October 5, 2020

Submitted electronically via: https://www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs [CMS-1736-P]

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) Proposed Rule on Changes to Hospital Outpatient Prospective Payment as published in the *Federal Register* on August 17, 2020.

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:

- **Cardiac PET and PET-CT New Technology APC placement**
- **Add-on Payments for non-HEU Sourced Radiopharmaceuticals**
- **Pass Through for Radiopharmaceuticals**
- **Prior Authorization for Outpatient Department Services**

CARDIAC PET AND PET-CT NEW TECHNOLOGY APC PLACEMENT

As a general matter, ASNC is appreciative of CMS' acknowledgement of nuclear medicine as a clinically unique family that requires special inputs around the handling and disposal of radiopharmaceuticals. As such, **we appreciate CMS maintaining PET/CT CPT codes 78431, 78432 and 78433 in the new technology Ambulatory Payment Classification (APC) groups as they were in CY 2020 while adequate claims data can be developed for appropriate APC placement and rate**

setting. Because the COVID-19 pandemic has caused patients to defer needed tests and medical practices disrupted — particularly early in the pandemic when knowledge of COVID-19 was sparse and rapidly evolving. It is possible CMS will not have next year a true representation of volumes for an appropriate rate setting for these services for CY 2022. We are also aware of incorrect NCCI edits in early 2020, which have been resolved but could have contributed to a lack of claims in the early months following implementation of this new APC. As such, CMS should maintain these services in their current APC through CY 2022.

Add-on Payments for non-HEU Sourced Radiopharmaceuticals

ASNC appreciates the Agency's continued acknowledgment of the added costs associated with the production of radioisotopes produced from non-Highly Enriched Uranium (HEU) sources and the corresponding add-on payment. **We ask CMS to finalize the continuation of separate payment for non-HEU Sourced Radiopharmaceuticals using HCPCS code for Q9969 for CY 2021.**

Pass through for Radiopharmaceuticals

The topic of bundling versus separate payment of radiopharmaceuticals has a long history of controversy since CMS began to "package" diagnostic radiopharmaceuticals into APCs in 2008.

In its June 2020 report, the Medicare Payment Advisory Commission (MedPAC) concluded that "Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion."[1]

Radiopharmaceuticals and other agents used for nuclear cardiac imaging are not ancillary, as they are integral to the test. ASNC hopes CMS will continue to seek adequate reimbursement policies for the radiopharmaceuticals which are indispensable to the field nuclear cardiology and will look to ASNC as resource on this subject matter.

Prior Authorization for Outpatient Department Services

In the rule, CMS states "…we are continuing our routine analysis of data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting." Based on this analysis, CMS is making a determination of unnecessary increases in volume for which prior authorization is required.

CMS states in the rule it found the total Medicare allowed amount for the outpatient department services claims processed in 2007 was approximately $31 billion and increased to $68 billion in 2018, while during this same 12-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.9 percent.

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[1] Medicare Payment Advisory Commission's June 2020 Report to the Congress: Medicare and the Health Care Delivery System. http://medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0

A recent MedPAC analysis found spending per beneficiary in Medicare Advantage is growing faster than original Medicare at $11,822 and $10,813, respectively, in 2019.[2] Because prior authorization and other cost control mechanisms are widely employed by Medicare Advantage plans, it is curious that Medicare Advantage spending is growing faster than Medicare fee for service.

Among the greatest barriers to access to care is the prior authorization process. Prior authorization not only constitutes a barrier to treatment but imposes a tremendous financial burden and time constraint on physician practices. Physicians complain about inconsistencies in the applications and misinterpretation of guidelines during the prior authorization process which result in treatment denials, test and drug substitutions, and treatment delays. A 2018 survey conducted by the American College of Cardiology and the Association of Black Cardiologists found that utilization of prior authorization often disrupts patient care. That survey found 67 percent of cardiovascular specialists say prior authorization requirements take time away from their focus on patients; 61 percent cited interruptions in patient treatment; and 43 percent of cardiovascular specialists say they do not have appropriate employee resources in place to properly manage prior authorizations.[3]

Physicians should be focused on patient care and not on navigating the prior authorization process to get patients their recommended procedures and treatments. Payment models that put health care providers at greater downside risk for quality and cost should be CMS' focus and any use of prior authorization in both original Medicare and Medicare Advantage should require a standard electronic prior authorization process, including the electronic transmission of prior authorization requests and responses, as well as a real-time process for items and services that are routinely approved. According to the 2019 CAQH Index, on average, providers spent almost $11 per transaction to conduct a prior authorization manually and nearly $4 using a web portal.[4]

We appreciate your attention to our comments in this regard as CMS considers expanding the use of prior authorization to other services in future years.

CONCLUSION

ASNC thanks CMS for the opportunity to comment. Questions or requests for additional information should be directed to Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

Sharmila Dorbala, MD
President, American Society of Nuclear Cardiology

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[2] Context for Medicare Payment Policy, September 3, 2020; http://www.medpac.gov/docs/default-source/meeting-materials/medpac_context_sept_2020.pdf?sfvrsn=0

[3] http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf

[4] 2019 CAQH Index. https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf?token=SP6YxT4u