



December 11, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-F
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program--Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions from the Medicare Shared Savings Program--Accountable Care Organizations--Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (**CMS-1693-F**)

Dear Administrator Verma:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) final rule (CMS-1693-F), published on November 23, 2018, in the *Federal Register*, regarding the final policy revisions to the CY 2019 Medicare Physician Fee Schedule (PFS).

ASNC is a 4,500 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 within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

ASNC offers comments on the following components of the proposed rule:

- Appropriate Use Criteria Program
- Evaluation and Management Visits
- Multiple Procedure Payment Reductions
- Quality Payment Program

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING

ASNC has a long commitment to the use of appropriate use criteria (AUC) for advanced diagnostic imaging for cardiovascular disease- the society's first AUC documents date to 2006. ASNC views appropriate use criteria as crucial guidelines to ensure the right patient receives the right test, yet they are not to be used as an overly prescriptive framework which restricts clinical decision making. Therefore, ASNC continues to express its opposition to the implementation of Section 218 of the Protecting Access to Medicare Act of 2014 (PAMA). The Medicare AUC Program remains an overly complex and prescriptive program with no distinct link to quality improvement. **We are grateful for the time that CMS staff dedicated trying to fulfill a complex mandate, but we do not think it will have any added measurable effect on utilization of advanced diagnostic imaging tests beyond the Quality Payment Program (QPP). ASNC is consequently opposed to the agency's intention to begin program implementation in 2020.**

ASNC is steadfast in its contention that health care professionals be deemed compliant with the AUC Program if they meet the requirements of the QPP. This approach will afford clinicians maximum flexibility in the use of AUC in the least administratively burdensome manner possible while meeting the intent of PAMA.

Administrative and Cost Burden

In comments to the proposed rule, ASNC, like many medical societies, noted the AUC Program's considerable administrative and financial burden. However, CMS largely ignored the administrative and financial burdens in its comments and focused solely on the mechanics of consulting and reporting these consultations on Medicare claim forms. This is a critical oversight as the consulting and reporting mechanics cannot be separated from the administrative and financial burden.

ASNC supports the clarification that "auxiliary personnel" be clinical staff employed by the ordering professional. However, ASNC restates its contention that the use of clinical personnel will not dramatically reduce the ordering professional's administrative burden. CMS needs to account for new patients with new complaints that need a fresh physician evaluation, as well as for complex patients with prior complex medical and cardiac histories that need to be integrated into physician decision making. The evaluation of new patients and existing patients with new or worsening conditions calls into question the agency's prior estimate that consultation would take two minutes [CMS-1676-F].

This two minute estimate from the CY 2018 Medicare Physician Fee Schedule final rule suggests a critical misunderstanding of appropriate use criteria. AUC are based not on a single ICD-10 code but on a constellation of ICD-10 codes required to get to a response of appropriate, inappropriate, or uncertain. In addition to integrating the clinical scenario, many of the tools present an array of test substitutions which span from rarely appropriate to appropriate, and

which are not necessarily specific to a given patient. Clearly, the consultation of AUC through a CDSM requires a considerable degree of physician engagement and is not an automated process as described by CMS.

In the CY 2019 final rule, CMS adopted its proposal that AUC data will be reported by furnishing professionals on the Medicare claim form using a series of G codes and modifiers. **CMS adopted these G codes and modifiers despite the following difficulties: CMS has yet to propose how the transfer of AUC information will occur between the ordering and furnishing professions, nor how it will identify outlier ordering professionals who will be subject to prior authorization.** Moreover, the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC) — which together provide a broad perspective on data reporting and claims processing needs impacting the industry — reviewed aspects of the AUC Program, expressed their concerns, and provided recommendations to CMS in a July 5, 2018 letter. In the letter, the NUCC and NUBC stated that all options to report AUC data, including reporting HCPCS G-Codes and modifiers, will be burdensome and costly for ordering and furnishing professionals. **Despite these concerns, the agency's discussion of the G codes and modifiers failed to take into consideration the cost to the furnishing provider's office to receive the required AUC information for documenting Medicare claims, including the time that may be required in some cases to retrieve missing information from the ordering provider.**

ASNC reiterates its concerns regarding the new AUC consultation requirement without proper education of ordering professionals, especially clinical personnel, of how to use AUC. In September 2014, ASNC commissioned a behavioral and performance needs assessment of inter-professional referrals and collaboration in nuclear imaging. ASNC found referrers are challenged to apply AUC when selecting patients for nuclear imaging. The worst case scenario is that misapplication of AUC will result in serial testing. At a minimum, complex patients will either require a physician to directly consult AUC or added time for a nurse practitioner or physician assistant to consult the ordering physician. **Education of ordering professionals on application of AUC should be factored into CMS' cost burden analysis.**

Moreover, CMS failed to estimate the percentage of ordering professionals who will decide not to use a qualified CDSM and instead refer the patient to a specialist for a consult or order a test that is not implicated in the AUC Program. This will result in added costs to the Medicare program and to patients. We believe this is a significant oversight in CMS' analysis.

It bears noting that CMS' estimated cost burden to providers far exceeds the approximately \$200 million over 10 years that the Congressional Budget Office estimates that Section 218 of the PAMA would save Medicare — savings most likely the result of identification of outlier ordering professionals. Furthermore, CMS' regulatory impact analysis does not include the additional costs Medicare would incur to process prior authorization requests. In a 2014 Medicare proposed rule describing the process of prior authorization for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items [CMS-6050-P], CMS estimated \$50 to review each request for prior authorization. This means that it would take just more than 4,000 requests for advanced diagnostic test prior authorization for the cost burden to exceed CBO's estimated cost savings.

Lastly, CMS has explained that it used family and general practitioners for their cost estimates because they are the largest group of practitioners who order applicable imaging services and would be required to consult the proposed process under this program [CMS-1676-P]. ASNC contends it will take family and primary care providers and their clinical personnel even longer to complete AUC consultation, in effect punishing the providers who in fact will be most challenged in applying AUC for a large range of conditions. CMS acknowledged in the CY2018 Medicare Physician Fee Schedule final rule that its estimated cost burden is imprecise since the Bureau of Labor Statistics National Occupational Employment and Wage Estimates do not provide all specialty specific wage estimates [CMS-1676-F]. Therefore, even if CMS re-assumes that less than 40 percent of all advanced diagnostic imaging services will be ordered by non-physician practitioners, the cost estimate will still likely be lower than what it would be if specialty physicians who order advanced diagnostic imaging tests are appropriately accounted for in the estimate.

Transfers from Ordering Professionals to Qualified CDSMs and EHR Systems

CMS assumes three potential scenarios as low (free CDSM), medium (purchase CDSM to integrate into EHR), and high (purchase EHR system with integrated CDSM) burden assessments of the consultation requirement. CMS estimates that as many as 75 percent of an assumed annual 40 million orders for advanced diagnostic imaging services could occur at no additional cost beyond the time and effort to perform the consultation. For physicians with EHRs, CMS estimates ordering professionals will spend an estimated \$15,000 for a one-time purchase of an integrated qualified CDSM with a \$1,000 annual maintenance cost.

In comments to the proposed rule, ASNC requested CMS provide additional information as to how it arrived at the maintenance estimate of \$1,000 per year for an integrated CDSM. ASNC also suggested that CMS had erred in its estimate by not accounting for the cost to practices for installing a free CDSM on accessible computers. Moreover, most health systems prefer to go with a commercial product for accountability, “attempted standardization,” and support when a system goes down or requires updating. This is costly. We are not convinced that the “free option” is pragmatically available. **ASNC regrets the agency’s decision to forego substantiating its estimates in the final rule.**

EVALUATION AND MANAGEMENT VISITS

Changes to Documentation

In comments to the proposed rule, ASNC expressed support for CMS’ broad commitment to regulatory relief and the agency’s specific proposals to reduce redundancy in E/M documentation. We support the adoption of the following proposals:

- Eliminating the requirement to document the medical necessity of furnishing visiting in the home rather than the office.

- Physicians will not be required to re-record elements of a patient's history and physical exam when there is evidence that the information has been reviewed and updated.
- For both new and established E/M office visits, a chief complaint or other historical information already entered into the record by ancillary staff or the patient may simply be reviewed and verified rather than re-entered by the physician.

ASNC is appreciative that CMS finalized these documentation requirement changes for CY 2019, as they will not necessitate changes to coding and payment.

Evaluation and Management Coding and Payment Policy Reforms

In comments to the proposed rule, ASNC highlighted the work of the American Medical Association (AMA) working group. **ASNC is cautiously optimistic that CMS has built in a two-year delay into its coding and payment reforms. We urge CMS to work with the AMA and the house of medicine to adopt payment and coding reforms which will reduce administrative burden, encourage physicians to spend more time with their patients, and maintain the link between payment and patient complexity.** ASNC maintains its contention that the payment collapse for office visits delinks work from payment, since an identical payment would be made for Levels 2 through 4 visits within each code family. CMS altered its proposal in the final rule to maintain a level 5 visit, yet we do not agree that this relatively minor alteration may account for Medicare patients with complex diseases and multiple chronic conditions, which is often the case with cardiovascular disease patients.

Although delayed until 2021, ASNC reiterates its contention that separate add-on payments for primary (GPC1X) and complex (GCG0X) care do not capture the complexity of primary and specialty care. Rather than patching together add-on codes in an attempt to fill the gap that will result from a reduction in levels 4 and 5 payments, physicians will be more likely to shorten office visits for Medicare patients and/or spread their care over multiple visits. We do not believe this is the end result CMS envisioned.

MULTIPLE PROCEDURE PAYMENT REDUCTIONS

ASNC strongly opposed CMS' proposal to expand the MPPR policy to include office visits performed on the same day as a separately billable procedure and asserted the policy was another reason why CMS should not finalize its proposed E/M payment changes. CMS stated in the proposed rule that the efficiencies associated with furnishing an E/M visit in combination with a same-day procedure are "similar enough to those accounted for by the surgical MPPR to merit a reduction in the relative resources of 50 percent."

ASNC commends CMS for its decision not to finalize the MPPR policy.

QUALITY PAYMENT PROGRAM

ASNC defers to the AMA's detailed comments concerning proposed changes to the QPP for the 2019 performance year. For the purposes of this comment letter, ASNC is focusing its comments on proposals that would have implications for Qualified Clinical Data Registries (QCDRs), including ASNC's ImageGuide.

Clinical Expertise in Quality and Measure Development for Registries

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directed the Secretary of Health and Human Services to encourage the use of QCDRs [Social Security Act §1848(q) (1) (E)]. ASNC appreciates the continued integration of QCDRs in a number of areas in the Quality Payment Program and is encouraged that the clinical utility of QCDRs is being optimized.

ASNC is pleased that CMS finalized its proposal to update the definition of a QCDR to require that it is "an entity with clinical expertise in medicine and quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient care and disease tracking to foster improvement in the quality of care provided to patients. **ASNC is pleased that CMS recognizes the importance of requiring clinical expertise and experience in measure development for QCDRs. ASNC strongly supports this definition of QCDRs and is in agreement that entities that lack clinical expertise and experience in measure development do not conform to the objective intent of QCDRs.**

We urge CMS to further clarify what constitutes "experience in measure development" in future rulemaking. ASNC recommends that a prior successful self-nomination with approved measures should be sufficient experience in measure development. CMS could establish other provisions for sufficient experience in measure development for QCDRs that are new and do not have prior successful experiences in a self-nomination cycle.

ASNC develops its measures with a group of leading experts in the fields of nuclear cardiology and echocardiography. Measures are reviewed and critiqued by a specialty-focused committee and are then reviewed by a larger Registry oversight committee to ensure that the measures are robust and clinically useful.

Given their lack of clinical expertise, commercial entities are unable to use registry data to guide targeted education efforts to clinicians. ASNC is able to create continuing medical education and maintenance of certification courses and tailor specialty-specific education quickly based on areas of needed improvement observed in registry data.

We thank CMS for finalizing the modification of the definition of QCDRs and appreciate CMS' continuing efforts to guarantee the integrity of QCDRs and the QPP.

Requirement to Enter License Agreement with CMS as a Condition of Measure Approval

In the CY2019 final rule, CMS did not finalize the requirement that owners of QCDR measures enter into a license agreements stipulating that a QCDR may submit data on any other QCDR-owned measures as a condition of approval for inclusion in the MIPS program beginning with the 2021 payment year.

ASNC is in agreement that harmonizing measures across QCDRs is important and that data collection where measures are not standard across all registries is a challenge. CMS did not rule out finalizing this proposal in future rulemaking. Should CMS choose to revisit this proposal, ASNC is adamant that CMS must develop a process to communicate to measure owners that another entity intends to use their measure. In addition, CMS will have to act as the arbiter of each measure across registries to ensure that measure numerators, denominators, and all other measure specifications are consistent across all entities that report on the measure.

QCDR Benchmarking

CMS solicited comment on benchmarking for QCDRs and took note of many of the technical challenges associated with QCDR benchmarks and will consider them in future rulemaking. We are encouraged that CMS is carefully considering the feasibility of QCDR benchmarking and working through solutions before finalizing any policy.

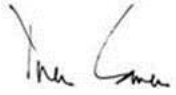
We reiterate that the use of historical data presupposes that a QCDR has been in existence for many years and has a wealth of data using the same measure specifications from which to draw. There are a few QCDRs that have been operational for many years and may have data available to draw upon. However, the vast majority of QCDRs were developed within the past five years and would not have data available to draw upon. The less established QCDRs must be given the opportunity to establish reliable data and a period of stability where measures are not modified from year to year so that any benchmark developed from measures is a reliable measurement of clinical performance.

CMS finalized the proposal to extend the use of ABC™ methodology and equal range methods to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures. We urge CMS to work with individual QCDRs and release any information that will be reported on Physician Compare to the QCDRs prior to publication.

CONCLUSION

ASNC thanks CMS in advance for consideration of its comments. Should the Agency have questions or require additional information, please contact Andy McKinley at amckinley@asnc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Prem Soman". The signature is written in a cursive style with a large initial "P" and "S".

Prem Soman, MD, PhD
President,
American Society of Nuclear Cardiology