December 22, 2016

Tamara Syrek Jensen, JD
Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Sent via e-mail

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017

Dear Ms. Syrek Jensen:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (ADIS) provisions of the calendar year (CY) 2017 Medicare Physician Fee Schedule (MPFS) Final Rule.

The final rule outlines CMS' continued plan for implementing Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA), establishing a program to promote the use of AUC for ADIS. CMS notes in the final rule that it continued to consult with physicians, practitioners and other stakeholders in advance of proposals to implement the program. The ACR greatly appreciates CMS' willingness to engage us and other stakeholders in this process and for the consideration of our input during this rulemaking cycle. We look forward to continued collaboration in future rulemaking cycles.

The ACR supports a program by which healthcare providers can collaborate on the appropriateness of care, transparency, and quality improvement through AUC, without the influence of non-provider-led entities focused on commercial gain. We believe this is the best way to achieve the program's goal of promoting "the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging."

Headquarters
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

Government Relations
505 9th Street NW, Suite 910
Washington, DC 20004
(202) 223-1670

Clinical Research
1818 Market St, Suite 1600
Philadelphia, PA 19103
(215) 574-3150

Implementation Timeline

While the ACR objected to the delay to the statutorily required January 1, 2017 implementation date for ordering professionals (OPs) to consult the AUC prior to referring Medicare patients for advanced imaging services in our 2016 MPFS comment letter, we understand the limitations of using the rulemaking process and support the proposed January 1, 2018 implementation date. The ACR strongly believes that implementation can occur on this date and urges CMS not to delay implementation beyond January 1, 2018.

As you know, the ACR is prepared to execute its AUC program under this schedule and can assist CMS in achieving the implementation date. The ACR's AUC, together with a delivery mechanism capable of housing multiple AUC, have already been integrated with major electronic health record (EHR) solutions and have been widely deployed in the market. Further, the ACRSelect® free web portal, providing access to ACR and other AUC, is active and operational in the market and provides OPs access to the AUC, including the ability to generate and share evidence of the AUC consultation for those providers without integrated access. The system is currently installed at over 800 sites that are already using AUC to manage utilization for at-risk payment models and have implemented in anticipation of the PAMA requirements.

Definition of Consult/Consultation

Background

In the MPFS final rule, the terms ***consult*** and ***consultation*** are used throughout the regulation without clear definitions of their meaning. Inconsistent interpretation of these terms by clinical decision support mechanism (CDSM) developers and end users creates potential for poor compliance with the regulation, which could have significant impact of the ultimate value of quality improvement aspects of the program, undermining the intent of the statute.

Result

There is currently no regulatory requirement for an OP to select any indication/reason for the examinations other than those that show the AUC related to the priority clinical areas (PCAs). In fact, there is a strong incentive for the OPs to NOT choose any indication related to the PCAs and either check an 'Other' indication or enter free text that cannot be tracked to a PCA. Free text is unfortunately often cryptic, inaccurate or lacks clinical specificity (e.g. "…", "#", "1", "pain"), or unrelated to the actual clinical condition for which imaging is requested.

This current lack of definition creates several compliance issues which are at odds with the program's intent:

- Circumventing the intent of the legislation for OPs to be required to consult AUC for ALL advanced diagnostic imaging services (ADIS),

- Inaccurate determination of outliers, as those OPs that do not select a scorable indication will be removed from the denominator of all PCAs, and
- Inability to monitor the use of non-PCA indications for future year identification of PCAs.

Solution

To prevent unintended regulatory interpretation of the term ***consult/consultation***, it is recommended that ***consult/consultation*** be defined in 42 C.F.R. § 414.94(b) as:

The action of an ordering professional to select or enter structured indications relevant to the patient's clinical scenario into the qualified CDSM for the determination of the presence or absence of an appropriate AUC. This selection must occur prior to the determination of whether a priority clinical area applies so that the qualified CDSM system can determine the appropriate AUC (when available) and present them to the ordering professional along with a determination whether a priority clinical area applies.

Details

A ***consult*** must be invoked by the selection of one or more structured indications whose codification is mapped to one or more standard clinical vocabularies which will determine the presence or absence of associated AUC. Regardless of where invoked in the workflow, PCA status cannot be determined until this step is accomplished by the OP.

It is our belief that the use of free text should be completely eliminated. If it is determined by CMS that some option for 'other' is necessary, its use must be generally discouraged and when this term is used as an indication, it must be qualified with free text. The use of 'other' should be included in the denominator for the determination of outlier status to determine whether there was meaningful interaction with the qualified CDSM by the OP. If 'other' represents a significant component of an OP's indications, there could be significant unintended impact on the determination of an OP's outlier status for all PCAs.

Criteria for CDSMs

Although the ACR believes that there are adequate well-established AUC across enough clinical areas and scenarios to warrant the creation of a comprehensive outlier program (as intended in the statute), we understand CMS' position that OPs may choose to thoroughly improve their understanding of, and focus their internal quality improvement programs on, identified priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

The ACR expressed concern with the proposal that required a CDSM to only maintain the minimum number of specified applicable AUC to reasonably encompass the entire scope of the PCAs. We remain concerned with the modified minimum floor requirement in the final rule indicating that CMS does not expect this requirement to be met by AUC that address only a

narrow clinical aspect of a priority clinical area. The finalized requirements keep the AUC floor but allow the requirement to be fulfilled if specified applicable AUC address less than the entire scope of the priority clinical areas and instead "reasonably address the common and important clinical scenarios within each priority clinical area." Our concern is that without more specific guidance from the agency, there may be a misunderstanding regarding the scope of PCA implementation which will lead to significant market confusion. Additionally, while the proposed rule included a list of ICD-9-CM codes that correlated with the proposed PCAs, the final rule did not contain a corresponding list for the final list of PCAs. This is likely to lead to confusion among CDSM developers as they attempt to determine the requisite appropriate use topics and clinical scenarios required to cover the entire clinical scope of the PCA.

According to the statute and CMS' definitions, a CDSM has two primary responsibilities. First, the CDSM must be able to process a consultation and render a determination for each ADIS requested by an OP, and second, the CDSM must provide evidence to the furnishing provider (FP) that such consultation occurred. To blend CMS' phased-in PCAs with the statutory requirements, the agency acknowledges that although a CDSM may make available a limited set of AUC just related to the PCAs, the CDSM must also provide the OP with a determination of "not applicable" if there is no AUC related to his or her patent's clinical scenario.

Although some stakeholders may strongly agree with CMS' proposal to limit the number of clinical areas used to determine an OP's outlier status, we see no advantage in allowing a CDSM to maintain only the limited sets of AUC related to the PCAs. As shown in the Medicare Imaging Demonstration (MID), if OPs consistently see "not applicable" as a decision support determination, they will quickly become frustrated and dissatisfied with the entire program. Staged implementation with a high percentage of no meaningful determinations would not be successful in any other utilization management program. Other utilization management programs would not be implemented in this fashion, and neither should this program. By allowing a CDSM the option of reporting a "not applicable" determination for as many as 60 percent of ADIS, the AUC program will meet the statutory requirement requiring that all ADIS orders have a decision support consultation, but not the statutory intent that whenever possible the CDSM delivers a meaningful evidence-based decision support determination to the OP.

Finally, with regard to removal of potentially harmful AUC, CMS did not believe at the time the final rule was written that there was enough information about the types of CDSMs that will seek qualification to know their abilities to react quickly in these situations. The ACR shares the agency's belief that expeditious removal is critical. As CMS considers this issue for future rulemaking, we encourage CMS to include not only the CDSMs but the provider led entities (PLEs) into this discussion to determine the best way to rapidly communicate and remove potentially harmful AUC.

Priority Clinical Areas (PCAs)

The ACR's principal concern with the list of PCAs in the proposed rule was the absence of a PCA for joint pain. We appreciate CMS' recognition of the omission of musculoskeletal indications from the proposed list and the addition of hip pain and shoulder pain (to include suspected rotator cuff injury) to the final rule list of PCAs.

The College also is concerned with the removal of suspected stroke from the PCA list. The final rule indicated that CMS expects that the exception for emergency medical services may disproportionally apply to suspected stroke and that there may be some overlap of the clinical areas of stroke and headache. The ACR disagrees with the premise that headache will cover most suspected strokes. For example, a hemorrhagic stroke due to subarachnoid hemorrhage would not necessarily present with a headache and accounts for 10 percent of stroke. On the point of the emergency medical services exemption, recent protocols have prompted an increasing number of outpatient MR examinations in the setting of suspected stroke. The ordering of these examinations should be subject to the provisions of AUC.

Consultation by OP and Reporting by FP

As indicated in our comments on the proposed rule, the ACR strongly believes that all orders for ADIS should include a unique consultation identifier to indicate that consultation with CDS took place. We applauded CMS for including in the proposed regulation the requirement that "certification or documentation must be issued each time an OP consults a qualified CDSM" and "certification or documentation must include a unique consultation identifier generated by the CDSM," and we agreed that this unique code could assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement and to iteratively improve the AUC itself. We asked the agency to finalize these requirements. We are disappointed that CMS feels it is not feasible at this time to require qualified CDSMs to create such a defined identifier. We would like to continue to work with the agency to look into options to determine possible future roles for that identifier as we believe it is essential to the long-term success of the program.

We believe it is imperative for CMS to implement PAMA's statutory requirements as Congress intended and require all OPs to consult applicable AUC through a qualified CDSM for every applicable imaging service that is furnished in an applicable setting so that payment may be made. We support CMS' regulation text that consulting and reporting requirements are not required for orders of applicable imaging services made by OPs that meet the emergency services, inpatient, and significant hardship exceptions and ask CMS to further clarify in the CY 2018 rulemaking cycle that consultation is indeed required in *all* other instances, *including* when outside a PCA.

Although the statute mandated implementation by January 1, 2017, and the ACR encouraged implementation by that date, we understand the agency's desire to proceed through rulemaking and delay implementation until January 1, 2018. That said, we urge CMS to hold fast to this

implementation timeline and not delay beyond this date. We continue to encourage CMS to use subregulatory guidance wherever possible to expedite implementation.

Reporting, Claims Processing, and Hardship Exceptions

In the proposed rule, CMS indicated an interest in receiving feedback related to reporting and claims processing for use in CY 2018 rulemaking. In response to this request, we submitted a memo from Donald Moran, President of The Moran Company, outlining three potential routes for inserting the requisite information into the claims processing system (attached). We look forward to continuing to work with CMS on this issue in the CY 2018 rulemaking process.

Qualified Provider-Led Entities (PLEs)

The ACR requested in our proposed rule comments that in the spirit of transparency, CMS release the applications from the approved qualified PLEs detailing how they meet the requirements laid out in the 2016 MPFS final rule. This is consistent with CMS' implementation of Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requiring suppliers of the technical component of ADIS to be accredited by a designated accrediting organization to receive Medicare reimbursement. Information on the details of the organizations that accredit suppliers furnishing the technical component of ADIS is available to the public on the CMS website.

We are disappointed in CMS' decision not to publish the PLE applications and remain concerned that the approved qualified PLEs may pave the way for the involvement of Radiology Benefit Management Companies (RBMs) in the AUC development process and implementation of CDS contrary to the intent of the statute and the previous letter to CMS, with support from multiple medical societies including the AMA, representing a large cross section of the referring provider community. We are concerned that RBM-developed AUC will focus primarily on limiting the utilization of diagnostic imaging rather than assisting OPs to select the most appropriate imaging examination for their patients' conditions and will not properly take into account the medical necessity of tests on an individual patient basis. Denial of medical services based on criteria designed solely to decrease the utilization of medical imaging runs counter to the underlying goal of the PAMA AUC policy as well as CMS' goal of supporting physicians in providing beneficiaries with the right test at the right time.

Conclusion

The ACR appreciates the opportunity to provide comments on the CY 2017 MPFS final rule. We encourage CMS to continue to work with stakeholders to ensure successful implementation of the statutorily required AUC program. The ACR looks forward to continued dialogues with CMS officials. If you have any questions or comments on this letter, please contact Kathryn Keysor at 800-227-5463 ext. 4950 or via email at kkeysor@acr.org.

Respectfully Submitted,

William T. Thorwarth, Jr, MD, FACR
Chief Executive Officer

Cc: Joseph Hutter, MD, CMS
JoAnna Baldwin, CMS
Sara Fulton, CMS
Ezequiel Silva III, MD, Chair, ACR Commission on Economics
Cynthia Moran, ACR
Angela J. Kim, ACR
Kathryn Keysor, ACR