September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The American College of Radiology (ACR), representing nearly 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS) Proposed Rule. In this comment letter, we address the following important issues:

Payment Provisions

- Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS)
- Clinical Labor Pricing Update
- Codes Involving Innovative Technology
- Valuation of Specific Codes
- Proposal to Remove Selected National Coverage Determinations (NCDs)
- Billing for Physician Assistant (PA) Services
- Physician Self-Referral Updates
- Telehealth

Quality Payment Program

- Advancing to Digital Quality Measurement and Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs
- Closing the Health Equity Gap in CMS Clinician Quality Programs

- Transforming Merit-Based Incentive Payment System (MIPS): MIPS Value Pathways (MVPs)
- MVP and Subgroup Implementation Timeline
- Selection of Measures and Improvement Activities within an MVP
- Public Reporting of MVP Data
- Facility-Based Measurement
- MIPS: Claims Reporting for Small Practices
- MIPS: Quality Measures Scoring
- MIPS Quality Performance Category: Removal of Bonus Points
- MIPS: Quality Measure Data Completeness
- MIPS: Quality Measures Proposed for Removal
- MIPS: Reweighting Policy for Small Practices
- MIPS: Cost Performance Category
- MIPS: Improvement Activities (IA) Performance Category
- MIPS: Performance Categories that Must Be Supported by Third Party Intermediaries
- Qualified Clinical Data Registry (QCDR) Not Approved or Not in Good Standing
- QCDR Measure Testing Requirements for CY 2023 and Beyond

PAYMENT PROVISIONS

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS)

Proposal

The AUC program, mandated by the Patient Access to Medicare Act of 2014 (PAMA) is currently scheduled to enter the payment penalty phase on January 1, 2022. However, there remain many complexities around the scope and application of AUC program claims processing edits. In addition, given the circumstances of physicians and other practitioners due to the public health emergency (PHE) for COVID-19, CMS recognizes 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 proposed 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. In addition, CMS requested feedback on whether claims that do not pass the AUC claims processing edits should be returned to the provider to be corrected and resubmitted or should be denied to allow the provider to appeal.

The proposed rule also includes proposals to address outstanding claims processing issues to ensure that claims are not inappropriately denied once the program enters the penalty phase.

CMS proposed to repurpose modifier MH to describe situations in which the ordering professional is not required to consult AUC (e.g., critical access hospital claims and Maryland Total Cost of Care Model). The MH modifier is currently used in the educational and operations testing period to identify claims for which AUC consultation information was not provided to the furnishing provider and facility.

ACR Perspective and Comments

The PAMA AUC policy for advanced diagnostic imaging services is designed to curb patient exposure to unnecessary radiation, reduce Medicare spending on low-value advanced imaging procedures, promote the movement towards value-based care, and be a more credible policy alternative to the imposition of burdensome advanced imaging prior authorization programs in Medicare. The ACR is committed to continuing to work with CMS to ensure the program's successful implementation as soon as possible.

Understanding the hardships healthcare providers have faced during the COVID-19 PHE, the **ACR supports CMS' proposal to begin the penalty phase of the AUC program on January 1, 2023, or the January 1 following the end of the PHE.** In the meantime, CMS should continue education efforts and encourage providers to submit AUC consultation information with applicable advanced diagnostic imaging claims. As acknowledged in the rule, while there are providers who have had to pause efforts to include AUC consultation in workflows, many other providers have already invested significant time and expense in qualified clinical decision support mechanisms.

The ACR understands the challenges CMS has faced with developing claims processing edits to implement the PAMA AUC program in a way that ensures claims are not inappropriately denied when the penalty phase of the program begins. The College believes that the solutions proposed in this MPFS rule are good workable solutions to identifying claims that are not subject to the PAMA AUC mandate. However, the ACR has concerns about repurposing modifier MH, 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, to report claims that are not subject to the AUC mandate (e.g., critical access hospitals) once the penalty phase begins. Rather, the **ACR requests that CMS create a new modifier to identify such claims to avoid any confusion and/or continued use of the MH modifier for claims where AUC consultation information was not provided.**

CMS requested feedback on whether, once the penalty phase of the AUC program begins, claims that do not properly include AUC consultation information should be initially returned to the health care provider to be corrected and resubmitted or if such claims should be denied so they can be appealed. **The ACR feels that given the complex nature of the claims requirements, claims that do not properly include AUC consultation should be returned to the provider to be corrected and resubmitted.**

The ACR appreciates CMS' ongoing commitment and efforts to fully implement this important PAMA AUC program despite challenges and the PHE. As stated above, the proposals in this

MPFS rule are workable and a positive step toward fulfilling the Congressional mandate. The ACR is committed to continuing to work with CMS to ensure the success of the AUC program and for all Medicare patients to receive the right advanced diagnostic imaging tests at the right time.

Clinical Labor Pricing Update

Proposal

CMS is proposing to update prices for clinical staff for the first time since 2002. This review is partially in response to 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 clinical labor would also maintain relativity within the direct practice expense (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 yield an overall negative impact on some physician specialties such as vascular surgery, radiation oncology, and interventional radiology (Table 6 of the MPFS Proposed Rule). 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 as a result of an increase in the clinical labor wages.

Of note for radiology, the BLS data did not have wage data specific for a Mammography Technologist. Instead, CMS used data from Salary Expert and 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 75th percentile of the average wage data for a general 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.

ACR Perspective and Comments

The ACR believes that CMS' proposal to update the prices of clinical staff has merits since it hasn't been updated since 2002. While we understand the reason for the update, **we are deeply concerned about the timing and the devastating redistributive effect this update will impose upon radiology, especially interventional radiology and radiation oncology services, as well**

as other medical specialties where the practice expense costs rely primarily on supply or equipment items.

Taking into account that the updated pricing for supplies and equipment is in its final year of transition, the sizeable cuts to other services as a result of the recent evaluation and management (E/M) increases and the impact on all physicians in the continuing battle with COVID-19, radiology practices including many other physician practices are already facing a myriad of economic hardships. In light of these substantial financial uncertainties for health care practices, the **ACR requests that CMS transition the clinical labor update over five years, with the first year at zero percent.** This will allow the Agency and stakeholders time to further evaluate how the BLS data is used and applied, including the implications the disproportionate effects will have on certain specialties. We also request additional time to consider whether the application of BLS data is appropriate, such as the use of the 2002 benefits multiplier.

The **ACR also believes that the updates to direct practice expense components should take place on a regular basis to prevent significant redistributive effects to specialties in the future.** These negative impacts not only hurt physician practices who are already struggling to keep their doors open; they also impact patients and their access to services and quality care. Physicians should be able to expect year-to-year stability in their payment rates rather than continuing annual large changes to payment rates that make budgeting and planning extremely difficult and uncertain. CMS should make year-to-year payment stability a goal of the MPFS and large redistributive impacts on payment should occur infrequently.

While we support updated clinical staff pricing to reflect inflation, **we strongly disagree that this should be done within the confines of a budget neutral system, unless there are concomitant inflationary updates to the entire fee schedule.** Under this logic, a physician office would have to choose between paying clinical staff fairly, or maintaining current investment in equipment, supplies, other facility costs, and/or physician compensation. Of course, we have all given our clinical staff raises over the past two decades, so the staff pricing updates only serve to redistribute payments amongst specialties within a fixed fee schedule.

The ACR appreciates CMS providing the BLS crosswalks they used to update the clinical labor pricing and allowing stakeholders the opportunity to provide comment on the appropriateness of those crosswalks where BLS data is not available for the staff types:

- For a mammography technologist, the ACR supports CMS' proposed crosswalk to a respiratory therapist (BLS 29-1126).
- For a CT technologist, the ACR supports CMS' proposed crosswalk to the MRI technologist (BLS 29-2035).
- For an angio technician, CMS proposes a crosswalk to "Other Healthcare Provider" (BLS 29-9000). In the past, an angio technician has been crosswalked to a radiologic technologist (BLS 29-2034). However, based on educational requirements and clinical similarities, the ACR recommends that the wage for an angio technician be crosswalked to that of an MRI technologist (BLS 29-2035) instead. An angio technician requires more

training and credentials beyond that of a radiologic technologist and performs procedures with higher intensities more in line with an MRI technologist.

- For the vascular technician, the ACR supports CMS' proposed crosswalk to a medical scientist (BLS 19-1040).
- For the medical physicist, CMS proposes a crosswalk to the 75th percentile of the average wage of a general physicist (BLS 19-2012). CMS acknowledges that a general physicist is paid lower than a medical physicist, which is why they proposed the 75th percentile. However, the ACR is concerned that the crosswalk will not accurately capture the wage of a medical physicist. Instead, we propose that CMS use the 2020 salary data collected by the American Association of Physicists in Medicine (AAPM). This is consistent with the methodology applied in 2002, when CMS used AAPM survey data instead of the BLS data.

Comment Solicitation for Codes Involving Innovative Technology

Proposal

In the proposed rule, CMS states that recent technological advances such as artificial intelligence (AI) may increase patients' access to care, improve outcomes, and possibly substitute or augment physician work. However, CMS is requesting feedback from stakeholders to help them understand the resource costs associated with procedures using AI or software algorithms. CMS admits that the current PE methodology does not capture indirect costs such as software and licensing fees that the innovative technologies rely on.

CMS poses several questions to stakeholders about how AI technologies and software contribute to physician work, as well as the resource costs associated with these procedures. CMS is soliciting feedback on the effects of AI on physician work, time and intensity, how to best capture AI costs, the risk of fraud and abuse over its utilization, and how it contributes to improvements in quality of care.

ACR Perspective and Comments

The ACR addresses CMS' questions below:

1) To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?

The ACR is currently unaware of any services involving innovative technologies that have made a significant impact in the workflow for radiologists. Most of the Food and Drug Administration (FDA) approved AI software algorithms are simple detection algorithms which compliment only one of many tasks a radiologist must perform during diagnostic interrogation of an imaging modality. These simple algorithms require a radiologist validation, therefore are not supplanting any human work, and may in fact add work. Overall, we believe that these services do not replace physician work.

2) How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?

The ACR believes that services involving innovative technologies, through detection of critical findings and prioritization of examinations, have the potential to improve patient care by assisting the physician in making a critical diagnosis more rapidly. However, the process of validating AI inferences while fully interpreting the examination for any associated or incidental abnormalities does not change the intensity of the physician work and may contribute to increased interpretation time.

3) How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?

The ACR believes that innovative technologies such as software algorithms for diagnostic imaging should be considered part of the service provided to the patient. It is likely that some AI software models will be able to use data collected as part of a previous imaging service or even amalgamate data from disparate sources to provide inferences that allow physicians to augment the care provided to their patients. While there should not be duplicative costs associated with data from examinations and other resources already performed, there could be costs associated with the amalgamation of the models' input data when it comes from disparate sources. At present there is no standard model or pricing for how end-users of AI technologies are paying the software vendors. For diagnostic imaging, in some cases, the addition of AI will be a standalone service in the workflow process. Currently, identification of single diseases is typical for models currently in clinical use. However, we should anticipate that models that are able to detect multiple diseases will become available and could impact cost-efficiency. In other cases, AI models may become embedded in the modalities themselves, with the AI cost becoming embedded in the overall pricing of the modality. We expect the delivery of AI to evolve synergistically with adoption of payment policies for AI. Adoption of new technology and the potential for increasing efficiency over time has long been considered by CMS. Payment policy for new technologies are reevaluated through the Relative Value Scale Update Committee (RUC) process and recommendations are given to CMS for their consideration. As such, we anticipate the long term efficiencies for innovative technologies such as AI will continually be monitored through the RUC valuation process as well.

4) How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to

Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care?

It is too early to tell whether AI will affect access to care or whether there will be disparity in whether certain beneficiaries have access to innovative technology. We are optimistic that AI will help our health systems overcome disparities in care by identifying patients at high risk for disease and alert those patients and their healthcare providers. We also believe AI will be able to monitor patients' compliance with therapy to ensure downstream care is obtained and identify and mitigate the potential barriers to care for some patients. It is also too soon to know whether there will be disparities in the use of AI among Medicare beneficiaries. We see both challenges and opportunities for rural practices. Rural practices are typically smaller and may be more limited in resources. A recent survey conducted by the ACR Data Science Institute (Allen B, Agarwal S, Coombs L, Wald C, Dreyer K. 2020 ACR Data Science Institute Artificial Intelligence Survey. Journal of the American College of Radiology. 2021 Apr 20) showed that only 23% of practices were using AI in their clinical workflow and the use of AI in smaller practices was significantly lower than in larger practices, in part because they believe AI could make them less efficient due to redundancy in physician work. At the same time, it is possible that innovative technology such as AI can enable smaller practices to more efficiently augment the care they currently provide. To facilitate that process, we believe that government entities should support cloud-based solutions for healthcare to increase access to these healthcare services. We look forward to working with the Agency as this process evolves to determine ways to close any potential gaps concerning access to care for all Medicare beneficiaries.

5) Compared to other services paid under the MPFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?

The potential to improve population health by identification of diseases prior to the onset of symptoms is one of the strengths of AI for healthcare. Quantification of liver fat, pulmonary emphysema, coronary artery disease, bone density and potentially many other disease processes is something human interpreters cannot do as part of routine interpretation of imaging studies. We know early treatment of these disease processes in the right patient populations can improve outcomes. However, there is always concern for potential over treatment and associated downstream costs for what some might consider unnecessary care. An anecdotal example is a suggestion from pulmonary physicians that quantitative AI be performed on every patient to identify patients for escalation of care including the placement of endobronchial valves. We should be mindful that while AI quantification will be a useful adjunct to care, it should not be the driver for care escalation. The ACR believes that the Agency should closely monitor the downstream consequences of the use of these types of innovative technologies in the fee-for-service environment. If there is inappropriate downstream utilization and escalation of costs

without demonstrable benefit, then CMS should consider whether these types of opportunistic screening examinations are only appropriate in value-based payment systems. Another consideration is that AI can inappropriately increase sensitivity by detection of subtle findings. In isolation, this has the potential to escalate care and is a reminder both radiological expertise and clinical judgement must be used in concert with AI to avoid inappropriate care escalation that may be unnecessary and wasteful.

6) Compared to other services paid under the MPFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?

The ACR is certainly mindful that bias can be introduced into AI models if training datasets are not typical of patient populations where the models will be used. End-users cannot expect AI to perform as expected without local evaluation and downstream monitoring. Unfortunately, the current U.S. FDA clearance process does not ensure generalizability in AI models and, as such, end-users have to assume responsibility for confirming the AI inferences and continuously monitor algorithm performance over time to ensure there is no degradation from changing equipment, protocols or patient population. Throughout the product life cycle, developers should consider unintended bias and provide transparency regarding datasets used for training, testing, development and validation. This should be a multi-agency effort, with involvement from the FDA, to ensure that a given vendor creates algorithms that are unbiased from a health equity lens.

7) How might CMS consider updating such data to reflect ongoing advances in technology so that we could establish appropriate relative values without resorting to crosswalks?

The number of AI models receiving FDA clearance is escalating and there are currently approximately 130 FDA cleared models for diagnostic imaging. As this process continues, we anticipate thousands of AI models could become available for clinical use over the next decade. New technologies are being categorized by the FDA into discrete groups of tools based on similarities in intended use and how the models function. The ACR believes that CMS should be cognizant of those categories but also consider whether resources to provide the service are disparate, and based on those observations consider creating an APC-like model for new technologies in which there are 4 to 5 payment categories (each with a standard crosswalk based on intended use, functionality and resources required) for these services to be placed into in order to streamline the process of updating the data based on technological advancement.

Proposed Valuation of Specific Codes for CY 2022

Needle Biopsy of Lymph Nodes (CPT code 38505)

Proposal
CPT Code 38505 (Biopsy or excision of lymph node(s); by needle, superficial (e.g., 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.

ACR Perspective and Comments
The ACR supports CMS' proposal to accept the RUC recommendation for physician work and PE inputs for CPT code 38505.

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

Proposal
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 iNsight 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.

ACR Perspective and Comments
The ACR supports CMS' proposal to accept the physician work valuation for CPT codes 77X01 and 77X04, both at 0.20 RVUs. However, the ACR disagrees with the PE crosswalk of CPT codes 77X01 and 77X03 to CPT code 71101. The procedures are not analogous, and we urge

CMS to reconsider the RUC's PE recommendations. The iNsight software is priced per scan at $25, which the RUC agreed is appropriate to list as a single-use supply item, as equipment inputs are typically allotted minutes. Currently, some of CMS' approved equipment inputs include software, so this is not a new precedent.

Proposal to Remove Selected National Coverage Determinations (NCDs)

Proposal

CMS proposed 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 to 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 Medicare Administrative Contractors (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 proposed 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 did not propose 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.

ACR Perspective and Comments

The ACR supports CMS' proposal to remove the NCD for PET Scans (220.6), allowing coverage decisions to be made by MACs. In addition to new non-oncologic PET agents that have been approved by the FDA, significant evidence in support of the use of 18F FDG in specific non-oncologic applications has also been developed. There is broad support in the literature and current practice for the use of 18F FDG in non-oncologic applications. The Society of Nuclear Medicine and Molecular Imaging has developed and published procedure standards for infection and inflammation.

Billing for Physician Assistant (PA) Services

Proposal

Historically, nurse practitioners (NPs) and clinical nurse specialists (CNSs) have been authorized to bill the Medicare program and be paid directly for their professional services, while payment for physician assistant (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 MPFS. 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 updating its regulations to conform with the CAA provision.

ACR Perspective and Comments

The ACR understands the need for equal treatment between PAs, NPs, and CNSs under CMS billing policy. The ACR continues to believe that PAs, and other non-physician practitioners (NPPs) are valuable members of physician-led health teams. **The ACR would like to reiterate our concerns regarding the scope of practice of NPPs.** Any new policies that take major steps that move patient care away from a physician-led team and more towards allowing PAs and advanced practice registered nurses (APRNs) to work in independent practice are a concern for radiological care.

The ACR has three principles that apply to NPPs working in radiology practices. All NPPs should work under the direct supervision of a radiologist. Importantly, no NPP should ever be allowed to interpret images, and none are meant to be trained to work in independent practice. NPPs are not interchangeable with radiologists or other physicians. Physicians are highly educated and must complete between 10,000 and 16,000 hours of clinical education. In comparison, most APRNs are only required to complete between 500 and 720 hours of clinical training. Loosening CMS' national policies on the supervision of NPPs and more broadly deferring to state law and scope of practice could detract from quality patient care. For example, at the state level there are many laws that allow for APRN's to perform and interpret X-rays under general supervision. From a medical training and malpractice perspective, this is a dangerous path to take regarding quality patient care and patient safety.

To ensure safety and quality standards for radiology services, NPPs should practice under direct supervision of a physician. NPPs offer value in providing quality patient care. However, accurate diagnosis and treatment of disease and injury commonly depends on proper interpretation of imaging exams by highly trained radiologist physicians. CMS should not compromise quality patient care and safety by deferring solely to state law and scope of practices which vary widely from state-to-state.

Physician Self-Referral Updates

Proposal

CMS proposes to revise its Stark physician self-referral regulations relating to indirect compensation arrangements. Under the Stark statute, these arrangements involve an "unbroken chain" between the referring physician and the entity providing designated health services (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.

ACR Perspective and Comments

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 inadvertently did not 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 proposed revising 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 they personally perform.

ACR supports CMS' proposal. We believe that it would reinforce CMS' longstanding position that certain economic and clinical arrangements remain problematic for quality patient care. Per-unit or per-service space or equipment rental might well compromise physicians' decisions and lead to overutilization or patient steering. The ACR advocated in 2008 for CMS to restrict such arrangements in imaging and radiation therapy. CMS did so then in the fiscal year (FY) 2008 IPPS final rule. If CMS adopts its proposal in this MPFS rule, patients will benefit because the Government could enforce the Self-Referral Law against a wider array of compensation scenarios.

Telehealth

Proposal

CMS created Category 3 telehealth services on a temporary basis in response to the COVID-19 PHE. Category 3 includes services for 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. In an effort to collect sufficient evidence, CMS is proposing to retain all Medicare telehealth 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. CMS has found that audio-only E/M visits has been one of the most utilized services during the PHE, with most beneficiaries receiving mental health services. In response, CMS is proposing to define interactive telecommunications systems to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, and treatment of mental health furnished to established patients when the originating site is the patient's home.

Through the end of the year in which the PHE ends, CMS is allowing direct supervision to include immediate availability through a virtual presence using real-time audio/video technology. CMS is seeking comment on the extent to which this flexibility is being utilized during the COVID-19 PHE, and on whether it should be made permanent.

ACR Perspective and Comments

The ACR recognizes the value of telehealth services, particularly in rural areas, and the extent to which they have been utilized during the PHE. The **ACR urges CMS to monitor health outcomes and utilization of imaging in telehealth.**

QUALITY PAYMENT PROGRAM

Updates to the Quality Payment Program (QPP)

CMS introduces multiple requests for information (RFI) on areas that would impact traditional Merit-Based Incentive Payment System (MIPS) and future MIPS Value Pathways (MVPs) participation and seeks input on the following proposals.

Advancing to Digital Quality Measurement and Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

Proposal

The CMS RFI *Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs* discusses transitioning CMS quality reporting and value-based purchasing programs to digital quality measurement (dQM) by 2025. The shift to 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 (ONC) for Health Information Technology (HIT) has finalized policies in the Cures Act regarding "complete access, exchange, and use of all electronically accessible health information."

ACR Perspective and Comments

The ACR supports the concept behind CMS' adoption of FHIR to reduce the collection and analysis burden imposed by current electronic clinical quality measures (eCQMs). **However, we request a delay to the aggressive 2025 transition deadline**. We encourage the use of the data collection structure and single terminology to obtain eCQM data. We urge CMS to propose

guidance for measure developers, vendors, and other stakeholders to inform the necessary details to transition to FHIR-based eCQMs. For instance, which version of FHIR would vendors implement, what degree of complexity is expected of the FHIR queries, and what type of subject matter expertise is needed to engage in the transformation successfully (i.e., ensuring technical specifications capture the required data elements to assess performance)?

The ACR anticipates translating radiology eCQMs to dQMs will be complex. While most data elements may be extracted from electronic health record systems, much of it lives in non-structured data fields that lack the necessary standardized terminology for translation required of FHIR resources. It is possible to do the translation but prioritization of resources to do such will likely be at issue. We are encouraged by the intention for dQM to contain language that would process digital data for determining measure scores, thereby promoting quality feedback reports more rapidly. Such rapid performance feedback would inform practices with data for making "actionable" improvements in care as immediately as possible. The prompt receipt of performance reports and the proposal to redesign quality measures as "self-contained tools" using dQM software incorporates end-to-end measure calculation solutions would make participation in quality programs, including MIPS, seamless.

The ACR is interested in learning more about CMS' plan for prioritizing components that would support the dQM portfolio, like measurement topics, measure development/digitization requirements, and data standards. We also request more information regarding dQM criteria; this would clarify the expertise required by measure developers and stewards for developing and digitizing measures for the eventual transition. **Given the complexities of transitioning to dQM, the ACR recommends that CMS delay the timeline for complete dQM transition at least until two years after the end of the PHE and to allow for greater availability of information and guidance for stakeholders.**

Closing the Health Equity Gap in CMS Clinician Quality Programs

Proposal

CMS' RFI on *Closing the Health Equity Gap in CMS Clinician Quality Programs* 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 proposes the following changes regarding the Complex Patient Bonus.

- Limiting the bonus to clinicians with a median or higher value for at least one of the two risk indicators (Hierarchical Condition Category and dual proportion).
- Updating the formula to standardize the distribution of two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients.
- Increasing the bonus to a maximum of 10 points.

ACR Perspective and Comments

The ACR applauds CMS' initiative on improving the health equity gap across its quality programs and including its clinician quality programs. Health care inequities are prevalent, as emphasized by the continuing COVID-19 PHE. CMS is using a definition of equity as described in the recent Executive Order that identifies systemic racism as the basis for differences in health outcomes between socially defined racial groups nationally. We agree with CMS' plan to transparently provide health disparity data 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.). By including this information in the context of the reports in which stakeholders are already familiar, improvements to close health equity gaps may be more quickly implemented by practices.

We encourage CMS to carefully standardize demographic data collection across quality programs and measures while retaining key current elements that serve as proxy demographic data until a fuller set of demographic data is standardized for capture in measure data sources. We agree that a method for reporting health equity performance results across multiple measures would illustrate a narrative for informing MIPS eligible clinicians on the disparities in their care. However, we emphasize that the desired new or additional data elements captured should not negatively influence the clinical workflow, increase the burden of quality measure data collection, or duplicate other similar data collection programs.

The ACR agrees with including improvement activities in MIPS that address creating and implementing anti-racism plans. We anticipate that activities like this could trigger the other CMS quality measurement program participants (e.g., facility-level program) to detail anti-racism strategies for their specific level of measurement.

We recognize that radiologists are well-intentioned regarding providing high-quality, equitable care; and find that the proposed MIPS improvement activity acknowledges practices' insufficiency of formal plans for gathering and analyzing data by race and documenting disparities by different population groups. The ACR is interested in working with our stakeholders to revise existing activities and measures to address the health equity gap. The ACR recommends modifying the measures and activities to include specifications linking them to closing the health equity gap. However, we stress the importance of retaining the original measure's action or core activity without solely shifting their focus on health equity.

The ACR also supports the proposed revisions regarding the complex patient bonus calculation methodology. We are encouraged by program flexibilities which award additional points to clinicians with a higher percentage of *medically* and *socially* complex patients and do not lower the standard of care.

Transforming MIPS: MIPS Value Pathways

Proposal

As part of CMS' transition from traditional MIPS to MVPs, the proposed rule includes a comprehensive set of policies and procedures that inform the sunsetting of traditional MIPS and MVP implementation and scoring (including category reweighting) of MVPs for eligible clinicians participating in MIPS (as individuals and groups). CMS maintains that MVPs would be incrementally added to the QPP upon availability as part of rulemaking. Traditional MIPS would sunset once there is a comprehensive inventory of MVPs for all eligible clinicians to participate. CMS highlights that stakeholders largely support the MVP Framework goals.

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.

ACR Perspective and Comments

ACR applauds the efforts associated with CMS creating a pathway for MIPS eligible clinicians participating in MVPs to receive their MIPs performance feedback more granularly and rapidly, thus, granting the opportunity for these clinicians to make precise changes to their practice that expediently improve patient care. **However, we request clarification on conflicting proposals included in the rule that suggests otherwise.**

In the section titled, “Proposed Enhanced Performance Feedback in MVPs,” CMS acknowledges the importance for MIPS participating clinicians to “receive more timely and actionable feedback during the performance period.” The proposed rule further states that CMS’ process to pursue the receipt of such timely feedback is complex and would require several solutions for this to be enabled. For instance, accessing the data and sharing performance feedback requires clinicians to submit data earlier to provide the enhanced performance feedback during the performance period - necessitating significant investments in time and money for CMS, third-party intermediaries, and clinicians. The ACR is concerned that the transition to dQM misaligns with efforts to provide enhanced performance feedback in MVPs. In other words, resources that could support solutions for third-party intermediaries and CMS to provide the enhanced feedback are uncoordinated with the dQM transition efforts. Unfortunately, this misalignment between these performance feedback initiatives could hinder medical specialties’ transition to dQM.

We appreciate CMS' efforts in working with stakeholders, like medical professional societies, regarding proposed MVPs before they are subject to rulemaking. By doing this, CMS acknowledges the vital role that medical specialty societies play in organizing subject matter expertise for providing input on MVP development for their medical specialty. The ACR is in the early phases of MVP conceptualization. We request clarity on the following.

The limitations in traditional MIPS that most radiologists face prevent them from earning scores for the Cost and Promoting Interoperability performance categories. Therefore, most radiologist

participants' scores are reweighted to the Quality and Improvement Activities performance categories. We are cautious about future radiology-focused MVPs that comprise the complete set of promoting interoperability measures and episode-based cost measures. We are concerned by CMS' assumption that radiology-focused MVPs should comprise all promoting interoperability and population-based cost measures. However, most MIPS radiology participants have been excluded from being scored on these measures. As such, we question CMS' objective in completing MVP transition from traditional MIPS as early as the performance year 2028.

Furthermore, we welcome CMS' proposal for external entities to develop episode-based cost measures, since until now, CMS has supervised their development solely through its contractors. The ACR recognizes this as a step in the right direction by acknowledging that stakeholders can develop cost measures unique to their specialty, possibly bolstering the broader episode-based cost measures included in MIPS. However, diagnostic radiology does not readily fit into episode-based care models. Given these radiologists' role as consultants to referring clinicians, they collaborate with patients' treatment teams by providing imaging results and care recommendations as a part of an episode. They do not own condition or procedure-based episodes the way pulmonologists or cardiologists do. MVPs would better serve radiology practices and patients by measuring imaging costs against a national radiology spending benchmark determined for a particular condition, like lung cancer. The ACR urges CMS to consider non-episode-based cost measures for development by stakeholders and their inclusion in future MVPs.

We caution CMS with sunsetting traditional MIPS until CMS demonstrates that MVP reporting has proven effective and meaningful for a specific medical specialty and there is buy-in by those MVP participants. Feedback from radiologists indicates low acceptance regarding the benefits of MVP reporting. There may be a limited inventory of meaningful radiology quality measures proposed available for inclusion in future MVPs due to the number of ACR measures on the topped-out measure cycle (including two proposed for removal this year).

MVP and Subgroup Implementation Timeline

Proposal

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. Within this proposed rule, CMS also 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 would allow each MIPS eligible clinician to receive feedback from CMS on the care they are directly attributed, providing the opportunity for all clinicians in a 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.

ACR Perspective and Comments

The ACR agrees with CMS that the proposed subgroup reporting option is essential for those in MIPS reporting under a multispecialty group. To date, multispecialty groups report the same set of measures, which are often irrelevant and/or lack meaning to a portion of specialists. For instance, radiologists who participate within a multispecialty group are unable to use MIPS measure performance feedback to improve patient care because the measure set chosen by the practice does not reflect the care that they provide.

We are uneasy with CMS' ambitious timeline for multispecialty groups' mandatory reporting as subgroups in MVPs beginning in 2025. As previously stated, radiologists and MVP developers face obstacles with the Cost and Promoting Interoperability performance categories. MVP developers are to some extent limited in developing a radiology MVP that meets the criteria for rulemaking. The ACR is uncertain of the MVP(s) that may become available for radiologists required to participate as a subgroup under their multispecialty group. **Should a radiology MVP not be available when multispecialty subgroup reporting becomes mandatory, how would those multispecialty group participants excluded from an MVP be scored in MIPS?**

Proposal

CMS outlines several methods for potential restrictions on subgroup composition such as limiting to a subgroup of clinicians of the same or related specialty or a threshold of 75% of eligible clinicians in a subgroup be of the same or related specialty; or limiting by practice location, clinical setting, patient population or scope of care provided by a subgroup.

CMS further proposes that determination for special statuses, i.e., low volume threshold or non-patient facing status continue to be determined at a group level and not allow a special status designation at the subgroup level, even if a subgroup is eligible for special status designation.

ACR Perspective and Comments

CMS' rationale for the restriction on subgroup special status designation is that it would deter construction of subgroups that would inappropriately create special status determination such as a subgroup of 15 or fewer eligible clinicians. The ACR recognizes there could be scenarios in which a subgroup with a low volume threshold special status could be inadvertently created or even purposefully designed to carry the associated exemptions. However, it does not follow that intentional crafting of a radiology subgroup to create special status exemptions would occur. If CMS implements the subgroup limitation of same/related (or 75% threshold same/related) specialty composition and disallows special status designation and associated exemptions, that will place a radiology subgroup in a position of needing to meet requirements for all four MIPS categories, when it is known that most radiologists will not have Cost and Promoting Interoperability measures (or Quality population health measures) attributable to them. The ACR

strongly recommends that CMS not implement the single specialty subgroup composition limitation and allow special status designation to carry through to a subgroup.

Additionally, the ACR believes that subgroup composition would not benefit from the constraints that CMS proposes, particularly the limitation to a single specialty but also based on other factors such as geographic location or practice setting. This restriction would inhibit a multi-specialty group's clinical team from forming a subgroup for a clinical condition- or episode-based MVP such as stroke care. Such patient care requires multi-disciplinary involvement – neurologists, cardiologists, emergency physicians, neuroradiologists, etc. – to provide patient-focused quality care. That condition and patient focus is one of the guiding principles of the MVP framework. Also, if each specialty in a multi-specialty group were required to form separate subgroups to participate in such a condition-focused MVP, radiologists may be unfairly impacted due to the non-patient facing special status removal and the associated exemption/reweighting allowed for Cost and Promoting Interoperability. In contrast, radiology groups or other specialty groups with their own distinct Taxpayer Identification Numbers (TINs) who have special status designation would retain that determination and exemptions when participating in the same condition-based MVP. As such, we strongly support CMS' special status determination for non-patient-facing MIPS eligible clinicians and rural or small practices be carried through to subgroup reporting and recommend that CMS encourage multispecialty groups to form subgroups to achieve the desired patient outcomes of the MVP without additional artificial reporting barriers. The ACR would like to engage in dialogue with CMS so that MVP development, implementation, and adoption are seamless in capturing the performance of all radiologists despite their degree of patient engagement, practice size, or location. The ACR is interested in accurately demonstrating the essential role that radiologists provide patients and the impact on care value.

Selection of Measures and Improvement Activities Within an MVP

Proposal

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. Within this rule, CMS is proposing participation requirements for MVP reporting. The following details the components as they would apply to participating radiologists.

Proposed requirements necessitating MVP participant action—

- *Quality Performance Category*: If applicable, four quality measures, including an outcome measure or high-priority measure (in the absence of an outcome measure).
- *Improvement Activities Performance Category*: Attestation of one high-weighted activity or two medium-weighted activities.
- *Promoting Interoperability Performance Category*: Report all Promoting Interoperability measures.

Proposed requirements for which CMS is responsible—

- *Cost Performance Category*: CMS automatically determines according to the administrative claims information. No additional data submission by the MVP participant is required by CMS.
- *Quality Performance Category—Population Health Quality Measure*: Administrative-based claims quality measure focused on public health priorities

ACR Perspective and Comments

The ACR appreciates the level of detail included in the proposed requirements for MVP participation. Previously, CMS stated the requirements would be reduced when compared to traditional MIPS. Due to the details in the proposed rule, participating radiologists can recognize MVPs' role in reducing MIPS participation burden. The ACR supports CMS' reduction of participation requirements for the Quality and Improvement Activities Performance categories. Provided that MVPs applicable to radiology care become available, submitting data for four quality measures and no more than two improvement activities (according to their assigned weight) are strongly preferred.

The ACR urges CMS to adopt flexibilities for non-patient-facing clinicians, like diagnostic radiologists, as they likely would be unable to collect data for promoting interoperability measures that apply to patient-clinician encounters. Moreover, we recognize that the proposed inclusion of administrative claims-based population health measures would not add to MIPS participants' quality reporting burden. However, we are very concerned that no population health quality measures are attributable to radiologist care. As such, we encourage CMS to implement scoring flexibilities that prevent penalizing MVP participants' Quality Performance category scores due to the lack of applicable claims-based population health measures.

Public Reporting of MVP Data

Proposal

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. 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.

ACR Perspective and Comments

The ACR requests clarification on the public reporting proposals included in the rule. As previously described, we are unaware of how ready radiologists practicing in a multispecialty group would be by 2025 to form a subgroup and participate in an applicable MVP. As such, it is unclear to us how publicly reporting performance data on Care Compare for some but not all

clinicians in a multispecialty practice would impact those without available MVPs. The ACR requests that CMS ensure details are provided on the Care Compare website that explains (in a user-friendly manner) why particular specialists within the multispecialty practice do not have quality data published to the site and what this means about the care that these specialists provide.

Facility-Based Measurement

Proposal
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 the facility-based clinician or group MIPS final score is higher through another MIPS submission method. 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.

ACR Perspective and Comments
The ACR appreciates CMS' diligence in addressing this error with facility-based measurement. We agree that the higher of two scores should be used when determining the final score for clinicians and groups eligible for facility-based measurement.

MIPS: Claims Reporting for Small Practices

Proposal
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 clinical quality measures (CQMs) as a group. If they do not report at least one performance category as a group, they will be considered individual submitters.

ACR Perspective and Comments
The ACR supports this proposal and believes that it will prevent cases of clinicians receiving group scores when that is not the reporting intention.

MIPS: Quality Measure Scoring

Proposal
CMS has proposed to raise the scoring floor for new, non-benchmarked measures from three to five points during their first two years in the MIPS program. CMS also proposes to award zero points to a non-benchmarked measure if it remains non-benchmarked beyond this two-year period.

ACR Perspective and Comments

The ACR supports CMS' proposal to raise the scoring floor to five points for new measures in the program; however we strongly suggest extending this grace period to four years rather than two years. We believe that a five-point score will increase participation in new quality measures, but we also acknowledge that it takes time for clinicians and practices to adopt new measures. As stewards of MIPS measures and developers of Qualified Clinical Data Registry (QCDR) measures, we know firsthand that it can be a struggle to submit new measures. Recognizing that valuable practice resources are necessary to begin using new measures, many practices are disincentivized to submit non-benchmarked measures that may only receive a minimum default score. Not only are technical and administrative resources required to begin abstracting the data for new measures, but using new measures also affects the radiologists' workflow and requires time for changes to be implemented. The ACR is also concerned with how this policy will be adopted for measures new in 2020 and 2021 which have had a low adoption rate due in large part to the COVID crisis. Both performance years allowed automatic exemption for non-reporters; therefore, it is possible that new measures implemented within that timeframe may show low adoption rates and fall below the threshold for benchmarking. For these reasons, we strongly encourage CMS to expand the proposal to a four-year grace period. This would prevent premature removal of meaningful measures from the program.

MIPS Quality Performance Category: Removal of Bonus Points

Proposal

CMS proposes to end the practice of awarding bonus points for additional high priority or outcome measures.

ACR Perspective and Comments

The ACR strongly opposes the proposal to eliminate bonus points from the quality performance category. We believe this proposal would unfairly penalize specialties such as radiology who already have a small pool of reportable, benchmarked measures, many of which are capped at seven points, and may make it nearly impossible for some practices to reach the neutral performance threshold of seventy-five points. If a practice is only able to report topped-out measures, even if receiving seven points for perfect performance, there is potential to receive a negative adjustment.

The ACR also believes that the bonus point policy benefits the entire MIPS program. The prospect of receiving bonus points encourages use of non-benchmarked measures and incentivizes practices to submit more complete data. This contributes to more robust benchmarking for all quality measures and faster adoption of new measures. The ACR strongly believes that practices should continue to be awarded for going above and beyond in their quality reporting.

MIPS: Quality Measure Data Completeness

Proposal
CMS proposes to maintain the data completeness threshold of 70% through 2022, but to increase it to 80% for the 2023 MIPS performance period.

ACR Perspective and Comments
The ACR appreciates that CMS wishes to maintain the data completeness at 70% through 2022. However, we would suggest a more incremental approach to raising data completeness in future years. The ACR believes that small and rural practices will find it difficult to reach 80% data completeness, therefore we suggest maintaining the completeness threshold at 70% for a longer period. Additionally, during the PHE much of quality reporting work was postponed, delaying integration of additional locations or data sources into the collection process. There should be a window of time following lifting of the PHE to allow practices to catch up on expanded reporting. **ACR also requests that CMS clarify what they view to be the future upper bound of data completeness for quality reporting. Assuming 100% will never be feasible, does CMS expect 80% to be the ultimate goal for data completeness?**

MIPS: Quality Measures Proposed for Removal

Proposal
CMS has proposed to remove the MIPS quality measures #195: *Stenosis Measurement in Carotid Imaging Reports* and #225: *Reminder System for Screening Mammography*.

ACR Perspective and Comments
The ACR strongly opposes the removal of these measures, and we believe they continue to contribute to improving standards of care. Measure #195 continues to be endorsed by the National Quality Forum. During the most recent National Quality Forum Neurology Committee Standing Committee endorsement period, ACR staff examined the performance and patient volume data from MIPS participating radiologists. When comparing it to the claims data for exams that included the type of imaging included in this measure denominator, ACR staff discovered a variation between those who submitted this measure and those who could have submitted it but did not. In other words, there is a portion of eligible radiologists who selected not to use this measure.

Given the adoption disparities with measure #195 the ACR strongly recommends that CMS remove its topped-out status and begin working with stakeholders to identify solutions for engaging those eligible radiologists to use it and reduce disparities in this area.

Measure #225 is currently the only MIPS measure applicable to dedicated breast imagers following removal of numerous applicable measures from the program. The ACR also notes that data in publications has shown lower return to screening by patients during the COVID crisis, particularly in safety-net hospitals and under-served, rural and minority populations. See, for example, the article "Trends in Breast Cancer Screening in a Safety-Net Hospital During the

COVID-19 Pandemic", which was published in JAMA on August 6, 2021. We are also concerned that the removal of measure #225 from MIPS may make it more difficult to create a potential mammography MVP in the future, as this MVP would certainly rely on existing MIPS mammography measures when establishing quality scoring. We strongly believe there is value in maintaining both measures in the MIPS program.

More generally speaking, **the ACR strongly advises that CMS redefine topped-out measures by expanding the definition to include analysis of participation rates for a particular measure, rather than just the percentage of those who perform and their scores. We have found that this would help address closing the health equity gap.**

MIPS: Reweighting Policy for Small Practices

Proposal

CMS proposes to change the reweighting percentages for small practices that are exempt from both the promoting interoperability (PI) and cost categories. With this new proposal, a group or individual from a small practice who is exempt from PI and cost would have their quality category weighted at 50% and their improvement activities category also weighted at 50%. Practices who are exempt from PI only would have quality weighted at 40%, improvement activities (IAs) weighted at 30% and cost weighted at 30%.

ACR Perspective and Comments

The ACR supports this proposal but suggests it be similarly applied to all practices. With the new performance threshold proposed at seventy-five points and many measures being capped at seven points, it is becoming increasingly difficult for groups to obtain even the neutral adjustment when the quality category is weighted so highly. Most radiologists are non-patient-facing and exempt from PI and cost, indicating the need for a broader application of CMS' proposal.

MIPS: Cost Performance Category

Performance Category Reweighting

Proposal

CMS is seeking comments on additional circumstances that may limit the ability to reliably calculate cost measure scores to adequately capture and reflect performance (such as external factors beyond the control of MIPS clinicians and groups), and that may inform the decision to reweight the cost performance category to provide scoring flexibility in the future.

ACR Perspective and Comments

The ACR encourages CMS to continue monitoring the PHE throughout 2021 and provide category reweighting of 0% towards the final MIPS score if clinicians are adversely affected by the PHE.

Proposed New Cost Measures

Proposal
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.

ACR Perspective and Comments
The ACR commends CMS and its contractor, Acumen, for developing these new cost measures. The measure development process has been transparent and efficient, with various stakeholders involved in several different committees. ACR members have been involved in some of the Acumen committees and have no objections to these five proposed measures.

Cost Measure Development

Proposal
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 Measures Under Consideration (MUC) process. 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.

ACR Perspective and Comments
The ACR strongly agrees with allowing stakeholders to submit candidate cost measures to CMS through a Call for Cost Measures. The ACR encourages CMS to convene a group of stakeholders from various specialties to outline priority areas and performance gaps within cost measurement. CMS should provide more guidance on developing cost measures and the pre-requisites on specifications and testing. It would be helpful to have a document, like the Measures Management System (MMS) Blueprint, to assist measure developers with cost measurement development methodology and specifications.

Regarding future cost measures, the ACR suggests developing a breast cancer screening episode-based measure that encompasses screening mammography through cancer diagnosis or return to annual screening. This episode is almost entirely under the radiologist's direct oversight, making it feasibly attributable to a radiology group. There are well-established quality metrics that breast imaging physicians use that could be linked to this cost measure as an MVP. Previously included in MIPS as QCDR measures, cancer detection rate, recall rate, and true/false positive rates would be a fair balance to a breast cancer screening (BCS) cost measure. The ACR would advocate reintroducing these to MIPS, linked to a BCS cost measure. This suite of measures, including a cost measure, could provide a comprehensive view on the quality and efficiency of diagnostic care in this area to the benefit of patients and could potentially be a candidate for a CMS MVP.

A significant challenge that radiologists confront is a lack of opportunity to be recognized for care coordination and the inability to be rewarded for team-based care led by radiologists. Management and care coordination of imaging incidental findings, incorporating both prevention of unnecessary or repeat testing and assurance that evidence-based follow-up recommendations are completed, are concepts worthwhile to explore as cost measures for radiology. Across an incidental finding episode, prevention of low-value follow-up testing, or a "null event" may be assessed as part of the full episode, like a low back pain episode-based cost measure for orthopedics, where surgery was avoided, and costs attributed would be limited to evaluation and management codes. For example, an abdominal CT incidental-finding episode may begin with the CT exam, carry through any downstream management or referrals to specialists, and compare costs of the episode when radiologist recommendations stated "no follow-up necessary" to cases where radiologist guidance was not explicit. Overdiagnosis of benign incidental findings places patients at risk for anxiety and unnecessary harm from diagnostic procedures and treatment. A standardized approach to managing incidental findings is desirable to reduce practice variation, decrease costs, limit the potential for harm from unnecessary therapies (biopsies or surgeries) and alleviate unnecessary patient and physician anxiety. Additionally, MIPS quality measures focused on incidental finding-appropriate recommendations currently exist, providing an opportunity for balance with cost measure(s) for this concept.

Proposal
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.

ACR Perspective and Comments
The ACR agrees that there should be a transparent process for evaluating substantive changes to cost measures, similar to quality measures. A contractor may facilitate this process more easily. Service codes and measure elements should be reviewed on an annual basis. Substantive changes, such as risk adjustment methodologies, must be put in the proposed rule for stakeholder comment.

MIPS: Improvement Activities Performance Category

Call for Improvement Activities

Proposal
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 PHE. CMS is proposing to revise that exception; all nominations during a PHE must be submitted by January 5 of the activity implementation year.

ACR Perspective and Comments
The ACR has no objections to this proposal.

Proposal
CMS is 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.

ACR Perspective and Comments
The ACR agrees with CMS that this proposal will increase the chances of an improvement activity's acceptance to the program. The ACR requests that CMS clarify what is considered "standard clinical practice", so stakeholders can better understand improvement activity requirements.

MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

Proposal
CMS proposes that beginning with the 2023 MIPS performance period, QCDR and qualified registries must support MVPs that apply to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APM Performance Pathway (APP).

ACR Perspective and Comments
We anticipate that ACR's QCDR, the National Radiology Data Registry (NRDR) MIPS Portal, would be capable of supporting applicable MVPs as they become available. As part of our QCDR self-nomination for the calendar year 2022, the ACR is requesting to jointly license a subset of QCDR measures with other QCDRs appropriate for radiology. We anticipate that engaging in this type of measure sharing would prepare ACR with the capacity to support MVPs with QCDR measures from other radiology-focused QCDRs.

Considering the language used in the proposed rule that communicates explicitly that QCDRs would be required to support MVPs by 2023, we request clarification of the proposed requirement regarding QCDRs supporting the APP. **Is the expectation that QCDRs would support APP participation through QCDRs beginning in 2023, as well?** The ACR is concerned that although the set of APP quality measures includes MIPS CQMS, these are not measures that our QCDR would typically support, given the measures' topic areas and unlikely participation by radiologists. As such, the ACR is uncertain of the resources required for supporting these MIPS CQMs in our registry and whether there would be any return on investment associated with supporting the APP quality measure set.

QCDR Not Approved or Not in Good Standing

Proposal

CMS proposes that for QCDRs to use QCDR measures stewarded by another QCDR, CMS must approve the QCDR measure during the self-nomination process. Therefore, QCDRs stewarding the measures subject to inclusion in another QCDR must be approved and in good standing with CMS.

ACR Perspective and Comments

The ACR requests clarifications to this proposal. Our concerns apply to those QCDR measure stewards whose entities no longer support a QCDR for various reasons, excluding CMS termination or poorly specified QCDR measures. The ACR disagrees that QCDR measures become invalid if the QCDR from which they originated is dormant. There are instances when dormant QCDRs maintain the former QCDR measures in their clinical quality data registry. Continuing to include the measure for quality improvement projects would require the measure to be maintained by the measure steward. These measures would likely continue to be approved during self-nomination had the entity submitted a QCDR self-nomination. **The ACR urges CMS to consider that QCDR measures remain available for inclusion in another QCDR. We also find that it is essential that QCDR measure stewards who no longer wish to maintain QCDR measures make reasonable efforts to transition them to an appropriate steward.**

QCDR Measure Testing Requirements for Calendar Year 2023 and Beyond

Having sufficient quality measures available for radiologists is a top priority of the ACR's measurement strategy experts. It is necessary to develop a subset of radiology QCDR measures prior to submitting them to the Measures Under Consideration pre-rulemaking process for eventual adoption into MIPS. We appreciate CMS' intention to balance the volume of MIPS CQMs with QCDR measures when approving candidate MVPs. As a result, the ACR finds it essential that CMS return to the less restrictive MUC process performed before 2017. Over the last four years, the number of measures approved via the MUC has declined precipitously from several dozen measures to four quality measures last year. Combined with measure attrition, radiology groups' availability of quality measures to report has become increasingly limited. **CMS should reinstitute the MUC process that ensued before 2017 to support a more extensive inventory of radiology-focused MIPS measures, thereby encouraging the ACR and other radiology QCDRs to submit QCDR measures through the MUC process**.

The ACR is aware that efforts to expand the inventory of radiology quality measures would be challenging due to requirements by CMS regulation. We are very concerned about CMS' QCDR measure testing policy scheduled for 2023 and beyond. Per the calendar year 2021 QPP final rule, CMS determined it sufficient for QCDR measures submitted for use in the QPP performance year 2022 to undergo face validity testing to be approved. However, for QCDR measures approved for use in 2023 (and beyond), CMS requires "full testing." Given the methods for "fully testing" measures, the ACR faces limitations to the extent we may test several

measures mainly because there is no immediate incentive for routine practices participating in our QCDR to participate in this testing. Ultimately, it is unlikely that we could collect the volume of data necessary to demonstrate empirical validity for many of the newer measures within the CMS designated time.

We recognize that CMS intends to implement the testing requirements over the next year. We believe that "fully" testing more than a dozen QCDR measures on data that is not readily accessible will not be feasible even with this time lag. In 2020 and again in 2021, CMS rightly allowed groups disrupted by the COVID-19 pandemic to apply for and receive a hardship exemption. That policy, however, reduced the amount of data available for QCDR measure testing. **Because the extreme and uncontrollable circumstances policy decreased the number of groups reporting to MIPS via our QCDR, or the measures that were reported, we request that the measure testing requirements (excluding face validity testing) be delayed until two years after the PHE ends.**

Moreover, CMS proposes several changes to MIPS that would transform measure development and testing in the next five to ten years. CMS has an opportunity to align measure testing with its more significant priorities regarding digital quality measurement, health equity, and the implementation of MVPs. The ACR urges CMS to gradually implement this testing policy over two years following the expiration of the PHE and work with individual measure stewards on prioritizing measures and identifying the appropriate measure testing methods per measure. The ACR is also concerned by CMS' timeline for migrating to digital quality measurement, specifically, if stratifying measures by socioeconomic, racial, and ethnic characteristics, as this could complicate measure testing. Requiring "fully tested" measures by 2023 is unlikely to meet CMS' expectations.

In addition to CMS delaying measure testing beyond the PHE by two years, the ACR recommends that medical specialty society QCDR measure stewards proactively share testing plans for CMS review, resulting in feedback for achieving approval. Further, the ACR recommends that measures undergo this degree of testing once unless a measure is substantively updated. Therefore, such testing should be required to ensure that the revised measure retains its scientifically acceptable standards. The ACR encourages that CMS develop a consistent evaluation method of measure testing data, including those responsible for reviewing the methods and results, guidance regarding CMS' determination of insufficient data, and the availability of an appeals process. The ACR also encourages CMS to promote a broad-based improvement activity that would provide MIPS practices the opportunity for earning MIPS points for participating in their respective QCDR's measure testing process. Such an improvement activity would ensure that practices participate in QCDR measure testing, incentivize their participation in MIPS, and satisfy the requirement for QCDR measures to be "fully tested."

Conclusion

The ACR appreciates the opportunity to provide comments on the CY 2022 MPFS proposed rule. We encourage CMS to continue to work with physicians and their professional societies through the rulemaking process in order to create a stable and equitable payment system. The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Angela Kim at 800-227-5463 ext. 4556 or via email at akim@acr.org.

Respectfully Submitted,

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