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September 2, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

RE: CMS-1654-P, Revisions to Physician Fee Schedule Payment Policies

Dear Administrator Slavitt:

The Radiology Business Management Association (RBMA) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS) proposed rule for the Calendar Year (CY) 2017 Medicare Physician Fee Schedule (MPFS) as published in the *Federal Register* on July 15, 2016.

Founded in 1968, the RBMA represents over 2,300 radiology practice managers and other radiology business professionals. In the aggregate, RBMA's influence extends to over 24,000 radiologic technologists and 26,000 administrative staff. RBMA is the leading professional organization for radiology business management, offering quality education, resources and solutions for its members and the healthcare community, and helping shape the profession's future.

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General Comments

RBMA appreciates CMS using the CY 2017 MPFS proposed rule to expand on innovative policy ideas and to address past industry concerns. However, RBMA remains concerned about the continued reduction of payments to providers of imaging services. Over the course of the past 10 years, these cuts to imaging payments under Medicare have imposed severe financial hardships on radiology practices and facilities and have challenged the efforts of these practices to provide and maintain a high quality of radiology services.

The CY 2017 MPFS proposed rule continues this trend. CMS proposes updates to the practice expense (PE) Relative Value Units (RVUs), which will have a negative impact on a range of imaging specialties, including radiology, diagnostic testing facilities, and interventional radiology. RBMA is particularly concerned about the estimated 7 percent reduction to interventional radiology**.**

As RBMA has expressed in the past, there are few businesses or professions that can absorb this degree of payment reduction and remain financially viable. RBMA is concerned that continued erosion of Medicare payments for imaging services will have serious consequences to not only providers, but also to Medicare beneficiaries. The ongoing reduction in payments to radiology practices and other providers of high-quality and appropriate imaging services threatens to undermine the existing quality standard, which requires an increasingly higher level of training for radiologists, technologists and medical information technology personnel, as well as continuous maintenance and replacement of expensive imaging equipment and related software. A number of lower cost imaging centers have closed in the last year and we expect further access challenges in the near future. These payment reductions may have unintended consequences of an unforeseen magnitude, as commercial payors often follow CMS' lead in reducing payments for services, which, of course, further exacerbates the impact of these policies.

Comments on Specific Issues in the Proposed Rule

Appropriate Use Criteria

In the CY 2016 MPFS rule CMS began to implement the appropriate use criteria (AUC) program established by the Protecting Access to Medicare Act of 2014 (PAMA). Specifically, CMS established process and transparency requirements for the development of AUC, defined provider-led entities (PLE), and created a process through which a PLE may become qualified to develop AUC. CMS posted the first list of qualified PLE on its website in June 2016. RBMA commends the forward progress made by CMS in establishing the PLE. In the current proposed rule, CMS addresses the next phase of implementation: establishing requirements and specifications for clinical decision support mechanisms (CDSM).

RBMA has been an early and strong supporter of the AUC program established by PAMA. We continue to work with other industry leaders in helping to build a common understanding and consensus in order to assure that the law is implemented in a thoughtful, workable manner. Our members desire practical, standards-based guidelines and fair timelines for an efficient implementation – from IT procurement through configuration, testing, education and integration.

Timeline for CDSM Requirement Proposal:

One of RBMA's primary issues has been timing. Assuredly, the implementation of Section 218(b) is a challenging task and there are many issues that need to be addressed within a condensed time frame. To date, this reality has led the agency to announce delays to the statutory deadlines related to the selection of qualified CDSM and the date on which ordering physicians must begin consulting AUC prior to referring Medicare beneficiaries for applicable advanced diagnostic imaging services. The current pace of implementation could lead to further delays, especially given the need to (i) educate the provider community regarding these

requirements and (ii) implement numerous changes to multiple systems. We ask that CMS pursue a realistic and comprehensive timeline for implementation, rather than subject the provider community to the uncertainty of annual delays.

As RBMA did when it met with the agency more than a year ago, we continue to urge CMS to act expeditiously to address the issue of how consultation of AUC can and should be entered onto the CMS-1500 claim forms. In this rulemaking, CMS proposes that a qualified CDSM must, in each case that AUC is consulted, provide certification or documentation that includes a unique "consultation identifier" to the ordering professional as to (i) which CDSM was consulted, (ii) the name and National Provider Identifier (NPI) of the ordering professional, and (iii) whether the service ordered would adhere/not adhere to the specified AUC or whether such AUC was not applicable to the ordered service. This is an appropriate requirement, but the failure to proactively address issues pertaining to claims documentation inhibits the progress of interested parties that wish to develop CDSM and gain qualified status. This information is critical to the overall design and implementation of the AUC initiative.

A dearth of information related to claims processing specifications prevents EMR, RIS and CDS vendors from finalizing design specifications, in turn delaying the development and release of CDSM products. These realities prevent ordering providers from finalizing their workflow, which, in turn, prevents rendering providers – including imaging facilities, hospitals and ambulatory surgery centers – from finalizing the design and implementation for ingesting the information from the order. This further inhibits transferring relevant information through the multiple systems (*e.g,*. radiology information system, transcription, et al.) to the revenue cycle management system for inclusion on the CMS-1500 claim form. Therefore, the release of this information is among the most critical steps in the overarching effort to implement this policy in a timely and orderly fashion.

We therefore join other industry leaders in again requesting that CMS expedite the pace of regulatory and administrative implementation of the AUC program by issuing a separate proposed rulemaking that addresses various claims processing issues simultaneously, instead of continuing to utilize the annual physician fee schedule rule to address these issues in a staged, sequential manner.

Priority Clinical Areas:

RBMA also joins other industry leaders in urging CMS to concurrently address the qualified CDSM requirements and specifications for all advanced diagnostic imaging services that must consult AUC under the PAMA requirements, rather than just 8 priority clinical areas as outlined in the Proposed Rule. RBMA strongly believes consultation of imaging AUC by ordering physicians should not be restricted to a select group of clinical conditions with additional clinical conditions rolled out in future rulemaking. The use of priority clinical areas could undermine the ability of this utilization management program to accurately eliminate inappropriate or duplicative advanced diagnostic imaging services. In addition, we are concerned that a piecemeal approach will increase cost, confusion, and frustration.

Furthermore, we are particularly concerned that limiting the CDSM consultation requirements to clinical priority areas will result in a confusing and unworkable system for many, if not nearly all community-based ordering and furnishing professionals. While limiting the consultation requirement to clinical priority areas may appear to be an attractive and easy introduction to Clinical Decision Support, from a practical implementation perspective it is not: determining whether an exam qualifies as a clinical priority area will often not be an easy yes-or-no decision for the ordering professional, and it may potentially expose furnishing professionals to inappropriate denials when the original reason for the exam does not fall into a clinical priority area, but the post-exam diagnosis does. For example, a patient may be referred for a CT Thorax for shortness of breath or a cough (not a clinical priority area); however, the exam results in a diagnosis of cancer (a clinical priority area) which is how the exam will be coded by the furnishing professional.

We agree this is a large and complex program, and want its implementation to go as smoothly as possible. However, limiting the consultation will effectively increase, rather than decrease, the program's complexity and uncertainty for the professionals involved. RBMA supports requiring ordering professionals to consult and furnishing professionals to report, the consultation for all advanced diagnostic imaging services, and then limit the outlier evaluation process to the clinical priority areas. This is clear and understandable for all involved.

Systems Revisions Urgency: Recommendation for a Hash Number:

RBMA supports the Imaging eOrdering Coalition's recommendation made last year that CMS adopt a hash number (*i.e.*, a unique character set that incorporates three data elements) that would be generated by the qualified CDSM and provided by the ordering professional to the rendering facility and furnishing professional. The hash number would ideally be located in Box 23 (Prior Authorization Number) on the CMS-1500 claim form. We agree that a hash number is a viable solution that is likely to be the easiest for ordering and furnishing professionals to implement and use.

PACS Workstation

CMS proposes updates to the PE input pricing for digital imaging services, specifically with regard to the Picture Archiving and Communication System (PACS) equipment. In the FY 2015 MPFS rule, CMS first created the equipment item as a proxy for the PACS workstation, and subsequently updated the price for the PACS workstation in the CY 2016 MPFS from $2,601 to $5,557. CMS now proposes a further update by distinguishing between a workstation used by clinical staff to acquire images and provide the technical component (TC), and a workstation used by a radiologist to interpret images and provide the professional component (PC). The price of the technical PACS station will remain the same. However, the price of the professional PACS workstation will be raised to $14,616.93.

We thank CMS for this change and for continuing to evaluate the costs associated with this fast-changing area of medical information technology. RBMA supports the increase in price for the professional workstation, but continues to have concerns that even the increased price significantly underestimates the cost of a PACS workstation. Accordingly, RBMA urges CMS

to further evaluate the true cost of the PACS workstation to ensure that providers are adequately reimbursed for this complex technology.

Mammography – Computer Aided Detection Bundle (81 FR 46252)

In the CY 2017 MPFS proposed rule, the CPT Editorial Board deleted certain codes and created three new CPT codes to describe mammography services bundled with computer aided detection (CAD). Further, CMS reviewed these coding changes and recommends changes to the valuation for CY 2017. Currently, CPT codes are based on digital imaging G-codes, with a separate add-on code for CAD. The proposed revisions would mitigate the need for separate add-on coding. In totality, these revisions would lead to drastic reductions in overall Medicare payments for mammography services and would have a particular impact on the technical component of these services. CMS expects that payment for the technical component could be reduced by up to 50 percent relative to the PE RVUs currently used for payment. As such, CMS proposes to adopt only the new coding, including the elimination of CAD add-ons, without implementing recommended resource inputs. Those recommended inputs will be further considered before revising PE values through subsequent rulemaking.

RBMA appreciates CMS' approach to these revisions, and thanks CMS for delayed implementation of revisions to the technical component of payment. The drastic reductions that would result from implementing both revisions simultaneous would adversely impact both patient access and quality of mammography imaging services. We ask that CMS meet with stakeholders, including the RBMA, to discuss the proposed practice expense revisions and the impact any payment reductions will have on beneficiary access to mammography services.

Procedures subject to MPPR

Section 502(a)(2) of the Consolidated Appropriations Act of 2016 revised the MPPR for the professional component of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount, effective January 1, 2017. RBMA believes the prior 25 percent reduction dramatically overestimated the perceived efficiencies within the professional component. The proposed reduction to 5 percent more appropriately reflects peer-reviewed statistical analysis of Medicare data showing that the professional component efficiencies vary depending on modality and range from a low of 2.96% for CT to a high of 5.45% for ultrasound. RBMA applauds CMS' decision to revise this reduction to more accurately and appropriately reflect the efficiencies found within the professional component.

Clinical Labor Tasks Associated with Digital Imaging (81 FR 46175)

As noted in the proposed Rule, CMS continues to improve the direct PE input database by specifying for each code both the number of images to be reviewed, and also the complexity of those images. CMS does not agree that the variance in amount of clinical labor needed to check images at a PACS workstation precludes the agency from establishing standard clinical labor task times. Accordingly, CMS proposes establishing standard clinical labor minutes for digital imaging.

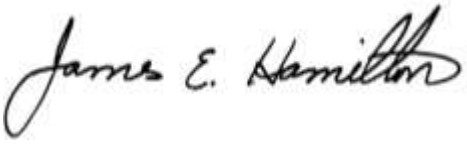
The proposed ranges for clinical labor times underestimate the amount of time required for these digital imaging services, thus RBMA requests that CMS reevaluate the proposed revisions to the direct PE input database. The direct PE input database should reflect the actual clinical labor task times that occur in imaging facilities across the country based on a valid study of times for specific modalities.

Physician Self-Referral

CMS is re-proposing to add certain requirements to the Stark Law exception for arrangements that involve the rental of office space or equipment. Specifically, CMS is re-proposing that office space and equipment rentals may not be based on a per-unit of service rental charges. RBMA commends CMS for continuing to address areas of concern within the regulatory exceptions to the Stark Law. However, we believe the more important issue CMS should consider is overuse of the in-office ancillary services exception (IOAS Exception) by referring physicians who order and provide advanced diagnostic imaging services in their offices. Numerous studies over the past decade have identified the extent to which the IOAS Exception is being abused by referring physicians for advanced diagnostic imaging services. This over-utilization costs the federal health care programs millions of dollars annually. We urge CMS to take this notice and comment opportunity to reflect on the changes that should be implemented to protect program abuse as a result of the over-utilization of advanced diagnostic imaging services via the IOAS Exception. We encourage CMS to implement more stringent requirements on the self-referral of advanced diagnostic imaging services so that referrals reflect the clinical needs of the patient and not the referring physician's financial motivations. Further, we encourage CMS to keep in place the relevant restriction on per-unit arrangements when payments are made to referral sources.

Thank you for your attention to our concerns. RBMA and its members stand ready to assist the agency as you move forward. Please contact either myself (jhamilton@mipimaging.com) or Liz Quam, RBMA Federal Affairs Committee Chair (lquam@cdirad.com) if you wish clarification of any of our comments or wish to discuss further.

Sincerely yours,



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