

## **Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2022 Detailed Summary of the Payment and Quality Payment Program Provisions**

The American College of Radiology (ACR) has prepared this detailed analysis of proposed changes to the Medicare Physician Fee Schedule (MPFS) in calendar year (CY) 2022. The ACR will submit detailed comments to Centers for Medicare and Medicaid Services (CMS) by the September 13<sup>th</sup> comment period deadline. If finalized, the rule changes will be effective Jan. 1, 2022.

### **Conversion Factor and CMS Overall Impact Estimates (Page 1178)**

CMS estimates a CY 2022 conversion factor of \$33.5848 compared to the 2021 conversion factor of \$34.8931. CMS estimates an overall impact of the MPFS proposed changes to radiology to be a 2 percent decrease, while interventional radiology would see an aggregate decrease of 9 percent, nuclear medicine a 2 percent decrease and radiation oncology and radiation therapy centers a 5 percent decrease if the provisions within the proposed rule are finalized. Part of the decrease is due changes in RVUs, redistributive effects of the CMS proposed clinical labor pricing update, and phase-in implementation of the previously finalized updates to supply and equipment pricing.

The Consolidated Appropriations Act, 2021 (P.L.116-260) included a 3.75 percent adjustment to the 2021 conversion factor which contributed to the reduction of payment cuts to radiologists from 10 percent to approximately 4 percent. If Congress does not intervene and there is no 3.75 percent bump to the proposed 2022 conversion factor, the potential higher end of the overall percent reduction for 2022 is approximately 6 percent for radiology, 13 percent for interventional radiology, 5 percent for nuclear medicine, 14 percent for radiation therapy, and 8 percent for radiation oncology.

### **Appropriate Use Criteria for Advanced Diagnostic Imaging (Page 383)**

#### *Background and Overview*

The Protecting Access to Medicare Act of 2014 included a provision for the mandatory use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The program was initially slated to begin on January 1, 2017, but faced a series of setbacks as CMS has gone through the rulemaking process to lay out the details of AUC program implementation. An “educational and operations testing period” began on January 1, 2020, and was extended through the end of 2021 due to the COVID-19 public health emergency (PHE).

Through the CY 2016 rulemaking process, CMS addressed the initial component of the AUC program, specifying applicable AUC. CMS established a process for the development of AUC, defined provider-led entities (PLEs), and established the process by which PLEs may become qualified to develop AUC. The first list of [qualified PLEs](#) was posted on the CMS website in late June 2016.

The CY 2017 MPFS final rule identified the requirements clinical decision support mechanisms (CDSMs) must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified. The first list of [qualified CDSMs](#) was posted to the CMS website in conjunction with this proposed rule.

CMS also defined applicable payment systems under this program (MPFS, Hospital Outpatient Prospective Payment System (HOPPS), and Ambulatory Surgical Center (ASC) payment system), specified the first list of priority clinical areas for the identification of outlier ordering professionals, and identified exceptions to the requirements that ordering professionals consults specified applicable AUC when ordering applicable imaging services. In the CY 2019 MPFS final rule, independent diagnostic testing facilities (IDTFs) were added to the definition of applicable settings.

The CY 2018 MPFS final rule addressed consultation and reporting requirements. In this rule, CMS established a program start date of January 1, 2020, beginning with a one year “educational and operations testing period”. CMS specified that for services ordered on or after this date, ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. CMS specified that during the testing period, claims would not be denied for failure to include proper AUC consultation information. In addition, CMS established a voluntary reporting program from July 2018 through the end of 2019. Consultation of AUC using a qualified CDSM was designated as a high-weight improvement activity for ordering professionals for the Merit-based Incentive Payment System (MIPS) beginning January 1, 2018.

When the AUC program is fully implemented, the following information must be included on all claims for applicable advanced diagnostic imaging services:

1. The qualified CDSM consulted by the ordering professional;
2. Whether the service ordered would or would not adhere to specified AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and
3. The NPI of the ordering professional.

Detailed claims processing [instructions](#) are published on the CMS website.

CMS will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services.

#### *Timing of Payment Penalties*

The AUC program is currently scheduled to enter the payment penalty phase on January 1, 2022. However, given the many complexities around the scope and application of AUC program

claims processing edits, CMS believes that notice and comment rulemaking is the most appropriate means to discuss the implementation and claims processing issues and to obtain stakeholder feedback. In addition, CMS recognizes the circumstances of physicians and other practitioners due to the PHE for COVID-19 and that additional time may be needed to prepare for the payment penalty phase.

The earliest the CMS claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. CMS notes that an effective date for the claims processing edits in October is not aligned with typical annual updates to the systems used by healthcare providers. Therefore, the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

**CMS is proposing a flexible effective date for the AUC program payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19.**

CMS acknowledges that the AUC program has been significantly delayed and that some practitioners and institutions have already invested in qualified CDSMs while others have had to redirect resources due to the PHE. **CMS seeks public comment on the payment penalty start date and the readiness of practitioners, facilities, and EHR and CDSM vendors.**

#### *Proposed Clarification of AUC Program Scope*

##### *Modified Orders*

CMS acknowledges that updates or modifications to orders for imaging services may be necessary in certain situations once the beneficiary is under the care of the furnishing professional. The AUC program does not allow furnishing professionals to consult AUC on behalf of or in place of the ordering professional. Chapter 15, sections 80.6.1-4 addresses situations where the furnishing professional performs imaging services that are different from ordered services. The rules state that a different or additional imaging service not included on the order generally may not perform the test until a new order from the treating physician/practitioner has been received. If the treating physician/practitioner cannot be reached, the furnishing physician or testing facility may perform the additional services under the following conditions as documented in the patient's medical record:

- The treating physician/practitioner could not be reached,
- The ordered test is performed and an additional diagnostic test is medically necessary because of the abnormal result of that test,
- Delaying performance of the additional test would have an adverse effect on the patient's care,
- The result of the additional test is communicated to and used by the treating physician/practitioner in the patient's treatment, and
- The interpreting physician documents in the report the reasons for the additional testing.

**CMS proposes that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the above circumstances, neither the ordering professional nor the furnishing professional are required to consult AUC for the additional service(s). In these situations, the furnishing professional would report the AUC consultation information from the original order on the claim for the additional service(s). Similarly, if the furnishing professional modifies the order for an advanced diagnostic imaging service without obtaining a new order from the ordering professional, the AUC consultation information provided by the ordering professional with the original order should be reported on the claim.**

#### *Extreme and Uncontrollable Circumstances Hardship Exception*

In the CY 2019 final rule, CMS describes the extreme and uncontrollable hardship exception as including natural or man-made disasters that have a significant impact on healthcare operations, area infrastructure or communication systems. CMS acknowledges that stakeholders have endured challenges in continuing to prepare for the payment penalty phase of the AUC program due to the COVID-19 PHE. **The proposed rule states that stakeholders may attest to a significant hardship exception for the AUC program due to COVID-19 throughout the PHE. When the AUC program progresses into the payment penalty phase, this option will continue to be available for ordering professionals beyond the date the PHE expires.**

#### *Claims Processing*

CMS has encountered a number of operational and administrative issues with reporting and processing claims containing AUC consultation information. The Agency's main concern is ensuring that only appropriate claims are subject to AUC claims processing edits so claims are not inappropriately denied during the penalty phase. CMS acknowledges that inappropriate denials would disproportionately impact radiologists, hospital outpatient departments and freestanding imaging centers. A review of CY 2020 Medicare claims estimates that approximately 9-10 percent of all claims subject to the AUC program reported information sufficient to be considered compliant with the program (noting that the AUC program is in the educational and operations testing period). An additional 6-7 percent of claims subject to the AUC program included some relevant information, demonstrating an awareness of the AUC program.

#### *Ordering Professional NPI*

There are locations on both the practitioner and institutional claim types to report the NPI of the ordering professional. The institutional claim uses the K3 segment and the practitioner claim uses the referring professional field. In order to fully implement the AUC program, CMS must establish a claims processing edit to require these fields to be populated on all advanced diagnostic imaging claims subject to the AUC program.

In addition, there currently are situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim. This would not be workable for purposes of reporting AUC consultation information because the referring professional field is reported at the claim-level and not at the claim line- or service-level for professional claims. Therefore, the furnishing professional will need to submit separate claims for the services ordered by each referring or ordering professional since only one ordering professional can be reported per claim.

#### *Critical Access Hospitals*

Imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program. Generally, all claims for advanced diagnostic imaging services, both the professional component (PC) and technical component (TC), must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. When advanced diagnostic imaging services are performed in the CAH setting, this is not an applicable setting and as such, neither the PC nor TC claim is required to include AUC consultation information.

**CMS proposes that claims submitted by physicians or practitioners for the PC of an advanced diagnostic service when the TC was not furnished in an applicable setting would not be subject to the AUC program.** There is currently not a systems-based way for CMS to recognize a PC claim that was performed in a CAH. Place of service codes reported on practitioner claims are not specific enough. Therefore, **CMS is proposing to establish a separate HCPCS modifier that will be used to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program.**

#### *Maryland Total Cost of Care Model*

Similarly to the CAH issue described above, if both the PC and TC for advanced diagnostic imaging services are not paid under an applicable payment system, neither the PC nor TC claim is required to include AUC consultation information. **Advanced diagnostic imaging services furnished in outpatient departments of Maryland hospitals that participate in the Hospital Payment Program within the Maryland Total Cost of Care Model are not subject to the AUC program because these services are not paid under an applicable payment system.**

CMS believes they can identify all institutional claims from a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model based on their CMS Certification Number (CCN) and allow those claims to bypass AUC program claims processing edits. The Agency understands that when the TC and PC of advanced diagnostic imaging services are billed separately, the professional claim must identify in box 32 the location where the TC of the imaging service was furnished to the patient. Therefore, CMS will have the ability to identify situations in which the imaging service was furnished in a hospital that is paid under

the Hospital Payment Program within the Maryland Total Cost of Care Model and exclude those claims from being subject to AUC program claims processing edits. This can be accomplished by using the CCN and CMS will continue to work to determine if a list of CCNs can be used as the source of our edits in addition to determining the frequency that the list will be updated.

Note that advanced diagnostic imaging services performed in hospital outpatient departments of hospitals in the state of Maryland that bill under the Hospital Outpatient Prospective Payment System are subject to the AUC program.

**CMS seeks comments on other similar models that may be exempt from the AUC program.**

*Inpatients Converted to Outpatients*

There are uncommon situations where a beneficiary's hospital inpatient status is changed to outpatient. If the criteria for this to occur are met, condition code 44 (inpatient admission changed to outpatient) is appended to the institutional claim. CMS proposes to allow institutional claims with condition code 44 to bypass AUC claims processing edits. Professional claims in this situation would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is an inpatient status.

*Deny or Return Claims that Fail AUC Claims Processing Edits*

Once the penalty phase of the AUC program begins, claims that do not properly include AUC consultation information will not be paid. **CMS is considering whether claims that do not pass the AUC claims processing edits 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. CMS is requesting comments to help them better understand which path would be most appropriate once the program is fully implemented. CMS is also seeking comment on whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time.**

*Medicare as a Secondary Payer*

CMS has heard from stakeholders that in some electronic health records (EHRs), the primary payer information is readily available and known to the ordering professional, but secondary payer information is not typically available. In addition, in many cases where Medicare is the secondary payer, no Medicare payment is made after the primary payer makes payment. Medicare is reported as a secondary payer in approximately 1.5 percent of advanced diagnostic imaging claims that are subject to the AUC program. **CMS proposes to exclude claims that identify Medicare as the secondary payer from the AUC program.**

### *Date of Service and Date of Order*

Medicare claims include a date of service, but not the date of an imaging order. **CMS proposes that the AUC program claims processing edits for the payment penalty phase will be applicable for advanced diagnostic imaging services furnished on or after the effective date of the AUC program. For imaging services ordered prior to, but furnished on or after the effective date, the furnishing professional would apply the separate HCPCS modifier described in the CAH section of the rule to indicate that the claim is not subject to the AUC program.**

### *HCPCS Modifiers*

CMS has established two sets of modifiers for the AUC program. The first set is to be included on the same claim line as the G-code identifying the CDSM that was consulted and reports whether or not the imaging service adheres to the AUC.

- Modifier ME – Imaging service adheres to the AUC
- Modifier MF – Imaging service does not adhere to the AUC
- Modifier MG – The qualified CDSM does not contain AUC that applies to the order

The second set of HCPCS modifiers is available for use when the ordering professional does not consult a qualified CDSM. These claims would not include a G-codes for a CDSM since there was no consultation and as such, the modifier would be included on the same line as the procedure code for the imaging service that was performed.

- Modifier MB – Insufficient internet access
- Modifier MC – EHR or CDSM vendor issues
- Modifier MD – Extreme and uncontrollable circumstances
- Modifier MA – Patients with a suspected or confirmed emergency medical condition

Modifier QQ was created for use during the voluntary reporting period before more detailed modifiers and codes were created. This modifier continues to be available for use through the educational and operations testing period, but CMS intends to end the use of that modifier when the penalty phase begins.

Modifier MH was created for use during the educational and operations testing period to identify claims for which AUC consultation information was not provided to the furnishing professional and facility. When the AUC program enters the penalty phase, this modifier will no longer be available since all claims will be required to include AUC consultation or a specific reason the information is not required. **Beginning for services furnished on and after the effective date of the penalty phase of the AUC program, CMS proposes to redefine modifier MH to describe situations in which the ordering professional is not required to consult AUC (e.g. CAH claims and Maryland Total Cost of Care Model).**

*Additional Claims Processing Information*

**For institutional claims, CMS proposes to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient).** This claim type code encompasses the hospital outpatient department and the emergency department which represent all applicable settings under the program that would bill Medicare using institutional claims.

**For practitioner claims, CMS proposes to limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC).** These place of service codes should encompass all applicable settings under the AUC program. Because these type of bill and place of service codes reflect the applicable settings within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements, CMS believes setting these parameters will allow them to more accurately pay claims while avoiding the need for other types of professionals and facilities to append modifiers to their claims.

**CMS requests feedback on all of the above claims processing proposals, whether additional scenarios require consideration and whether the proposed claims processing solutions will adequately address the issues raised. CMS also requests feedback on areas that stakeholders believe more education is needed to inform its ongoing outreach and education efforts.**

Interesting to note: There is a section of the rule that discusses valuation of new technologies and artificial intelligence. In this section, CMS mentions the AUC program for advanced diagnostic imaging as a model to promote appropriate use and seeks comments on whether services involving innovative technology should require mechanisms such as AUC to “guard against overutilization, fraud, waste, or abuse.”

**Billing for Physician Assistant (PA) Services (pg. 272)**

Historically, nurse practitioners (NPs) and clinical nurse specialists (CNSs) are authorized to bill the Medicare program and be paid directly for their professional services, while payment for PA services must be made to the PA’s employer. The payment amount for the services of PAs, NPs, and CNSs is equal to 80 percent of the lesser of the practitioner’s actual charge or 85 percent of the amount that would be paid to a physician under the PFS. The regulation also specifies that a group of PAs that incorporate to bill for their services is not a qualified employer. Given the statutory requirement that CMS make payment to the PA’s employer, PAs are precluded from directly billing the Medicare program and receiving payment for their services, and do not have the ability to reassign Medicare payment rights for their services to any employer, facility, or billing agent. The Consolidated Appropriations Act (CAA) of 2021 made amendments to remove the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022.

With the removal of this requirement, PAs will be authorized to bill the Medicare program and be paid directly for their services in the same way that NPs and CNSs do. CMS proposes to



amend pertinent sections of their regulations to reflect the amendment made by section 403 of the CAA. CMS proposes to amend § 410.74(a)(2)(v) to specify that the current requirement that PA services must be billed by the PA's employer in order to be covered under Medicare Part B is effective only until January 1, 2022. Additionally, CMS proposes to add a new paragraph that will be effective for services furnished on or after January 1, 2022, that payments will be made to a PA for their professional services, including services and supplies furnished incident to their services. CMS will update their program manual instructions to reflect the statutory change made by section 403 of the CAA and the changes to these regulations.

### **Market-Based Supply and Equipment Pricing Update (Page 39)**

In 2019, CMS contracted with StrategyGen to review and update the prices for over 1300 medical supplies and 750 equipment inputs. As a result of this effort, many codes had a significant decrease in their PE RVUs. For existing codes with a decrease over 19 percent, CMS proposed a four-year phase-in of the PE RVU reduction. 2022 marks the last year of the phase-in.

For 2022, CMS received updated invoices for eight supply and equipment items. However, none of these items pertain to Radiology.

The full list of updated prices for CMS supplies and equipment inputs are available on the CMS website. CMS continues to welcome stakeholder feedback on the updated pricing of supplies and equipment, and will consider any new invoices submitted.

### **Clinical Labor Pricing Update (Page 48)**

CMS is proposing to update their prices for clinical labor staff, which has not been updated since 2002. This review is partially in response to the recent efforts to update the supply and equipment prices, and also due to stakeholders' concerns about clinical labor costs not being reflective of current wages. Updating the clinical labor would also maintain relativity within the direct PE, since the supply and equipment are reaching the end of their four-year phase-in.

CMS is proposing to use 2019 data from the Bureau of Labor Statistics (BLS), citing it as the most accurate source. However, they will use other resources such as Salary Expert, or a crosswalk methodology, where appropriate, if the BLS does not contain the staff type. Based on the proposed pricing update provided by CMS in Table 5 of the MPFS Proposed Rule, it appears that all of the clinical labor types will receive a positive increase. However, these increases have yielded an overall negative impact on some specialties such as vascular surgery, radiation oncology, and interventional radiology. Practice Expense is budget neutral. Therefore, specialties with most of their direct costs linked to supplies and equipment are more likely to experience a negative impact with an increase in the clinical labor wages.

Of note for Radiology, is that the BLS data did not have wage data specific for a Mammography Technologist. Instead, CMS used data from Salary Expert to identify and use Respiratory Therapist BLS data as a proxy to calculate the proposed wage for a Mammography Technologist. Similarly, since BLS data only contains wage data for a general physicist, CMS is proposing to

apply the 75<sup>th</sup> percentile of the average wage data for the physicist to determine the wage for a Medical Physicist.

CMS is considering a four-year phase-in of the updated clinical labor pricing, similar to what they did for the supply and equipment pricing updates. CMS welcomes stakeholder feedback on the updated pricing, especially for the clinical staff types for which they did not have direct BLS data and utilized proxies to calculate the wage. They are looking for sources of direct wage data, as well as suggestions for more appropriate proxies to use from the BLS data.

### **Potentially Misvalued Services Under the PFS (Page 66)**

Nine CPT codes were nominated as potentially misvalued through public nomination. However, none of those codes pertain to Radiology.

### **Proposed Valuation of Specific Codes for CY 2021 (Page 131)**

*Needle Biopsy of Lymph Nodes (CPT code 38505) (Page 146)*

CPT Code 38505 (*Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)*) was identified on a screen for Harvard Valued codes with utilization over 30,000. The code was reviewed at the January 2020 RUC meeting, at which the RUC approved an increased work RVU of 1.59, due to changes in technology and the dominant specialty. CMS is proposing to accept the increased work RVU of 1.59, as well as the RUC-recommended PE inputs.

*Trabecular Bone Score (TBS) (CPT codes 77X01, 77X02, 77X03, and 77X04) (Page 171)*

Four new codes for Trabecular Bone Score (TBS) were created by the CPT Editorial Panel: 77X01 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual x-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk*), 77X02 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere*), 77X03 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only*), and 77X04 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture risk only, by other qualified healthcare professional*). Two of the codes, 77X02 and 77X03 are PE-only codes and do not have a physician work component.

One of the new PE supply inputs recommended by the RUC for CPT codes 77X01 and 77X03 is the “TBS iN Sight Software,” which is priced “per click” for use with the software. This type of input does not translate into the current PE methodology, as it would typically be considered an indirect input. For this reason, CMS is proposing to crosswalk the PE values for the TBS code family, using CPT code 71101 (*Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views*), as a comparator at 0.94 PE RVUs. The sum of 77X02, 77X03, and 77X04 should equal that of 77X01. CMS is looking for feedback on the use of this methodology to value the PE for the TBS codes, as well as general comments on the PE methodology.

## **Removal of Selected National Coverage Determinations (Page 407)**

CMS periodically identifies and removes National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. When an NCD is removed, coverage decisions are then deferred to local Medicare Administrative Contractors (MACs).

Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare and initial coverage determinations for those items and services are made by MACs. On the other hand, removing an NCD that does not allow coverage for an item or service allows MACs to cover the item or service if the MAC determines that such action is appropriate. Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses.

**CMS is proposing to remove the NCD for Positron Emission Tomography (PET) Scans (220.6).** CMS believes that allowing local contractor discretion to make a coverage decision for PET scans better serves the needs of the Medicare program and its beneficiaries. This NCD was established in 2000 and indicated broad national non-coverage for non-oncologic indications of PET. This meant that CMS required that every non-oncologic indication for PET must have its own NCD in order to receive coverage.

In 2013, CMS reconsidered the NCD to allow coverage for diagnostic PET imaging for oncologic uses not already determined by an NCD, to be made at the discretion of local MACs, due to “various improvements in the technical, regulatory and professional aspects of PET imaging for diagnosis.” Since the 2013 reconsideration, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents.

CMS believes that local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates for non-oncologic indications. Therefore, CMS is proposing to eliminate subsection 220.6 to remove the broad national bar to coverage of PET scans for non-oncologic indications, thus allowing local Medicare contractors to make a coverage determination. CMS is not proposing to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 would not be changed by this proposal.

**CMS is soliciting comment on the proposed elimination of the NCD for PET Scans as well as comments recommending other NCDs for CMS to consider for future removal. The Agency requests that commenters include a rationale to support comments.**

**Proposal for Regulations Governing Prepayment and Post-Payment Medical Review (Page 597)**

CMS identifies improper payments in the Medicare Fee-for-Service (FFS) program through a variety of program integrity-related activities, and use a network of contractors to carry out program integrity initiatives, including Recovery Audit contractors (RACs), the Supplemental Medical Review Contractor (SMRC), Unified Program Integrity Contractors (UPICs), Medicare Administrative Contractors (MACs), and the Comprehensive Error Rate Testing (CERT) contractor. Both prepayment and post-payment medical reviews are used by CMS contractors to determine, among other things, whether items or services are reasonable and necessary under section 1862(a)(1) of the Act.

**Despite the statutory authority authorizing CMS contractors' activities, there are no regulatory provisions governing certain medical review activities, specifically prepayment and post-payment medical reviews.**

In this proposed rule, CMS is proposing 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 contractors. **CMS believes that adding these provisions in regulation will enhance provider and supplier understanding of CMS' review processes, as well as improve consistency among the contractors.**

*Proposed Key Terms and Definitions*

To ensure consistency across prepayment and post-payment reviews and establish clear requirements, CMS proposes adding the following key terms and their definitions to § 405.902:

- *Additional documentation* - the information requested by a contractor when conducting a prepayment review or post-payment review.
- *Additional Documentation Request (ADR)* - a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review.
- *Post-payment medical review* (or post-payment review) - a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate.
- *Prepayment medical review* (or prepayment review) - a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

**The proposed definitions outlined above would be consistent with longstanding manual language and common use of these terms by CMS contractors.**

### *Prepayment Medical Review Provisions*

CMS proposes adding a new regulation § 405.903 to outline the prepayment medical review provisions. CMS is proposing to codify its contractors' authority to conduct prepayment medical review on selected claims to determine whether and how much payment should be made. They are proposing language detailing the contractors' authority to request additional documentation while conducting a prepayment review. CMS proposed that a provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request. The contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation. Lastly, CMS proposed to specify that a contractor's prepayment review will result in an initial determination under § 405.920. These provisions reflect longstanding requirements MACs have used in conducting prepayment reviews.

### *Post-Payment Medical Review*

CMS proposes adding a new regulation § 405.929 to outline the post-payment medical review provisions. Similar to pre-payment provisions, CMS is proposing language outlining its contractors' authority to select claims and conduct post-payment medical reviews and that specifies the contractors' authority to request additional documentation. Additionally, the contractor will give a provider or supplier 45 calendar days to submit additional documentation in response to a request. A contractor may accept documentation received after 45 calendar days for good cause. **Good cause is defined the same for pre-post payment reviews. CMS proposes that when conducting a post-payment review, a contractor's review will result in either no change or a revised determination under § 405.984.**

CMS is also proposing to add new § 405.930 to clearly outline its contractors' authority to deny a claim should a provider or supplier fail to convey the additional documentation in response to a request. The proposed language clarifies that the contractor must give the provider or supplier notice and time to respond to the additional documentation request.

Lastly, CMS is proposing to revise the section heading of § 405.986(a) to read, "Establishing good cause for reopening." This revision clarifies the distinction made between the process for establishing good cause to reopen an initial determination made on a claim, and the good cause factors that may be applied in accepting documentation submitted after the applicable timeframes. In establishing criteria to determine whether to accept late documentation in response to an ADR, CMS is adopting the criteria set forth in §§ 405.903 (pre-payment provisions) and 405.929 (post payment provisions), and **CMS is not utilizing the good cause criteria for reopening an initial determination on a claim in § 405.986. CMS believes this change will add further clarification to the substantive text to reflect that the section only applies to reopening of initial determinations on a claim.**

As with prepayment reviews, these provisions reflect longstanding requirements contractors have used in conducting post-payment reviews.

Last year, the Centers for Medicare and Medicaid Services (CMS) issued MLN Matters Number: [MM11659 Special Provisions for Radiology Additional Documentation Requests](#) with an implementation date of December 1, 2020. This change request discusses a pilot process enabling Medicare Administrative Contractors (MACs) to request pertinent documentation from the treating/ordering provider during medical review, to support the necessity and payment for radiology service(s) or item(s) billed to Medicare. ACR encourages Medicare Administrative Contractors to provide the physician community with updates on the outcomes and future directions of this valuable program integrity initiative.

**CMS is not soliciting additional comments on this section of the rule.**

#### **Evaluation and Management Visits (Page 241)**

CMS clarifies and refines policies related to split (or shared) E/M visits.

A split (or shared) visit refers to an E/M visit that is performed (“split” or “shared”) by both a physician and a NPP who are in the same group. For visits in the non-facility (for example, office) setting for which the physician and NPP each perform portions of the visit, the physician can bill for the visit rather than the NPP as long as the visit meets the conditions of payment for services furnished “incident to” a physician’s professional services.

For visits furnished under similar circumstances in facility settings (for example, in a hospital), CMS current regulations provide for payment only to the physician or NPP who personally performs all elements of the service, and no payment is made for services furnished “incident to” the billing professional’s services.

Medicare Part B pays for services and supplies furnished “incident to” a physician’s (or other practitioner’s) professional services if those services and supplies are provided in a noninstitutional setting to noninstitutional patients. In certain institutional (or “facility”) settings, CMS longstanding split (or shared) billing policy allows a physician to bill for an E/M visit when both the billing physician and an NPP in their group each perform portions of the visit, but only if the physician performs a substantive portion of the visit.

CMS is making a number of proposals to improve transparency and clarity regarding CMS policies on billing for split (or shared) visits, to update them to account for recent revisions to E/M visit coding and payment, and to revise their regulations to reflect these policies. Also to account for changes that have occurred in medical practices, including the evolving role of NPPs as part of the medical team.

#### *Definition of Split (or Shared) Visits*

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, in accordance with

applicable laws and regulations. CMS proposes to define split (or shared) visits as services that are 1) Furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under CMS' regulation and 2) Furnished in accordance with applicable law and regulations, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit). CMS proposes to revise their regulations to codify this definition. CMS proposes to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain skilled nursing facility/nursing facility E/M visits.

#### *Definition of Substantive Portion*

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

#### *Distinct Time*

CMS 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 and who provided the substantive portion (and therefore bills for the visit). This would be consistent with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).

#### *Qualifying Time*

CMS proposes a listing of activities that could count toward total time for purposes of determining the substantive portion. For visits that are not critical care services, CMS proposes the same listing of activities that can count when time is used to select E/M visit level, when performed and regardless of whether or not they involve direct patient contact.

CMS is seeking public comment on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits.

#### *Applications to Prolonged Services*

CMS proposes to allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit. The physician or practitioner who spent more than half the total time (that is, performed the substantive portion) would bill for the primary E/M visit and the prolonged service code(s) when the service is furnished as a split (or shared) visit, if all other requirements to bill for the services were met. The physician and NPP would sum their time together, and whomever furnished more than half of the total time, including prolonged time, (that is, the substantive portion) would report both the primary service code and the prolonged services add-on code(s), assuming the time threshold for reporting prolonged services is met.

*New and Established Patients, and Initial and Subsequent Visits*

CMS proposes to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits.

*Setting of Care*

CMS regulations define the non-institutional setting as all settings other than a hospital or SNF. CMS proposes to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting and proposes to codify the definition of facility setting in their regulation.

*Same Group*

CMS proposes that a physician and NPP must be in the same group in order for the physician and NPP to bill for a split (or shared) visit. CMS seeks comments on whether they should further define “group” for purpose of split (or shared) visit billing.

*Medical Record Documentation*

CMS proposes that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore bills the visit) would be required to sign and date the medical record.

**Physician Self-Referral Updates (Page 611)**

The physician self-referral law, popularly known as the Stark law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she, or an immediate family member, has a financial relationship, unless an exception applies. This prohibits the entity from filing claims with Medicare (and many Medicaid programs) or billing another individual, entity, or third-party payer for those referred services. The statute establishes several specific exceptions and grants the Secretary of HHS the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

CMS is proposing to revise its Stark regulations relating to indirect compensation arrangements. Under the Stark statute, these arrangements involve an “unbroken chain” between the referring physician and the entity providing DHS of at least one individual or entity that has a financial relationship between them. Thus, each link in the chain must have an ownership or investment interest or compensation arrangement with the prior link. In these arrangements, the referring physician or immediate family member receives aggregate compensation from the individual or entity in the chain with which the physician or family member has a direct financial relationship that varies with the volume or value or referrals or other business that referrer generates for the entity furnishing the DHS. Additional factors regarding compensation must apply as well. Any ACR member who engages in an indirect compensation arrangement must satisfy the requirements of an applicable exception in order to avoid the referral and billing prohibitions of the law.



In 2020, CMS modified its test to determine whether an indirect compensation arrangement exists. It attempted to balance safeguarding against the risk of patient or program abuse or compromised program integrity, with granting more flexibility to industry participants. However, CMS apparently forgot to include in the definition of “indirect compensation arrangements” a component of “unbroken chains” of compensation arrangements that it has targeted for years: certain arrangements with unit of service-based payment to rent office space or equipment.

Therefore, CMS would revise its regulation to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician, or immediate family member of the physician, involves compensation for anything other than services that he or she personally performs.

Historically, CMS allocated a reduced level of risk of program or patient abuse where compensation to a physician, or his or her immediate family member, is solely for services that he or she personally performs. The proposed changes would require a two-step analysis of any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician is for anything other than services personally performed by the physician, including arrangements for the rental of office space or equipment. CMS maintains that arrangements involving unit of service-based compensation for the rental of office space or equipment, whether direct or indirect, may pose a significant risk of program abuse, and is proposing to ensure that the prohibition on certain unit of service-based compensation formulas for the rental of office space or equipment applies to all compensation arrangements that include them.

Specifically, CMS would revise the regulation to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of to be an indirect compensation arrangement for purposes of the Stark law if the unit of compensation received by the physician, or immediate family member, is payment for anything besides services the physician (or immediate family member) personally performs. CMS also proposes to clarify that these conditions relate to the formula for calculating the amount of compensation per unit. As proposed, CMS would mandate that the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services and the individual unit of compensation received by the physician (or immediate family member):

1. Is not fair market value for items or services actually provided;
2. Is calculated using a formula that includes the physician's referrals to the entity furnishing DHS as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity;
3. Is calculated using a formula that includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the amount

of compensation per unit that positively correlates with the physician's generation of other business for the entity; or

4. Is payment for anything other than services personally performed by the physician (or immediate family member).

Notably, CMS clarified it would consider services that any person other than the physician (or immediate family member) performs, including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member) not to be personally performed by the physician.

To facilitate compliance with the physician self-referral law as it applies to indirect compensation arrangement, CMS is proposing to clarify how to identify the unit of compensation and analyze whether an indirect compensation arrangement exists that must satisfy the requirements of an applicable exception. Under this proposal the individual unit is:

1. time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided;
2. service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided; and
3. time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

CMS seeks comment on its proposals and whether it should issue additional guidance on whether an indirect compensation arrangement exists.

These proposed changes underscore CMS' views that certain economic and clinical arrangements remain problematic. Per-unit or per-service space or equipment rental might compromise physicians' decisions and lead to overutilization or patient steering. ACR successfully advocated in 2008 for CMS to restrict such arrangements in imaging and radiation therapy. CMS did so then. If it adopts its proposals in this rule, it may enforce the law more extensively against a wider array of compensation scenarios.

### **Telehealth (page 78)**

#### *Category 1 and Category 2 Telehealth Services*

Category 1 telehealth services include services that are similar to professional consultations, office visits, and office psychiatry visits that are currently on the Medicare telehealth services list. Category 2 telehealth services include services that are not similar to those on the current Medicare telehealth services list, and the criterion for adding services under category 2 is that there is evidence of clinical benefit if provided as telehealth. CMS received several requests to permanently add various services to the Medicare telehealth services list effective for CY 2022. However, **CMS found that none of these services (received by the February 10 deadline)**

met the criteria for **Category 1 or Category 2 services for permanent addition to the Medicare telehealth services list.**

### *Category 3 Telehealth Services*

In the CY 2021 MPFS final rule, CMS created a third category of criteria for adding services to the telehealth services list on a temporary basis in response to the COVID-19 public health emergency (PHE). Category 3 telehealth services include services which CMS believes there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence to be Category 1 or 2. Services on the Category 3 telehealth list will be temporary and remain on the telehealth services list through the end of the calendar year in which the COVID-19 PHE ends. There have been stakeholder concerns surrounding uncertainty of when the PHE will end and concerns that services added to the telehealth services list on a temporary basis could be removed from the list before there is enough time to compile and submit evidence to support permanent addition of the service as a Category 1 or 2 service. In response, **CMS is proposing to retain all Medicare services added on a Category 3 basis until the end of CY 2023**, to allow more time to collect information on utilization of these services.

There are services that were added to the Medicare telehealth services list on an interim basis to respond to the COVID-19 PHE, but were not extended on a temporary basis as Category 3 services in the CY 2021 MPFS final rule. These services will be removed from the Medicare telehealth services list as of the date that the PHE ends. CMS is **soliciting comment on whether any of services that were added to the Medicare telehealth list for the duration of the PHE for COVID-19 should now be added to the Medicare telehealth list on a Category 3 basis to allow for additional data collection.**

### *Consolidated Appropriations Act, 2021*

The Consolidated Appropriations Act, 2021 (CAA) made numerous provisions to the Medicare telehealth services list. In order to implement the new statutory requirement to specify when an in-person service is required, CMS proposes that, as a condition of payment for a mental health telehealth service the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service.

### *Audio-Only Telehealth Services*

In the CY 2021 MPFS final rule, CMS explained its belief that the regulatory definition of “telecommunications system” included two-way real-time, audio/video communication technology and did not include audio-only services. However, CMS believes it is reasonable to reassess the concerns with audio-only services given the widespread utilization during the COVID-19 PHE.

**CMS is proposing 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 has found that audio-only E/M visits have been one of the most commonly performed telehealth services during the PHE, with most beneficiaries receiving mental health services. Given the mental health professional shortage and areas in which beneficiaries have limited broadband access due to geographic area or socioeconomic challenges, CMS believes beneficiaries may have come to rely on these audio-only mental health care services and that a sudden discontinuation could have a negative impact on access to care.

**CMS is also proposing to limit payment for audio-only services** to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing 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 is also seeking comment on whether, for purposes of the proposed audio-only mental health telehealth services exception, the Agency should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis.

#### *Expiration of Virtual Direct Supervision, PHE Flexibilities*

Outside the PHE, direct supervision requires the immediate availability of a supervising physician or other practitioner, but they do not need to be in the same room. Through the end of the year in which the COVID-19 PHE ends, CMS is allowing direct supervision to include immediate availability via a virtual presence using real-time, audio/video technology. **CMS is seeking comment on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the PHE, and whether physicians and practitioners anticipate relying on this flexibility after the end of the PHE. CMS is seeking comment on whether this flexibility should potentially be made permanent.**

#### **Medicare Shared Savings Program (MSSP) (page 429)**

The Affordable Care Act established the Medicare Shared Savings Program (MSSP) to facilitate coordination and cooperation among healthcare providers to improve quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce Medicare expenditures. Eligible groups of providers and suppliers may participate in the MSSP by forming or participating in an Accountable Care Organization (ACO). Under the MSSP, participants in an ACO continue to receive traditional FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. In the CY 2021 MPFS final rule, CMS finalized that for performance year (PY) 2021 and subsequent years, MSSP participants are required to report quality data via the alternative payment model performance pathway (APP), and finalized a phased-in approach to the new MSSP quality performance standard.

### *Amending the Reporting Requirements under the APP for PY 2022 and 2023*

ACOs only need to report one set of quality metrics via the APP to satisfy the quality reporting requirements under MIPS and the MSSP. Stakeholders have expressed concern about CMS requiring ACOs to report eCQMs/MIPS CQMs via the APP, due to the cost of purchasing and implementing the infrastructure/EHR. As a result, **CMS is proposing to extend the CMS Web Interface as a collection type for the MSSP ACOs reporting under the APP for PY 2022 and PY 2023.** The proposed modification to the quality measure set is as follows: for PY 2022, an ACO would report on either 1) the ten CMS Web Interface measures and administer a CAHPS for MIPS Survey or 2) the three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey; for PY 2023, an ACO would report on either 1) the ten CMS Web Interface measures, at least one eCQM/MIPS CQM measure, and administer a CAHPS for MIPS Survey or 2) the three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey. **Additionally, CMS is seeking comment on if the CMS Web Interface collection type should be extended past the two years.**

### *Addressing Health Disparities and Promoting Health Equity*

CMS believes that the move to eCQM/MIPS CQM measures is the appropriate next step for ACO quality measurement, and that assessing MSSP ACO quality performance on a broader population can have a positive impact on the quality of care for all groups. The Agency expects that the transition to eCQM/MIPS CQM measures will help to address health disparities and promote health equity by promoting a single standard of care across all patients receiving care from a practice participant in an MSSP ACO and regardless of location or racial/ethnic group. **CMS is seeking comments and recommendations on how ACOs can utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location, or income status, have access to equal care and how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that exist in healthcare. CMS is also seeking comments on how the Agency can encourage health care providers serving vulnerable populations to participate in MSSP ACOs.**

### *Reporting Options for Specialist Providers within an ACO*

CMS has heard from stakeholders that the population health/primary care focused measures in the APP are not applicable to specialty providers in ACOs. CMS is seeking comment on allowing ACO participant TINs to report either the eCQM/MIPS CQM measures in the APP measure set at the TIN level or the applicable MIPS Value Pathway (MVP). **CMS also seeks comment on the role specialists play in ACOs and what specialty measures in the current eCQM or MIPS CQM measures set should be considered for inclusion in the MSSP quality measure set in future performance years.**

### *MSSP Quality Performance Standard*

The quality performance standard is the minimum performance level ACOs must achieve in order to be eligible to share in any savings earned, avoid maximum losses, and avoid quality-related compliance actions. In the CY 2021 MPFS final rule, CMS finalized a gradual phase in of the revised performance standard: for PY 2021 and 2022 the 30<sup>th</sup> percentile across all MIPS quality performance category scores; and for PY 2023 the 40<sup>th</sup> percentile. **CMS is proposing to freeze the quality performance at the 30<sup>th</sup> percentile MIPS quality performance category score for an additional year (PY 2023), and to raise the quality performance standard in conjunction with the transition into eCQM/MIPS CQM measures by all ACOs in 2024.**

CMS seeks comment on whether publicly displaying prior year performance scores that equate to the 30<sup>th</sup> or 40<sup>th</sup> MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the MSSP.

CMS is proposing to update the extreme and uncontrollable circumstances policy to align with the proposal outlined above, and to set the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances during PY 2023 to the 30<sup>th</sup> percentile. Similarly, for PY 2024 and subsequent years, CMS is proposing to set the minimum quality performance score for an ACO affected by extreme and uncontrollable circumstances to the 40<sup>th</sup> percentile MIPS quality performance category score.

### **Medicare Provider and Supplier Enrollment Changes (Page 582)**

The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items provided to Medicare patients meet all federal and state requirements to do so. CMS proposes several changes to their existing provider enrollment regulations.

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

If excluded by the OIG, CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier. CMS proposes to expand the categories of parties within the purview of these denial and revocation provisions to include excluded administrative or management services personnel who provide services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist. This proposal would align with existing OIG guidance stating that providers and suppliers may not employ excluded persons to provide management or administrative services that are payable by a federal health care program.

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

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

*Creation of Specific Rebuttal Rights for Deactivation*

Deactivation means that the provider's or supplier's billing privileges are stopped, but not revoked or terminated. This 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: (1) does not submit any Medicare claims for 12 consecutive calendar months; (2) fails to report certain changes in its enrollment information within required timeframes; or (3) fails to fully and accurately comply with a CMS revalidation request within 90 days. To reactivate one's billing privileges, current regulations state that 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. CMS has outlined deactivation rebuttal procedures in subregulatory guidance, these procedures are not reflected in regulations. CMS proposes to revise 42CFR part 424, subpart P to describe the deactivation rebuttal process in detail, a process that would generally mirror our existing subregulatory procedures on the topic.

*Modernizing Enrollment Policies for Emerging Technologies in Independent Diagnostic Testing Facilities (IDTFs)*

There are provisions with which IDTFs must comply in order to enroll in (and maintain enrollment in) Medicare. This includes requirements for supervising physicians, nonphysician personnel, and the ordering of tests. And various certification standards that IDTFs must meet. CMS established these standards to help ensure the quality and safety of IDTF diagnostic testing and to strengthen their ability to verify the IDTF's compliance with enrollment requirements.

IDTF standards were designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. However, some health care entities have developed or utilize diagnostic tests that do not require this form of interaction. Certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. The service is often conducted by a technician who undertakes a computer analysis offsite or at another location at which the patient is not present. The physician then reviews the image to determine the appropriate course of action.

The issue is that these entities often cannot meet certain IDTF requirements (and thus cannot enroll in Medicare) strictly because of the test's indirect nature. To address this issue, CMS is proposing that IDTFs that have no patient interaction, treatment, or testing at their practice location and would be exempt from specific IDTF requirements.

CMS proposes that nonphysician personnel performing test in an exempted IDTF must meet all applicable state licensure requirements and the IDTF must maintain documentation available for review that these requirements have been met.

CMS proposes that the following IDTF certification standards would not apply to exempted IDTFs.

- The IDTF must have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF.
- The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. For mobile IDTFs, this documentation would be stored at their home office.
- The IDTF must openly post the standards outlined for review by patients and the public.

Regarding liability that could involve an exempted IDTF, CMS is soliciting public comment on the types of situations where this could arise as well as on the following issues: (1) whether exempted IDTFs should indeed be required to maintain a \$300,000 liability policy; (2) whether a liability amount of less than \$300,000 is warranted and, if so, what that amount should be (for example, \$50,000 or \$100,000 or \$200,000); and (3) whether no liability policy should be required.

#### *Proposed Revisions Related to Revocation*

CMS may revoke a provider's or supplier's enrollment if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. The purpose of this provision is to place providers and suppliers on notice that they are legally obligated to always submit correct and accurate claims and that failing to do so could lead to the revocation of their enrollment.

CMS has encountered situations where providers and suppliers have engaged in periods of non-compliant billing that, though comparatively brief, have or could have harmed the Medicare program. While CMS has attempted revocation action per against such providers and suppliers, the current wording in their regulations, have hampered their ability to do so. To increase their flexibility to address periods of abusive billing irrespective of their duration, CMS proposes to revise their revocation provisions.



## **Quality Payment Program**

CMS introduces multiple requests for information (RFI) on areas that would impact traditional MIPS and future MVP participation, and seeks input on the following.

- *Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – RFI* (p. 676) and transitioning CMS quality reporting and value-based purchasing programs to digital quality measurement by 2025. The shift to digital quality measurement (dQM) is an overarching initiative by CMS to modernize their "quality measurement enterprise" and maintain alignment with the Department of Health and Human Services (HHS) encompassing strategy to promote data interoperability and access in conjunction with other federal agencies. For instance, the Office of the National Coordinator for HIT's (ONC) finalized policies in the Cures Act regarding "complete access, exchange, and use of all electronically accessible health information." CMS is interested in feedback on the following set of considerations. Additionally, a comprehensive list of this RFI's comment solicitation may be found on page 690 of the proposed rule.
  - Adoption of FHIR to reduce the collection and analysis burden imposed by current electronic quality measures. Under the HL7 framework, quality data reporting programs would utilize a standardized data collection structure and single terminology to collect electronic measure data.
  - Enhancement of the definition of dQM so that it contains language regarding proposed software that processes digital data to determine measure scores.
  - Redesign quality measures as "self-contained tools" that dQM software incorporates end-to-end measure calculation solutions.
  - Alignment of quality measure reporting programs across federal and state agencies and other sectors via the adoption of a dQM Portfolio.
  - Prioritization of components supporting the dQM portfolio, like measurement topics, measure development/digitization requirements, and data standards.
- *Closing the Health Equity Gap in CMS Clinician Quality Programs— (RFI)* (p. 693) is consistent with the executive order on Advancing Racial Equity and Support for Underserved Communities through the Federal Government, CMS issued an RFI from stakeholders to achieve health equity for all patients by implementing new policies. CMS requests comments on the below approaches to ensure the delivery of health equity.
  - Provision of transparency of health disparities by integrating information presented in existing CMS reports and tools (e.g. CMS Mapping Medicare Disparities Tool, Rural-Urban Disparities in Health Care in Medicare Report, etc.)
  - Standardization of demographic data collection across quality programs and quality measures for the possible creation of developing a method to report health equity performance results across multiple measures publicly. Notably, Appendix 2 of the

proposed rule includes a new improvement activity on creating and implementing an anti-racism plan. CMS highlights that this improvement activity acknowledges the insufficiency of gathering and analyzing data by race and documenting disparities by different population groups. It emphasizes systemic racism is the basis for differences in health outcomes between socially defined racial groups. Further, CMS proposes modifying five existing improvement activities to address health equity. The activities explicitly link the activities to health equity without altering the core activity through the proposed modifications, shifting the activity focus on health equity.

- Application of the complex patient bonus in MIPS, which awards additional points to clinicians with a higher percentage of medically and socially complex patients and does not lower the standard of care.

*Transforming MIPS: MIPS Value Pathways (p. 716)*

As part of CMS' transition from traditional MIPS to MIPS Value Pathways (MVPs), the proposed rule includes a comprehensive set of policies and procedures that inform the eligibility, implementation, and scoring of MVPs for eligible clinicians participating in MIPS (as individuals and group). CMS maintains that MVPs would be incrementally added to the QPP upon availability as part of rulemaking. CMS highlights that stakeholders largely support the MVP Framework's goals. However, there are concerns regarding incorporating the four MIPS performance categories, setting performance thresholds, the annual quality measure selection process, and performance category weights.

Using MVPs, CMS anticipates collecting more granular level data on measures and activities for a specific medical specialty, condition, episode of care, or procedure. Therefore, clinicians would receive performance feedback reports that immediately inform a practice's strengths and weaknesses, thereby designating distinct areas for care improvement by practice. Although proposing seven new MVPs for utilization beginning in the performance year 2023 (Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia), CMS acknowledges the gaps in quality and cost measurement that could impede the development of MVPs for particular medical specialties. CMS seeks input on the types of MVPs, quality, and cost measures needed to meet their objective of complete MVP transition from traditional MIPS as early as the performance year 2028.

Considering CMS' understanding of the problems with immediately developing MVPs for all specialties due to the lack of currently available measures, they propose expanding the MVP Guiding Principles to address external-stakeholder cost measure development (a function only available to CMS until now).

### *MVP Participant*

CMS proposes that **MVP Participants are individual MIPS eligible clinicians, single-specialty groups, subgroups, or APM Entities assessed on an MVP. Therefore, resulting in the gradual transition of requiring multispecialty groups to form subgroups if they want to report MVPs.** CMS explains that the formation of subgroup reporting is important, as currently, multispecialty groups report on the same set of measures, which are likely irrelevant or lack meaning to a portion of specialists that participate within the multispecialty group—preventing these specialists from improving the care they provide to patients.

### *MVP and Subgroup Implementation Timeline (p. 729)*

As mentioned previously, MVPs proposed for adoption in this rule are unavailable for reporting *voluntarily* until the performance year 2023. CMS anticipates that *mandatory* reporting of MVPs would not begin before MIPS performance year 2028. They also propose sunsetting the traditional MIPS program to coincide with the mandatory MVP requirement. CMS explains that supporting both versions of MIPS is resource-intensive and beyond their capabilities. Noting that the MVP portfolio must be robust enough to support the wide range of clinicians under Medicare Part B, they request comments on handling situations when an MVP participant is so highly specialized that they do not fit into any MVP developed in the ensuing years.

CY 2021 QPP final rule modified the MVP guiding principles to reference subspecialty group reporting. Within this proposed rule, CMS details the implementation timeline and other considerations for subgroup reporting. Beginning in MIPS performance year 2023 through 2024, CMS proposes that recognized groups begin voluntarily forming subgroups and participating in MVPs. Subgroups would comprise a subset of MIPS eligible clinicians who share the same medical specialty-type within their groups' practice. Participation in MVPs through subgroup reporting allows each MIPS eligible clinician to receive feedback from CMS on the care they are directly attributed, providing the opportunity for all clinicians in the multispecialty practice to make data-driven improvements on the quality of care provided. CMS further proposes that beginning in MIPS performance year 2025, multispecialty groups must form subgroups to report MVPs.

### *Catalyst for Reporting MVPs (p. 736)*

Within this proposed rule, CMS recognizes that there may remain hesitancy for MIPS eligible clinicians to transition to MVPs. Lacking the financial resources to reward early MVP adopters for incentivizing MVP participation, CMS proposes that MVP policies incentivize MVP adoption. For example, MVP participation policies reduce the volume of measures and activities required to achieve MIPS performance scores. Further burden reduction is achieved when participating in MVPs because measures and activities are more relevant to the clinical topic, condition, procedure, or care episode beginning reported on through a particular MVP. Further, CMS asserts that MVP and subgroup reporting will collect granular-level data, thereby

enhancing feedback reports providing more meaningful comparisons to similar clinicians, making the data more helpful in making care improvements. Notably, CMS also refers to the alignment of MVP participation with CME and MOC requirements, suggesting that accrediting organizations work with MVP submitters for consideration of awarding CME and/or MOC credit for those reporting MVPs.

*Subgroup Composition (p. 738)*

CMS would continue to define groups as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. However, some groups' characteristics could impact subgroup eligibility and special status within subgroups. CMS proposes the following designations required to form subgroups:

1. A subset of a group with at least one MIPS eligible clinician identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI.
2. Groups would identify their affiliated subgroups, and those subgroups would submit data on the MVPs which are clinically meaningful to MIPS eligible clinicians within a subgroup or their patients.
3. Each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment this would allow for an exception for subgroups to receive a final score based on the subgroup's combined performance.

Stakeholders have impressed upon CMS the importance of accurately assessing team-based care as part of MVPs, as well as mitigating the potential for subgroup competition. **Comments are sought on special status designation regarding the eligibility for establishing subgroups as well as rules informing the composition of subgroups. They specifically request input on including clinical relevance, scope of care, and patient population as part of the criteria.** CMS' special status determination (finalized in CY 2018 QPP final rule) applies to non-patient facing MIPS eligible clinicians, rural area, or small practices.

*Subgroup Eligibility (p. 746)*

Given the scarcity of MVPs during the initial MVP participation years, CMS is proposing application of a low-volume threshold; application of special status designation; and subgroup inclusions and exclusions. **Input is requested on subgroup limitations.**

CMS proposes multiple approaches for identifying appropriateness for eligible clinicians to participate in a particular subgroup. The methods include implementing PECOS specialty designations, attestation of eligible clinicians in a subgroup practice with similar care scope, or use Medicare Part B claims billing patterns to validate the appropriateness of eligible clinicians included in a particular subgroup. Alternatively, CMS is considering eligible clinicians selecting MVPs from a CMS-approved list. Additional details associated with subgroup eligibility is included in the proposed rule's RFI on page 762.

*MVP Development and Maintenance (p. 763)*

Several elements that support the formation of MVPs (i.e., factors MVP submitters need to consider before submitting to rulemaking) were finalized in the CY 2021 QPP final rule. This proposed rule augments the guidance, policy, and procedures previously finalized and establishes a detailed compendium of information on MVP candidate submission, participation, and scoring. CMS, again, stresses the importance of team-based care when approaching MVP development (when appropriate). With respect to MVP maintenance, CMS describes their plan for MVPs to be available for public comment regularly, ensuring that the measures and activities within MVPs are agile and significant.

*Selection of Measures and Improvement Activities within an MVP (p.764)*

Since its introduction in the CY 2018 QPP final rule, CMS highlighted the role of MVPs in reducing MIPS participation burden by lowering the MIPS reporting requirements. Comparisons between MV composition and participation requirements against traditional MIPS requirements are in the table below.

<b>Performance Category</b>	<b>Traditional MIPS Reporting Requirements <i>To Earn Full MIPS Score</i></b>	<b>MVP Reporting Requirements</b>
<b>Quality</b>  <b>**Population Health Measurement</b>	Report <b>6</b> quality measures, including an outcome measure or high-priority measure (in the absence of an outcome measure).  <b>**Not Applicable.</b>	If applicable, <b>4</b> quality measures, including an outcome measure or high-priority measure (in the absence of an outcome measure).  <b>** Administrative claims based. No data submission requirement for the clinician.</b>
<b>Improvement Activities</b>	Attest to: <b>1 high-weighted</b> activity  <b><u>AND</u></b> <b>2 medium-weighted</b> activities,  <b><u>OR</u></b> <b>4 medium-weighted</b> activities	Attest to: <b>1 high-weighted</b> activity  <b><u>OR</u></b> <b>2 medium-weighted</b> activities
<b>Promoting Interoperability</b>	Unless designated otherwise, report all 6 Promoting Interoperability measures.	Report all Promoting Interoperability measures (unknown how many measures there will be).

		<i>Not all applicable to radiologists. CMS considering flexibilities.</i>
<b>Cost</b>	Administrative claims based. No data submission requirement for the clinician.	Administrative claims based. No data submission requirement for the clinician.

*Scoring and Re-weighting in MVPs*

CMS proposes MVP scoring policies as follows:

Population health measures will be included in the Quality performance category score. As in traditional MIPS, these measures would be excluded from scoring if the measure does not have a benchmark or case minimum is not met. Subgroups would receive the population health measure score of their affiliated group, if applicable, in the event that the measure selected by the subgroup doesn't have a benchmark or meet case minimum. Other Quality category scoring policies would align with those in traditional MIPS, as proposed in this rule and described in the Quality Performance Category section below.

Improvement Activity category scoring would assign each medium-weighted activity 20 points and each high-weighted activity 40 points. Cost category scoring policies align with traditional MIPS category weights with cost measures included in the MVP only being scored.

Final scoring policies would generally align with traditional MIPS scoring. Performance category weights would be consistent with traditional MIPS performance category weights. Reweighting policies for the redistribution of category weights would also align with traditional MIPS, with the exception that the quality performance category would not be reweighted if a score cannot be calculated for a MIPS eligible clinician due to lack of an applicable MVP quality measure.

The scoring hierarchy would be updated to include subgroups where a MIPS eligible clinician would receive the highest final score that can be attributed to their TIN/NPI combination from any reporting option (traditional MIPS, APM Performance Pathway (APP) reporting, or MVP reporting) and participation option (as an individual, group, subgroup, or APM Entity), with the exception of virtual groups. CMS believes that including subgroups in the scoring hierarchy would allow for meaningful data collection and assessment under MVPs, while applying existing policy of allowing clinicians to receive the highest final score and payment adjustment that can be attributed to them.

*Public Reporting of MVP Data (p. 1042)*

CMS proposes that for individuals, groups, and subgroups participating in MVPs, there will be a one-year delay on publicly reporting new Improvement Activities and Promoting Interoperability measure performance. CMS believes that this will encourage clinician participation in MVPs

while also allowing them to transition into the new framework. As previously finalized, CMS will continue not to publicly report Quality measures that are in their first two years of existence. CMS further emphasized that subgroup performance will maintain a separate workflow from traditional MIPS and MVP group public reporting. In other words, MVP subgroup reporting data will be linked to the practices' Care Compare profile page, where it would describe who is attributed to the subgroups' performance.

Public reporting information for MVP participants as well as standard MIPS participants will continue to be available via the Department of Health and Human Services' [Compare Tools website](#).

#### *MIPS Category Weighting (p. 987)*

The proposed category weights for the 2022 performance year are: **Quality – 30%, Cost – 30%, PI – 25%, and IAs – 15%.**

In accordance with the 2020 MPFS Final Rule, CMS has proposed to lower the weight of the Quality category to 30% in 2022 and beyond. Cost has increased to 30% for the 2022 performance year. These percentages are likely to stay fixed for the future of the MIPS program.

The proposed rule continues to offer category reweighting for physicians who are unable to submit data for one or more performance categories. In most cases, the weight of these categories will continue to be redistributed to the Quality category.

#### *MIPS Performance Threshold and Incentive Payments (p. 1007)*

The MIPS performance threshold is the value which determines whether a MIPS participant will receive a positive, negative or neutral payment adjustment during the associated MIPS payment year. During the first two MIPS performance years, this value was set at 3 points and then 15 points (out of 100) to allow clinicians to transfer into the new payment program more easily. The Bipartisan Budget Act of 2018 gave CMS the flexibility to set a performance threshold for three additional years (program years 2019-2021) to continue this process of incremental transition. During the following three years, the performance threshold was set at 30 points, 45 points, and finally 60 points for the 2021 performance year.

From 2022 onward, CMS is required to set the MIPS performance threshold at either a mean or median value based on previous years' scoring data. CMS has analyzed mean and median performance data from 2017 through 2019 and found a range of scores between 74.65 (the 2017 performance year mean) and 99.63 (the 2018 performance year median).

**Beginning with performance year 2022, CMS is proposing to raise the performance threshold to 75 points, which represents the mean of 2017 performance year data. This**

means that clinicians scoring 75 points or higher will receive a neutral or positive payment adjustment, while clinicians falling below 75 points will receive a negative adjustment.

**CMS is also proposing to set the exceptional performance threshold at 89 points, representing the 25<sup>th</sup> percentile of final scores above the performance threshold from the 2017 performance year.** Clinicians scoring above the exceptional performance threshold will receive an additional bonus to their payment adjustment. (p. 1010)

CMS finalized the payment adjustment of +/- 9% for performance years 2020 and beyond. No changes have been proposed to the MIPS adjustment.

*Low-Volume Threshold and Small Practice (15 or fewer eligible clinicians) Considerations (p. 747)*

CMS has not proposed any changes to the low-volume threshold criteria as previously established. To be excluded from MIPS in 2022, clinicians or groups would need to meet one of the following three criteria: have  $\leq$  \$90K in allowed charges for covered professional services, provide covered care to  $\leq$  200 beneficiaries, or provide  $\leq$  200 covered professional services under the Physician Fee Schedule. CMS proposes no changes to the opt-in policy established which allows physicians who meet some, but not all, of the low-volume threshold criteria to opt-in to participate in MIPS.

CMS is maintaining the small practice bonus of 6 points that is included in the Quality performance category score. CMS also continues to award small practices 3 points for submitted quality measures that do not meet case minimum requirements or do not have a benchmark. (p. 950)

In previous MIPS performance years, small practices had been allowed to submit Quality measure data via claims reporting rather than registry-based reporting. The 2022 Proposed Rule continues to allow claims submission for small practices, but they acknowledge that this has caused some unintended consequences, such as physicians who may be exempt from MIPS due to the low-volume threshold receiving MIPS scores because their group has submitted claims data. **CMS proposes to require that claims-reporting small practices who wish to submit MIPS data as a group must signal their intention to participate as a group by submitting either Improvement Activities, Promoting Interoperability measures, or MIPS CQMs as a group.** If they do not report another performance category as a group, they would be considered individual submitters. (p. 715)

#### *Quality Performance Category*

CMS has signaled their intention to lower the Quality category weight to 30% in previous rules, therefore CMS is confirming in this proposed rule that the weight of the Quality performance category will be set at 30% for 2022 (down from 40% in 2021).



**CMS has also proposed extensive changes to the measure scoring system.** In previous years, non-benchmarked measures which met data completeness were eligible to receive 3 points, with the possibility of a higher score if enough data was received to establish a same-year benchmark. Benchmarking measures were scored between 3 and 10 points if they met data completeness.

**Beginning with performance year 2022, CMS proposes three major changes: first, they intend to change the scoring range for benchmarked measures to 1 to 10 points, doing away with the 3-point floor; second, they intend to score non-benchmarked measures at 0 points even if data completeness is met; third, for new measures which do not yet have a benchmark, the scoring floor will be raised to 5 points for their first two years in the MIPS program.** These new measures will still be able to achieve higher points during their first two years if a same-year benchmark is established. If a benchmark is not established after two years in the MIPS program, that measure will not achieve any points.

The exception to this policy is small and rural practices, who, as noted above, will be awarded 3 points for measures which either do not have a benchmark or do not meet case minimum. (p. 795)

#### *Quality Measures Proposed for Removal (p. 1397)*

CMS has proposed the removal of several measures which have historically been used by radiologists reporting through ACR's NRDR QCDR (p. 1397):

- #21: Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin
- #23: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)
- #144: Oncology: Medical and Radiation - Plan of Care for Pain
- #154: Falls: Risk Assessment
- **#195: Radiology: Stenosis Measurement in Carotid Imaging Reports**
- **#225: Radiology: Reminder System for Screening Mammograms**
- #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Regarding their methodology for scoring topped out measures, CMS proposes to continue capping measures at 7 points (out of a possible 10) if they have been topped out for two or more performance years but will adjust the score if the measure ceases to be topped out upon completion of data submission for the current performance year.

#### *Quality Category Bonus Points (p. 955)*

**CMS has proposed to end the practice of awarding bonus points for additional high priority or outcome measures beyond the required one measure.** CMS notes that their

previous policy of awarding bonus points for additional high priority or outcome measures was a transitional policy designed to encourage the reporting of such measures. They believe it may no longer be necessary to incentivize high priority measures in this way.

Similarly, CMS also proposes to discontinue the end-to-end reporting bonus which incentivized users to report measures using Certified Electronic Health Record Technology (CEHRT).

CMS notes that they believe that the creation of MVPs will allow new methods of incentivizing high priority measures, outcome measures and end-to-end reporting. They invite stakeholders to comment on these proposals.

*Quality Data Completeness Requirements (p. 813)*

No changes to data completeness requirements were proposed for 2022, so quality measure submission must continue to account for at least 70% of total exam volume. This number defines the minimum subset of patients within a measure denominator that must be reported. **CMS is proposing to increase this threshold to 80% beginning with the 2023 performance year.**

*Quality Measure Benchmarking (p. 940)*

Because of the complications related to the COVID-19 emergency—specifically the allowances made to exempt non-submissions from receiving negative payment adjustments during the 2020 MIPS performance year—CMS believes that the available data from the previous year may not be sufficient for establishing Quality measure benchmarks. For this reason, CMS is proposing two different methods of benchmarking Quality measures for the 2022 performance year.

First, as they had originally suggested in the 2021 Proposed Rule, CMS is considering establishing a performance period benchmark for 2022 rather than using historical benchmarks. This would mean the exact performance benchmarks for 2022 wouldn't be known until the performance year has concluded, and they acknowledge that this may cause difficulty for clinicians in determining whether to submit certain measures.

Their other suggestion is to use historical benchmarks based on data from the 2019 performance year. This data was determined to be sufficient despite the onset of the COVID-19 emergency during the MIPS submission deadline in March 2020, which they initially feared may have skewed reporting for that year.

CMS invites stakeholders to comment on the above benchmarking proposals for the 2022 performance year.

*Cost Performance Category (p. 841)*

**CMS is proposing to add five new episode-based cost measures in the 2022 performance year and beyond: Melanoma Resection, Colon and Rectal Resection, Sepsis, Asthma/Chronic Obstructive Pulmonary Disease (COPD) and Diabetes.** The first three cost measures (Melanoma Resection, Colon and Rectal Resection and Sepsis) follow the same

framework as the previously established cost measures currently in use in MIPS. The last two measures (Asthma/COPD and Diabetes) are chronic conditions and are calculated using claims data from Medicare Parts A, B and D. The patient population is stratified into smaller, clinically similar cohorts, to ensure an accurate comparison of costs across clinicians. A more in-depth summary of the chronic condition cost measure framework can be found on [CMS.gov](https://www.cms.gov). The proposed specifications, measure constructs, attribution methodology and measure codes for all five measures may also be found on [CMS.gov](https://www.cms.gov).

Table 1. Proposed Episode-based Cost Measures for PY 2022.

Measure Name	Episode Type
Melanoma Resection	Procedural
Colon and Rectal Resection	Procedural
Sepsis	Acute In-Patient Medical Condition
Asthma/COPD	Chronic Condition
Diabetes	Chronic Condition

CMS is interested in creating a process for stakeholders to develop cost measures. To ensure new cost measures align with program needs, CMS will conduct an environmental scan to outline priority areas and clinical performance gaps. Similar to the Call for Quality Measures, CMS would conduct a Call for Cost Measures and review all candidate measures through the MUC list. Candidate measures must be fully specified, feasible, and scientifically acceptable. **CMS is requesting feedback on this proposal, as well as specialties or specific conditions that would support future or proposed MVPs.**

**CMS would like to establish criteria for evaluating cost measures for substantive changes.** Examples of changes to measures include service codes, types of costs, measure elements and risk adjustment methodologies. CMS requests public comment on this proposal.

*Improvement Activities Performance Category (p. 872)*

**CMS is proposing to revise group reporting requirements to prepare for MVP subgroup reporting.** The 50 percent threshold requirement for group reporting will also apply to subgroup reporting an improvement activity.

In 2020, CMS finalized an exception to the Call for Improvement Activities timeline, allowing stakeholders to submit an improvement activity nomination at any time during a public health emergency (PHE). **CMS is proposing to revise that exception; all nominations during a PHE must be submitted by January 5 of the activity implementation year. CMS is also proposing two new criteria for candidate improvement activities: they should not duplicate other improvement activities and should drive improvements that go beyond standard clinical practice.** To increase the chances of an improvement activity’s acceptance to the program, **CMS is proposing that the six previously established factors for submissions should be optional factors beginning in 2022:** alignment with patient-centered medical homes, support for the patient’s family or personal caregiver, responds to a public health emergency as

determined by the Secretary, addresses improvements in practice to reduce health care disparities, focus on meaningful actions from the person and family’s point of view, and representative of activities that multiple individual MIPS eligible clinicians or groups could perform. **Beginning with 2022, CMS proposes to suspend improvement activities that might raise patient safety concerns or are obsolete.** These activities would then be proposed for removal in the next rulemaking cycle.

There are seven improvement activities proposed for adoption, 15 improvement activities with modifications, and six improvement activities for removal.

Table 2. Improvement Activities Proposed for Adoption.

Improvement Activity Title	Description	Category Weight
Create and Implement an Anti-Racism Plan	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools. The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one.	High
Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols	Create or improve, and then implement, protocols for identifying and providing appropriate support to: a) patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.)	Medium
Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice	Create and implement a plan for trauma-informed care (TIC) that recognizes the potential impact of trauma experiences on patients and takes steps to mitigate the effects of adverse events in order to avoid re-traumatizing or triggering past trauma.	Medium
Promoting Clinician Well-Being	Develop and implement programs to support clinician well-being and resilience—for example, through relationship-building opportunities, leadership development plans, or creation of a team within a practice to address clinician well-being—using one of the following approaches: <ul style="list-style-type: none"> <li>• Completion of clinician survey on clinician well-being with subsequent implementation of an improvement plan based on the results of the survey.</li> </ul>	High

	<ul style="list-style-type: none"> <li>Completion of training regarding clinician well-being with subsequent implementation of a plan for improvement.</li> </ul>	
Implementation of a Personal Protective Equipment (PPE) Plan	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients.	Medium
Implementation of a Laboratory Preparedness Plan	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities.	Medium
Application of CDC's Training for Healthcare Providers on Lyme Disease	Apply the Centers for Disease Control and Prevention's (CDC) Training for Healthcare Providers on Lyme Disease using clinical decision support (CDS). CDS for Lyme disease should be built directly into the clinician workflow and support decision making for a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include but are not limited to: electronic health record (EHR) based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.	Medium

Table 3. Improvement Activities Proposed for Removal.

Improvement Activity Title	CMS' Rationale
Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms	There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.
Participation in CAHPS or other supplemental questionnaire	This improvement activity is duplicative of another activity.
Use of tools to assist patient self-management	This improvement activity is duplicative of another activity.
Provide peer-led support for self-management	This improvement activity is duplicative of another activity and there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.

Implementation of condition-specific chronic disease self-management support programs	This improvement activity is duplicative of another activity and there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.
Improved practices that disseminate appropriate self-management materials	This improvement activity is duplicative of another activity and there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.

*Promoting Interoperability Performance Category (p. 886)*

In the 2022 Proposed Rule, CMS proposes to maintain the Promoting Interoperability minimum performance period of any continuous 90-day period within CY 2022. They also maintain that small practices would obtain a hardship exception and be reweighted by default if they do not report data for this category.

CMS proposes a new SAFER Guides objective and measure beginning in CY 2022 that MIPS Eligible Clinicians would need to attest yes or no to having conducted an annual self-assessment using the [High Priority Practices Guide](#) at any point during the calendar year. This measure would need to be reported but would not affect the score for the category.

CMS proposes that the Electronic Prescribing Objective’s “Query of Prescription Drug Monitoring Program (PDMP)” measure would continue to be optional and worth 10 bonus points in CY 2022. CMS requests comments on provider readiness for Query of PDMP measure reporting.

CMS proposes that MIPS Eligible Clinicians ensure that health information shared as part of the “Provide Patients Electronic Access to the Health Information” measure be available to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR technology that the clinician uses. Additionally, the information saved would be on all patient health information from encounters on or after January 1, 2016.

CMS proposes to only require “Immunization Registry Reporting” and “Electronic Care Reporting” measures under the Public Health and Clinical Data Exchange Objective. “Public Health Registry Reporting,” “Clinical Data Registry Reporting,” and “Syndromic Surveillance Reporting” measures would be optional and available for bonus points beginning in CY 2022.

Finally, CMS proposes to eliminate two of the three yes/no attestation statements previously required for information blocking prevention.

CMS requests information on various Promoting Interoperability subtopics, such as:

- How the Health Information Exchange and Public Health/Clinical Data Exchange objectives can be furthered through use of FHIR-based API solutions.
- How to assess patient access outcomes when they use applications to access data.
- How the “Provide Patients Access to Their Health Information” measure can better support clinical notes availability.

#### *Facility-based Measurement (p. 1002)*

Facility-based scoring was implemented in 2019. Clinicians and groups would not need to elect or opt-in to facility-based measurement if they were eligible and benefitted from having a higher combined quality and cost performance score.

CMS is proposing changes to determine the final score for clinicians and groups eligible for facility-based measurement. **Beginning with the 2022 performance year, the MIPS quality and cost performance category scores will be based on facility-based measurement unless their MIPS final score is higher through another MIPS submission.** This proposal would calculate two final scores for clinicians and groups who are facility-based: one for the clinician or group’s performance and the weights of the performance categories if facility-based measurement did not apply, and another based on the application of facility-based measurement. CMS will accept the higher of the two scores.

#### *Advanced Alternative Payment Models (page 1052)*

An Advanced APM is an APM that: 1) requires participants to use certified EHR technology (CEHRT), 2) provides payment for covered services based on quality measures comparable to MIPS, and 3) requires participating entities to bear more than nominal financial risk or participate as a Medical Home Model. For payment years 2019 through 2024, Qualifying APM Participants (QPs) receive a 5 percent APM Incentive Payment. Starting in payment year 2026, the update to the PFS CF for QPs will be 0.75%. The Consolidated Appropriations Act, 2021, froze the APM payment incentive thresholds for performance years 2021 and 2022 (payment years 2023 and 2024). Therefore, in CY 2022, the QP payment amount threshold will remain at 50 percent of Medicare payments and the QP patient count threshold will remain at 35 percent of Medicare patients.

#### *APM Incentive Payment Recipient*

In the CY 2021 MPFS final rule, CMS finalized a hierarchy to identify potential payee Taxpayer Identification Numbers (TINs) in the event that the QP’s original TIN is no longer active. This process has improved CMS’ ability to make more payments to TINs with up-to-date and valid affiliations. **CMS proposes to revise their decision hierarchy for making APM payments** so that the Agency would first seek to identify a TIN associated with the QP during the base year,

and if no such TIN is identified in the base year, CMS would then seek to identify a TIN associated with the QP during the payment year.

The Radiation Oncology Model is expected to be an Advanced APM in the 2022 QP performance period.

ACR staff continue to further analyze the proposed rule and will be submitting comments to CMS by September 13<sup>th</sup> deadline.