

August 31, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program: Payment Policies under the Physician Fee Schedule; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release for Calendar Year 2017; Proposed Rule 1654-P

Dear Administrator Slavitt:

We are writing in response to the Calendar Year (CY) 2017 Medicare Physician Final Rule, published July 15, 2016 in *Federal Register* Vol. 81 No. 136 p. 46162. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 17,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research and practice. We appreciate the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the MPFS.

We offer comments and recommendations on the following topics addressed in this Proposed Rule:

- Refinement Panel
- Payment Modifier for X-ray Films
- Elimination of Physician Payment Increase
- Appropriate Use Criteria

Refinement Panel

CMS has convened the Refinement Panel to carefully review public comments, hear testimony from practicing physicians and independently recommend refinements to relative values for more than 25 years. Until recently, the Refinement Panel conclusions were uniformly implemented by the Agency. In 2011, CMS modified the process to only consider appeals which include "new clinical information." Additionally, the Agency began to independently review each of the Refinement Panel decisions when determining which values to actually finalize. Since the implementation of these changes, CMS has rejected the majority of requests for Refinement Panel review and only accepted 36 percent of recommendations from the Panel. With the dysfunctionality of the current iteration of the Refinement Panel process, CMS no longer relies upon outside stakeholders to provide accountability. Absent any independent mechanism for appeal, CMS officials are free to make valuation decisions without having to provide a compelling rationale when rejecting relative value recommendations from the RUC and other stakeholders.

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In the CY 2016 NPRM, CMS proposed to permanently eliminate its Refinement Panel process. In the CY 2016 Final Rule, instead of finalizing the exact language of that proposal, CMS announced they would “...retain the ability to convene Refinement Panels for codes with interim final values” and that “...CY 2016 is the final year for which we anticipate establishing interim final values for existing services.” The Agency did not have to formally announce the process’ elimination to achieve the same outcome, since there will no longer be any codes eligible for review. SNMMI objects to the CMS intention to make this vital process obsolete due to a technicality. We strongly urge CMS to open Refinement Panel review to all procedures and services that are under CMS review during the current rulemaking process. In addition, as part of their original proposal to eliminate the Refinement Panel, current CMS officials objected to the widely-held understanding that the Refinement Panel served as a formal appeals process prior to 2011.

The original Refinement Panel process, coupled with the input from the AMA/Specialty Society RVS Update Committee (RUC), would provide the best mechanism to utilize the expertise from physicians and other health care professionals to determine the resources utilized in the provision of a service to a Medicare beneficiary. We are hopeful that CMS will return to a Refinement Panel process that is fair to physicians, other health care professionals and the patients that they serve.

Recently the Refinement Panel reviewed CPT Code 78264, Gastric Emptying Study. SNMMI believes this example demonstrates how CMS correctly used the panel to implement a change due to a refinement panel decision. After review and deliberation, the Panel voted to increase the RVU to 0.79 from interim value of 0.74.

Payment Modifier for X-Ray Films

SNMMI understands that CMS has a statutory requirement from Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub.L 114-113) amended section 1833(t)(16) of the Act by adding new subparagraph (F), that services furnished during 2017 or any subsequent year, the payment under the OPSS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPSS (without application of this paragraph and before application of any other adjustment) shall be reduced by 20 percent. However, we do not believe CMS have provided sufficient information on this proposed policy change. SNMMI recommends that CMS clarify the intent of this law. Specifically, CMS should state that the law only applies (and requires use of a modifier) to sites that use X-ray as a single method for image capture. CMS should clarify that if a site uses both X-Ray film and electronic capture of images and maintains digital archives, by a picture archiving communication system or other electronic method, that the site is not required to report the modifier.

Elimination of Physician Payment Increase

The society opposes CMS' plan to eliminate the physician payment increase that Congress provided for 2017 in the MACRA legislation and repurpose that money to fund a newly proposed add-on payment for services provided to patients with mobility impairments. The society does support efforts to improve access to care for patients with these and other impairments, however, there is no justification for

funding the service with an across-the-board cut in payment rates. The proposal also raises program integrity questions and seems likely to increase out-of-pocket costs for patients with disabilities.

Appropriate Use Criteria (AUC)

SNMMI believes the eight priority clinical areas CMS developed and proposed to be an odd mix of symptoms and diagnoses with several omissions. In addition, some groupings are exceptionally broad, while others seem unnecessarily narrow. Following are a few more specific comments on some of these areas.

The ‘headache’ priority clinical area seems to be an exceptionally narrow category, albeit one that could generate requests for diagnostic imaging. However, there is possibility of overlap with the two other categories relating to the head (altered mental status and suspected stroke), and the possibility of combining headache and altered mental status into one area should be considered. This is particularly relevant because the types of imaging that might be considered for such patients are similar.

The ‘abdominal pain’ priority clinical area is very broad, which is reasonable to the extent that there are innumerable reasons for the presenting complaint. Nevertheless, the list contains both symptoms and diagnoses (e.g. cholelithiasis) which would not be known without imaging, presumably based upon prior studies performed before the current presentation. Several codes in the list are rather weak as solitary indications for advanced imaging (constipation and vomiting (with or without nausea), given their commonness in patients with gastroenteritis and other non-specific gastrointestinal complaints. The society questions whether the objectives of the CMS AUC implementation be weakened by inclusion of too many minor or common symptoms in the data gathering process.

The ‘chest pain’ priority clinical area is dominated by cardiac symptoms and diagnoses. The only two codes involving the lung are painful respiration and pulmonary embolism/infarct. This is not adequate given the myriad other reasons for chest pain from lung and thoracic cavity pathology, including but not limited to pneumo- and hemothorax, pleural effusion, pneumonia, bronchitis, airway obstruction, and pneumonitis. Other causes of chest pain could be vascular (e.g. aortic dissection, venous obstruction) and traumatic (e.g. skeletal fractures, osteomyelitis).

Regarding the ‘low back pain’ priority clinical area, virtually all the diagnostic codes relate to mechanical or neurological abnormalities in the lumbosacral spine. Common entities such as vertebral compression fractures (osteoporotic or traumatic), facet joint disease, tumor, and infection are not included in the known or suspected diagnoses that would justify advanced imaging.

Finally, with regards to the ‘cervical or neck pain’ priority clinical area, the question posed in relation to ‘low back pain’ applies equally well to this area.

SNMMI appreciates the opportunity to comment on the MPFS CY 2017 Proposed Rule to the CMS. As always, SNMMI is ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Susan Bunning, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Respectfully Submitted,

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