

September 11, 2023

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services US Department of Health & Human Services 200 Independence Avenue SW Washington, DC 20543

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure,

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments on the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1784-P) as published in the *Federal Register* on August 7, 2023.

ASNC is a 4,900 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification with the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Specifically, ASNC offers comment on the following:

- Medicare Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging
- Promoting Continuous Improvement in the Merit-based Incentive Payment System (MIPS)
- Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation
- Request for Comment About Evaluating E/M Services More Regularly and Comprehensively
- Rebasing and Revising the Medicare Economic Index (MEI) & Indirect Practice Expense Methodology

MEDICARE APPROPRIATE USE CRITERIA (AUC) PROGRAM FOR ADVANCED DIAGNOSTIC IMAGING

ASNC strongly supports CMS' proposals to pause implementation of the AUC Program for reevaluation and to rescind the current AUC program regulations, effectively ending the educational and operations testing period.

ASNC and its cardiovascular partner societies have led the way with the development of AUC for diagnostic imaging, and we continue to advocate for its use to help guide the appropriate utilization of cardiovascular tests.

Although Congress may have believed the AUC Program was a straight-forward approach to encourage the consultation of AUC by clinicians, ASNC has long held the law is overly prescriptive, complex, and siloed from, rather than integrated with, other CMS quality improvement programs. ASNC is grateful for the numerous opportunities of public comment and engagement that CMS has afforded ASNC and other interested parties.

We support that CMS has reached the conclusion the real-time, claims-based reporting requirement prescribed by the *Protecting Access to Medicare Act (PAMA)* presents an "insurmountable barrier" for CMS to fully operationalize the AUC program, including because the existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that would or would not be subject to the AUC program requirement to report AUC consultation information as required. Without these capabilities, there is risk of inappropriate claims denials and CMS would be unable to accurately collect information on AUC consultation and imaging patterns that would ultimately identify outlier ordering professionals who would be subject to prior authorization.

CMS has noted in previous rulemaking the complexity and challenging nature of the AUC Program mandate. Indeed, there is no other requirement in Medicare in which the health care professional rendering a service is financially at risk for the conduct of the health care professional ordering a service. As CMS accurately points out in the proposed rule, this process puts furnishing professionals, including free-standing and hospital-based facilities, in the position of attesting to the credibility and accuracy of information provided to them by an ordering professional and, consequently, they may find themselves subject to audits or post-pay review.

Beyond the technical challenges associated with AUC Program implementation, we appreciate CMS' acknowledgment of the burden of adding to the workload of health care professionals who order and/or furnish advanced diagnostic services. A flaw of the statute was the vastness of the program requiring AUC consultation and claims documentation for every advanced diagnostic imaging test. Future efforts designed to encourage consultation of AUC should be focused on areas of low-value care.

As CMS points out in the proposed rule, the AUC Program could produce risk to beneficiaries in receiving timely imaging services and potentially bringing financial liability for advanced diagnostic imaging service claims denied by the Medicare program because the law does not separately establish protections to Medicare beneficiaries from financial liability for advanced diagnostic imaging service claims not paid by Medicare as required under the AUC Program.

CMS states an interest in the proposed rule to continue efforts to "identify a workable implementation approach" to the AUC Program and will "propose to adopt any such approach

through subsequent rulemaking." We assume that given the prescriptive nature of the current statute, an alternative approach would need to fall within CMS' current administrative authorities and would require repeal of the AUC Program mandate under Section 1834(q) of the *Social Security Act*, as added by section 218(b) of *PAMA*.

It is clear that thoughtful redesign of the Merit-based Incentive Payment System (MIPS) is needed, including by removing silos between the four MIPS performance categories, in order for the program to achieve its original intended goals of reducing burden, driving meaningful improvement in clinical outcomes, and moving physician practices to innovative value-based care models. In the process, **MIPS**, as well as other CMS value-based programs, should be leveraged to encourage the consultation of AUC and in such a manner that promotes flexibility.

Ordering clinicians must not be confined strictly to the use of a CMS qualified, and proprietary, Clinical Decision Support Mechanism (CDSM) for consulting AUC. Other decision support tools and clinical guidelines embedded into electronic health record systems must also be recognized. Confining consultation to a qualified CDSM increases cost and takes away the ability of physicians to consult AUC developed by their specialty society. For example, cardiologists have experienced situations in which a qualified CDSM eliminates their ability to continue consultation of AUC developed by cardiovascular societies (including ASNC and the American College of Cardiology (ACC)) and forces them to consult AUC developed by the American College of Radiology which vary from the ACC/ASNC AUC in their structure, approach, and appropriateness ratings.

A just-published study in the *Annals of Internal Medicine* concluded that substantial discrepancies in the scope, methods, and formatting of provider-led entity (PLE)-developed AUC for imaging in suspected coronary artery disease (CAD) exist.¹ The study looked at the seven PLEs that had published AUC related to CAD and found:

- The PLEs used several different methods for reviewing relevant literature, constructing clinical scenarios, and grading appropriateness.
- The evaluation of chest pain suspected to be cardiac in origin was common to all of the AUC, but the scope of the documents beyond that one clinical situation ranged substantially, with the the number of clinical scenarios for the evaluation of cardiac symptoms ranging from 6 to 210.
- There were discrepant ratings of what imaging test would be appropriate for common clinical scenarios related to CAD.
- There were large variations in how AUC were described and displayed.

This study underscores the problems with the AUC Program are no just limited to the real-time claim reporting requirement, but with the basic underpinnings of the program. As CMS reevaluates the AUC Program, the simplest solution is to incorporate AUC into other

¹ Winchester DE, Keating FK, Patel KK, Shah NR. The Medicare Appropriate Use Criteria Program: A Review of Recommendations for Testing in Coronary Artery Disease; 2023. Ann Intern Med. doi:10.7326/M23-1011

value-based purchasing programs, including allowing institutions working under alternative payment models to adopt locally run AUC programs as part of their movement toward quality. ASNC encourages CMS and Congress to abandon a one-size-fits-all approach to AUC consultation and to continue to work with stakeholders to identify ways to encourage the consultation of AUC in a manner that is meaningful and has the potential to improve patient outcomes.

Promoting Continuous Improvement in the Merit-based Incentive Payment System (MIPS)

Through their medical societies and institutions, physicians have led the way with the development of AUC for diagnostic imaging, and they continue to advocate for its use. MIPS can and should be leveraged to encourage the consultation of AUC even in absence of the AUC Program.

CMS is proposing to remove the following improvement activity: "Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support when Ordering Advanced Diagnostic Imaging" effective the 2024 performance year. The activity was first designated as an activity for the 2018 performance year. We appreciate it was included as an activity for purposes of developing a direct tie between MIPS and the AUC Program, as well as to incentivize early use of qualified CDSMs to consult AUC by eligible clinicians looking to "improve patient care and to better prepare themselves for the AUC program."²

CMS states it is proposing the activity's removal because the Agency is proposing to discontinue the AUC Program. We disagree the AUC improvement activity is "obsolete" and that it would be impossible to attest to consultation of AUC in the absence of the AUC Program. Clinicians consult AUC using mechanisms other than a CDSM. Further, CDSMs are already in use by clinicians and other health care professionals.

Just because CMS is no longer qualifying CDSMs doesn't mean they are not being used to consult AUC. In fact, in the proposed rule, CMS states that clinical decision support tools can be beneficial in assisting with clinical decision making and encourages continued use of clinical decision support in a manner that best serves and assists clinicians. In addition to modifying the activity to allow eligible clinicians to consult AUC using a mechanism of their choosing, including a CDSM, both ordering and furnishing clinicians should be eligible to report the activity.

OFFICE/OUTPATIENT (O/O) E/M VISIT COMPLEXITY ADD-ON IMPLEMENTATION

Implementation of G2211 — (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)) — and the

² Medicare Programs: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. <u>https://www.regulations.gov/document/CMS-2017-0092-1623</u>

resulting -2.17 percent reduction to the Medicare conversion factor underscores the need for fundamental reform of the Medicare PFS to eliminate the requirement of budget neutrality. We appreciate that CMS has reduced the estimated utilization assumption of G2211 from 90 percent in the 2021 rule to 38 percent when the code is initially implemented, and then to 54 percent when the code is fully adopted. However, given the significant impact the implementation of this code has on the conversion factor and because CMS states there are "many visits" with new or established patients where the code would not be appropriately reported and because it is unreportable with modifier -25, we ask CMS to reevaluate its utilization estimates. In doing so, we recommend that CMS include an examination of actual utilization of similar codes implemented in recent years, such as chronic care management and transitional care management services.

Further, we ask that CMS clarify the exact additional resources it intends to capture with G2211. Necessity, use and reporting of this code are very confusing as the resources utilized in performing visits for which the code could apply have already been incorporated into the typical patient described in the evaluation and management (E/M) office visits or reported with a higher level of visit using medical decision making or time for reporting. Finally, we ask CMS to publish the exact methodology it used to derive new utilization assumptions.

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

ASNC would like to respond to CMS' request for feedback about whether the current AMA RUC is the entity "best positioned" to provide recommendations to CMS on resource inputs for work and practice expense valuations, as well as to establish values for E/M and other physicians' services, or if another entity would "better serve" CMS and interested parties in providing these recommendations.

The RUC is an independent entity which involves the participation of more than 100 national medical specialty societies and other health care organizations. These organizations devote significant resources and expertise to conducting physician surveys which is supplemented, when possible, by extant data.

CMS states in the proposed rule that commenters have suggested that independent assessments could support CMS and the broader health delivery and health finance community in addressing "growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management visits and other non-procedural/non-surgical services." These suggestions minimize the value of the RUC and foster division within medicine.

It is important to emphasize the RUC submits recommendations to CMS regarding resources required to provide a service and CMS determines the payment amount through rulemaking that is open to public comment during which stakeholders can provide data and information regarding the proposed valuation of services. In fact, CMS has not always accepted the RUC recommendations.

The AMA RUC should remain the principal vehicle for refining the work and practice expense components of the resource-based relative value scale. One improvement, however, that CMS should consider is restoring the Refinement Panel process, that served as an appeal process for those commenting on CMS proposed relative values. The refinement panel was comprised of physicians and contractor medical directors, and, in 2016, the AMA, with more than 90 specialty societies, requested the restoration of the refinement panel.

Rebasing and Revising the Medicare Economic Index (MEI) & Indirect Practice Expense Methodology

As ASNC has previously commented, we appreciate the need to update MEI weights. The MEI weights, that are the basis for current CMS rate setting, are based on data obtained from the American Medical Association's (AMA) physician practice information (PPI) survey which was last conducted in 2007/2008 and collected 2006 data. ASNC supports consideration of more frequent updates, and that any significant data updates — PPI survey results, supply and equipment pricing, and clinical staff wage rates — occur simultaneously and be transitioned to avoid abrupt impacts to individual services and specialties.

The AMA and Mathematica formally launched a PPI survey on July 31, 2023, which was supported by <u>173 healthcare organizations</u>, including ASNC. The survey will provide more than 10,000 physician practices with the opportunity to share their practice cost data and number of direct patient care hours provided by both physicians and qualified health care professionals.

In last year's Final Rule, CMS finalized updated MEI weights for the different cost components of the MEI using a new methodology based primarily on a subset of data from the 2017 U.S. Census Bureau's Service Annual Survey (SAS). Because these updated MEI weights would result in significant redistribution within physician payments, we support CMS 'proposal to not implement its updated MEI cost weights again for 2024 while the AMA completes its data collection efforts.

Use of 2017 data from the SAS would result in significant fee schedule redistribution in large part because of an error in CMS analysis which omitted nearly 200,000 facility-based physicians. It is critical the data collection effort includes a representative sample of specialties and practice characteristics. The CY2010 physician payment fee schedule included drastic cuts to cardiology services, including cuts of roughly 36 percent for nuclear cardiology, as a result of the use of PPI survey data that reflected a small, unrepresentative sample of cardiologists who did not face financial pressures of typical practicing cardiologists. In the intervening years, significant practice consolidation has occurred, driven by declining reimbursement and significant regulatory burden. We are pleased the AMA recognized early in its current data collection effort that a shift in the focus of the data collection format is necessary due to practice consolidation and that financial experts should be specifically targeted as part of its efforts.

We appreciate the AMA has committed significant resources in its data collection effort. The PPI survey will be in the field through April 2024 and data would be shared with CMS in early 2025 for the 2026 Medicare physician payment rulemaking process. Until CMS has the benefit of the new PPI survey data, we ask that implementation of updated MEI weights be postponed.

Conclusion

Thank you for the opportunity to comment on the CY2024 PFS proposed rule and issues of importance to nuclear cardiologists. Any questions or requests for additional information should be directed to Georgia Lawrence, ASNC's Director of Regulatory Affairs at glawrence@asnc.org.

Sincerely,

Mouaz Al-Mallah, MD

President, American Society of Nuclear Cardiology