure they result in fair, equitable performance comparisons across MIPS clinicians and groups.

What You Can Do:

- ✓ **Participate in an Aug. 12 AHA members-only webinar at 2:30 ET to provide feedback on this proposed rule. Register here.**
- ✓ Share this advisory with your chief medical officer, chief financial officer and other members of your senior management team, key physician leaders and nurse managers.
- ✓ Assess the potential impact of the proposed payment and quality changes on your Medicare revenue and operations.
- ✓ Submit comments to CMS with your specific concerns by Sept. 13 at www.regulations.gov.

Further Questions:

For additional questions, please contact Shira Hollander, AHA's senior associate director for payment policy, at 202-626-2329 or shollander@aha.org.

Key Takeaways

CMS proposes to:

- **Payment Update:** Reduce the PFS conversion factor by 0.14% for CY 2022, as well as eliminate the single-year CY 2021 3.75% conversion factor increase
- **AUC:** Delay implementation of the penalty phase of the AUC program to the later of Jan. 1, 2023, or the Jan. 1 that follows the end of the COVID-19 public health emergency
- **Telehealth:** Allow providers to receive payment for mental health services provided via telehealth if they conduct initial and periodic in-person visits, as well as allow audio-only behavioral health services in certain circumstances
- **Rural Providers:** Allow rural health clinics and federally qualified health centers to report and receive payment for mental health visits furnished via telehealth, including via audio-only connection in certain circumstances
- **E-prescribing:** Extend the compliance date for e-prescribing of controlled substances to 2023
- **MIPS Value Pathways:** Implement seven optional MIPS Value Pathways beginning in 2023
- **MIPS Performance Threshold:** Increase the MIPS performance threshold
- **MIPS Complex Patient Bonus:** Update the MIPS complex patient bonus calculation
- **MSSP:** Phase-in the MSSP requirement to report the MIPS APM Performance Pathway (APP) measure set over the course of 2022 and 2023 and modify other MSSP requirements

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Background

The Centers for Medicare & Medicaid Services (CMS) July 13 issued a proposed rule for calendar year (CY) 2022 with changes to the Medicare physician fee schedule (PFS) and other revisions under Medicare Part B. The rule also includes several proposals to implement changes to the Quality Payment Program (QPP) created by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. Comments are due to CMS by Sept. 13, with changes generally effective Jan. 1, 2022.

Changes to the CY 2022 PFS

Conversion Factor

The proposed payment update for CY 2022 reflects several different factors, some of which are unique to this year to account for policy changes implemented last year. The Consolidated Appropriations Act of 2021 (CAA) provided a 3.75% increase in the PFS conversion factor for CY 2021 *only*. This one-time increase was meant to offset the significant, 10.20% physician fee schedule (PFS) conversion factor decrease that CMS finalized for that year. Because the CAA instructed CMS to ignore the 3.75% increase when determining PFS payment rates for subsequent years, the agency calculated the CY 2022 conversion factor as though the 3.75% increase never occurred. Thus, CMS proposes a slight decrease in PFS payment rates of 0.14% in CY 2022.

However, the actual change from the final CY 2021 conversion factor of $34.89 to the proposed CY 2022 conversion factor of $33.58 is a decrease of $1.31, or 3.89%. This reflects the expiration of the 3.75% payment increase, a zero-percent update factor as required by MACRA and a budget-neutrality adjustment.

Appropriate Use Criteria

Appropriate Use Criteria (AUC) are a set of individual criteria that present information linking a specific clinical condition or presentation with one or more services and an assessment of the appropriateness of the services. The Protecting Access to Medicare Act (PAMA) of 2014 required CMS to establish a program to promote the use of AUC for advanced diagnostic imaging that integrates AUC into the clinical workflow. The statute requires that payment be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC.

CMS has implemented the AUC program over several years. In 2020, it began the educational and operations testing period. During this period, ordering professionals must consult specified applicable AUC through qualified CDSMs and furnishing professionals must report the AUC consultation information on Medicare claims, but

CMS continued to pay claims whether or not they correctly included AUC information. In response to the COVID-19 public health emergency (PHE), the agency extended the educational and operational testing period through 2021.

The payment penalty phase of the program was thus set to begin on Jan. 1, 2022. **However, in light of the ongoing PHE and the complexities of the AUC program, CMS proposes to delay the payment penalty phase of the program to the later of Jan. 1, 2023, or the first of the January that follows the end of the PHE.** The agency seeks comment on the proposed start date for this payment penalty phase and whether it sufficiently accounts for the COVID-19 pandemic. Also related to the PHE, CMS clarifies that stakeholders may continue to attest to a significant hardship under the AUC program due to extreme and uncontrollable circumstances related to the PHE and that such an attestation may be used as needed throughout the PHE.

CMS also makes several other proposals relating to the implementation of the AUC program, as described below.

Modified Orders. CMS addresses the situation in which beneficiaries already under the care of the furnishing professional need additions or modifications to their treatment. In this situation, CMS proposes that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described in the Medicare Benefit Policy Manual, neither the ordering professional nor the furnishing professional are required to consult the AUC for the additional services(s). Instead, the AUC consultation information from the original order should be reported on the claim line for the additional service(s).

Claims Processing. In this rule, CMS discusses the operational and administrative issues related to implementation of the payment penalty phase and its proposals for addressing them. The agency recognizes that it needs to develop edits for the two main Medicare claims types subject to claims processing edits in the AUC program, the CMS-1500 and the UB-04, and that due to the different data elements for these two claims type, the claims processing edits will have to be tailored to each one. CMS discusses and requests comments on issues surrounding implementation of the payment penalty phase, including:

- establishing claims processing edits to (1) enable the fields for reporting the ordering professional's NPI to be populated on all advanced diagnostic imaging claims subject to the AUC program and (2) identify advanced diagnostic imaging services furnished in critical access hospitals, which are not subject to the AUC program;
- exempting from the AUC program advanced diagnostic imaging services not wholly furnished (professional and technical components) in an applicable setting;
- determining whether claims that fail AUC processing edits, which thereby would not be paid, should be initially returned to the health care provider so they can be corrected and resubmitted, or should be denied so they can be appealed;

- allowing claims that identify Medicare as the secondary payer to bypass the UC program claims processing edits; and
- establishing two primary sets of HCPCS modifiers for the AUC program, one to be included on the same claim line as the G-code identifying the CDSM that was consulted and one to be used when the ordering professional does not consult a qualified CDSM.

Changes to Payment for Medicare Telehealth Services and other Communications Technology-based Services

This rule includes several proposals to extend temporary coverage of some telehealth services and make permanent coverage and payment for other services.

Category 3 Services. To assess requests for adding or deleting services from the Medicare telehealth list of services under Section 1834(m) of the Social Security Act, CMS historically assigned the requests to one of two categories. Category 1 services are similar to services that are currently on the Medicare telehealth list, whereas Category 2 services are not similar to services on the list, and, as such, CMS requires supporting evidence of the clinical benefit of a service to add it to the list. In the CY 2021 PFS final rule, CMS added a third category of criteria for adding services to the Medicare telehealth list on a temporary basis following the end of the COVID-19 PHE. This "Category 3" describes services added during the PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under Category 1 or Category 2 criteria. Any service added under Category 3 will remain on the Medicare telehealth services list through the calendar year in which the PHE ends and then would need to meet the Category 1 or 2 criteria to be added on a permanent basis. Also in the CY 2021 rule, CMS added numerous services to the Medicare telehealth list on this Category 3 basis.

In this rule, CMS recognizes the uncertainty of when the PHE will end and the impact that could have on Category 3 services; specifically, that these services could be removed from the list before practitioners have had time to compile and submit evidence to support the permanent addition of these services on a Category 1 or Category 2 basis. **To that end, CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023.** CMS is also seeking comment on whether any of the services added to the Medicare telehealth list for coverage and payment during the PHE that were not extended on a temporary Category 3 basis in the CY 2021 PFS final rule should now be added to the Medicare telehealth list under Category 3. Table 11 in the rule lists these services.

Telehealth Services for Diagnosis, Evaluation, or Treatment of Mental Health Disorder. Section 1834(m) of the Social Security Act limits the provision of Medicare telehealth services to certain geographic areas largely representing rural parts of the country and to the listed originating sites in which a patient must be located to receive telehealth. The CAA waived these geographic restrictions and added the patient's home as a permissible originating site for telehealth services furnished for the purpose of

diagnosis, evaluation or treatment of a mental health disorder, effective for services furnished on or after the end of the COVID-19 PHE.

The CAA also required that the provider furnishing a telehealth service must furnish an in-person service within six months prior to the telehealth service and thereafter, at such times the Secretary of Health and Human Services determines appropriate. **To implement this provision, CMS proposes to require providers to conduct an in-person, non-telehealth service within six months prior to providing an initial mental health telehealth service, and at least once every six months thereafter.**

The CAA mandated that these in-person requirements apply only to the mental health telehealth services made possible by the CAA; that is, they apply only to mental health services delivered to patients in their homes (regardless of the geographic location of the patient) and services delivered to patients in geographic locations beyond those currently authorized for Medicare telehealth services. This does not include services furnished for treatment of a diagnosed substance use disorder or co-occurring mental health disorder, as the SUPPORT Act already authorized these services to be provided to patients in their homes and in any geographic area of the country.

CMS seeks comment on whether it should adopt a claims-based approach to differentiate between the mental health services for which payment was newly authorized by the CAA and those for which payment was authorized before the CAA. CMS also seeks comment on whether the required in-person, non-telehealth service could be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service.

Rural Emergency Hospitals (REH). As directed by the CAA, CMS proposes to amend its regulations to add REHs, a new provider type created by the CAA, to the list of approved telehealth originating sites. This would begin in CY 2023, when REHs are officially implemented. In the CY 2022 Outpatient Prospective Payment System (OPPS) proposed rule, CMS includes a request for information on a range of issues related to establishing the new REH provider type.

Payment for Medicare Telehealth Services Furnished Using Audio-only Communication Technology. Section 1834(m) specifies that for Medicare payment, telehealth services must be furnished via a “telecommunications system.” In regulations at 42 CFR § 410.78(a)(3), CMS defines “telecommunications system” to mean an “interactive telecommunications system,” which the agency further defines as “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.” During the PHE, CMS waived the requirement that telehealth services be delivered with video technology to allow the provision of certain behavioral health, counseling, and evaluation and management (E/M) services via audio-only communication.

Over the course of the PHE, CMS has observed that audio-only E/M visits have been some of the most commonly performed telehealth services and that most beneficiaries receiving these services were receiving them for the treatment of a mental health condition. In light of the shortage of mental health care professionals and the limited access to broadband in certain areas, CMS believes a sudden discontinuation of audio-only flexibilities at the end of the PHE could negatively impact access to care. **In light of this, CMS proposes to amend its regulations to define "interactive telecommunications system" to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home.** CMS proposes to limit audio-only telehealth to services in patients' home because it believes the other originating sites enumerated in statute are medical settings that are more likely to have access to reliable broadband.

Additionally, CMS proposes to limit payment for audio-only mental health services to physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. CMS proposes to create a service-level modifier to identify these mental health services furnished via audio-only connection. CMS seeks comment on these proposals and on whether it should require additional documentation to support the clinical appropriateness of audio-only services. CMS also requests comments on whether it should exclude from this proposed audio-only flexibility certain higher-level services, such as Levels 4 or 5 E/M visits when furnished alongside psychotherapy services.

Expiration of PHE Flexibilities for Direct Supervision Requirements. During the PHE, CMS allowed providers to satisfy "direct supervision" requirements for diagnostic tests, physicians' services and some hospital outpatient services through virtual presence, using real-time audio/video technology. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the later of the end of the calendar year in which the PHE ends or Dec. 31, 2021. **In this rule, CMS seeks comment on whether it should make this flexibility permanent or if it should temporarily continue it beyond the current timeframe and on several other issues related to executing this flexibility.**

Interim Final Provisions in the CY 2021 PFS Final Rule. In the CY 2021 PFS final rule, CMS established on an interim basis coding and payment for an extended virtual check-in under new HCPCS code G2252. CMS made clear that this check-in could be provided using any form of synchronous communication technology, including audio-only communication. **In this rule, CMS proposes to permanently adopt coding and payment for HCPCS code G2252.**

Remote Therapeutic Monitoring (RTM). A collection of five codes (created by the CPT Editorial Panel in October 2020 and valued by the RUC in January 2021), including three PE-only codes and two codes that include professional work, make up the suite of

RTM services. CMS notes two key differences between the RTM codes and the seven existing Remote Physiological Monitoring (RPM) codes: (1) the primary billers of RTM codes are expected to be nurses and physical therapists and are considered general medicine codes vs. E/M codes; and (2) the RTM codes monitor health conditions and allow non-physiologic data to be collected.

CMS, based on modeling, believes the RTM codes are "incident to" services and therefore cannot be billed independently by physical therapists and other practitioners who are not physicians or non-physician practitioners (NPPs). In addition, as "incident to" services, direct, as opposed to general, supervision requirements would apply. CMS seeks comments on how to remedy the issues with the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill these codes.

Additionally, CMS notes that the data collection for the RTM codes includes certain non-physiologic data to be self-reported as well as digitally uploaded in contrast to RPM which requires data to be physiologic and digitally uploaded. CMS further highlights that for both RTM and RPM the device must meet the FDA definition of a medical device and requests comments on the types of devices and associated costs that might be used to collect the data types included in the RTM code descriptors.

For CY 2022, CMS is proposing:

- The RUC-recommended work RVU of 0.62 for CPT code 989X4 (RTM treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes) and RVU of 0.61 for its add-on code CPT code 989X5 (RTM treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes). This is intended to maintain parity with the two RPM treatment management codes upon which these RTM codes are based.
- The RUC-recommended direct PE inputs for 989X4 and 989X5 without refinement.
- To value the PE for CPT code 989X1 (RTM [e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response]; initial set-up and patient education on use of equipment) by cross-walking to the PE RVU for RPM code 99453 upon which the RTM code is based.
- To value the PE for CPT code 989X2 (RTM [e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response]; device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system; each 30 days) and CPT code 989X3 (RTM [e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response]; device(s) supply with scheduled (e.g., daily recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system; each 30 days) by cross-walking to the PE RVU for RPM code 99454, a

code that includes payment for the medical device used to collect and transmit the data.

Proposals and Comment Solicitation Regarding Innovative Technology

CMS is actively considering approaches to better account for innovative technologies, such as software algorithms and artificial intelligence (AI). Historically, the agency considered most computer software and related analysis and licensing fees to be indirect costs tied to associated medical equipment.

Remote Retinal Imaging. CMS proposes to use its crosswalk approach to establish values for remote retinal imaging (CPT code 92229) and therefore this service would no longer be contractor-priced. Specifically, CMS proposes to crosswalk this code to CPT code 92325 (Modification of contact lens (separate procedure), with medical supervision of adaptation), a PE-only code used for the eye. CMS believes this reflects similarities in the total resource costs and seeks comments on whether other codes would provide a more appropriate crosswalk.

Fractional Flow Reserve Derived from Computed Tomography (FFRCT). CMS seeks comments on a similar crosswalk approach for the technical component only code (CPT code 0503T) for FFRCT which uses a proprietary data analysis process. CMS identifies two cardiac catheterization codes (CPT codes 93455 and 93458) that have similar resource costs and requests feedback on whether these codes would be appropriate crosswalks for FFRCT or whether other codes would be more appropriate.

Evolving Innovative Technology. CMS more broadly solicits public comments in an effort to better understand the resource costs for services involving innovative technologies. Specific areas of interest include:

- To what extent are services involving innovative technologies, such as software algorithms and AI, substitutes or supplements for physician work?
- How is innovative technology, such as software algorithms and AI, changing cost structures in the physician office setting?
- How is innovative technology affecting beneficiary access to Medicare-covered services?
- Are services driven or supported by innovative technology at greater risk of overutilization, fraud, waste or abuse?
- Are services driven or supported by innovative technology associated with improvements in quality or health equity?
- How might CMS consider updating the underlying data in its PE methodology to reflect ongoing advances in technology so that it could establish appropriate relative values instead of using crosswalks?

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

CMS makes several proposals in this rule to modify payment for services provided by RHCs and FQHCs, including:

- modifying the per-visit payment limit to which independent and provider-based RHCs in a hospital with 50 or more beds are subject and implementing other per visit payment limit provisions of the CAA;
- as directed by the CAA, authorizing physicians, nurse practitioners and physician assistants employed by, or contracting with, an RHC or FQHC to provide hospice attending physician services; and
- allowing RHCs and FQHCs to concurrently bill for transitional care management and other care management services furnished for the same beneficiary during the same service period, provided other requirements are met.

CMS also solicits comment on various topics relating to payment for Indian Health Service- and tribally-operated facilities.

RHCs and FQHCs – Telecommunications Technology. CMS proposes to use its authority to extend the CAA provisions relating to mental health telehealth services to RHCs and FQHCs. **Specifically, CMS proposes to allow RHCs and FQHCs to conduct mental health visits through interactive, real-time telecommunications technology for the purposes of diagnosing, evaluating, or treating a mental health disorder.** To do so, and to avoid patients of RHCs and FQHCs losing access to their providers, the agency proposes to revise its requirement that an RHC or FQHC mental health visit must be a face-to-face (i.e., in-person) encounter to also include virtual encounters. **CMS also proposes to allow RHCs and FQHCs to furnish mental health visits using audio-only communication in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction.**

These changes would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. To track utilization of these services, CMS proposes to require RHCs and FQHCs to append the 95 modifier for audio/video mental health visits and a new service level modifier for audio-only visits. CMS seeks comment on whether it should impose a requirement similar to that specified by the CAA that there be an in-person service within six months prior to the furnishing of the telehealth service and every six months thereafter. CMS asks commenters whether such a requirement could be especially burdensome for beneficiaries that receive treatment at RHCs and FQHCs.

Payment for Evaluation & Management Visits

Over the course of several years of PFS rules, CMS has engaged in an ongoing review of payment for office/outpatient E/M visit code sets. In this rule, CMS makes various proposals to refine some aspects of other E/M visit code sets, including: (1) “split” or shared E/M visits; (2) critical care services; and (3) teaching physician services.

Split (or Shared) E/M Visits. A “split” or “shared” E/M visit is one that is performed by both a physician and a non-physician practitioner (NPP) in the same group. Because Medicare provides higher PFS payment for services furnished by physicians than those

furnished by NPPs, in this rule CMS address when physicians can bill for split visits. This issue arises for visits in facility settings, where Medicare pays either the physician *or* the NPP who personally performs all elements of the visit and makes no payment for services furnished "incident to" the billing professional's services.

Physicians in a facility setting may bill for an E/M visit when both the billing physician and an NPP (including nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwives) in the same group each perform portions of the visit, but only if the physician performs a substantive portion of the visit. In that situation, Medicare payment is equal to 80% of the otherwise applicable payment of the PFS, which is the lesser of the actual charge or the fee schedule amount for the service. If the physician does not perform a substantive part of the split visit and the NPP bills for it, Medicare will pay 80% of the lesser of the actual charge or 85% of the fee schedule rate. Due to changes to Medicare Claims Policy Manual sections that covered split visits, along with recent revisions to E/M visit coding and payment, CMS decided to address specifications around billing split visits through rulemaking this year.

To that end, CMS includes the following proposals related to split (or shared) visits:

- *Definition.* CMS proposes to define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group. CMS proposes to define facility setting as an institutional setting in which "incident to" payment is prohibited.
- *New and established patients; initial and subsequent visits*. CMS proposes to modify existing policy so as to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients and for both initial and subsequent visits.
- *Substantive portion.* CMS proposes to define the "substantive portion" of the split (or shared) visit as more than half of the total time spent by the physician and non-physician practitioner performing the visit. CMS further proposes that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time of the visit. This would establish who provided the substantive portion of the visit and therefore bills for it. CMS explains that only the time of one individual should be counted when two or more practitioners jointly meet with or discuss the patient.
- *Qualifying activities.* CMS includes in the rule a list of activities that it proposes to count toward total time for purposes of determining the substantive portion of the visit. See page 248 of the display copy of the rule for this list.
- *Claim identification*. CMS proposes to create a modifier to describe split (or shared) visits that providers would be required to append to claims for these visits.
- *Critical care services*. The agency proposes to allow critical care visits to be furnished as split (or shared) visits and delineates a unique list of qualifying activities as well as other policies specific to split (or shared) critical care.

CMS also proposes to apply its policies on split (or shared) visits to prolonged visits described by the HCPCS code G2212 finalized last year, critical care services and

Skilled Nursing Facility/Nursing Facility (SNF/NF) visits that are not required by regulations to be performed in their entirety by a physician. CMS declines to propose a definition of "same group" in this rule, but seeks comment on whether it should do so in future rulemaking.

Critical Care Services. In this rule, CMS makes several proposals related to critical care visits, including to account for the recent revisions to E/M coding and payment. Specifically, CMS proposes to adopt the prefatory language of the CPT Professional Codebook that defines critical care[1] and delineates where, when and by whom critical care services may be delivered. The CPT Codebook also describes the time duration for the correct reporting of critical care services by a single physician or QHP, which CMS proposes to adopt.

Regarding concurrent care, which the agency proposes to define as more than one physician or qualified NPP furnishing services to the same patient on the same day, CMS proposes to allow critical care services to be furnished as concurrent care if medically necessary and not duplicative. CMS seeks comment on current clinical practice for critical care and when it would be appropriate for more than one physician or NPP of the same or different specialties, within the same or a different group, to provide critical care services. CMS also includes proposals that would govern concurrent critical care furnished by practitioners in the same specialty and same group, such as for follow-up care to critical care services that the group furnished earlier in the day. CMS also proposes to bundle critical care visits with procedure codes that have a global surgical period.

Teaching Physician Services. As part of its overhaul of the office/outpatient E/M visit coding set, CMS finalized a policy last year to permit the use of medical decision making (MDM) or time to select and bill the appropriate E/M visit level rather than history and exam, which CMS deemed no longer necessary unless medically indicated. In this rule, the agency responds to questions on this MDM or time policy as it relates to teaching physicians who involve residents in furnishing care.

In general, Medicare pays for services furnished in a teaching hospital 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, subject to certain exceptions. Specifically, a teaching physician can bill for a service in which a resident participated only if the teaching physician is present for the key or critical portion of the service. **Here, CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included.** CMS believes this approach is appropriate because Medicare pays separately for residents' services through the graduate medical education program. During the COVID-19 public health emergency (PHE), time when

[1] The CPT Codebook definition of critical care is the direct delivery by a physician(s) or other qualified healthcare professional (QHP) of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition.

the teaching physician is present through audio/visual real-time communications technology can be counted toward the total time for visit level selection, but when the PHE declaration expires, virtual presence can only count in residency training sites that are located outside of a metropolitan statistical area.

CMS also includes in the rule a proposal related to the "primary care exception" policy, under which Medicare makes payment in certain teaching hospital primary care centers for certain services of lower and midlevel complexity furnished by a resident without the physical presence of a teaching physician. Specifically, the proposal would require the use of MDM – and prohibit the use of time – to select the office/outpatient E/M visit level for residents' services under the primary care exception.

Billing for Physician Assistant (PA) Services

Under Medicare regulations, PAs are authorized to furnish services that would be physicians' services if they were furnished by a physician. However, PAs are not authorized to bill Medicare and be paid directly for their services. Instead, payment for PA services may only be made to the qualified employer of a PA. The CAA reversed this policy, removing the requirement to make payment for PA services only to the employer of a PA effective Jan. 1, 2022. This would allow PAs to bill and be paid directly for their services. These changes would also allow PAs to reassign their rights to payment for their services or choose to incorporate as a group and bill Medicare. Thus, CMS proposes to amend relevant sections of its regulations to reflect the changes instituted by the CAA.

Payment for Therapy Services

As it has done in prior rulemakings, CMS in this rule implements sections of the Bipartisan Budget Act (BBA) of 2018, which required that outpatient physical and occupational therapy services furnished in whole or in part by a therapy assistant on or after Jan. 1, 2022 must be paid at 85% of the PFS amount. In the CY 2019 PFS rulemaking, CMS established two modifiers: CQ, which identifies services furnished in whole or in part by a physical therapist assistant (PTA), and CO, for services furnished in whole or in part by an occupational therapy assistant (OTA). CMS also finalized a definition of "in whole or in part" as visits during which more than 10% of the therapy service is furnished by a therapy assistant. This is known as the "*de minimis* standard." The modifiers were required on all claims beginning on Jan. 1, 2020.

In the CY 2020 PFS final rule, CMS finalized the *de minimis* standard to apply only to the minutes that the therapy assistant spends independent of the therapist. In other words, "time spent by a physical therapy assistant or occupational therapy assistant to furnish concurrent therapy, or at the same time, with the therapist, will not count for purposes of assessing whether the 10 percent standard has been met." In those situations when a therapist and an assistant furnish services simultaneously, CMS will view the service as having been fully furnished by the therapist.

In that rule, CMS further specified the situations in which the CQ/CO modifiers apply (and thus signal to Medicare to make a payment cut) and when they do not, as follows:

- Portions of a service furnished by the PTA/OTA independent of the PT/OT, that *do not exceed* 10% of the total service (or a 15-minute unit of a service), are not considered in whole or in part by a PTA/OTA, so are not subject to the payment reduction.
- Portions of a service that *exceed* 10% of the total service (or a 15-minute unit of a service) when furnished by the PTA/OTA independent of the therapist are considered to be furnished in whole or in part by a PTA/OTA, and are subject to the payment reductions.

In other words, if a PTA/OTA furnishes independently more than 10% of the total service, the CQ/CO modifiers must be appended to the claim for that service and will be paid at 85% of the PFS amount. The modifiers and *de minimis* standard apply to both untimed and timed codes.

In March 2021, CMS posted guidance on how to assign the modifiers in different billing scenarios. In this rule, CMS notes that it received feedback indicating the guidance created confusion, especially regarding how the *de minimis* standard applies to a final unit of a multiple-unit timed service. **Thus, CMS proposes that the CQ/CO modifiers would apply when the PTA or OTA furnishes 8 or more minutes of a timed unit of service, regardless of the minutes of service provided by the PT/OT. Similarly, for timed services in which a PT/OT provides 8 or more minutes of service, the modifiers would not apply, regardless of the minutes of service provided by the PTA/OTA.** This proposal rests on the "8-minute rule" under which therapists that provide services past the 15-minute midpoint of a timed service have met the Medicare billing requirements without any additional minutes furnished by the assistant.

If finalized, this revision would apply to cases where one remaining unit of a multi-unit therapy service is billed and to a limited number of cases where more than one unit of therapy, for a total time of 24-28 minutes, is being provided. In these limited cases where there are two 15-minute units left to bill and both the therapist and the assistant each provide between 9 and 14 minutes of the same service, CMS proposes to allow one 15-minute unit to be billed with the modifiers and one to be billed without.

CMS summarizes its proposals as follows, stating the *de minimis* standard would continue to apply in the following scenarios:

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

As previously finalized, the CQ/CO modifiers do not apply when the PTA/OTA and the PT/OT furnish different services or when they furnish concurrent services. Time spent

by the PT/OT and PTA/OTA providing services together is considered time spent by the PT/OT for purposes of applying the *de minimis* standard.

Request for Comments Regarding Vaccine Administration Services

CMS is soliciting comments on the costs involved in furnishing preventive vaccines, like pneumonia, flu and hepatitis B. In the proposed rule, the agency acknowledges an almost 30% decrease in Medicare payment rates over the last several years for the administration of certain preventive vaccines. CMS intends to use the information it receives to assist in developing more accurate rates for the provisions of these services. Specifically, the agency seeks information on the following:

- the different types of health care providers who administer vaccines and how that has changed since the beginning of the pandemic;
- how the costs of furnishing flu, pneumococcal and hepatitis B vaccines compare to the cost of furnishing COVID-19 vaccines; and
- how the PHE may have impacted costs, including whether those costs will continue beyond the PHE.

Additionally, CMS seeks input on the current $35 add-on payment for certain vulnerable beneficiaries who receive the COVID-19 vaccine at home, as well as what should qualify as “home” to ensure beneficiary access without sacrificing program integrity. Finally, in its proposal, the agency asks for input on whether COVID-19 monoclonal antibody treatments should be treated in the same way other physician-administered drugs and biological products are under Part B.

Laboratory Specimen Collection and Travel Allowance under the Clinical Laboratory Fee Schedule (CLFS)

The CLFS provides a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses (referred to as the travel allowance) for trained personnel to collect specimens from homebound patients and nonhospital inpatients. The travel allowance is paid only when the nominal specimen collection fee is also payable.

During the COVID-19 PHE, CMS changed the Medicare payment rules to provide payment to independent laboratories for specimen collection from beneficiaries who are homebound or nonhospital inpatients for COVID-19 testing under certain circumstances and increased payments from $3-$5 to $23-$25. Although the agency expects that the increased specimen collection fees will end at the termination of the COVID-19 PHE, it is seeking comments on its policies for specimen collection fees and the travel allowance as it considers updating these policies in the future through notice and comment rulemaking. Specifically, CMS is requesting comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and nonhospital inpatients. CMS is also requesting comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients.

Finally, CMS is also announcing that it is making permanent the option for laboratories to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample.

Beneficiary Coinsurance for Colorectal Cancer Screening Tests

In general, beneficiaries are not required to pay Medicare Part B coinsurance for colorectal cancer screening tests. However, colonoscopies and sigmoidoscopies that begin as a screening service, but have a polyp or other growth removed as part of the procedure, are no longer considered "screening" tests, and instead carry coinsurance requirements for beneficiaries. This has resulted in beneficiaries facing unexpected coinsurance charges because the procedure was classified as a diagnostic test instead of a preventive service screening test. The CAA addresses this issue by successively reducing, over a period of years, the percentage amount of coinsurance for all colorectal cancer screening tests (including a screening flexible sigmoidoscopy or screening colonoscopy test) so that for services furnished on or after Jan. 1, 2030, the coinsurance will be zero. CMS proposes to modify its regulations to implement these changes.

Expansion of Coverage for Pulmonary Rehabilitation

CMS proposes to expand coverage of outpatient pulmonary rehabilitation services to beneficiaries diagnosed with "severe manifestations" of COVID-19. CMS would define "severe manifestations" as patients requiring hospitalization in the ICU or otherwise who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge. CMS seeks comment on this proposal given the limited evidence to assess the benefits of pulmonary rehabilitation for patients diagnosed with COVID-19.

Physician Self-Referral Updates

In this rule, CMS focuses on "indirect compensation arrangements," the definition of which the agency revised in the December 2020 final rule, "Modernizing and Clarifying the Physician Self-Referral Regulations." CMS proposes to clarify that the "streamlined" two-step analysis of such arrangements that were finalized in 2020 will apply to *any* unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything *other than* services personally performed by the physician; this includes arrangements under which unit-based payments are made for leasing (or purchasing) office space or equipment.

This proposal arises out of CMS's desire to distinguish unit-based lease agreements from unit-based compensation paid for personally performed services, and thereby subject lease agreements to greater scrutiny. CMS believes that the latter such agreements are more susceptible to abuse and thus should remain subject to existing exceptions to the statute instead of coming under the less-onerous unit-based compensation rule that plays a prominent role in the streamlined analysis. To that end, CMS proposes to modify its definition of "indirect compensation arrangements" for the

purposes of the Stark law, to specifically include arrangements under which the unit of compensation received by the physician (or immediate family member) is payment for anything *other* than services personally performed by the physician (or immediate family member).

To subject this subset of indirect relationships to heightened scrutiny, CMS poses a definition to draw lines around the limited universe of service arrangements that will be subject to the unit-based compensation rule. CMS proposes to define *personally performed services* to "not include services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member)."

Addressing confusion surrounding the definition of "unit-based compensation," CMS notes that it views all compensation as essentially unit-based; as such, an underlying unit may be a discrete item, a unit of service, a unit of time or a unit that results from combining different types of units into a single unit used to calculate the compensation. The agency believes that compensation that has both time-based and service-based unit components is appropriately analyzed by converting it to compensation for a unit of time. For example, physician contracts that pay an annual salary and a productivity bonus based on work RVUs would be evaluated as unit-based compensation arrangements, where the unit of measurement is a year of service for the aggregate compensation. CMS proposes to add new language identifying the unit to consider for purposes of determining the existence of indirect compensation arrangements.

Open Payments Program

Under the "Transparency Reports and Reporting of Physician Ownership or Investment Interest" rule, known as the "open payments" rule, manufacturers of covered drugs, devices, biologicals and medical supplies ("applicable manufacturers") must submit information about certain payments or other transfers of value made to physicians and teaching hospitals ("covered recipients") during the preceding calendar year. Applicable manufacturers and applicable group purchasing organizations (GPOs) must also disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors.

In this rule, CMS proposes several changes to the Open Payments requirements, including:

- Add a context field that applicable manufactures/GPOs must complete for payments or transfers of value attributed to teaching hospitals to provide more information for these hospitals without them having to take burdensome steps to capture it.
- Add an option for a company to attest that it does not have reportable payments or transfers of value for a program year.

- Include physician-owned distributorships (PODs) as a subset of applicable manufactures/GPOs and require PODs to self-identify when registering or recertifying for the Open Payments program.
- Add a new policy that prohibits an entity that has reported payments or transfers of value under the Open Payments rule from removing, deleting, or altering the records in the Open Payments system.
- Eliminate the ability to delay general payments from publication and only permit publication delay of research payments.
- Clarify that short term equipment loans cannot exceed 90 days for an entire year, regardless of whether the days are consecutive.

Proposed Revisions to Provider Enrollment Requirements

Expansion of Authority to Deny or Revoke Based on Office of Inspector General (OIG) Exclusion

Currently CMS denies or revokes a provider's or supplier's enrollment if they, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is excluded by the OIG. **CMS proposes to expand the categories subject to these denial and revocation provisions to include excluded administrative or management services personnel who furnish services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist.** This change is not limited to services only reimbursable by Medicare or furnished by individuals listed on a Medicare enrollment application.

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

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

Creation of Specific Rebuttal Rights for Deactivations

"Deactivation" means that the provider's or supplier's billing privileges are stopped, but not revoked or terminated. Deactivation is intended to protect the provider or supplier from the misuse of its billing number and to safeguard the Trust Funds from unnecessary overpayments. Under existing regulations, a provider's or supplier's billing privileges may be deactivated if the provider or supplier: does not submit any Medicare claims for 12 consecutive calendar months; fails to report certain changes in its enrollment information within required timeframes; or fails to fully and accurately comply with a CMS revalidation request within 90 days. To reactivate billing privileges, the deactivated provider or supplier must recertify that their enrollment information on file with Medicare is correct and must furnish any missing information as appropriate.

Current regulations permit the affected provider or supplier to file a rebuttal for Medicare payment deactivations. However, while CMS has outlined deactivation rebuttal procedures in subregulatory guidance, these procedures are not reflected in regulation. **Therefore, CMS proposes to include in regulation a detailed description of the deactivation rebuttal process, consistent with its existing subregulatory guidance.**

Proposed Expansion of Authority to Deny or Revoke a Provider's or Supplier's Medicare Enrollment

CMS may revoke a provider's or supplier's enrollment if it determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In determining whether a revocation is appropriate, CMS considers, as applicable, a number of factors, including: the percentage of submitted claims that were denied; the reason(s) for the claim denials; whether the provider or supplier has any history of final adverse actions and the nature of any such actions; the length of time over which the pattern has continued; how long the provider or supplier has been enrolled in Medicare; and any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

CMS notes that it has recently encountered situations where providers and suppliers have engaged in periods of non-compliant billing that, though comparatively brief, could harm the Medicare program. In attempting to take a revocation action against such providers and suppliers, the agency has been hampered by the current wording of some of the factors outlined above. To increase its flexibility to address periods of abusive billing irrespective of their duration, **CMS proposes to revise the current factors it uses to determine whether a revocation is appropriate to be:**

(A) The percentage of submitted claims that were denied during the period under consideration.
(B) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.
(C) The type of billing non-compliance and the specific facts surrounding said noncompliance (to the extent this can be determined).
(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

CMS believes that these updated criteria permitting it to address a wider range of non-compliant billing periods in order to protect the Medicare program while still giving the provider or supplier fair consideration in its determinations.

Provider/Supplier Medical Review Requirements

CMS identifies improper payments in the Medicare Fee-for-Service (FFS) program through a variety of program integrity-related activities and uses a network of contractors to carry out program integrity initiatives. Both prepayment medical reviews and post-payment medical reviews are used to determine, among other things, whether

items or services are reasonable and necessary. Despite the statutory authority authorizing CMS contractors' activities, the agency does not have regulatory provisions governing certain medical review activities, specifically prepayment and post-payment medical reviews.

Therefore, CMS proposes key terms and definitions associated with these two review types; language codifying a contractors' authority to request additional documentation within established timeframes; and provisions detailing a provider's or supplier's responsibility to comply with requests for additional documentation, including the impact should a provider or supplier fail to comply with a request. These provisions are based on existing operational practices used by the agency's contractors. CMS believes that adding these provisions in regulation would enhance provider and supplier understanding of its medical review processes and improve consistency among its contractors.

Provisions Related to Opioid Use Disorder (OUD)

Opioid Treatment Program (OTP) Provisions

In the CY 2020 and 2021 PFS final rules, CMS implemented several definitions, requirements, payment methodologies and other programmatic aspects of a new Medicare Part B benefit for OTPs as mandated by Section 2005 of the Substance Use-disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018. In this rule, CMS proposes modifications to regulations regarding the benefits.

Take-home Supply of Naloxone. In the CY 2021 PFS final rule, CMS added dispensing of naloxone to the list of eligible opioid use disorder treatment services furnished by an OTP and established two new add-on codes (one for nasal naloxone and one for injectable naloxone) to apply to weekly bundles to account for this service. The codes cover the supply of the drug as well as dispensing and education services; CMS prices the non-drug services based on a crosswalk to the Medicare payment rate for CPT code 96161 (administration of caregiver-focused health risk assessment instrument (e.g. depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument).

CMS believes it needs to apply adjustments to the payment rates for these codes to take geographic variations in wage costs into account. Thus, the agency proposes to adjust payment rates for the non-drug component of the add-on code using the Geographic Adjustment Factor (GAF) and the Medicare Economic Index (MEI). CMS finalized the application of the GAF and MEI to payments for the non-drug component of the OTP bundled payments as well as for the add-on payments for non-drug services in the CY 2020 PFS final rule.

In addition, CMS proposes to add regulatory language to clarify its policy regarding duplicative payments. In previous rulemaking, CMS established that it can recoup payments to an OTP for services or medications provided if a claim for the same service or medication is separately paid under Medicare Part B or D for the same beneficiary on the same date of service. In this rule, CMS proposes to revise previously codified language to explicitly state that this policy also applies when those services are paid for as part of an adjustment (i.e., with use of an add-on code) to the weekly bundle.

Finally, CMS proposes to create an additional G-code to cover a take-home supply for a new, higher dose naloxone product recently approved by the FDA. Under this proposal, CMS would price the new add-on code using the same, previously finalized pricing methodology:

- Drug component: Box of two 8mg nasal sprays priced at average sales price with no add-on percentage (CMS does not currently have any pricing information for this product)
- Non-drug component: CY 2020 Medicare payment rate for CPT code 96161
- Frequency limitation: Once every 30 days, except when a further take-home supply is medically reasonable and necessary

Payment for Audio-Only Counseling and Therapy Services. In the CY 2020 PFS final rule, CMS finalized its proposal to allow OTPs to furnish the counseling and therapy portions of the weekly bundle via two-way interactive audio/video communication technology. Due to the PHE for COVID-19, CMS issued an interim final rule on Apr. 6, 2020 allowing OTPs to furnish these services using audio-only telephone calls for the duration of the PHE. After further consideration of public comments and stakeholder feedback noting that allowing audio-only telephone calls for counseling and therapy improves access to care, CMS proposes to allow OTPs to continue to provide these services via audio-only telephone calls beyond the end of the PHE in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met. CMS defines “not available to the beneficiary” as circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction.

After the conclusion of the PHE for COVID-19, OTPs would be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to claims for the counseling and therapy add-on code, HCPCS code G2080, when delivered via audio-only telephone call (but not when delivered via two-way interactive audio/video services). CMS would also require claims to include a new service-level modifier to certify that the practitioner had the capacity to furnish the services using two-way, audio/video technology but used audio-only instead. OTPs would be required to document in the beneficiary’s medical record why services were delivered via audio-only telephone call.

These requirements would take effect on Jan. 1, 2022, but would apply only for services furnished after the end of the PHE for COVID-19. If the PHE extends into 2022, the requirements would take effect when the PHE ends. CMS seeks comment on whether

the agency should implement any conditions on use of audio-only to ensure program integrity and patient safety.

Electronic Prescribing of Controlled Substances (ECPS) for Part D Drugs

In the CY 2021 PFS final rule, CMS implemented Section 2003 of the SUPPORT Act that requires prescribing of Schedule II-V controlled substances under Medicare Part D to be done electronically. In that rule, CMS finalized its proposals to require all prescribers to conduct EPCS using the NCPDP SCRIPT 2017071 standard with a mandatory compliance date of Jan. 1, 2022 (rather than the SUPPORT Act's deadline of Jan. 1, 2021) to allow flexibility in light of the PHE for COVID-19. In this rule, CMS proposes revisions to this timeline and proposes regulations for determining and enforcing compliance.

Extended Compliance Date. Because the agency believes that EPCS improves access as well as safety and security, CMS maintained Jan. 1, 2021 as the implementation date of the EPCS requirements, meaning that the agency encouraged providers to adopt the required standard as soon as possible, but delayed any enforcement activity until 2022. However, the agency notes that the challenges of the COVID-19 pandemic as well as the ongoing development of Department of Justice requirements for multifactor authentication (which would make implementing EPCS easier) has led it to reconsider the timeline to require EPCS. Accordingly, CMS proposes to change the compliance date to Jan. 1, 2023.

In addition, CMS proposes to further extend the deadline for long-term care (LTC) facilities until Jan. 1, 2025, except for prescriptions written for beneficiaries who are residents of nursing facilities and whose care is provided under Medicare Part A. CMS notes that LTC facilities face additional barriers to EPCS adoption, including a lack of appropriate guidance on the NCPDP SCRIPT 2017071 standard as well as insufficient capabilities to support the standard in rural communities. The agency states that it believes LTC-specific guidance on the NCPDP SCRIPT standard as well as improved rural broadband access will be available by the time LTC facilities are required to adopt EPCS in 2025, and thus they do not anticipate extending the timeline again.

Compliance Threshold and Exceptions. CMS believes that there are situations where EPCS may be infeasible for prescribers who otherwise would issue prescriptions electronically, including cases of temporary technological failures or when delays due to EPCS processes would adversely impact patients. Based on its review of prescription drug event data, the agency estimates that these circumstances apply in no more than 30% of instances; the agency thus proposes that providers must prescribe at least 70% of their Part D controlled substance prescriptions electronically in a calendar year to be considered compliant.

CMS notes in the rule that it believes there are very few specific scenarios where it would waive the EPCS requirement altogether. The agency proposes the following exceptions:

- when the practitioner issuing the prescription and dispensing pharmacy are the same entity;
- individual prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year, regardless of the size of the group practice to which they belong;
- prescribers who are prescribing during a recognized (i.e., declared by a federal, state, or local government entity) emergency, such as a natural disaster, a pandemic, or similar situation where there is an environmental hazard; or
- prescribers who are facing extraordinary circumstances that prevent them from EPCS but who are not in an emergency or disaster area and have received a waiver from CMS.

CMS considered, but ultimately declined to propose, the following exceptions; providers would still be held to requirements in these circumstances:

- prescriptions for drugs for which the FDA requires a prescription to contain elements that cannot be included in electronic prescribing, like risk evaluation and mitigation strategies that include elements to assure safe use (including opioids);
- prescribers working under a research protocol;
- prescriptions made for an individual enrolled in hospice; and
- prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits.

Compliance Actions. CMS has sought feedback through various requests for information and rules on appropriate penalties for non-compliance with the EPCS requirement in order to ensure the agency does not place too much burden on prescribers and inadvertently discourage appropriate prescriptions of controlled substances. CMS believes it needs additional time to gather more stakeholder feedback on the most effective and appropriate types of penalties. For now, the agency proposes to send letters to prescribers they believe to be violating the EPCS requirements during Jan. 1, 2023 through Dec. 31, 2023. The letters will provide information and resources on how to come into compliance or request a waiver. CMS will re-evaluate whether further compliance actions are necessary in future rulemaking.

Changes to the Quality Payment Program

The rule proposes updates to the requirements of the QPP for physicians and other eligible clinicians mandated by the MACRA. The QPP includes two tracks – the default Merit-based Incentive Payment System (MIPS) and advanced alternative payment models (APMs). Most of the rule's proposed policies apply to what eligible clinicians must report for the QPP's 2022 performance period, which affects eligible clinicians' payment under the Medicare PFS in CY 2023.

For the CY 2024 payment year, CMS estimates that approximately 810,000 clinicians will be MIPS-eligible clinicians and that the budget-neutral program will result in the redistribution of $587 million. CMS also would pay out $500 million in MIPS exceptional performance bonuses, as permitted under the MACRA. For the advanced APM track, CMS estimates that 225,000 and 290,000 clinicians will become qualifying participants (QPs) for the CY 2024 payment year, resulting in $600 – $700 million in lump sum bonus payments.

In this rule, CMS proposes to begin implementing voluntary MIPS Value Pathways (MVPs) beginning with the CY 2023 reporting/CY 2025 payment years. CMS also proposes several changes within each of the MIPS categories. To supplement the proposed rule, CMS has provided detailed summaries of the proposed policy changes on its QPP resource website.

Overview of the MIPS

Eligible clinicians participate in the MIPS either as individuals or as groups. Individual eligible clinicians are defined as a single clinician identified by national provider identifier (NPI) tied to single tax identification number (TIN). Groups are defined as two or more clinicians -- as identified by NPI -- that have reassigned their billing rights to a single TIN.

CMS assesses performance on four categories: quality measures, cost/resource use measures, improvement activities and promoting interoperability. Each MIPS performance category has a weight, as outlined below in Table 1. The Bipartisan Budget Act (BBA) of 2018 permits CMS to adopt a more gradual increase of the weight of the MIPS cost category – with corresponding decreases to the quality category. The BBA requires the equal weighting of cost and quality categories at 30% each starting with the CY 2024 payment year.

Table 1: MIPS Performance Category Weights, CY 2019 – CY 2024 Payment Years

MIPS Performance Category	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024[S]
Quality	60%	50%	45%	45%	40%	30%
Cost / Resource Use	0%	10%	15%	15%	20%	30%
Improvement Activities	15 %	15%	15%	15%	15%	15%
Promoting Interoperability	25%	25%	25%	25%	25%	25%

S = Statutory requirement

CMS combines the scores across the categories to create a MIPS "final score." Based on their MIPS final score, eligible clinicians and groups will receive positive, neutral or negative payment adjustments under the Medicare PFS of up to 9% in CY 2022 and beyond.

MIPS Value Pathways (MVPs)

In prior rulemaking, CMS adopted a framework for MVPs that the agency intends as a replacement for the current MIPS. MVPs organize the measure and reporting requirements for each MIPS category around specific medical conditions, clinical specialties or episodes of care. CMS has indicated it belief that MVPs would improve upon the "traditional MIPS" program by providing a "more cohesive participation experience" by aligning MIPS reporting requirements around specific topics.

In this rule, CMS proposes to implement seven optional MVPs beginning with the CY 2023 performance period. The MVPs include rheumatology, stroke care and prevention, heart disease, chronic disease management, lower extremity joint repair (e.g., knee replacement), emergency medicine, and anesthesia. The agency also proposes additional MVP development criteria, along with eligibility requirements, registration process, reporting requirements and scoring approach for MVP participants. CMS also invites comments on – but does not formally propose – a timeline in which MVP participation would become required of all MIPS participants.

MVP Development Criteria. In prior rulemaking, CMS adopted several criteria to guide its development and implementation of MVPs. In this rule, CMS proposes to add the criteria listed below:

- MVPs must include at least one outcome measure that is relevant to the MVP topic.
- Each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included
- In instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic
- Allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP.
- Each MVP must include at least one high priority measure that is relevant to each clinician specialty included.
- To be included in an MVP, a qualified clinical data registry (QCDR) measure must be fully tested.

MVP Eligibility. CMS proposes a phased approach by which eligible clinicians and groups could opt into participating in MVPs. For the CY 2023 and 2024 performance periods, CMS proposes to allow the following types of MIPS-eligible clinicians to participate:

- Individual clinicians
- Single specialty groups, which CMS proposes to define as a group in which the eligible clinicians have only one specialty type, as identified using Medicare's Provider Enrollment, Chain and Ownership System (PECOS).
- Multi-specialty groups, which CMS proposes to define as a group that consists of eligible clinicians from two or more specialty types as identified in PECOS

- Subgroups of multi-specialty groups (described in next section)
- APM entities that are assessed on an MVP for all MIPS performance categories

The formation of subgroups would be optional for multi-specialty practices for the CY 2023 and 2024 performance periods. However, beginning with the CY 2025 performance period, CMS proposes to require that any multi-specialty group practices that wish to participate in MVPs form subgroups.

MVP Subgroups. CMS indicates it received feedback suggesting that group practices would like the opportunity to have the various specialties in their groups scored on measures that are directly relevant to the care they deliver. For that reason, CMS proposes a definition and process for creating "subgroups" within multi-specialty groups.

CMS proposes to define a subgroup as follows:

> *A subset of a group that contains at least one MIPS-eligible clinician and is identified by a combination of the TIN, a subgroup identifier, and each eligible clinician's NPI*.

CMS intends to establish subgroup identifiers as part of the MVP registration process (described in the next section). CMS also proposes that subgroups would inherit the eligibility and special status determinations (e.g., small practice, hospital-based, non-patient facing) of the affiliated group. CMS notes that multi-specialty groups could form multiple subgroups and eligible clinicians with more than one specialty type also could be part of more than one subgroups.

Multi-specialty groups would not be required to form subgroups to participate in MVPs for the CY 2023 and 2024 performance periods. However, CMS encourages such groups to do so to gain familiarity with the process in advance of the required formation of subgroups for CY 2025 and beyond.

MVP Reporting Requirements. For each MVP, CMS would specify the measures for each MIPS category from which participants would choose to fulfill MVP reporting requirements. The measures for the seven proposed MVPs are provided in Appendix 3 of the proposed rule. CMS proposes the following reporting requirements for all MVP participants:

- A "foundational layer" comprised to two requirements that apply to all MVP participants. First, MVP participants would be required to select one population health measure that CMS would add to the quality score. CMS anticipates that the population health measures would include the hospital wide all-cause readmission measure it finalized for the MIPS program in last year's PFS final rule and a proposed risk-adjusted admissions measure. Second, MVP participants would be required to meet the same Promoting Interoperability category requirements as traditional MIPS.

- For the MIPS quality category, four measures selected from the measures available within each MVP. One of the selected measures must be an outcome measure or a high priority measure (in cases where an outcome measure is not available). CMS would outcome-based administrative claims measures to count towards this total.
- For the MIPS improvement activity category either two medium weight improvement activities, or one high weighted improvement activity. CMS would automatically recognize participation in a certified or recognized patient-centered medical home (PCHM) as a high weight activity.
- For the MIPS cost category, MVP participants would be scored on the cost measures CMS specifies for each MVP. These measures can be either overall or condition-specific cost measures.

The proposed MVP reporting requirements are summarized in Table 2.

Table 2: Proposed MVP Reporting Requirements

Quality	Improvement Activities	Cost
Select four measures from those available in given MVP: • One measure must be an outcome measure (or a high priority measure if an outcome is not available or applicable). • As applicable, an administrative claims measure, that is outcome-based, may be selected at the time of MVP registration.	Select from list available in a given MVP: • Two medium weighted improvement activities **OR** • One high weighted improvement activity. **OR** • Participate in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice	Scored on the cost measures included in the MVP they select and report.
Foundational Layer (applies to all MVP Participants) • Select one population health measure at the time of MVP registration (added to quality score) • Fulfill Promoting Interoperability requirements		

MVP Registration. CMS proposes to establish a registration process for MVP participants. In general, participants would be required to register between April 1 and Nov. 30 of the performance year (or later if specified by CMS). However, those groups, subgroups and APM entities that report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey would be required to complete the registration process by June 30 to align with the CAHPS for MIPS registration deadline.

At the time of registration, all MVP participants would be required to identify:

- the MVP they intend to report;
- the population health foundational measure on which they wish to be scored; and
- if applicable to the MVP, any outcomes-based administrative claims measures on which they intend to be scored.

In addition, CMS proposes that subgroups registering for the MVP would be required to:

- identify the clinicians in the subgroup by NPI and TIN; and
- provide a "plain language" name for the subgroup that CMS would use for public reporting purposes.

CMS would then assign the subgroup a unique subgroup identifier separate from the individual NPI, TIN and MVP identifiers. CMS notes that no changes to the registration would be permitted after the deadline and no late registrations would be allowed.

MVP Scoring Approach. CMS proposes that the approach to determining MVP category and MIPS final scores would generally align with those of the traditional MIPS programs, with some limited exceptions. CMS has proposed several changes to its scoring approach for the traditional MIPS, which are detailed in the MIPS Scoring section of this advisory.

MVP Performance Feedback and Public Reporting. In its annual confidential MIPS performance feedback reports, CMS proposes to show the performance of similar clinicians who report on the same MVPs. CMS also intends to report the performance of MVPs – including MVP subgroups – publicly on its *Care Compare* website. The agency proposes to begin reporting subgroup-level MVP performance beginning with the CY 2024 performance year given the novelty of subgroup reporting. CMS also proposes that it would not publicly report the first year of any newly added improvement activities or promoting interoperability measures.

MIPS APM Performance Pathway (APP)

Beginning with the CY 2021 performance period, CMS sunset the MIPS APM scoring standard and replaced it with the APP. The APP is similar to the former APM scoring standard in several ways. For example, clinicians participating in the MIPS APP are not scored on the MIPS cost category, as CMS believes APM participants already are responsible for managing costs in their APMs. In addition, CMS continues to assign MIPS improvement category scores automatically by comparing the list of available improvement activities to the APM's participation agreement and other relevant regulations. However, to qualify for the APP, clinicians and groups are required to report on a common set of six quality measures reflecting patient experience, diabetes control, depression screening, and hospital admissions and readmissions. This requirement would apply to APP participants, regardless of the APM model in which they participate.

To align with its proposals for MVPs, CMS proposes to allow MIPS eligible clinicians to report the APP as a subgroup. Subgroup definitions and eligibility are the same as those proposed for the MVPs. CMS notes that because APMs already have participant lists, subgroups reporting the APP would not be required to follow the registration process that CMS proposed for MVPs.

MIPS Eligible Clinician Definition

Beginning with the CY 2022 performance year, CMS proposes to add two additional clinician types to its list of MIPS eligible clinicians – clinical social workers and certified nurse midwives. CMS suggests this proposal is responsive to stakeholder feedback and aligns more effectively with the APM eligible clinician definition. In addition, CMS believes it has sufficient quality measures for these two clinician types to report beginning in CY 2022, including a new clinical social worker measure set.

MIPS Quality Category

For CY 2022 quality reporting, CMS would mostly carry over CY 2021 reporting requirements and scoring approaches. However, in addition to updating the inventory of available quality measures, CMS proposes several notable changes to reporting requirements and category scoring.

Measure Benchmarks. For the CY 2022 performance period, CMS proposes to use data from either the performance period itself to establish quality measure benchmark scores, or from an earlier performance year (such as CY 2019). Under existing MIPS policy, CMS uses data from two years prior to the performance period to establish quality measure benchmarks. For performance year 2022, the benchmark period ordinarily would be CY 2020. However, in light of the COVID-19 PHE, CMS is not sure whether it will have sufficiently representative data to establish benchmarks. The agency is continuing to analyze data submitted from the 2020 performance to determine to what extent it could be used to establish benchmarks.

Data Completeness. Beginning with the CY 2023 reporting period, CMS proposes to raise the quality data completeness standard from the current level of 70% to 80%. In other words, eligible clinicians and groups would be required to submit data on 80% of the patients eligible for inclusion in a given measure's denominator.

Quality Category Scoring Changes. CMS proposes several changes to its approach to scoring measures in the quality category. The current scoring policy and proposed changes, which are outlined in Table 3 below, generally apply to MVP participants as well.

Table 3: Current and Proposed MIPS Quality Category Scoring Policies

Scoring Policy	Current	Proposed (CY 2022 Reporting and Beyond)
New measures	Award three points for any new measure	Establish a five point floor for meeting the first two performance periods
Measures with benchmarks	Award minimum of three points for successfully reporting measures with a benchmark	Award scores of 1-10 points for successful points • Exception for small practices, which would continue to receive minimum of three points
Measures without benchmarks	Award three points for reporting measures that do not meet case minimum of 20 cases • Does not apply to administrative claims measures, which are	Award zero points for measures that do not meet case minimum • Exception for small practices, which would continue to receive three points • Does not apply to administrative claims measures, which are excluded if case minimum not met

	excluded if case minimum not met	
High-priority measure bonus	Award two bonus points for reporting additional outcome or high-priority measures beyond the one required outcome/high-priority measure	No bonus points for reporting high-priority measures
End-to-end Electronic Reporting Bonus	Award one bonus point for each measure reported using end-to-end electronic reporting. • Measures do not need to meet data completeness or case minimum requirements	No bonus points for end-to-end electronic reporting.

MIPS Cost Category

As in prior years, CMS would continue to score clinicians and groups on overall and episode-based cost measures calculated from Medicare claims data. Clinicians and groups are scored on only those measures for which they have a sufficient number of attributed cases.

CMS proposes to add five episode-based cost measures to the list of measures on which eligible clinicians and groups could be scored:

- Melanoma resection
- Colon and rectal resection
- Sepsis care
- Diabetes
- Asthma/Chronic Obstructive Pulmonary Disease (COPD)

MIPS Improvement Activity Category

The MACRA requires that CMS establish a MIPS performance category that rewards participation in activities that improve clinical practice, such as care coordination, beneficiary engagement and patient safety. Most of the requirements for the improvement activity category finalized in prior rulemaking would carry over for CY 2022 and beyond. As it does each year, CMS proposes updates to the improvement activity inventory by proposing seven new improvement activities, three of which are focused on promoting health equity. CMS also proposes to modify 11 activities and remove six previous adopted activities.

CMS proposes two additional key changes to the improvement activity category. First, CMS proposes a process to suspend and remove improvement activities that the agency believes raise patient safety concerns or are obsolete. CMS would use subregulatory processes (e.g., listservs or the QPP webpage) to suspend any affected improvement activities and then use notice-and-comment rulemaking to formally propose the removal of the improvement activity. Second, CMS proposes to update the

criteria used in selecting new improvement activities. The agency would consider whether an activity under consideration duplicates existing activities already in CMS inventory. The agency also would consider whether the candidate improvement activity drives improvements that go beyond standard clinical practice.

MIPS – Promoting Interoperability Category

Performance Period. As previously finalized, for the 2024 MIPS payment year (CY 2022 performance year) and future payment years, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year.

Objectives and Measures. CMS proposes to retain certain policies as well as make a number of changes to measures and other requirements beginning in 2022. Several proposals align with recent proposals for the Hospital Promoting Interoperability Program.

- *Electronic Prescribing Objective: Query of Prescription Drug Monitoring Program (PDMP) Measure*. Acknowledging continued stakeholder concerns that PDMPs are not yet consistently integrated into EHR workflows, CMS proposes to maintain this measure as optional for 2022, worth ten points. CMS seeks comment on the future direction of the measure, including what issues would need to be addressed before transitioning to a performance-based version of the measure and what exclusions, if any, should be made available.

- *Provider to Patient Exchange Objective: Provide Patients Electronic Access to their Health Information Measure.* Beginning in 2022, CMS proposes to modify the measure to require eligible clinicians to ensure that patient health information remains available indefinitely and using any application of the patient's choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR. This would include all patient health information from encounters on or after Jan. 1, 2016. CMS seeks comments on alternative encounter start dates for its proposal, including Jan. 1, 2012 and Jan. 1, 2019.

- *Public Health and Clinical Data Exchange Objective*. CMS proposes to require reporting "yes" or requesting exclusions for two of the existing measures (Immunization Registry Reporting and Electronic Case Reporting).
    - *Scoring.* Beginning with the CY 2022 performance period, eligible clinicians would receive 10 points for this objective if they report a "yes" response for the two required measures. They could also receive 10 points for the objective if they report a "yes" response for one of the measures and claim an applicable exclusion for the remaining measure. If applicable exclusions are claimed for both required measures, CMS proposes to redistribute the points for the objective to the Provider to Patient Exchange objective.

- *Optional Measures*. The remaining three measures (Public Health Registry Reporting, Clinical Data Registry Reporting and Syndromic Surveillance Reporting) would be optional and available for a total of 5 bonus points if a "yes" response is reported for any of the three optional measures.

- *Protect Patient Health Information Objective*. ONC originally developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014 which provide recommended safety practices during planned or unplanned EHR unavailability, due to events like system disruptions, systems failures or natural disasters. CMS proposes to require eligible clinicians to attest to having completed an annual assessment of the High Priority Practices Guide in a newly proposed SAFER Guides measure. Under this proposal, eligible clinicians would not be required to implement each practice described in the guide nor will they be scored on the number of practices fully implemented.

- *Prevention of Information Blocking Attestation Requirement*. As part of the Promoting Interoperability category, eligible clinicians are required to attest to three statements indicating that they do not limit or restrict the interoperability of certified EHR technology. CMS explains that the similarities between practices described in statements B and C, as well as the practices that could constitute information blocking under ONC's information blocking regulations, could create confusion for eligible clinicians. Therefore, CMS proposes to remove attestation statements B and C. Eligible clinicians would continue to be required to attest to statement A: "Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology."

Scoring Methodology. The table below includes objectives and measures as proposed for CY 2022 with associated points available for each. The Security Risk Analysis measure, SAFER Guides measure and Prevention of Information Blocking attestations would be required but would not be scored.

Scoring Methodology: Performance Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Optional: Query of PDMP	10 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points

	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	OR	
	HIE Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information*	40 points
Public Health and Clinical Data Exchange	Report the following 2 measures:* • Immunization Registry Reporting • Electronic Case Reporting	10 points
	Report any of the following 3 measures:* • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (bonus)*

* New proposals for 2022

Reweighting for Eligible Clinicians in Small Practices. Beginning with the CY 2022 performance period, CMS is proposing to no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. Instead, CMS would assign a weight of zero percent to the Promoting Interoperability category and redistribute its weight to another performance category or categories in the event no data is submitted for the Promoting Interoperability category. The small practice significant hardship exception would still be subject to annual renewal and verification as to whether the practice meets the definition of a small practice would still occur on an annual basis. CMS clarifies it is not the agency's intention to retain this policy indefinitely and requests feedback on barriers that prevent the adoption of certified EHR technology and the ability to submit Promoting Interoperability performance category measures.

Clinical Social Workers and Certified Nurse-Midwives. CMS proposes to add clinical social works and certified nurse-midwives to the definition of a MIPS eligible clinician. For the CY 2022 performance period, CMS is proposing to apply the same reweighting policy adopted previously for Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists and Certified Registered Nurse Anesthetists to clinical social workers citing that there may not be sufficient Promoting Interoperability category measures that are applicable to clinical social workers. CMS is not proposing the same policy for certified nurse-midwives but requests comment on whether there are sufficient measures available to certified nurse-midwives and what barriers exist that may warrant reweighting.

Requests for Information. CMS solicits feedback on the following topics.

- *Additional Objectives or Measures Adopting FHIR-based API Standards.* CMS indicates it intends to align the Health Information and Exchange and Public Health and Clinical Data Exchange objectives and measures with approaches using HL7 Fast Healthcare Interoperability Resources (FHIR) API functionality.

CMS seeks comments on a range of issues including current stakeholder use of APIs, how technical approaches using FHIR could enhance existing data flows under the public health measures and policy and program changes that could reduce provider and health IT developer burden under these measures.

- *Patient Access Outcomes Measures.* CMS seeks comments on potential changes to the Promoting Interoperability category to better target patient access outcomes related to the use of patient portals or third-party applications.

Clinical Notes. CMS seeks input on changes that will better support the availability of clinical notes for patients. Areas of interest include changes to the Provide Patients Access to their Health Information measure, development of a mandatory measure to allocate points for the use of clinical note types and feedback on the types of clinical notes commonly requested by patients but not easily accessible to them.

MIPS Final Performance and Payment Adjustment Approach

As required by the MACRA, CMS calculates a final composite score of zero to 100 points for each eligible clinician and group in the MIPS. The MIPS final score is used to determine whether the clinician or group receives positive, neutral or negative payment adjustments under the MIPS. CMS carries over most aspects of the scoring approach finalized in the CY 2018 QPP final rule. The AHA's 2018 QPP Final Rule Regulatory Advisory includes more details on the approach.

CMS proposes notable changes to the MIPS complex patient bonus, facility-based measurement and the performance threshold scores for payment adjustments.

Complex Patient Bonus. Since the CY 2018 performance period, CMS has calculated a "complex patient bonus" to better account for the clinical and sociodemographic differences across patient populations. This bonus awards up to five points to the MIPS final scores of clinicians and groups based on their hierarchical condition category (HCC) scores and their ratio of patients dually eligible for Medicare and Medicaid.

For the CY 2021 reporting period, CMS proposes to continue the temporary increase to the number of complex patient bonus points available to account for the impact of the COVID-19 PHE that it adopted for CY 2020 reporting period. Specifically, CMS would double the complex patient bonus such that clinicians can have up to 10 complex patient bonus points added to their MIPS final score. CMS would calculate each clinician's/practice's complex patient bonus under the previously finalized approach and simply multiply it by two.

In last year's rule, CMS indicated it would continue to assess the extent to which the complex patient bonus was benefiting clinicians and practices treating larger proportions of patients with greater medical and social risk. The proposed rule includes a CMS analysis using MIPS data from the 2018 reporting period. CMS found that clinicians with a higher share of complex patients had lower MIPS final scores on average than other clinicians. Furthermore, CMS suggests there was limited correlation between both HCC and dual proportion and MIPS final scores among the clinicians treating a lower share of

complex patients. In addition, CMS asserts that while its two chosen risk indicators for patient complexity (dual proportion and HCC) correlated substantially to one another, each score is calculated on a different scale. Furthermore, the distributions of dual proportion and HCC scores around the mean scores is different. Taken together, CMS believes these findings suggest that its current approach to the complex patient bonus may award bonus points to practices for which the impact of patient complexity is lower, while potentially not targeting the bonus sufficiently to those clinicians and practices treating larger shares of complex patients.

As a result, CMS proposes several significant changes to its approach to the complex patient bonus beginning with the CY 2022 performance period. First, CMS proposes to update its formula to standardize the distribution of HCC scores and dual proportions for calculating the complex patient bonus. MIPS eligible clinicians and groups could have up to 10 complex patient bonus points added to their MIPS final score using the following process:

1. CMS would calculate standardized risk scores for "medical" and "social" risk. The formulas are as follows:
    a. Standardized Medical Risk Score = (observed HCC score – mean HCC score)/standard deviation of HCC scores
    b. Standardized Social Risk Score = (observed dual proportion – mean dual proportion)/standard deviation of dual proportions
2. CMS would calculate the number of medical and social risk points using the following formulas:
    a. Medical Risk Bonus Points = 1.5 + 4 x (Standardized Medical Risk Score)
    b. Social Risk Bonus Points = 1.5 + 4 x (Standardized Dual Proportion Score)
3. CMS would sum the medical and social risk bonus points, awarding between zero and 10 points

Second, CMS proposes to limit the eligibility for a complex patient bonus to those eligible clinicians and groups that have least one complex patient risk indicator (i.e., HCC score or dual proportion) score at or above the median risk factor score.

Facility-based Measurement. Beginning with the CY 2019 QPP, facility-based clinicians have the option of having their MIPS quality and cost scores tied to their hospital's CMS value-based purchasing (VBP) program total performance score (TPS). For the most part, CMS's approach to facility-based measurement is unchanged from prior rulemaking with one change. CMS previously finalized that clinicians and groups meeting the eligibility criteria for facility-based measurement would be scored using the facility-based measurement methodology unless they received a higher combined MIPS cost and quality category score using another MIPS data submission.

This approach basic approach remains largely unchanged, but beginning in CY 2022, CMS proposes that the agency would use the facility-based measurement scoring

methodology unless the clinician or group receives a higher **MIPS final score** through another MIPS submission.

MIPS Final Score Thresholds. MACRA requires CMS to implement MIPS payment adjustments in a budget-neutral manner. That is, the agency may not pay out more in incentive payments than it recoups in penalties. However, for CYs 2019 through 2024, CMS also must pay out $500 million in "exceptional performance bonuses" to groups that perform exceptionally well on the MIPS. This exceptional performance bonus is above and beyond the budget-neutral MIPS payment adjustment.

As outlined in Figure 1, CMS is required by law to identify several final score thresholds to translate MIPS final scores into a payment adjustment:

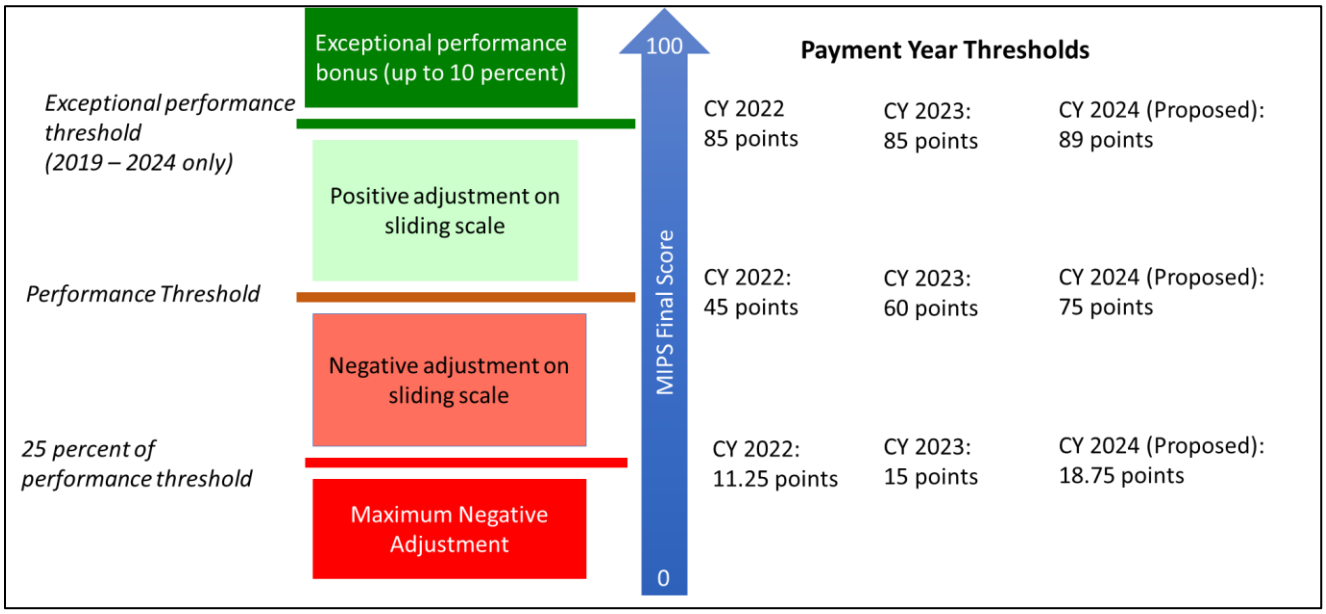
- **A performance threshold** *above which* there are positive payment adjustments on a sliding scale, and *below which* there are negative payment adjustments on a sliding scale. The MACRA requires that CMS publish this number prior to the start of the performance period so that MIPS participants know what level of performance is expected in order to receive positive or negative adjustments. For the CY 2024 MIPS payment adjustments, the performance period is CY 2022.

  CMS proposes to increase the performance threshold for the CY 2022 performance/CY 2024 payment year from 60 to 75 points. As required by law, beginning with the CY 2022 performance period, CMS must set the performance threshold at the either the mean or median MIPS performance score from a prior payment adjustment year. In this case, CMS chose the CY 2019 payment year because it would result in a more gradual increase than the alternatives.

- **25% of the performance threshold final score,** *at or below which* MIPS-eligible clinicians and groups receive the maximum negative payment adjustment (-9% in CY 2024). As a result of CMS's proposed increase to the performance threshold score, this score would change to 18.75 points beginning with the CY 2022 performance/CY 2024 payment years.

- **An exceptional performance threshold final score** *at or above which* MIPS-eligible clinicians and groups are eligible for an additional bonus beyond their positive MIPS adjustment. CMS proposes to increase this threshold to 89 points for CY 2022 performance/CY 2024 payment years. Clinicians and groups receiving a score at or above 89 points would receive exceptional performance bonuses of up to 10% on a sliding scale. **As required by law, the CY 2024 payment year is the final year in which CMS may award exceptional performance bonuses.**

Figure 1: Translating MIPS Final Score into Payment Adjustments
CY 2022 – CY 2024 Payment Years



Advanced APMs

The MACRA provides incentives for physicians who participate in advanced APMs. These include a lump-sum bonus payment of 5% of payments for professional services in 2019 through 2024; exemption from MIPS reporting requirements and payment adjustments; and higher base payment updates beginning in 2026. In 2016, CMS finalized the criteria by which clinicians will be determined to be qualified APM participants to receive these incentives. CMS will assess clinicians' participation in APMs in 2022 for the 2024 incentive payment. Advanced APM criteria and processes carry over from prior rulemaking with no significant updates.

Request for Information - Health Equity

CMS includes in the proposed rule several RFIs asking for feedback on a range of ideas for advancing health equity using its physician quality measurement programs.

Improving Demographic Data Collection. CMS notes that there are significant gaps in the availability of demographic and social risk data that prevent it from identifying the existence of disparities and tracking them over time. For that reason, the agency asks for feedback on how it could expand demographic data collection. This could include using certified information technology to collect such data, while possibly requiring clinicians to collect a "minimum set" of demographic, social, psychological and behavioral data elements using structured, interoperable data standards.

Additional Reporting of Stratified Measure Data. CMS seeks input on the future potential stratification of individual clinician quality measure results by race and ethnicity, along with potentially sharing the results of these stratified measures confidentially and publicly.

Use of Indirect Estimation. CMS also recognizes that the collection and reporting of demographic data can be resource-intensive and would take time to ramp up. For that reason, the agency is considering other intermediate ways of producing analyses of health disparities using the data it currently has. Thus CMS asks for feedback on whether and to what extent it should use a statistical modeling technique called "indirect estimation." That is, CMS could use data from existing sources like the US Census and Medicare administrative data (e.g., first and last names or the racial and ethnic composition of the patient's neighborhood) to "impute" (i.e., infer) the demographic composition of hospitals' patient populations. CMS states it would not use indirect estimation to infer the race and ethnicity of individuals; rather, the approach would be used for making clinician, group and and population-level estimates. While CMS believes that indirect estimation is statistically reliable, they recognize it could unintentionally introduce measurement bias, especially if the source data used to infer population-level race and ethnicity are inaccurate.

Request for Information - Digital Quality Measurement and Use of Fast Healthcare Interoperability (FHIR) Standards

The proposed rule includes a wide-ranging request for comment on CMS's plans to advance the use of digital quality measures (dQMs) and expand the agency's use of FHIR standards and Application Programming Interfaces (APIs) for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025. Along those lines, CMS solicits comments on several policy concepts.

CMS asks for comment on a standardized definition of dQMs that it would use across its quality measurement programs:

> *"Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a software that processes digital data to produce a measure score or measure scores. Data*

sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources."

CMS also asks for comment on a number of steps it is considering taking that it believes would enable a full transition to digital quality measures by 2025. This includes:

- Converting current CMS eCQMs to FHIR-based standards, thereby transitioning away from current quality data model (QDM) standards.
- Requiring the use of FHIR-based APIs for any measures that utilize EHR data, including eCQMs.
- Implementing dQMs that are "self-contained tools." That is, CMS is interested in promoting software solutions for dQMs that could, among other things:
    - Support the calculation of single or multiple quality measures
    - Obtain data via automated queries from a broad range of digital sources (initially EHRs, but potentially also from claims data, patient-reported outcomes and patient-generated health data
    - Generate measure score reports
    - Be compatible with any data source
    - Exist separately from data source systems
    - Be tested and updated independently of data source systems
    - Operate in accordance with health information protection laws and regulations
    - Be usable by non-technical end users
    - Have the ability to adopt to emerging advanced analytic approaches like natural language processing

- Establishing and expanding policies for data aggregation by third-parties, including health information exchanges (HIEs) and clinical registries.
- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector. The agency believes this would require a multi-stakeholder, joint Federal, State and industry effort to align measure concepts, specifications and data elements.

Medicare Shared Savings Program (MSSP)

In this rule, CMS includes proposals related to the MSSP quality measurement approach and other programmatic features of the MSSP.

Quality Measure Set and Reporting

In last year's PFS final rule, CMS adopted a policy in which it reduced the MSSP quality measure set to the same to the same six measures used in the MIPS APM

Performance Pathway (APP); eliminated the web interface reporting option and its associated measure set; and increase the quality performance standard ACOs would have to achieve to qualify for shared savings or avoid owning maximum losses.

In response to concerns about the proposal, CMS proposes a longer phase-in of the requirement to report the APP performance measure set and to delay the increase to the minimum quality standard.

Measure Reporting Requirements. For the CY 2022 MSSP performance year, ACOs would be permitted to report either the current MSSP measure set via the CMS web interface, or the MIPS APP measure set. In CY 2023, those ACOs that choose the report the web interface measure set also would be required to report at least one measure from the APP measure set. Additional details on CMS's proposals are provided in Table 4 below

Table 4: Proposed MSSP Quality Measure Reporting Requirements for CYs 2022 and 2023

Performance Year	Web Interface Option	APP Measure Option

2022	• Report the ten web interface measures
	  ○ Three measures* do not have performance benchmarks, but must still be reported
	• Report the CAHPS for MIPS survey
	• Be scored on the two APP administrative claims measures (i.e., hospital wide unplanned readmissions and hospital admissions for multiple chronic conditions)
		• Report the three APP MIPS CQM/eCQM measures:
		  ○ Diabetes Hemoglobin HbA1c Poor control (MIPS quality ID # 001)
		  ○ Preventive care and screening: Screening for depression and follow up plan (MIPS quality ID # 134)
		  ○ Controlling high blood pressure (MIPS quality ID # 236)
		• Report the CAHPS for MIPS survey
		• Be scored on the two APP claims-based measures

2023	Same as 2022, except: • Report at least one APP MIPS CQM/eCQM measure	Same as 2022

***Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438), Tobacco Cessation: Screening and Cessation Intervention (Quality ID# 236), Depression Remission at Twelve Months (Quality ID# 370)

Minimum Quality Standard. CMS proposes to delay the increase of the minimum quality standard from the 30th to the 40th percentile until the CY 2024 performance year. However, the exact ways in which the performance standards apply would vary slightly by the chosen reporting option. The details of CMS's proposals are provided in Table 5 below.

Table 5: Proposed MSSP Quality Performance Standard Policies, CYs 2022 - 2024

Performance Year	Web Interface Option	APP Measure Option
2022	ACO meets all data reporting and submission requirements and achieves quality performance score at or above the 30th percentile of all MIPS quality category scores.	ACO meets all APP data reporting requirements and achieves a quality performance score on *at least one APP measure* that is at or above the 30th percentile benchmark score for the measure.
2023	Same as 2022	Same as 2022
2024	Not available	ACO meets all APP data reporting requirements and achieves a quality performance score at or above the 40th percentile of all MIPS quality category scores

Revisions to the Definition of Primary Care Services Used in MSSP Beneficiary Assignment

Over the course of the MSSP, CMS has periodically updated the list of primary care services adopted for the purpose of beneficiary assignment. **In this rule, CMS proposes to add the following additional codes to the definition of primary care services for Performance Year 2022:**

- Chronic care management code 99X21, if finalized in through this rule;
- Principal care management codes 99X22, 99X23, 99X24 and 99X25, if finalized through this rule;
- Prolonged office or other E/M service HCPCS code G2212; and
- Communication Technology-Based Service (CTBS) HCPCS code G2252 (for a prolonged virtual check-in that can be provided via audio-only connection), if payment for this code is made permanent through this rule.

CMS also proposes to extend the timeframe for which CPT codes 99441 through 99443 (telephone E/M services) may be used for beneficiary assignment to allow time for analysis of the use of these codes and a final decision as to whether to add these formerly non-covered services to the Medicare telehealth list. **Specifically, CMS proposes to allow these telephone E/M codes to continue to be used for beneficiary assignment until they are determined to no longer be payable under Medicare FFS telehealth policies.**

Revisions to Regulations Governing Repayment Mechanisms

Through its experience to date with the MSSP, CMS has determined that the repayment mechanism amounts most ACOs are required to establish are significantly larger than needed to cover actual losses. The agency makes several proposals to address this issue, including:

- Changing the methodology used to calculate the repayment mechanism amount so as to lower the required amount;

- Changing the methodology for the annual repayment mechanism amount recalculation to more clearly specify the assigned population used as a multiplier in calculating the repayment mechanism amount; and
- Offering ACOs already in two-sided participation agreements a one-time opportunity to decrease the amount of their repayment mechanism.

Reducing Shared Savings Program Application Burden

CMS shares its finding in this rule that the MSSP application document submission requirements substantially increase applicant burden without providing significant value. Thus, CMS proposes to modify three provisions of its application requirements. First, CMS proposes that the prior participation disclosure requirement be prescribed only at the request of the agency during the application process, rather than as a mandatory submission with the ACO's initial or renewal application. Second, CMS proposes to remove provisions that require an ACO to submit sample ACO participant agreements during the application process. While ACOs would still be required to certify that their participant agreements comply with the requirements of the MSSP, they would have to submit sample participant agreements only if requested by CMS. Third, CMS proposes to remove provisions requiring an ACO to submit an executed agreement for each ACO participant at the time of its initial application or participation agreement renewal process. An ACO would still need to submit an executed ACO participant agreement for each ACO participant that it wishes to add to its list of participants.

Beneficiary Information Notice for ACOs with Prospective Assignment

In this rule, CMS indicates that the existing requirement for ACOs to provide notifications to all FFS beneficiaries prior to or at the first visit of the year is overly broad for ACOs that have selected prospective assignment. The requirement means that prospective assignment ACOs are providing beneficiary notifications to beneficiaries that will never be assigned to them and that beneficiaries are receiving information that will never be relevant to them. **Thus for prospective assignment ACO, CMS proposes to require the ACO or its participants to provide the standardized written beneficiary notice prior to or at the first primary care visit of the performance year only to those beneficiaries prospectively assigned to the ACO.** For ACOs that select preliminary prospective assignment, the ACO or its participants must continue providing the standardized written beneficiary notice to each FFS beneficiary prior to or at the first primary care visit of the performance year. This is because for ACOs under preliminarily prospective assignment with retrospective reconciliation, the preliminary prospective assignment list provided to the ACO at the beginning of the performance year does not include all FFS beneficiaries who may ultimately be assigned to the ACO.

CMS also seeks comment on whether it should modify the frequency at which the beneficiary information notice must be furnished, for example, by reducing the frequency of the existing requirement from annually to once per agreement period.

Request for Comment on Using Regional FFS Expenditures for ACOs' Historical Benchmark

To calculate ACOs' historical benchmark, CMS uses historical expenditures for the ACO's assigned beneficiaries and factors based on regional FFS expenditures, national FFS expenditures and a blend of the two. To calculate regional expenditures, CMS uses average county FFS expenditures for *assignable* beneficiaries, which includes the beneficiaries actually assigned to the ACO. **The AHA and other stakeholders have expressed concerns to CMS that this methodology penalizes efficient ACOs, especially in areas, such as rural areas, where an ACO may have high market penetration.**

In this rule, CMS discusses considerations and ideas to respond to these concerns, though the agency notes that any modifications to the MSSP would come from a separate notice and comment rulemaking. One such idea is an approach CMS believes would carry a limited operational burden and rely on data already computed under the current benchmarking methodology. Specifically, CMS describes an approach that relies on a premise that per-capita risk-adjusted regional FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of the FFS expenditures for the ACO's assigned beneficiaries (b) and the assignable beneficiaries in the region who are not actually assigned to the ACO (c). Under this approach, the weight on (b) would be the ACO's regional market share and the weight on (c) would be one minus the ACO's regional market share.

As an equation, this is:

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

To remove an ACO's assigned beneficiaries from the regional market expenditure calculation, CMS would solve for (c) as follows:

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

CMS simulated the use of this approach and found that the average increase in the updated benchmark by quintile ranged from 0.1% to 1.4%, although some ACOs saw decreases in their benchmarking amounts. ACOs with higher market shares tended to see slightly higher average increases than ACOs with lower market shares; rural ACOs saw slightly higher average increases than non-rural ACOs. **CMS seeks comment on several issues related to the use of regional FFS expenditures in benchmarks, including:**

- CMS' approach or alternative approaches to calculating regional FFS expenditures without including an ACO's assigned beneficiaries.
- Whether market penetration should be considered in benchmark calculations and what constitutes heavy penetration in the ACO's regional service area.
- Possible unintended consequences that could result from removing an individual ACO's assigned beneficiaries from regional calculations. For example, whether this could lead to ACOs seeking out healthier beneficiaries and avoiding at-risk or higher-cost beneficiaries, incent the formation of large ACOs, or create instability

in regional FFS expenditures from removal of an individual ACO's assigned beneficiaries.
- Whether removal of an ACO's assigned beneficiaries from regional FFS calculations brings about a need to remove ACO assigned beneficiaries from other MSSP financial calculations.
- Other approaches to calculating benchmarks that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure calculations, such as basing these expenditures on a larger geographic area, including using state-level data, Core-Based Statistical Area, or some other combination.

CMS also requests comment on issues related to its risk adjustment methodology. The current risk adjustment methodology that CMS uses to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries is subject to a cap of positive 3% for the agreement period. This means that that any risk score growth between Benchmark Year 3 and any performance year in the agreement period cannot be larger than 3%. CMS mentions that stakeholders (including the AHA) have expressed concern that this does not allow the agency to account for risk score growth in the ACO's regional service area, thereby penalizing ACOs.

To address these concerns, CMS seeks comment on the following issues:

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

Next Steps

The AHA will host a members-only webinar on Aug. 12 at 2:30 ET to discuss the provisions of the proposed rule and gather input from the field for AHA's comment letter and advocacy to CMS. Register for this webinar here.

The AHA encourages members to submit comments on how CMS's proposals would affect their facility. Comments are due Sept. 13 by 5 p.m. ET and may be submitted electronically at http://www.regulations.gov. Follow the instructions for "submitting a comment." CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

Further Questions

For further questions, please contact Shira Hollander, AHA's senior associate director for payment policy, at 202-626-2329 or shollander@aha.org, or Akin Demehin, AHA's director for quality policy, at 202-626-2365 or ademehin@aha.org.