November 17, 2015

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-3321-NC

Dear Acting Administrator Slavitt:

On behalf of the Imaging e-Ordering Coalition, I am submitting the following comments in response to the Centers for Medicare & Medicaid Services' (CMS's) "Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models" ("RFI").

Our comments relate to how Section 218(b) of the Protecting Access to Medicare Act (PAMA) can be integrated into the Merit Based Incentive Payment System and possible Alternative Payment Models that will be implemented pursuant to the Medicare Access and CHIP Reauthorization Act (MACRA).

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 requirements under Medicare. Our work supported the successful inclusion of Section 218(b) in the Protecting Access to Medicare Act of 2014,

[1] In 2014-15, the Coalition's membership included 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/
- 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/
- Medicalis Corp http://www.medicalis.com/
- Merge Healthcare http://www.medicalis.com/
- Radiology Business Management Association http://www.rbma.org/
- RadNet http://www.radnet.com/
- vRad http://www.vrad.com/

which directs the Department of Health & Human Services (HHS) to implement a CDS program for advanced imaging services provided under Medicare.

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 ordering advanced diagnostic imaging services. 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 imaging;
- 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. Overview of PAMA Section 218(b).

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) requires Medicare providers that order certain advanced diagnostic imaging services to consult Appropriate Use Criteria (AUC) via a clinical decision support mechanism. The services covered by this requirement include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (include positron emission tomography), and other diagnostic imaging services specified by CMS in consultation with the medical community and stakeholders, but excluding x-ray, ultrasound, and fluoroscopy services.

The four major components of the AUC program are: (i) establishment of applicable AUC in consultation with physicians, practitioners, and other stakeholders; (ii) identification of an initial list of qualified clinical decision support (CDS) mechanisms for ordering physicians to consult; (iii) consultation of AUC by ordering professionals and reporting on such consultation by furnishing professionals; and (iv) annual identification of outlier ordering professionals and establishment of a prior authorization requirement for such professionals. The Secretary has begun to implement this new program through the annual Medicare Part B Rulemaking process.

With regard to the consultation requirement, beginning January 1, 2017[2], with respect to an applicable imaging service in an applicable setting, an ordering professional shall consult a qualified decision support mechanism and provide to the furnishing professional information regarding (i) which qualified decision support mechanism was consulted; (ii) whether the service ordered would or would not "adhere" to the applicable AUC, or whether the AUC is inapplicable; and (iii) the National Provider Identification number of the ordering professional. Payment to the furnishing professional for the applicable imaging service (under the Physician Fee Schedule, HOPPS, or the ASC payment system as the case may be) will only be made if the claim includes the specified information.

[2] In the Medicare Physician Fee Schedule Final Rule, (42 CFR Parts 405, 410, 411, 414, 425, and 495) CMS established a new timeline for the "Medicare AUC Program." Notably, the provider implementation deadline of 2017 was delayed. It is important to note that CMS is only postponing the provider implementation deadline, not the program altogether. This year's rule finalized the AUC approval process, while CY 2017 and 2018 rules will finalize the additional components of the program.

III. PAMA Section 218(b) and Clinical Practice Improvement.

MACRA's *Clinical Practice Improvement Activity Requirement.*

MACRA directs the Secretary of HHS to establish an eligible professional Merit-Based Incentive Payment System (MIPS) to assess the performance of eligible professionals using a methodology that employs a composite performance score that involves the assessment of such professionals based on four performance categories – quality, resource use, clinical practice improvement activities and meaningful use of certified electronic health records technology.

With respect to clinical practice improvement activities (CPIAs), the Secretary is tasked with establishing activities under at least six subcategories identified in the legislation as well as any additional subcategories that the Secretary might add. MACRA instructs the Secretary to use a request for information to identify CPIAs and to specify criteria for such activities. The statute defines a CPIA as "an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines when effectively executed, is likely to result in improved outcomes."

The Appropriate Use program under PAMA Section 218(b) is an Ideal Clinical Practice Improvement Activity.

The Appropriate Use program under Section 218(b) is an ideal example of a program that should qualify as a clinical practice improvement activity when implemented by a radiology provider group in accordance with specified requirements. The Secretary's criteria should allow for consideration of adherence to the program as meeting the requirements for participation in a CPIA.

Advances in medical imaging technology have contributed significantly to improved health care quality and safety through faster and more accurate diagnoses, the avoidance of costly invasive procedures, and the improved effectiveness of interventions and treatments. The present challenge is to capture and document the health care quality and safety improvements as well as cost savings that advanced imaging services provide while obviating the adverse impacts that can result from the inappropriate use of imaging services -- whether through unnecessary ordering or through the ordering of inappropriate tests.

Several factors are commonly recognized as contributing to the potential inappropriate ordering of advanced imaging studies by referring physicians. One is fear of medical professional liability, which leads providers to order tests to rule out possible conditions regardless of how remote or unlikely. Another factor is the rapid pace of innovation in imaging technology, which has occurred over the past several years. This trend has placed many ordering practitioners in the difficult situation of knowing that there are modalities that can aid in diagnostic processes but lacking awareness in ordering the most appropriate exam. While radiologists and cardiologists, among others, have extensive experience in the use of imaging studies and procedures, the referring physicians who order the majority of advanced imaging services lack specialized training regarding when and whether to order an exam and, if so, which test is the right test.

Advanced imaging services by their nature are well suited to the application of evidence-based medical guidance. This is fundamentally a reflection of the simple fact that -- like prescription medications, lab tests and pathology exams -- imaging services must be ordered by a referring physician. The ordering process presents a discrete moment in time when evidence based medicine can be applied to guide the physician's decision making. Clinical decisions support systems for advanced imaging ordering have

demonstrated a positive impact in reducing the inappropriate utilization of such services by guiding ordering physicians to avoid unnecessary tests and to select the most appropriate test. Evidence accumulated from major studies by the Institute for Clinical Systems Improvement (ICSI) in Minnesota, Brigham and Women's Hospital in Boston and Massachusetts General Hospital are among a number of efforts that have documented the positive impacts of CDS on quality of care through appropriate advanced imaging ordering at the department, health system and community levels.

In the context of electronic health records, CDS systems for advanced imaging ordering can and frequently are readily incorporated into hospital and physician group practice electronic health records (EHRs) allowing for prospective feedback before the study is ordered. And, when combined with retrospective analysis of the imaging orders, examination of results and feedback to providers, a powerful capability to analyze and identify issues in physician ordering activity is created. This capability can drive substantial improvements in quality of care. And the capturing of this information allows for the building of databases of information that facilitate comparative analysis and, thereby, continuous process improvement approaches.

Recommendations.

In order for a program such as Section 218(b) to qualify as a CPIA, CMS needs to consider the following with respect to implementation of the CPIA component of MIPS –

- It is important that the term "relevant eligible professional organizations and other relevant stakeholders" include medical group practices, physician partnerships, and coalitions such as ours so that we may have an opportunity to petition for the program's inclusion as a CPIA.

- Similarly, the process will need to allow a broad range of stakeholders an opportunity to demonstrate that their proposed activities will be likely, when executed effectively, to result in improved outcomes.

- The consideration of whether a program or activity should be approved by the Secretary as a CPIA should be made with reference to the overall scope of the activity and whether it meets the central criteria: when effectively executed, is the activity likely to result in improved outcomes? An approach that requires a certain number of hours or reporting of a specified number of metrics may be useful for some CPIAs, but it should not be a criteria for all CPIAs.

IV. PAMA Section 218(b) and Alternative Payment Models.

Alternative Payment Models under MACRA.

MACRA establishes a process whereby eligible providers may seek to participate in Alternative Payment Models (APMs) and be reimbursed under a different set of rules from those that apply pursuant to MIPS. An APM can be a model under CMMI, a Medicare Shared Savings Program, a Demonstration under the Health Care Quality Demonstration Program (Section 1866C of the Social Security Act), or a demonstration required by federal law. An eligible professional can only participate in an APM through an Eligible Alternative Payment Entity. Such an entity must (i) require the participants in its APM to use electronic health records, (ii) pay for covered services based on quality measures comparable to those used in MIPS, and (iii) bear more than nominal risk for losses incurred under the APM (or, alternatively, be a medical home expanded by CMMI).

MACRA also establishes a process to promote Physician-Focused Payment Models ("PFPMs) and encourages the consideration of models that will be applicable to medical specialists. The Secretary is to develop criteria for the evaluation of PFPMs. Interested stakeholders are then to be given an opportunity to present proposed PFPMs to an ad-hoc Technical Advisory Committee that was recently appointed by the General Accountability Office. That committee will provide comments and recommendations on the proposed model and the Secretary will respond to those comments and recommendations.

The Appropriate Use Program under Section 218(b) is an example of a program that should qualify as an Alternative Payment Model when implemented by radiology providers.

As discussed above, the PAMA Section 218(b) program is a strong quality and efficiency improvement program. But it also embodies a significant alternative payment methodology. First, unlike programs whereby a provider might go at risk for some portion of their expected Medicare payments, the Appropriate Use program will put those who furnish radiology services 100% at risk for ensuring that a qualified decision support mechanism is consulted. Secondly, under the program's "outlier" component, physicians who show extremely low adherence to appropriate use criteria (no more than 5% of ordering professionals) will be subjected to a prior authorization requirement beginning in 2020. If implemented consistent with certain other requirements of MACRA, such a program should qualify for consideration as an Alternative Payment Model. For example, if a radiology provider group, medical group practice or other provider entity were to integrate the requirements for Electronic Health Record utilization and reimbursing based on MIPS quality metrics into their practice, such entities could also meet the definition of being at more than nominally at risk given that they are entirely at risk, in that they will receive no payments if they do not adhere to the requirement to capture and include on the claim the required information.

Recommendations:

In order for a program such as Section 218(b) to potentially qualify as an Alternative Payment Model, CMS needs to consider the following*:*

- We urge the Secretary to clarify that medical professional societies and organizations involved in the delivery of care (such as hospital systems or physician group practices) can serve as Eligible Alternative Payment Entities provided they otherwise meet the applicable requirements related to bearing risk, utilizing EHRs and reimbursing based on relevant quality metrics.

- Second, the Secretary needs to construe the requirement that an eligible alternative payment entity bear more than nominal risk for losses incurred under the APM to embody more possibilities than simply shared risk arrangements such as those seen under the Pioneer or Next Generation ACO programs. There are many other legitimate ways in which an entity can undertake more than nominal risk when implementing an APM. This would include recognizing the costs of APM infrastructure investment and reporting compliance, as well as recognizing that risk in arrangements whereby a provider *will not be paid at all* unless they adhere to certain quality and efficiency requirements.

- Third, CMS needs to ensure that the avenues to apply to be approved as an APM are as wide open and flexible as possible. The best way to do this is to clarify that the Secretary of HHS will be open to using the authority provided by Section 1866C to approve proposed APMs. In this manner, a

provider that is implementing a program such as Section 218(b) with adherence to other statutory criteria could seek approval as an APM.

We appreciate very much your consideration of the thoughts and recommendations contained in this correspondence. For further information, please contact Robert Bradner, Holland & Knight LLP, at Robert.Bradner@hklaw.com or 202-457-7004

Sincerely,

Robert Bradner
Partner
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