SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

August 26, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule CMS-1631-P

Dear Administrator Slavitt:

We are writing in response to the Calendar Year (CY) 2016 Medicare Physician Fee Schedule (MPFS) Final Rule, published July 15, 2015, in the *Federal Register* Vol. 80 No. 135 p. 41686. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 18,000 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 & Medicaid Services (CMS) in further refining the MPFS.

We offer comments and recommendations on the following topics addressed in this proposed rule:

- CY 2016 Identification of Potentially Misvalued Services
- Significant RVU Reductions
- Proposed Elimination of Refinement Panels
- Changes for CT Under PAMA
- Appropriate Use Criteria

Potentially Misvalued Services

Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or more

CMS identified the top 20 codes by specialty (using the specialties in Table 45) in terms of allowed charges. As CMS did last year, CMS excluded codes that they had reviewed since CY 2010, those with fewer than $10 million in allowed charges, and those that describe anesthesia or E/M services were excluded. CMS also excluded all codes with 10- and 90-day global periods since they believe these codes should be reviewed as part of the global surgery revaluation.

SNMMI has reviewed services that CMS has nominated as potentially misvalued, specifically "CPT code *78452 - Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection*"

and "CPT code 78306 - *Bone and/or joint imaging; whole body*." Both 78452 and 78306, as well as other services, were nominated as potentially misvalued since more than $10M is spent annually and has not been reviewed since 2009.

The current family of myocardial perfusion imaging codes was revised in 2008 in response to the American Medical Association's Relative Value Scale Update Committee (AMA RUC) Five-Year Review Workgroup project to address high volume and code pair issues. The revision change combined four base codes and two add-on codes into four bundled codes, where 78452 is the main code in this family. The predecessor code to CPT 78452, CPT 78465, was also reviewed during the third 5-year review in 2005. Utilization for 78465 was declining for several years before these services were bundled. CPT code 78452 has continued to decline since that time. This utilization trend suggests the payment is not too high and may instead be too low.

However, no changes in physician work or technology have taken place since the review. **After thorough research and analysis, SNMMI does not find evidence to support that these services are "potentially misvalued." CMS has identified this code entirely because it comprises payment of more than $10M.** We are concerned that societies are spending time surveying CPT codes and their families repetitively simply because they are high volume services. We believe CMS should consider, in addition to high volume, other screens that would target services that had potential for changes, rather than solely on volume. Otherwise, CMS would be requesting surveying the same well estabilished and surveyed multiple times without any justification or rationale for why the services might have changed. We agree with screens, such as year to year increased volume. We agree with site of service changes etc, however, we strongly disagree with surveys that are solely predicated on the fact that they are high volume. CMS has correctly excluded E/M visits and they should also consider other criteria in combination with the volume when selecting services for resurveying. Therefore, since CPT 78452 has been through the RUC survey process (several times in the last 15 years) with decreased in volume over time, **we recommend that the work and PE values for CPT 78452 be maintained. At this time there is no rationale to survey that family.** Similarly CMS has placed CPT 78306 Bone and/or joint imaging; whole body on the list as potentially misvalued. CPT 78306 has gone through several of the five year reviews and with no or minimal changes, we believe that over surveying brings our members with survey fatigue and is not a productive use of CMS, the RUC, or the society's resources. Again, we respectfully request that CMS use additional criteria, in combination with volume, so as not to survey services that have minimal probability of change. **We recommend that the work and PE values for CPT 78306 be maintained and conclude there is no reason, at this time, to survey that family.**

Phase in of significant RVU reductions – out of PAMA legislation

Identifying Services that are not new or revised codes. CMS proposes to apply this PAMA phase in legislation to all services that are described by the same, unrevised code in both the current and updated year, and to exclude codes that describe different services in the current and updated year. This approach would exclude services described by new codes or existing codes for which descriptions were altered substantially for the updated year to change the services that are reported using the code. We strongly disagree with this CMS approach as this would effectively exclude those services where societies are asked to develop bundled CPT codes. We do not believe the PAMA legislation intended to exclude bundled services from this phase in provision.

Additionally, CMS is proposing to consider a 19 percent reduction (as the maximum 1-year reduction) and to phase-in any remaining reduction greater than 19 percent in the second year of the phase-in. CMS believes this approach is more equitable for codes with significant reductions, but that are less than 20 percent. The SNMMI

disagrees with the CMS interpretation of the PAMA legislation as the approach is a cap rather than a phase-in. The difference between a one-time 19 percent reduction and a phase-in is the addition of cuts over time. We believe that the impact and planning for a greater than 20 percent reduction should be implemented as 50 percent the first year and 50 percent the second year. This approach allows for fiscal planning of the second years reduction. We do not believe the one-time 19 percent reduction should impact how CMS implements a reduction over 20 percent. A one-time reduction compared to a phase-in of a larger reduction should be managed more appropriately.

Therefore, we strongly urge CMS not to implement the proposal at 19 percent the first year, and instead implement the 50 percent phase-in each year, as the PAMA legislation intended.

Proposed Elimination of Refinement Panels

The SNMMI strongly objects to CMS proposal to eliminate refinement panels. In explaining the proposal to eliminate the refinement panel, under the current process, if a society disagrees with an interim final RUC value established by CMS, that society can seek a redress through the refinement panels. What is essential in this process is not only that medical specialties have an appeals option – it is also who the appeal to, their peers. The value of appeal to peers, as opposed to expert CMS staff, is both a new opportunity to review the facts, and an audience that is more likely to understand the service in question, and its role in clinical practice. The CMS proposal to eliminate the refinement panels effectively mean specialties can appeal to the very same people who made the decision the first time. We do not believe this approach is appropriate.

Recommendation: We urge CMS not to finalize its proposal to eliminate the refinement panels.

Changes for CT under PAMA

Section 218(a) of the PAMA legislation amends the statute by reducing payment for the technical component (TC) by 5 percent in 2016, and 15 percent in 2017, and subsequent years. The statutory provision required that information be provided, and attested to, by a supplier and a hospital outpatient department, indicates whether an applicable CY service was furnished that was not consistent with the NEMA CT equipment standard. As such, information may be included on the claim, and may be a modifier. CMS proposed to create modifier "CT," Computed tomography services furnished using equipment which fail to meet each of the attributes of the NEMA XR-29-2013 standard. Beginning in 2016, claims for CT scans described by above-listed CPT codes, and any successor codes that are furnished on non-NEMA Standard XR-29-2013 compliant CT scans, must include modifier "CT" and that modifier will resut in the applicable payment reduction. We agree with CMS's approach as we believe it is the least burdensome alternative. We would request that CMS provide additional clarification in the final rule regarding and appropriate example of an attention from the manufacturer, so that providers are clear of what such a letter should contain. For example, will the letter need the model number, serial number, and what degree of detail will be required in the letter for CMS to consider the equipment compliant.

> We should clearly thank CMS for proposing the least burdensome and then in our recommendation tell them to implement for CY 2016 as well as recommend adding clarification in the rule. Each set of comments should always be followed by our recommendation.

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

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The proposed MPFS rules have the laudable goal of encouraging the development and subsequent use of Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS). It is hoped that AUC will decrease the use of expensive imaging procedures when those procedures are not necessary for patient care. While the goal is laudable, the details behind implementation of the rules are not resolved and the details are indeed what will determine whether or not the rules will either achieve the laudable goals, or whether they will add substantially to the cost of medical care with minimal improvement in patient management and outcomes.

Firstly, the rigorous development of evidence-based AUCs is not a trivial matter. Development of these documents is an expensive, time-consuming process that requires individuals with a specific skill set and the development of an administrative and communications network that often is out of the financial reach of many specialty societies. Larger specialty societies may be better suited to buffer the expense of AUC development against their larger membership, but it is a mistake to assume that even the larger specialty societies have financial surpluses that would make this onerous task easy to accomplish.

Yet because the development of AUCs offer the promise of improved patient management and outcomes, and more cost-efficient health care, many specialty societies are willing to commit their limited resources toward this goal.

The many unknowns in the details of this process, however, may result in this widespread investment in time and resources simply adding substantially to the cost of health care without achieving the intended benefit. Before this process is mandated, a more thorough detailing of the process along with some evidence that it will improve health care is needed. It is interesting that the proposed rules include an emphasis on evidence-based medicine, yet the lack of detail in the proposed process means there is no evidence that the process itself will have any benefit whatsoever. The medical community is being asked to base medical care less on gut feeling and good intention, and more on evidence, yet the reasons behind the proposed rules themselves at this point are essentially based on gut feeling and good intention.

The problems behind evidence-based use of ADIS are many, not the least of which is that we live in an age that brings us frequent important improvements in computing power and imaging technology. When a new scanner that shows remarkable improvements in imaging detail and image analysis is unveiled, it may be eminently clear to the imaging and referring physicians that this will allow a more accurate assessment of pathology. Yet if outcomes-based evidence needs to be collected (at substantial expense) before this new technology will be reimbursed, by the time the outcomes information is available, there will likely be 2 or 3 generations of additional advance in imaging and imaging analysis technology, some of which could allow substantial decreases in the costs of unnecessary tests and futile treatments. If we indeed are dedicated to improving patient care, we cannot afford to delay the dissemination of obviously superior technology, waiting decades before older technology that has essentially become obsolete is deemed reimbursable.

The inappropriate use of imaging technology is clear, but the reasons for the inappropriate use are many. From lack of understanding of the limits of the technology to fear of legal reprisals if the rarest of diagnostic possibilities is missed when a patient presents with a complaint. As intended, AUCs may be helpful if they can serve as a quick reference to instruct physicians in the best use of this rapidly advancing imaging technology, and also possibly to serve as a document to show that standard of care was practiced, despite a possible unfavorable outcome.

For AUC to provide a net benefit to medical practice they need to be produced in a manner that does not impose undue financial hardship on the medical community; they need to be documents that can be rapidly developed and easily updated and made immediately available to the medical community for reference. While available literature should certainly be consulted and referenced, waiting for definitive outcomes studies would essentially set back the advance of imaging technology for decades, as it would for all of medical care. When there is lack of definitive studies available in the literature, expert opinion must be allowed to play a large role in the development of AUC.

It is interesting that the experts most knowledgeable about specific cutting-edge developments in health care are often personally involved in those developments and therefore subject to bias and conflict of interest. In addition, specialty societies that advocate a particular technology could be seen as biased in favor of that technology; yet the most knowledgeable experts on that technology are likely to be members of that specialty society. To avoid some of these biases, conflict of interest should be disclosed for all parties involved, AUC should not be developed under the sole influence of conflicted individuals, and multispecialty societies should join together to develop AUC whenever possible. Many of these specifics are well outlined in the IOM guidelines on the development of practice guidelines, and have been incorporated in the proposed rules.

To avoid hidden commercial and personal biases, experts should be clear about conflicts of interest, and they should be recruited from multiple specialty societies.

Substantial details concerning the development of AUC documents remain.

The financial costs are substantial and should be at least partially mitigated by governmental organizations, such as CMS. Tax incentives or grant money should be made available to specialty societies to help defray the costs of the development of these documents. A vast majority of the physicians serving to develop these documents volunteer time from their practices and personal time, yet the specialty societies must still hire dedicated personnel to manage the process, perform literature searches, and to hold regular meetings. Often the cost of developing one AUC can be hundreds of thousands of dollars. The investment of this money would go far toward allowing smaller specialty societies to the table to assure a more complete representation of expert opinion.

Evidence-based medical practice is certainly a laudable goal of the proposed rules. The development of AUC should always include a thorough search of the medical literature for evidence regarding the technology in question. . However, a health care utopia where all care has been thoroughly vetted in all populations under all circumstances is not possible. The nature of rapidly evolving technology and disease itself will always require reliance on expert opinion. However, “expert opinion” should not be considered on a par with guesswork. Expert opinion is, after all, based on data available and considered by experts. These data may be made available from conferences, discussion with colleagues, unpublished research and anecdotal experience. While these sources of information may not be as thoroughly reviewed as peer-reviewed literature, many of these data may eventually be published in the peer-reviewed literature.

AUC should be clear when expert opinion is being used to make recommendations, and when literature is available the quality of the literature used to formulate recommendations should be clearly described.

Even if AUC documents were to rely on published evidence, there will be different ways to interpret that evidence based on access to technology, regional practices, and the age of the available evidence. It is therefore unreasonable to expect that there will be a single consensus on the use of a particular technology. Therefore, ALL documents developed in the appropriate manner by multispecialty groups should be approved for inclusion in clinical decision support tools. While this may at first appear contrary to the goal of achieving a single "best practice", it allows for some variations in practice that might be caused by regional availability or customs, and at the same time could serve to eliminate the most egregious misuses of technology. This means SNMMI will be providing AUC that can be used to identify outlier ordering professionals.

The issue of how an AUC will be determined to be valid and included in a clinical decision support tool (CDS) remains. The National Guideline Clearing House could serve as a repository; however, there should be oversight as to the validity of each AUC. The proposed rules suggest specialty societies could be certified by CMS to develop AUC, and documents developed by certified organizations would therefore be automatically deemed valid. If disagreement is voiced between two organizations, those organizations should be encouraged to review the available evidence and opinion and develop a consensus statement discussing the disagreement, or they may be given the task of developing a mutually agreeable AUC together, or if needed, in conjunction with additional input from relevant specialty societies. While the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) does have experience in reviewing evidence, as discussed earlier, published evidence is often lacking and the expertise of physicians from the societies involved in the debate is likely to be broader and more relevant to the issue at hand.

In addition to the above, the SNMMI would like CMS to provide more information as to what will qualify as a "provider-led entity". Hospitals and Health Systems are conceivably more influenced by local/state regulations, access to technology, and financial considerations than medical specialty societies, and therefore may develop AUC that are restrictive elsewhere.

SNMMI appreciates the opportunity to comment on this CY 2016 MPFS Final 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, Vice President, Government Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Respectfully Submitted,

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