September 6, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

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

Re: CMS–1654–P, Revisions to Physician Fee Schedule Payment Policies

Dear Acting Administrator Slavitt:

On behalf of the Imaging e-Ordering Coalition, I am submitting the following comments in response to the above-captioned notice of proposed rulemaking.

I. Background on the Coalition.

The Imaging e-Ordering Coalition ("Coalition") is an informal organization that was created in 2009 for the purpose of proactively advocating with federal policymakers around certain issues related to medical imaging services.[1] In particular, the Coalition worked to promote the use of computerized clinical decision support (CDS) technologies that provide clinicians with guidance regarding the ordering of patient-appropriate imaging services. For a host of reasons, we believe this approach is far superior to the utilization of third parties to impose prior authorization under Medicare.

[1] In 2016, the Coalition's membership includes the following organizations:

- AHRA -- The Association for Medical Imaging Management https://www.ahraonline.org/
- American College of Cardiology http://www.acc.org/
- American College of Radiology http://www.acr.org/
- Applied Pathways http://appliedpathways.com/
- Association for Quality Imaging http://www.aqimaging.org/aws/AQI/pt/sp/home_page
- Center for Diagnostic Imaging http://www.mycdi.com/
- MedCurrent http://www.medcurrent.com/
- Merge Healthcare http://www.merge.com/
- Radiant Imaging http://www.radiantimaging.net/
- Radiology Business Management Association http://www.rbma.org/
- RadNet http://www.radnet.com/
- vRad http://www.vrad.com/

The membership of the Imaging e-Ordering Coalition is united by a common interest in promoting the successful adoption of electronic ordering for imaging and to promote the use, by relevant constituencies, of clinical decision support (CDS) tools that guide clinicians in the ordering of advanced diagnostic imaging services -- defined as magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine scans such as positron emission tomography (PET). The Coalition provides a forum for its members on electronic ordering and CDS issues, and develops materials to educate internal and external stakeholders. The Coalition strives to:

- Improve patient care through the appropriate use of advanced diagnostic imaging services;
- Successfully demonstrate the advantages of CDS over traditional techniques employed by radiology benefit managers;
- Ensure a smooth implementation and transition to CDS by ordering and rendering providers and facilities.

II. Comments regarding the CY 2017 Physician Fee Schedule Proposed Rule.

The proposed rule sets forth the second major set of directives around the implementation of Section 218(b) of the Protecting Access to Medicare Act (PAMA), which requires that ordering clinicians consult appropriate use criteria (AUC) in deciding whether to order certain advanced diagnostic imaging services. The proposed rule focuses on defining and providing a process for the qualification of clinical decision support mechanisms (qCDSMs). It also identifies eight "priority clinical areas (PCAs)" where the adherence of ordering clinicians to available AUC will be used to determine "outlier" physicians. Further, the Agency proposes that the qualified CDSMs should initially only be required to include AUC for the PCAs. The CY 2017 MPFS Proposed Rule identifies certain exemptions from the AUC program as well. We understand that CMS presently intends that future rulemakings will establish the process by which clinicians must document consultation with AUC for applicable advanced diagnostic imaging services on CMS claims. Future rulemakings will also further detail the process of identifying "outlier" physicians who will be subject to certain prior-authorization requirements; however, it appears that CMS will utilize the same priority clinical areas to formulate this policy, as well.

A. CMS needs to move more aggressively to implement Section 218(b) of PAMA.

As strong supporters of the appropriate use criteria program established by PAMA, the Coalition is united in wanting to see this law implemented in a thoughtful, workable manner. The Coalition and many of its individual members have worked with CMS to support the implementation process with information and recommendations.

We appreciate that implementation of Section 218(b) is a challenging task and that 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 qCDSMs and the date when ordering physicians must begin consulting AUC prior to referring Medicare beneficiaries for applicable advanced imaging services. We are concerned that the current pace of implementation not lead to further delays -- especially given the need to educate the provider

community on the new requirements and the time it takes to implement changes to multiple, interoperable systems. The majority of the Coalition's membership believes that CMS must adhere to the present implementation deadline for Section 218(b) of January 1, 2018.[2]

One critical issue that is not being addressed in a timely manner concerns how consultation of appropriate use criteria can and should be entered onto claims forms. In this rulemaking, CMS proposes that a qCDSM must, in each case that it is consulted, provide certification or documentation that includes a unique "consultation identifier" to the ordering professional as to (i) which qCDSM 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 claim documentation inhibits the progress of interested parties that wish to develop CDSMs and gain qualified status. This information is critical to the overall design and implementation of the AUC initiative.

This dearth of information related to claims processing specifications prevents portal, EMR, RIS and CDS vendors from finalizing design specifications. This, in turn, delays development and release of updated CDSM products and prevents ordering providers from finalizing design for including the information on the order and rendering providers from finalizing design and implementation for the ingestion of the information from the order and for passing this information through multiple systems (e.g. radiology information systems (RIS) and transcription) to the revenue cycle management system for inclusion on the claim. The release of claims processing specifications is one of the most critical steps in the overarching effort to implement Section 218(b) in a timely and orderly fashion.

Coalition members are actively identifying certain other workflow issues that they will need to resolve in the future and for which regulatory guidance is needed now. For example, CMS indicates that in future rulemaking cycles, they will communicate how the exception for an emergency medical condition will be identified on Medicare claims. They do not indicate that they will be addressing the exemption of ordering physicians who meet hardship exemptions for the Meaningful Use program. Again, CMS should be working now to determine how a radiologist will be able to ascertain if an ordering professional qualifies for a hardship exemption under the Medicare electronic health records (EHR) payment adjustment program.

It is imperative that CMS move with greater alacrity to address these and other implementation issues related to Section 218(b). We are concerned that a staged implementation process utilizing the annual PFS rulemaking is moving too slowly. We therefore recommend and request that CMS expedite the pace of regulatory and administrative implementation of the appropriate use criteria program by issuing a separate proposed rulemaking that addresses various claims processing and other issues simultaneously, instead of continuing to utilize the annual physician fee schedule rules to address these issues in a staged, sequential manner. We stand ready to engage with CMS in such a regulatory process to make implementation of the program both timely and successful.

[2] Coalition member AHRA does not support this position.

B. qCDSMs should have robust AUC content and CMS should ensure that providers consult such content for the broad range of applicable imaging services.[3]

The proposed rule creates some ambiguity and some concern regarding the breadth of AUC content that CMS intends to require qCDSMs to provide and clinicians to consult. The e-Ordering Coalition urges CMS to clarify these issues and to not limit AUC content to the eight priority clinical areas (PCAs) outlined in the proposed rule. While we support the use of PCAs as part of the forthcoming outlier policy, the Coalition believes consultation of imaging AUC by ordering physicians should not be restricted to a select group of clinical conditions. Our organizations are united in the belief that restricting consultation to PCAs will undermine the ability of this utilization management program to accurately eliminate inappropriate or duplicative imaging services. To do so would repeat many of the same mistakes witnessed in the Medical Imaging Demonstration (MID) project mandated by the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008**.** One of the major criticisms of the MID Demo was that the lack of granular content led to too many situations in which the consultation did not provide meaningful guidance to the ordering clinician Quite simply, the greater the scope and granularity of the AUC made available to ordering clinicians, the better the utility of the process will be to the education of that clinician, the improvement of ordering effectiveness for enhancing healthcare outcomes, the reduction in unnecessary or incorrect orders, and physician satisfaction and support for the program.

With respect to the requirements to be qualified as a CDSM, CMS indicates that, at a minimum, such a mechanism should make available specified applicable appropriate use criteria (AUC) that reasonably encompasses the entire clinical scope of all PCAs. As mentioned immediately below, we recommend a different approach to the identification of PCAs. However, in any event, we are also concerned that the PCAs CMS does identify in the proposed rule are a limited subset of situations in which a clinician may need to consider whether to order an advanced diagnostic imaging procedure. Again, irrespective of what subset of orders CMS uses for purposes of defining priority clinical areas, the Coalition is of the view that qCDSMs should have as robust and detailed content as reasonably possible.

The e-Ordering Coalition recommends that all qCDSMs provide evidence that a decision support "consultation" occurred for all advanced diagnostic imaging services, irrespective of whether they're within a priority clinical area. An AUC program that is not comprehensive will lead to decreased compliance on the part of ordering physicians and make obtaining evidence that a decision support transaction took place prior to performing an advanced diagnostic imaging service difficult for the furnishing provider. This would place the furnishing providers at significant financial risk if these exams are performed without evidence of a consultation. The best way to assure all examinations have a decision support consultation is for the qCDSM to provide AUC for as many clinical indications as possible and not just those limited to the PCAs.

C. CMS should not use ICD codes to define priority clinical areas.

In the proposed rule, CMS indicates that it went through a process of reviewing non-institutional claims data from its Chronic Conditions Data Warehouse (CCW) and ranking relevant ICD-9

[3] Coalition member Applied Pathways is not in concurrence with the views expressed in this subsection.

codes by the frequency they were used as the primary indication for specific imaging procedures. The agency extracted the top 135 ICD-9 codes and formed them into clinically related categories. A manual search was also performed to augment that data with other appropriate ICD-9 codes. The result was a set of eight priority clinical areas (PCAs) accounting for roughly 40 percent of advanced diagnostic imaging services paid by Medicare in 2014.

As we mention above, the e-Ordering Coalition opposes the use of eight priority clinical areas to define the minimum scope of AUC content for a qCDSM. But in any event, we also recommend and request that CMS reconsider the proposed code-based approach to identifying PCAs. Using ICD-9 codes makes the initial ordering process unduly cumbersome, as it effectively forces the ordering physician to make a decision on when to use decision support. For example, the basic problem with limited implementation based on symptoms is that, at the time a patient presents with clinical symptoms that warrant consideration of ordering an advanced diagnostic imaging service (and thus consultation with a qCDSM), it may not be known as to whether a particular code will ultimately be applicable to the patient's clinical episode or the services that are being rendered. For example, one of the clinical priority areas CMS is considering is "suspected stroke" which is a "rule-out" comment. The patient is most likely presenting with signs or symptoms of a stroke, such as facial numbness, slurred speech, or limb weakness.

From a clinical perspective, each PCA will require numerous clinical variants in order to provide useful information regarding the appropriateness of a range of imaging examinations to an ordering provider. Our concern is that without specific guidance from the Agency, there may be a misunderstanding regarding the scope of PCA implementation which will lead to significant market confusion. It is important for the Agency to emphasize that any qualified PLE or CDSM developer must recognize that the ICD-9 diagnoses are not the same as a clinical variant or an indication for an examination. Each of these diagnoses will have multiple clinical variants that comprise the reasons for the examinations. For example, in order to implement CDS for non-traumatic headache (ICD-9 code 784), a CDSM would need 22 clinical variants to cover the range in the presentations of non-traumatic headache – some of which require immediate imaging and many of which require no imaging at all. This essential granularity cannot be accomplished with a single indication and limited set of AUC for headache.

A better approach would be to organize around body systems and parts (e.g., advanced imaging of the chest, head, and spine) rather than a limited list based on patient symptoms. This approach would allow for easier incorporation of CDS during ordering and create a more robust data sets for outlier analysis.

D. An order based on equivocal guidance from a CDSM should not be considered to constitute non-adherence or to be inapplicable.

In its discussion of the proposed rule, CMS notes that some CDSMs provide feedback along a continuum of appropriateness (e.g. a numeric scale or color coding approach) while others may parse a user's proposed order and drive the user toward dichotomous "yes/no" feedback based on clinical inputs. The agency indicates that it does not presently have a preference for either approach but is interested in receiving comment on how various rating approaches can be applied

in determining whether an order "adheres" to the AUC that was consulted or if the AUC is "not applicable" to the order.

As we have previously commented, we think it important that, where a qualified CDSM provides feedback that is equivocal with respect to whether a particular applicable advanced diagnostic imaging service is appropriate, such feedback should not be considered as an indication the exam does not adhere to the AUC. However, it also should not be considered to be inapplicable unless so indicated. It would not be appropriate to consider feedback that is equivocal to be inapplicable.

E. Public disclosure of qPLE and qCDSM applications

The e-Ordering Coalition supports the qualified PLE and qualified CDSM application process as proposed by CMS. In the spirit of transparency and open government, our Coalition respectfully requests CMS release all applications from the approved list of qualified PLEs, as well as all forthcoming applications for qualified CDSMs. The release of this information is consistent with CMS' implementation of Section 135(a) of the Medicare MIPPA 2008 requiring suppliers of the technical component of advanced diagnostic imaging services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement. Information on the details of the accrediting organizations is available to the public on the CMS web site. Release of these applications will allow patients and physicians to better understand the key principles CMS employed when selecting qualifying PLE or CDSMs.

We appreciate the opportunity to provide these comments and we appreciate your efforts in implementing this important program. We look forward to continuing to work with you to ensure its success. Should you have any questions, please do not hesitate to contact Robert Bradner, Executive Director, e-Ordering Coalition, either via phone at 202.457.7004 or email at robert.bradner@hklaw.com and we will be happy to lend our expertise.

Sincerely,

Robert H. Bradner
Executive Director
e-Ordering Coalition