June 27, 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-5517-P

Dear Acting Administrator Slavitt:

On behalf of the Imaging e-Ordering Coalition, I appreciate the opportunity to submit comments in response to the proposed rule entitled "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models."

Passage of the *Medicare Access and CHIP Reauthorization Act of 2015* (P.L. 114-10) (MACRA) presents a significant opportunity to reform how providers are paid under Medicare and to advance payment systems that reward high quality and efficient care delivery. We look forward to working with you in your efforts to develop a new system focused on the delivery of quality care and value.

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

[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.medicalis.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/

to the utilization of third parties to impose provide prior authorization requirements under Medicare. Our work supported the successful inclusion of Section 218(b) in the Protecting Access to Medicare Act of 2014, 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. Comments Regarding Implementation of the Merit-Based Incentive Payment System.

Pursuant to MACRA, CMS is now tasked with implementing the new merit-based incentive payment system (MIPS) for Part B providers. The proposed rule articulates your agency's thinking regarding the four core elements of the new program: quality, resource utilization, advancing care information, and Clinical Practice Improvement Activities (CPIAs). Our comments are focused on the following subjects: (1) defining non-patient facing providers; (2) Clinical Practice Improvement Activities; and (3) Alternative Payment Models.

A. Non-Patient Facing Providers.

Many participants in the Coalition represent or employ significant numbers of radiologists, a substantial number of whom have limited face-to-face interaction with patients. Accordingly, we are keenly interested in the effort to develop a definition of non-patient facing MIPS-eligible providers, and to provide certain accommodations to such providers given the disconnect between many MIPS metrics and their practice environments.

The Coalition recommends: (1) the threshold be established at 100 encounters mirroring the e-prescribing minimum and (2) the definition of surgical services include only those with 10-day, or 90-day global periods (i.e., exclude services with 000 and XXX global periods).

In the rule, CMS proposes to define a non-patient-facing MIPS eligible clinician for MIPS at § 414.1305 "as an individual MIPS eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period." The Coalition appreciates the proposed flexibility towards referral-based specialties like radiology in the rule. We agree that referral-based specialties face challenges in attempting to comply with quality metrics, the majority of which are intended for treating physicians who manage patients' medical conditions ongoing. However, it may be confusing to physicians and their practices to have differing thresholds by program. Therefore, we recommend the non-patient-facing MIPS eligible clinician threshold be set at 100, the same as for the e-prescribing program. Not only would this establish a common threshold, it also reflects clinical practice in that radiologists do not

routinely write prescriptions for their patients nor do they routinely manage a patient's medical condition ongoing.

The agency considers a patient-facing encounter as "an instance in which the MIPS eligible clinician or group billed for services such as general office visits, outpatient visits, and surgical procedure codes under the PFS [Physician Fee Schedule]." The PFS' global period policy covers certain pre-operative, intra-operative, and post-operative services (including same day post-operative follow-up and post-operative hospital and office visits) inherent in major and minor surgical procedures. The Coalition agrees that major and minor surgical services with global periods of 90- or 10-days, respectively, and that include pre- and post-E/M services, should be considered patient-facing encounters. Since surgical services with 0-day and XXX global periods do not include post-operative E/M services, we recommend they not be counted as patient facing encounters.

B. Clinical Practice Improvement Activities (CPIAs).

The CPIA performance category emphasizes practice activities associated with improved outcomes and would comprise 15 percent of a provider's MIPS composite performance score. CMS proposes baseline requirements under this performance category and indicates that it will develop more stringent criteria in future years. CPIAs will be categorized into initiatives that address the following areas: expanded practice access; population management; care coordination; beneficiary engagement; patient safety and practice assessment; participation in an APM; promoting health equity and continuity; social and community involvement; achieving health equity; emergency preparedness and response; and integration of primary care. The first six of these areas were included in the statute and the last three are proposed to be added in this rule.

The proposed rule identifies more than 90 activities and an associated activity "weighting" system that provides either "high" or "medium" credit for each activity. We understand that CMS intends to create a process whereby new measures and activities can be proposed for the CPIA inventory. Additionally, a Patient Centered Medical Home (PCMH) as defined in the regulations would count for full credit under the CPIA category.[2] Outside of the PCMH option, providers have the opportunity to undertake as many CPIAs as the wish to aggregate credit toward the maximum of 60 points.

The Coalition appreciates very much that we, and many of our members individually, were consulted by CMS with respect to some of the challenges we face in meeting the MIPS criteria. We also appreciate that CMS acknowledged our issues and discussed them in the preamble to the proposed regulation. And, as mentioned above, we appreciate that it is being proposed that non-patient facing providers could receive full credit (60 points) under the CPIA category for undertaking a total of two activities.

In response to CMS' prior Request for Information (RFI), the Imaging e-Ordering Coalition had recommended that the Appropriate Use program under Section 218(b) of the Protecting Access to Medicare Act (PAMA) should qualify as a clinical practice improvement activity when implemented by a rendering provider, such as cardiologists and radiologists or when implemented by a facility in which a rendering provider delivers professional component services in accordance with specified

[2] The medical home needs to be a nationally recognized accredited PCMH, a Medicaid Medical Home Model, or have a National Committee for Quality Assurance (NCQA) Patient-Centered Specialty Recognition

requirements.[3] We recommended that the Secretary's criteria should allow for consideration of adherence to the program as meeting the requirements for participation in a CPIA.

We note that the discussion in the preamble to the proposed rule regarding CPIAs and non-patient facing providers discusses the role that appropriate use criteria (AUC) can play in activities that provide a meaningful chance for such providers to engage in clinical practice improvement. The discussion indicates that MIPS-eligible clinicians who are otherwise required to use AUC are encouraged to report a CPIA other than one related to appropriate use. It is also indicated that several of the 90 CPIAs in the current inventory include AUC components.

In our review of the inventory, it was unclear to us which, if any of the activities in the CPIA inventory involve the use of AUC. It also does not appear that an option identical to or akin to Section 218(b) of PAMA is presently included. Accordingly, we would appreciate clarification regarding this matter and affirmative inclusion of consultation with AUC for the ordering of advanced diagnostic imaging services as an identified CPIA. We do not think that the fact that such consultation will be required under Medicare as a condition-precedent for payment to the rendering clinician should exclude recognizing this activity as a CPIA. To the contrary, one of the reasons that Congress included Section 218(b) in PAMA was that the Coalition and others proposed it in response to requests by the committees of jurisdiction for innovative approaches to advance quality, accountability and efficiency in care delivery. It should not now be excluded as a CPIA simply because it was developed and proposed at an earlier point in the process. Section 218(b) embodies the essence of a CPIA and should be recognized as such.

C. Alternative Payment Models.

In the proposed rule, CMS is initially defining Alternative Payment Models (APMs) pursuant to the statutory definition: (1) Medicare Section 1115A models (other than HCIC awardees); (2) the Section 1899 shared savings model (i.e. one-sided ACOs); (3) a demonstration under Section 1866 (the Health Care Quality Improvement Act); or a demonstration required by law.

In proposed Section 414.1370, CMS sets out the criteria for what it terms a "MIPS APM". We understand that these criteria will guide activity around the identification of future MIPS APMs – either directly by CMS or through the Physician-Focused Payment Model (PFPM) process. The relevant criteria are: (1) the existence of an agreement between an APM entity and CMS; (2) the inclusion of one or more MIPS-eligible clinicians; and (3) APM payment is based on cost/utilization and quality measures.

We believe that the program under Section 218(b) of PAMA can form the basis for a MIPS APM. In this regard, we note that it was developed in significant part as a result of lessons learned from a large demonstration project conducted pursuant to Section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). That MIPPA demonstration project is listed on the Centers for Medicare and Medicaid Innovation (CMMI) website as an innovation model.[4] We would also note that the program bases payment to rendering clinicians (and by implication ordering clinicians) on adherence to quality metrics and includes an "outlier" program that will have payment implications based on utilization. Combined with a program of radiologist-led education for ordering clinicians and data-driven benchmarking and clinical guidance improvement that fuels the development of additional appropriate use criteria, we think all the essential elements for an APM are present.

[3] We have attached a copy of our prior comment letter for easy reference.
[4] https://innovation.cms.gov/initiatives/index.html#views=models

Given the very limited list of MIPS APMS being identified, and recognizing that the PAMA Section 218(b) program is a congressionally-recognized and well-developed model, we request some assurance and explanation from CMS regarding the potential for such an approach, subject to potential modifications, to be vetted and approved as a MIPS APM. Specifically, we believe that the proposed rule does not adequately explore the potential avenues that can be taken to have an APM reviewed and approved as a MIPS APM. Avenues can and should be provided outside of the PFPM Technical Advisory Committee (PTAC) process and outside of extensive, years-long CMMI review. For example, the Section 1866 authority could be used by CMS to designate promising demonstration projects. Alternatively, as CMS has now created a distinction between APMs, MIPS APMS, and Advanced APMs, we believe there is no impediment – legal or otherwise – to CMS adopting an expedited review and approval process for adding new MIPS APMs. We would respectfully request consideration and articulation of such pathways.

Finally, we encourage CMS to continue to find ways to advance interoperability to facilitate the flow of clinical information. Opportunities for improving interoperability in imaging include: (1) promoting the sharing imaging studies between facilities (thus possibly avoiding repeat exams), (2) encouraging health systems and other providers to make prior imaging studies and relevant health record information more readily available, (3) integrating more imaging provider options in order-entry systems, and (4) helping to educate referring providers on appropriate use criteria (AUC)/clinical decision support (CDS) for ordering advance diagnostic imaging services.

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
The Imaging e-Ordering Coalition