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BY ELECTRONIC DELIVERY

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Room 445-G
Washington, DC 20201

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

Dear Administrator Slavitt:

The Medical Imaging & Technology Alliance (MITA) appreciates the opportunity to submit comments on the referenced Centers for Medicare & Medicaid Services (CMS) calendar year 2016 (CY 2016) proposed rule regarding payment rates and policies under the Physician Fee Schedule (PFS) (Proposed Rule).[1] As the leading trade association representing medical imaging and radiopharmaceutical manufacturers, we have in-depth knowledge of the significant benefits of medical imaging to the health of Medicare beneficiaries. MITA is pleased to work with CMS on reimbursement and quality initiatives, including initiatives involving radiology practices and imaging centers, to encourage appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, treatment, and surveillance of many diseases. Our comments are directed to how the Proposed Rule will impact the appropriate use of and meaningful access to these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Medical imaging encompasses x-ray imaging, computed tomography (CT) scans, ultrasound, nuclear imaging (including positron emission tomography (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with a variety of medical conditions, often detecting morbidity earlier than would otherwise be possible, reducing the need for costly medical services and invasive surgical procedures, and improving patient outcomes.[2] In addition, medical imaging equipment

[1] 80 Fed. Reg. 41,868 (July 15, 2015).
[2] *See, e.g.*, Hughes, et al., "Perspectives on the Value of Advanced Medical Imaging: A National Survey of Primary Care Physicians," *Journal of the American College of Radiology*, 12 (2015): 458-462; Goldstein, et al., "The CT-STAT (Coronary Computed Tomographic Angiography for Systematic Triage of Acute Chest Pain Patients to Treatment) trial," *Journal of the American College of Cardiology* 2011; 58 (14): 1414-1422; Perrier, et al., "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," *New England Journal of Medicine*, 2005; 352: 1760-1768.

often is used to select, guide, and facilitate effective treatment, for example, by using image guidance for surgical or radiotherapeutic interventions.[3]

As described below, our comments address suggested improvements to the Proposed Rule's process to develop appropriate use criteria, on-time implementation of payment policies for CT scans furnished using technologies that meet high industry quality standards, updates to practice expense inputs for digital imaging services, the new timeline for identifying misvalued codes, the methodology to calculate payment targets and phase-in payments, new and revised relative values for imaging services, including the relative values for lung cancer screening, and quality measures, such as the new cross-cutting measure involving mammography services.

Summary of Comments

1. **In establishing both a process and appropriate use criteria (AUC) for imaging services, CMS should ensure a role for all stakeholders, including industry representatives other than providers and clinicians.** The Medicare statute provides that "the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria."[4] CMS proposes to rely on "provider-led entities" to develop the appropriate use criteria to assist ordering and furnishing physicians in decision-making about imaging services. MITA agrees with and strongly supports the proposed definition of provider-led entities. We urge CMS to finalize this definition. Whereas the criteria themselves must be developed by national professional medical specialty societies or other provider-led entities, MITA encourages CMS to take account of the experiences and insights of non-physician stakeholders in specifying the process used by these professional groups in the development of appropriate use criteria. MITA believes that manufacturers of imaging equipment and drugs and other stakeholders, including patient groups, have unique insight into the optimal uses of the equipment and should have a more visible role in the AUC process.

2. **MITA supports the proposed use of a modifier for reporting Computed Tomography (CT) services furnished with equipment that fails to meet National Electrical Manufacturers Association (NEMA) Standard XR-29-2013.** MITA applauds the CMS proposal to require specific reporting of CT services furnished with equipment that fails to meet the NEMA standard. In addition, we encourage CMS to provide certain clarifications on the source and content of information to be retained by hospitals and suppliers, and urge the on-time implementation of the payment provision.

3. **MITA encourages CMS to continue to examine and modify practice expense (PE) inputs for digital imaging services to ensure they capture accurate cost information.** CMS proposes several updates to practice expense inputs for digital imaging services. MITA appreciates CMS's proposal to increase the PE input for the Picture Archiving and Communications System (PACS) and clinical labor tasks associated with digital imaging. We also recommend additional revisions to direct practice expense inputs. Further, as MITA has commented in the past, we recommend that CMS adopt a variable or higher maintenance factor for determining direct PE inputs because the current five percent factor is generally both inaccurate and inadequate.

[3] *See, e.g.*, Sibbitt, et al., "A Randomized Controlled Trial of the Cost-Effectiveness of Ultrasound-Guided Intraarticular Injection of Inflammatory Arthritis," *Journal of Rheumatology* 2011; 38 (2): 252-263; Jelinek, JS et al., "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors," *Radiology*, 2002; 223 (3): 731-737.
[4] 42 U.S.C. § 1395m(q)(2)(A).

4. **MITA appreciates the new timeline and threshold policies for new and revalued codes.** Under the new CMS process, the Agency will propose new and revalued relative value units (RVUs) in the annual proposed rule and allow stakeholders to comment before the new values are adopted and go into effect. The formal notice and comment process in place prior to a rate change increases transparency and will help to identify and correct or otherwise address in a timely way any relevant issues associated with the proposal. CMS also proposes a target reduction methodology that takes into account all reduced expenditures from revaluations for services that are "deliberately addressed as misvalued codes, as well as adjustments such as film-to-digital and services that are redefined through coding changes as a result of the review of misvalued codes."[5] MITA appreciates the Agency's efforts to appropriately include the broader set of affected codes to apply the target reduction methodology. We urge CMS to ensure this methodology is implemented properly.

   CMS also proposes a two-year phase-in for revalued codes that see a reduction of at least twenty percent. MITA encourages CMS **not** adopt the proposal, but to instead phase-in reductions at the rate of fifty percent of the total reduction each year, to mitigate the financial impact of the reduction on affected physicians and suppliers. This would be consistent with the statutory directive and the general approach CMS employs for other payment changes.

5. **MITA urges CMS to modify the proposed payment rates for lung cancer screening with Low Dose Computed Tomography (LDCT) in 2016, and remains concerned about the lack of timely codes and payment rates for 2015.** In February 2015, CMS released a national coverage determination (NCD) to provide Medicare coverage for lung cancer screening with LDCT. CMS now proposes new HCPCS codes and payment rates for these services in 2016, but does not address coding or payment rates for 2015. MITA recommends modifications to the 2016 proposal, to adequately account for resources for the services. In addition, to meet the Medicare statutory provisions on NCD development, MITA urges CMS to adopt the same codes and payment rates for 2015 through a transmittal or other directive to Medicare Administrative Contractors. The codes and payment rates should be effective as of the effective date of the NCD.

6. **MITA disagrees with an adoption of the mammography cross-cutting measure.** CMS proposes a cross-cutting measure for breast cancer screening within 27 months for women between the ages of 50 and 74. MITA remains concerned that this may be viewed as an endorsement of a reduction in the frequency of screening and may compromise patient care.

7. **MITA agrees with the adoption and/or continuation of the nine quality measures addressing imaging services and urges CMS to encourage measure stewards to seek endorsements from the National Quality Forum (NQF).** MITA supports the inclusion of nine measures addressing imaging services under the Physician Quality Reporting System (PQRS). Although we recognize NQF endorsement may not always be available for the rulemaking schedule, because of the significant role played by the organization, we urge CMS to encourage developers to obtain NQF endorsement as soon as possible.

[5] 80 Fed. Reg. at 41,712.

Comments

I. CMS Should Ensure an Appropriate Role for Manufacturers of Imaging Equipment And Drugs and Other non-Provider Stakeholders In the Specification of Appropriate use Criteria (AUC)

MITA has long endorsed the use of AUC and clinical decision support tools that help physicians choose the right image for the right patient. We strongly support CMS's proposed definition of provider-led entity (PLE)[6] and the proposal that these AUC be developed only by qualified PLEs.

MITA also supports CMS's proposal for an AUC development process with flexibility for PLEs. The Proposed Rule describes a process for becoming a qualified PLE as part of the Agency's multi-step implementation for recognizing appropriate AUC. Once qualified, the PLE's AUC would be deemed accepted. MITA appreciates the proposed approach for stakeholder input during the rulemaking process, but urges the Agency to recognize a role for non-provider stakeholders such as medical imaging manufacturers during the process of identifying AUC to be adopted. Only in this way can CMS meet its obligations under the Medicare statute to ensure that AUC adoption is made "in consultation with physicians, practitioners, and other stakeholders [to] specify applicable appropriate use criteria."[7]

Pursuant to Section 218(b) of the Protecting Access to Medicare Act (PAMA), CMS is required to establish, by November 15, 2015, a program to promote the use of AUC for advanced diagnostic imaging services. The AUC are guidelines for the appropriateness of a particular imaging service for a particular condition or presentation. Under the AUC program, ordering professionals must consult applicable AUC using a qualified decision support (CDS) mechanism when ordering applicable diagnostic imaging services for which payment is made under applicable payment systems. Furnishing professionals must report the results of this AUC consultation.

As to stakeholder roles, Section 1834(q)(2)(A) of the Social Security Act requires the Secretary of HHS to "specify" applicable AUC for applicable diagnostic imaging services through rulemaking and in consultation with physicians and other stakeholders. Such AUC must be "developed or endorsed by national professional medical specialty societies or other provider-led entities."[8] Furthermore, the PAMA-added provision requires that, in "specifying applicable appropriate use criteria," the Secretary take into account three criteria, whether the AUC: "(i) have stakeholder consensus; (ii) are scientifically valid and evidence based; and (iii) are based on studies that are published and reviewable by stakeholders."[9]

MITA shares CMS's views described in the Proposed Rule that the approach to development of the AUC should account for the clinical needs of patients through the most effective use of resources.[10] CMS outlines the initial components of its AUC program, addressing the process it would use to specify the criteria. Most notably, CMS proposes a definition for PLE and a process by which PLEs become qualified by Medicare to develop or endorse AUC.[11] CMS proposes to define a PLE as a "national professional medical specialty society or an organization comprised *primarily* of providers that is actively engaged in the practice or delivery of healthcare."[12] CMS's proposed definition recognizes the need for AUC development by clinicians who have day-to-day experience caring for patients, as contemplated by

[6] *Id.* at 41,805 (proposed 42 C.F.R. § 414.94).
[7] 42 U.S.C. § 1395m(q)(2)(A).
[8] *Id.*
[9] *Id.* § 1395m(q)(2)(B).
[10] 80 Fed. Reg. at 41,802.
[11] *Id.* at 81,806.
[12] *Id.* at 41,805 (proposed 42 C.F.R. § 414.94) (emphasis added).

PAMA. MITA therefore strongly supports this approach. AUC developed by others, such as Radiology Benefit Managers, would not be developed by entities with the requisite direct clinician engagement contemplated by PAMA.

Once a PLE becomes qualified by CMS, the AUC then developed, modified, or endorsed by the PLE will become part of the AUC that ordering and furnishing professionals would consult.[13] CMS explains that it seeks to adopt this approach because it is not feasible for the Agency to review whether each AUC developed by PLEs meets the three statutorily-required criteria (described above). As far as CMS's process for "specifying" the criteria, which, as noted above, must have stakeholder input, the CMS proposal would only involve non-PLE stakeholders during the rulemaking process. Although MITA strongly supports the PLE definition, we are concerned that CMS's proposal does not take account of the requirement that the Secretary, in specifying AUC, provide for adequate stakeholder involvement. Also as noted above, the statute requires that the AUC "have stakeholder consensus."[14] To address these requirements, MITA urges CMS to support an advisory role for patient groups and manufacturers. This advisory role would retain the primary role providers must play in developing and endorsing AUC, while ensuring that the statutory criteria requiring stakeholder involvement are met.

MITA suggests that CMS add the following new paragraph (c)(viii) to proposed 42 C.F.R. § 414.94(c):

> (viii) The provider-led entity should have a process for receiving and considering, on a regular basis, feedback from representatives of non-provider stakeholders (*e.g.*, patient groups, manufacturers of imaging equipment and drugs).

MITA also suggests that this provision becomes effective as of the effective date of the entire regulatory section. In this way, those AUC already developed by certified PLEs prior to the effective date would not be implicated.

Non-clinical stakeholders, such as medical imaging manufacturers have important and valuable experience with medical imaging equipment and drugs, as well as insights into other aspects of medical imaging services and, logically, should have a voice in the AUC process. To retain transparency, the identities of consulted stakeholders may be posted on the PLE's website. In addition, to avoid conflicts of interest, CMS may require that such conflicts be disclosed in the same manner proposed under proposed section 414.94(c)(1)(iii). In this way, although the PLE would consult with other stakeholders, the provider entity remains the ultimate decision-maker as to what is included in the AUC.

In sum, medical imaging manufacturers bring a depth of experience and familiarity with imaging technologies, the research surrounding the technologies and their clinical use. Patient advocates can offer experiences of individual patients and the significance of advanced imaging services to patient treatment and quality of life. Together, these additional resources can help improve AUC guidelines by recognizing innovation that is supported by research findings and real-life experiences. Adding a criterion for approved PLEs to have an advisory process in place for feedback on newly developed or updated AUC may also be helpful in identifying AUC that are potentially not evidence-based. The involvement by other stakeholders is consistent with the plain language of the statute and, importantly, the criterion for an advisory process may improve the effectiveness of the AUC and, in turn, clinical outcomes.

[13] *Id.*
[14] 42 U.S.C. § 1395m(q)(2)(B).

II. CMS SHOULD IMPLEMENT ON TIME AND CLARIFY THE PROPOSAL TO REDUCE PAYMENT FOR COMPUTED TOMOGRAPHY (CT) SERVICES FURNISHED WITH EQUIPMENT THAT FAILS TO MEET NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION (NEMA) STANDARD XR-29-2013 AS DIRECTED IN SECTION 218 OF THE PROTECTING ACCESS TO MEDICARE ACT

MITA applauds CMS's efforts to implement appropriate quality incentives to promote patient safety and public health in diagnostic CT services, as directed by Section 218(a)(1) of PAMA.[15] Over the past decade, medical imaging manufacturers have developed innovative new technologies to reduce the radiation dose necessary for physicians to render an accurate diagnosis, dramatically cutting dose levels for common CT procedures. These "optimization" technologies help physicians limit the radiation dose to the amount necessary to achieve a diagnostic quality image, preventing not only incidents of over-exposure, but also a need for repeat scanning due to under-exposure. These technologies have been widely available for several years, yet a substantial number of CT equipment in use across the United States lack these features. With this new policy, CMS prudently pays differentially for diagnostic CT services based on the equipment attributes.

PAMA requires the Secretary to reduce payment for certain CT diagnostic services[16] that are furnished using equipment that does not meet NEMA's CT equipment standard as outlined in Standard XR-29-2013.[17] PAMA directs a five percent reduction in 2016 and a fifteen percent reduction in 2017 and later years. The statutory provision also requires that "information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard."[18] In addition, "[s]uch information may be included on a claim and may be a modifier," and "shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a) [of the Social Security Act]."[19]

To implement this requirement, CMS is proposing to establish a new modifier for claims that list CT services provided with equipment that does not meet each of the attributes of NEMA Standard XR-29-2013. Claims for applicable CT scans[20] furnished on equipment that is not compliant with this standard must include this modifier, which would result in the applicable payment reduction.

Although MITA fully supports the CMS proposal, and urges adoption in final rulemaking to allow for on-time implementation of the provision, we recommend that CMS clarify two points. First, CMS notes that suppliers and hospitals would be required to use this modifier for non-compliant CT equipment.[21] Because the term "supplier" is not expressly defined in the PAMA enabling statute nor in CMS's modifier proposal, MITA suggests that CMS clarify the entities or individuals who must provide the required information and attestations as suppliers (*e.g.*, physicians and independent imaging facilities) or hospitals or other providers of services that are furnishing the services, either directly or under arrangement. MITA recommends that CMS clarify that the "supplier" responsible for providing the

[15] *See id*. § 1395m(p).
[16] The affected CT services are those described by HCPCS codes 70450-70498; 71250-71275; 72125-72133; 72191-72194; 73200-73206; 73700-73706; 74150-74178; 74261-74263; and 75571-75574 (and any succeeding codes). 42 U.S.C. § 1395m(p)(2); *see also* 80 Fed. Reg. at 41,716.
[17] 42 U.S.C. § 1395m(p).
[18] *Id*.
[19] *Id*. Of note, in the context of periodic accreditation of advanced diagnostic imaging suppliers, § 1834(e) of the Social Security Act defines "supplier" in this subsection by reference to 42 U.S.C. § 1395x(d), which provides that the "term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this subchapter."
[20] The applicable CT scans are those identified by the CPT codes in footnote 16 above, or any successor codes.
[21] 80 Fed. Reg. at 41,716.

attestation above means the enrolled entity or individual that is furnishing the services and responsible for submitting a claim.[22]

Second, with respect to an attestation on the XR-29 standard it must first be noted that in order to achieve compliance, there are four dose reduction attributes that must all be fully implemented. The two most recently developed dose attributes are: (1) the Dose Check feature, which must comply to the NEMA XR-25 equipment design standard; and (2) the DICOM Radiation Dose Structured Report (DICOM RDSR), which must fully meet the DICOM PS 3.3-2011 Standard.

Dose Check serves both as a dose optimization as well as a radiation safety feature. Dose Check meets both its optimization and radiation safety features in large part because it is integrated into the CT system's internal scan control and is able to positively prevent scanning in high dose situations. DICOM RDSR is the key tool that is needed for both in-house dose monitoring and also for the reporting of dose to entities outside of the health care facility for quality and accreditation purposes. Similar to Dose Check, the DICOM RDSR must be populated with information that is only internally contained within the CT system's software.

As a result of the technological need to fully integrate Dose Check and DICOM RDSR into the CT system's software such that they are compliant to XR-25 and DICOM PS 3.3-2011, these activities must be performed either by the original equipment manufacturer (OEM) or a third party. The third party must be registered with U.S. Food and Drug Administration (FDA) as either a manufacturer or re-manufacturer and the design and development of their solution must be performed under their compliant quality management system, consistent with 21 C.F.R. Part 820 (Quality System Regulation).

As such, MITA urges CMS to require original equipment manufacturer (OEM) or appropriate third parties to provide vendor certificates stating that the particular CT system (with its unique identifier) is fully compliant to NEMA XR-29. If a duly FDA-registered third party has implemented its own product(s) onto an OEM CT system to meet XR-29, the OEM has no way to guarantee if the third party solution is XR-29 compliant. In such a case, the XR-29 certification must be provided by the third party manufacturer/re-manufacturer.

MITA's members who are CT manufacturers have committed to, and already have started providing XR-29 certifications to the owner/operator of the particular CT system. Suppliers, hospitals and other rendering entities furnishing the imaging services would then provide this certification certificate to CMS and/or an accreditation organization upon request.

MITA recommends that the OEM XR-29 certifications or those of duly qualified and FDA-registered third parties be required as part of the periodic accreditation of suppliers. We urge CMS to work with accrediting organizations to incorporate this requirement into their standards.

[22] *See supra*, note 19.

III. MITA APPRECIATES CMS'S PROPOSED UPDATES TO PRACTICE EXPENSE RELATIVE VALUE UNITS (PE RVUS) FOR DIGITAL IMAGING SERVICES, BUT ENCOURAGES CMS TO ENSURE THAT THE PROPOSED VALUES ACCURATELY RECOGNIZE ACQUISITION AND OTHER ASSOCIATED COSTS

The Proposed Rule includes several changes to the determination of PE RVUs that would have payment implications for medical imaging services. MITA's comments address three of the proposals: updates to the 5 percent maintenance factor, increases to the payment for PACS and other workstations, and updates for digital imaging.

Maintenance Factor

CMS previously noted concerns raised by several stakeholders who suggested that the 5 percent maintenance factor for equipment items does not adequately capture the variable costs associated with the particular equipment.[23] In its CY 2015 rulemaking, CMS solicited and received several invoices and data points regarding the costs for maintaining equipment items.[24] CMS concluded that the invoices it received, mostly for capital equipment, were not representative and did not reflect typical costs of all equipment maintenance; the Agency also noted that neither high-level summary data nor assertions without multiple invoices containing equipment prices and maintenance contracts would provide support for changing the currently assumed 5 percent.[25] CMS continued to review ways to obtain more accurate data to improve the accuracy of equipment costs in developing PE RVUs.

In the Proposed Rule, CMS acknowledges that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment items. CMS notes that if the fixed, 5 percent maintenance factor is to be changed to a variable factor, the Agency must maintain data on each equipment item for the PE input database, similar to the way it does for price and useful life.[26] Because of the difficulty associated with obtaining accurate pricing information, CMS seeks comments "on whether adding another item-specific financial variable for equipment costs will be likely to increase the accuracy of PE RVUs across the PFS."[27]

The collective experiences of MITA members has been that costs for maintenance of imaging equipment generally far exceeds the 5 percent amount for capital equipment used with imaging services. MITA agrees with CMS's observation, however, that there is no comprehensive data source for the maintenance information and, therefore, it would be difficult to implement a variable maintenance formula. Nonetheless, as CMS recognizes, Medicare suppliers and others must avail themselves of manufacturer-recommended services and parts to maintain imaging equipment. The Medicare conditions of participation for hospitals and ambulatory surgery centers require providers to maintain imaging or radiologic equipment according to the manufacturer's recommendations, and do not allow deviation from those recommendations as they do for other equipment.[28] As such, imaging equipment maintenance can be subject to both greater variability and greater costs.

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[23] *See* CY 2015 Proposed PFS Rule, 79 Fed. Reg. 40,318, 40,327 (July 11, 2014); CY 2015 Final PFS Rule, 79 Fed. Reg. 67,548, 67,567 (Nov. 13, 2014).
[24] *Id.*
[25] 80 Fed. Reg. at 41,695.
[26] *Id.*
[27] *Id.*
[28] *See, e.g.*, Medicare State Operations Manual (100-05), Appendix A ("Survey Protocol, Regulations and Interpretive Guidelines for Hospitals"): Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's

(continued…)

MITA appreciates CMS's struggle with developing a "systematic" way of varying the maintenance cost assumptions to different equipment.[29] If a fixed maintenance factor remains in place, MITA believes an increase from the current 5 percent amount is warranted and has suggested in prior comments that 10 percent is a more appropriate factor for imaging equipment.

Changes to PE Inputs for Digital Imaging Services

CMS proposes to update the price for the Picture Archiving and Communication System (PACS) from $2,501 to $5,557. This change comes after the Agency reviewed invoice information submitted subsequent to the CY 2015 rulemaking regarding pricing for items related to the digital acquisition and storage of images.[30] CMS also considers whether to include, as direct costs, separate workstations used by practitioners in interpreting digital images. Finally, CMS seeks comments on whether the PACS workstation used in imaging codes is the same workstation that is used in the post-processing described by CPT code 76377 (3D rendering with interpretation and reporting of CT, MRI, ultrasound, or other tomographic modality; requiring image postprocessing on an independent workstation) or if a more specific workstation should be incorporated in the direct PE input database.[31] In response, MITA offers the following comments and observations.

MITA supports the increase in pricing for the PACS workstation. Indeed, our members understand that the true cost for the PACs workstation may be even higher than the $5,557 proposed amount.

MITA members believe that the professional workstation used for interpretation of digital images should be assigned a direct PE input because it is a separate and direct expense. Among other things, the workstation is used for individual studies in the non-facility setting and frequently to provide bi-directional exchange between the technologist and radiologist while the service is performed. Consideration as a direct expense also is consistent with how digital inputs (replacing film) were viewed as necessary for the performance of the service.

With respect to the post-processing workstation, MITA's understanding is that post-processing described by CPT code 76377 is performed using a separate workstation from PACS. We recommend that, in addition to retaining the PACS direct input for this code, CMS determine pricing for the separate workstation in the PE input for this post-processing service, consistent with the American College of Radiology's (ACR's) recommendations.

Standardization of Clinical Labor Tasks

Current direct PE RVUs reflect labor minutes associated with film-based technology. Because most imaging services now use digital technology, CMS seeks to establish standard times for clinical labor

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> recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.
>
> ….
>
> Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) ***and must be maintained per manufacturer's recommendations.***

Tag A-0724 (emphasis added), addressing 42 C.F.R. § 482.41(c)(2).

> ***Hospitals must follow the manufacturer's instructions as to how to inspect and maintain radiologic equipment.*** This includes acceptance testing (i.e., upon initial installation and after major upgrades) as well as ongoing inspection and maintenance. Documentation of preventive maintenance, quality control tests, service records, and major software/hardware upgrades must be maintained by the hospital and be readily available for inspection.

Tag A-537 (emphasis added), addressing 42 C.F.R. § 482.26(b)(2).

[29] 80 Fed. Reg. at 41,695 (CMS explains that it lacks reliable data to "identify a systematic way of varying the maintenance cost assumption relative to the price or useful life of equipment.").

[30] *Id.* at 41,697.

[31] *Id.*

tasks associated with digital imaging.[32] Although MITA does not have direct information on the standard minutes proposed by CMS, we appreciate and support CMS's efforts to recognize the advancements in digital imaging and to take them into account through updated RVUs. In developing the accurate number of labor minutes, MITA encourages CMS to look to clinicians and others, such as ACR, with direct information.

IV. MITA SUPPORTS THE REVISED TIMELINE FOR ANALYSIS OF NEW AND REVISED CODES AND URGES CMS TO CONSIDER ALTERNATIVES FOR ADDRESSING THE TARGET AND PHASE-IN PERCENTAGES FOR MISVALUED CODES

Timeline for Analysis of New and Revised Codes

In previous years, CMS would accept comments only after publication of interim final RVUs for potentially misvalued codes, new codes, or other codes for which there were changes. Comments on the interim final rule would be considered during the following year's rulemaking cycle and only after the changes had gone into effect. In last year's PFS final rule, CMS finalized the new process for establishing values for new and revised codes.[33] Under the new process, in effect for CY 2016, CMS includes the RVU values in its proposed rulemaking.

Because this is the first year of this new process, CMS refers to CY 2016 as a "transition year."[34] CMS published new values for codes for which it has received recommendations from the American Medical Association/Specialty Society Relative Value Update Committee (RUC) by February 10, 2015. Recommendations regarding codes received after that date will still appear in the final rule as interim final values and CMS will consider comments for sixty days following the issuance of the final rule, consistent with past years. The new process will be applicable to all codes for the CY 2017 valuation.[35]

MITA agrees that this new timeline will better afford transparency and meaningful input on the RVU assignments for new and revalued codes. Although this rulemaking cycle only allows input on a subset of codes that were included in the RUC recommendations by February 10, 2015, MITA is pleased that CMS is moving towards this new schedule for all codes and looks forward to continued participation in future rulemaking cycles.

Target for Relative Value Adjustments to Misvalued Codes

PAMA establishes an annual target for reductions in PFS expenditures resulting from adjustments to RVUs for "misvalued codes." If the estimated net reduction in expenditures for a year is equal to or greater than the statutory target, any reduction attributable to such adjustments must be redistributed in a budget-neutral manner. In this way, overall spending under the physician fee schedule would not be reduced by the adjustments to the misvalued codes. If, on the other hand, the estimated net reduction in expenditures attributable to the misvalued codes falls short of the statutory target, the amount by which the target for the year exceeds such net reduction—called the "target recapture amount"—is not taken into account when applying budget neutrality calculations.[36]

To determine whether the target is met, CMS's proposes to include in its estimated net reductions, the reductions to affected codes, not just those identified as "misvalued."[37] MITA supports this proposal and

[32] *Id.* at 41,697-98.
[33] *See id.* at 41,716.
[34] *Id.*
[35] *Id.*
[36] *Id.* at 41,711-12.
[37] *Id.* at 41,712.

urges its adoption in the final rule. This is a reasonable and fair approach to implementation of the PAMA provisions and helps to ensure that the recapture is not smaller or larger than necessary.

Further with respect to CMS's proposed calculations of estimated net reductions, it appears that CMS may have included codes that are not misvalued, as required under PAMA.[38] For example, CMS includes two codes (99497 and 99498 for advance care planning services) as misvalued for purposes of determining whether the target was met. These codes were established for CY 2015, but are inactive codes; CMS has now assigned proposed values for these codes for the first time for CY 2016. The effect of the inclusion of these two codes appears to be an inaccurate net reduction, such that CMS must find more savings to meet the target. MITA therefore encourages CMS not to include these and other codes that are not misvalued or affected by misvalued codes, in the calculation of potentially misvalued codes.

Phase-in for Relative Value Adjustments to Misvalued Codes

Under section 220(e) of PAMA, reductions to RVUs for a service of 20 percent or more compared to the total RVUs for the previous year (except services described by new or revised codes) are to be phased-in over a two-year period. CMS proposes to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year. CMS further proposes to allow up to a 19 percent reduction as the maximum amount in the first year and the remainder in the following year. For most services, this means the majority of the reduction will take place in the first year.[39]

MITA disagrees with CMS's proposed phase-in percentages and recommends a 50 percent phase-in during the first and second years. Such a phase-in is not only more in line with past practices for transition years, but also is more equitable for the vast majority of codes that would otherwise see most of the reduction in the first year. The congressional intent of a phase-in was in large part to mitigate potential financial hardships on physician practices experiencing drastic reductions. We acknowledge that codes with reductions that are less than 20 percent and not phased-in may experience greater reductions in the first year. On balance, however, MITA believes that the more gradual phase-in for practices facing the steeper cuts, which is the overarching purpose for the PAMA directives, should be the paramount principle for any policy to transition cuts at or greater than 20 percent.

V. CMS SHOULD ADJUST PROPOSED PAYMENT RATES FOR LUNG CANCER SCREENING WITH LOW DOSE COMPUTED TOMOGRAPHY (LDCT) SERVICES IN 2016 AND ADOPT THE RATES FOR 2015

In February 2015, CMS released a national coverage determination (NCD) to provide Medicare coverage for lung cancer screening with LDCT. This coverage includes a lung cancer screening counseling and shared decision-making visit and, for appropriate beneficiaries meeting certain criteria, an annual screening for lung cancer with LDCT as a preventative service.

CMS has established new HCPCS code GXXX1 for the LDCT lung cancer screening and new HCPCS code GXXX2 for the counseling visit. CMS proposes a work RVU of 1.02 for code GXXX1, for the screening service, which is identical to CPT code 71250 (computed tomography, thorax; without contrast material). For the counseling and decision-making visit, CMS proposes an RVU of 0.52 for code GXXX2.[40] CMS notes that the proposed rates are lower than those proposed by the American College of

[38] *See* 42 U.S.C. § 1395w–4(c)(2)(K)(ii).

[39] 80 Fed. Reg. at 41,714-15.

[40] There is an inconsistency between the code references identified in the Proposed Rule and those that appear in the hospital outpatient prospective payment system notice of proposed rulemaking. *Compare* 80 Fed. Reg. at 41,779 *with* 80 Fed. Reg. 39,200, 39,301 (July 8, 2015). (*See also* Proposed Rule's Addendum on values for these codes.) The code references should be aligned in the final rules.

Radiology (ACR). MITA encourages CMS to adopt the higher rates proposed by ACR that take account of the added intensity of the services, including the various registry and quality requirements within the NCD.

Furthermore, MITA remains deeply concerned about the lack of current guidance or guidance going back to the effective date of the NCD. Under the Medicare statutory provisions on NCD development, CMS is directed to have coding in place to implement a new coverage determination.[41] The proposed codes and rates cover LDCT lung cancer screening services for 2016, but do not address 2015, even though more than six months have elapsed since the NCD was released. MITA strongly urges CMS to implement codes and payment rates, through transmittals providing billing guidance for LDCT services in 2015, going back to the effective date of the NCD.

Finally, MITA echoes the concern raised by the ACR regarding not only the differential work values from code 71250 for the LDCT service for cancer screening but also the need for separate payment for the shared decision-making visit when performed during an evaluation and management service. MITA urges CMS to increase the RVUs for the LDCT scan in light of the additional resources and intensity of those services. We also urge CMS to recognize payment for the counseling and decision-making visit, separate from evaluation and management services that may be performed on the same day.

VI. THE PROPOSED CROSS-CUTTING MEASURE FOR MAMMOGRAPHY MAY COMPROMISE PATIENT CARE

MITA is concerned that an adoption of the 27-month measure for mammography screening as a cross-cutting measure may impede access to care and result in less frequent mammography screenings. This, in turn, may compromise early detection of breast cancer, adversely affecting treatment outcomes and patient care. MITA therefore urges CMS not to include this measure as a cross-cutting measure.

Under the Physician Quality Reporting System (PQRS), eligible professionals (EPs) and group practices report information on certain quality thresholds to Medicare. The PQRS includes certain metrics, and individual EPs and group practices can quantify how often they meet these metrics. Beginning in 2015, EPs and group practices that did not report data on PQRS measures in 2013 experience a payment reduction for professional services of 1.5 percent. From 2016 through 2018, non-reporters will see payments reduced by 2 percent, with 2016 payment reductions based on 2014 reporting, 2017 payments based on 2015 reporting and 2018 payments based on 2016 reporting.[42] Successful reporters must report at least one cross-cutting measure, which is any measure that is broadly applicable across multiple clinical settings and EPs or group practices within a variety of specialties. EPs or group practices must report on at least one cross-cutting measure if they see at least one Medicare beneficiary in a face-to-face encounter.[43]

CMS proposes a cross-cutting measure for breast cancer screening within 27 months for women between the ages of 50 and 74. Current Medicare policies cover annual mammograms for women age 40 and older.[44] MITA recognizes that the U.S. Preventative Service Task Force (USPSTF) has issued a draft recommendation for biennial screening for breast cancer for women between the ages of 50 and 74. However, it remains uncertain whether the draft would be finalized and, if so, whether it would be adopted by CMS in any coverage decision-making. MITA therefore urges CMS not to adopt this cross-

[41] Once CMS makes a final decision "to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change." 42 U.S.C. § 1395y(l)(3)(C).
[42] 42 U.S.C. § 1395w-4(a)(8)(A)(i).
[43] *See generally* 42 C.F.R. § 414.90; CMS's "2015 Physician Quality Reporting System (PQRS): Implementation Guide" (July 23, 2015).
[44] CMS, Your Guide to Medicare's Preventive Services, at 11, *available at* https://www.medicare.gov/Pubs/pdf/10110.pdf.

cutting measure and consider revisions to existing quality measures that are inconsistent with current Medicare coverage criteria.

VII. MITA SUPPORTS ADOPTION AND/OR CONTINUATION OF THE NINE QUALITY MEASURES ADDRESSING IMAGING SERVICES

MITA encourages CMS to include in the PQRS those measures that support the use of the right imaging services at the right time. For this reason, MITA agrees that the following nine new and/or continued quality measures promote effective clinical standards for diagnostic imaging services:

1. Follow-Up Imaging for Incidental Abdominal Lesions.[45]
2. Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients.[46]
3. Imaging in Adult Emergency Department Patients with Minor Head Injury.[47]
4. Imaging in Pediatric Emergency Department Patients Aged 2 through 17 years with Minor Head Injury.[48]
5. Extravasation of Contrast Following Contrast-Enhanced CT.[49]
6. Overuse of Neuroimaging for Patients with Primary Headache and a Normal Neurological Examination.[50]
7. Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques.[51]
8. Unnecessary Screening Colonoscopy in Older Adults.[52]
9. Image Confirmation of Successful Excision of Localized Breast Lesion.[53]

Generally, CMS selects for adoption for PQRS, those quality measures that have been endorsed by the contracted consensus organization during a pre-rulemaking process.[54] This organization currently is the National Quality Forum (NQF). CMS has the authority to make exceptions and "may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity [i.e., the NQF]."[55] For meaningful and appropriate measures that have already been developed without NQF reviews, therefore, such as the nine listed above, MITA supports their adoption through the CMS rule-making process.

Although MITA recognizes that that the NQF process may not be timely for certain issues, the NQF offers important clinical validations and quality controls in a public forum. The NQF process provides an opportunity for public comment and engagement. For those meaningful measures that have already been

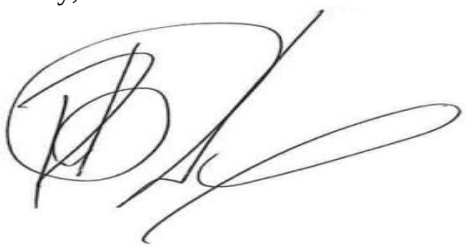
[45] 80 Fed. Reg. at 41,833.
[46] *Id.* at 41,834.
[47] *Id.* at 41,844.
[48] *Id.*at 41,843-44.
[49] *Id.* at 41,842.
[50] *Id.* at 41,846.
[51] *Id.* at 41,855.
[52] *Id.*at 41,857.
[53] *Id.* at 41,871.
[54] *See* 42 U.S.C. § 1395w-4(k)(2)(C).
[55] 80 Fed. Reg. at 41,827, *citing* 42 U.S.C. § 1395w-4(k)(2)(C)(ii).

developed without NQF reviews, MITA encourages their developers to undergo additional reviews through the NQF process. Because CMS relies on outside measure stewards and developers to maintain the measures, we urge the Agency to encourage the measure stewards to engage with NQF on such review. We also urge CMS to remove those measures that NQF has rejected.

* * * *

Thank you for this opportunity to comment on the CY 2016 Physician Fee Schedule Proposed Rule. We would be pleased to discuss or answer any questions you might have about these comments. Please contact me at (703) 841-3235 if MITA can be of any assistance.

Sincerely,



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