



September 6, 2016

The Honorable Andy Slavitt,
Acting Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
Submitted electronically at: <http://www.regulations.gov>

Re: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; esp. Section III.C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Dear Acting Administrator Slavitt:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding this Notice of Proposed Rulemaking (NPRM) regarding Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. This NPRM was published by the Centers for Medicare & Medicaid Services (CMS) in the July 15, 2016, issue of the *Federal Register*.

AMIA is the professional home for more than 5,000 informatics professionals, representing front-line clinicians, researchers and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient population

Our comments below focus on Section III.C. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services. AMIA supports the use of computer-based decision support to guide image ordering as an exemplar of how informatics tools and applications can assist clinicians at the point-of-care. By leveraging clinical decision support, founded on a range of data available through electronic health records, we believe the AUC Program can be a model for other informatics-informed approaches to improve health outcomes and lower costs. However, we urge CMS to be cognizant of the potential implementation challenges that could befall this emergent program.

While AMIA supports the step-wise approach taken by CMS to implement this program, we do not believe that ordering and furnishing professionals will be able to comply with proposed requirements starting January 1, 2018. AMIA members voice strong concerns with the proposed timelines for implementation – from a policy-making, technology development and workflow integration perspective. Developing clinical decision support mechanisms (CDSMs) to demonstrate

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prescribed functionality in response to this final rule by January 1, 2017 will not be feasible for many vendors. Subsequently expecting clinicians to purchase, implement, test and integrate CDSMs into their workflows between June 2017 and January 2018 is similarly problematic. All the while, CMS acknowledges in this NPRM that it will not finalize certain policies until well into 2017, such as how to interpret and record AUC scores on claims.

AMIA strongly recommends CMS reconsider its timeframe for implementation, and target 2019 as the first year in which ordering & furnishing professionals must participate in the Medicare AUC Program. Given the complexity of this program and its potential implications for other aspects of Medicare, we encourage CMS to take every step possible to ensure a successful rollout. By clearly stating its intentions to launch this program in 2019, ordering professionals, furnishing professionals, CDSM developers, and electronic health record vendors will have adequate time to maximize the intended impact of the program, while minimizing its impact on workflow.

We appreciate the methodical way CMS has chosen to find compromise between a “comprehensive” versus a “focused” approach to the AUC Program through a data-driven approach to identifying priority clinical areas. However, we note that effective decision support requires not just alerts as mandated by this program, but a comprehensive approach that includes institutional commitment, local data collection and analysis, systematic feedback, careful integration of CDS into clinical workflow, and provider education. And the value of each alert must be balanced against the risk of alert fatigue. **Therefore, we caution CMS from expanding beyond the identified eight priority clinical areas for the initial years of the program, and we discourage CMS from being overly prescriptive in determining which orders (imaging or otherwise) should require CDS on a national scale.** Our members note that while these eight areas make sense at a national level, there is likely to be variability across individual organizations that submit claims.

AMIA applauds the approach taken by CMS to describe required functionality for qualified CDSMs, rather than dictating how that functionality should be achieved. **However, we strongly recommend CMS to encourage development or identification of relevant, mature standards in the near- to mid-term.** Referencing and requiring use of technical standards, once they are sufficiently tested and matured, will help promote a healthy marketplace for CDSMs by lowering barriers for new market entrants and improve interoperability among AUC sets curated by different PLEs. We also note the importance of standards related to generating the outputs of CDSMs into orders and through the billing process. We understand CMS will engage in future rulemaking on capturing and reporting AUC scores, but there is a lack of clarity on how such information should be conveyed on claims, and we note that standards would likely prove beneficial for such tasks. Further, we believe specifying a standard for “strength of evidence,” such as the Oxford Levels of Evidence, would encourage development of higher quality AUCs. We believe these and other standards eventually will be needed to realize the benefits of the AUC Program.

Finally, AMIA wishes to underscore the importance of CDSM integration with electronic health records (EHRs). We understand CMS envisions a world where stand-alone CDSMs could be used

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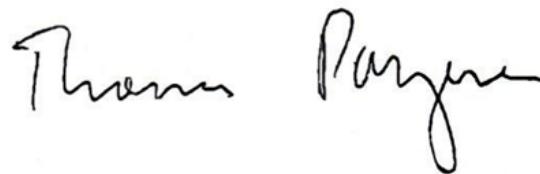
as an alternative to those that are part of EHRs, but experience to-date indicates such an approach would only exacerbate clinician complaints with health IT usability and effectiveness. **We, therefore, urge CMS to dedicate substantial time and effort working with vendors to understand their processes and challenges.** It is likely that such integration challenges, if left unaddressed or underappreciated, will ultimately befall the users of such technology, and imperil the success and acceptance of this program.

Below, we address specific sections of the NPRM related to the Medicare AUC Program. We hope our comments, attached below, are helpful as you undertake this important work. AMIA members have unique expertise with CDS, its integration into clinical workflow, and problem-solving within particular CDS domains. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,



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Enclosed: AMIA Response to CMS CY 2017 Physician Fee Schedule NPRM; Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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C.6.a. – Definitions

CMS provides a description of terms it proposes to codify to facilitate understanding and encourage public comment on the AUC program, including a definition of CDSM and of the applicable payment systems for the Medicare AUC program.

AMIA Recommendation: We support the definitions as proposed, and we underscore the value of reflecting statutory definitions for CDSM in regulation. Specifically, we urge CMS to reiterate where possible that CDSMs must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery.

C.6.b. – Priority Clinical Areas

CMS proposes the establishment of eight priority clinical areas as a means to strike a reasonable balance that allows it to focus on a significant range and volume of advanced diagnostic imaging services. While this year CMS is proposing priority clinical areas based on an analysis of claims data alone, it may use a different approach in future rulemaking cycles, such as prevalence of disease, variability of use of particular imaging services, strength of evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population. CMS considered extracting suspected pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. However, it decided not to identify pulmonary embolism separately, but are asking for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area. CMS encouraged public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that it should include among the list of priority clinical areas.

AMIA Recommendation: Consistent with recommendations conveyed above, AMIA supports the total number of priority clinical areas, but we would be hesitant to support expansion, especially at the outset of the AUC Program.

We do not support inclusion of pulmonary embolism as a separate category, as we believe eight areas is an appropriate number for the first year of the program. Further, and given the anticipated timeline for implementation, we do not encourage CMS to consider other clinical areas beyond what is listed in this NPRM at this time.

C.6.c. – CDSM Qualifications and Requirements

CMS believes that, initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, it is proposing an approach that focuses on the functionality and capabilities of qualified CDSMs. However, in the future, as more

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stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, CMS may consider pointing to such standards as a requirement for qualified CDSMs under this program.

AMIA Recommendation: AMIA supports the direction of this policymaking. As stated, we agree that a focus on functionality over standards is appropriate at this point in time. However, we recommend CMS work with other federal agencies and stakeholders to identify how standards could improve interoperability as well as provide for a robust market of CDSMs using multiple AUC sets. While we support the identified functionality, below AMIA offers comment on some of the specific CDSM requirements.

CDSM Requirements	
CMS propose that CDSMs applications must demonstrate how the CDSM:	AMIA Comment
1. Makes available specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered;	We support the inclusion of “related documentation,” but request clarification on what this documentation may include. We recommend CMS consider standard classifications for strength of evidence, as developed by organizations such as the Oxford Centre for Evidence-based Medicine Levels of Evidence. ¹ Further, we request CMS clarify that this documentation is for ordering professionals rather than information for the claim.
2. Identifies the appropriate use criterion consulted in the event the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario;	We support this functionality but ask that CMS address the potential for conflicting AUCs from different PLEs in the same CDSM.
3. Makes available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas identified in § 414.94(e)(5);	AMIA generally supports this functionality and believes it will be important for purchasers to have such assurance. However, we believe CMS could provide by way of example what “reasonably encompass” should entail.
4. Has the technical capability to incorporate specified applicable AUC from more than one qualified PLE;	AMIA supports this requirement in principle as a means to advance standards and a way to improve the current marketplace for CDSMs, by assuring that customers who purchase CDSMs are not restricted from the evidence they can bring to bear on order patterns.

¹ <http://www.cebm.net/ocebm-levels-of-evidence/>

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	<p>However, some members indicate this requirement will be difficult to comply with, given the proposed deadline.</p>
<p>5. Determines the extent to which an applicable imaging service is consistent with a specified applicable appropriate use criterion consulted for a patient's specific clinical scenario, or a determination of "not applicable" when the mechanism does not contain a criterion applicable to that patient's specific clinical scenario;</p>	<p>AMIA supports this functionality as long as the "not applicable" determination need not be presented to the ordering professional. This is <i>very</i> important for the subsequent claims analysis, but would violate decision support best practice by interrupting the ordering professional with an alert that does not provide useful information. A corollary scenario would be to require clinical decision support to alert ordering professionals every time there was "no drug / drug interaction."</p> <p>Further, we note a need for CMS to clarify "consistent," in this context, e.g. red/yellow/green indication or some other scale.</p>
<p>6. Generates and provides a certification or documentation each time an ordering professional consults a qualified CDSM that includes a unique consultation identifier to the ordering professional that documents which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, and whether the service ordered would adhere to specified applicable AUC or whether specified applicable AUC was not applicable to the service ordered;</p> <p>a. Certification or documentation must be issued each time an ordering professional consults a qualified CDSM.</p> <p>b. Certification or documentation must include a unique consultation identifier generated by the CDSM.</p>	<p>AMIA believes this is an area where CMS could improve its proposed approach. We agree with the need to track on a per-professional basis which CDSM was consulted and whether it would adhere to specified AUC. However, experience from our members indicates that placed/cancelled orders have a tendency to complicate such tracking. For example, a CDSM that was not well integrated with an EHR might require the user to cancel an inappropriate order and re-enter the appropriate one manually. This would trigger a second interaction with the CDSM in the same ordering session. We recommend CMS amend this provision to include (c) "multiple consultations related to the same order can be combined under the same identifier." until standards are available to enable immediate substitution of an appropriate order within the primary CDSM interaction.</p>
<p>7. Updates AUC content at least every 12 months to reflect revisions or updates made</p>	<p>While we agree with the need for CDSMs to have this functionality, AMIA is concerned that the proposed timelines for PLEs to</p>

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<p>by qualified PLEs to their AUC sets or an individual appropriate use criterion;</p> <p>a. Has a protocol to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed;</p> <p>b. Makes available for consultation specified applicable AUC that reasonably encompass the entire clinical scope of any new priority clinical area within 12 months of the priority clinical area being finalized by CMS;</p>	<p>update or modify their AUC sets could complicate this requirement. If PLEs do not update their AUCs until late in their window, it will have an impact on CDSMs and severely limit the time available for CDSMs to make their updates.</p> <p>Further, we encourage CMS to clarify this requirement so that when CDSMs update their AUC set, they must include AUCs that were available for a time-limited and defined period prior to the update, such as 6 months.</p>
<p>8. Meets privacy and security standards under applicable provisions of law;</p>	<p>AMIA requests sub-regulatory guidance on which applicable provisions of law would be germane.</p>
<p>9. Provides the ordering professional aggregate feedback regarding their consultation with specified applicable AUC in the form of an electronic report on an annual basis</p>	<p>We support this functionality and believe it can be a strong motivator for improvement. CDSMs are more likely to modify ordering behavior when combined with other forms of feedback.</p>
<p>10. Maintains electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years; and</p>	<p>AMIA supports this timeframe, but we request by way of example which data must be stored.</p>
<p>11. Complies with modification(s) to any requirements under § 414.94(g)(1) made through rulemaking within 12 months of the effective date of the modification.</p>	<p>AMIA supports this requirement.</p>

AMIA further recommends that CMS include a requirement for CDSMs to enable users to choose alternate orders, should AUC indicate an alternate order more appropriate, without creating two unique consultation identifiers. For example, should a potential MRI test be checked with the CDSM and the CDSM recommend a CT scan based on AUC, the same AUC consultation documentation that was generated for the MRI should be able to be used for the actual AUC-supported order for the CT scan. The guide for design and planning should be how seamlessly this process fits into the clinical setting, which may include discussion with the patient, shared decision-making, and use of commercial EHR computerized practitioner order entry software to communicate the order to the imaging department or service.

C.6.d. – Process for CDSMs to Become Qualified and Determination of Non-Adherence

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CMS proposes that CDSM developers must submit applications to CMS for review that document adherence to each of the CDSM requirements. Applications to be specified as a qualified CDSM must be submitted by January 1 of a year in order to be reviewed within that year's review cycle. As was the case for qualified PLEs, CMS will post a list of all applicants determined to be qualified CDSMs to a Web site by June 30. CMS proposes that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. CMS invites comments on how it could streamline and strengthen the approval process for CDSMs in future program years.

AMIA Recommendation: Given our discussion of the proposed timeline, AMIA suggests CMS consider the application due January 1, 2017 for qualified CDSMs as a commitment to support required functionality, rather than an attestation that the existing functionality is fully implemented in a CDSM. Alternately, CMS could extend this first application deadline. This flexibility could alleviate pressures for development and signal that developers will meet the June 2017 deadline to deliver qualified CDSMs. However, we note that ordering and furnishing professionals, in this scenario, are still in the untenable situation of having to adopt and integrate CDSMs into their workflows in six months.

AMIA also recommends CMS consider hosting or sponsoring/supporting one or more “connect-a-thons” to allow stakeholders, such as developers, EHR vendors, standards experts and health informatics professionals to test CDSM interoperability (e.g., AUC to CDSM to orders to billing) functionality in the near-term. Longer-term, it would be preferable for CMS to develop a testing framework and testing tools that are supported through standards and support the participation of multiple organizations. The results of such tests could then support a CDSMs application.

C.6.e. – Consultation by Ordering Professional and Reporting by Furnishing Professional

CMS anticipates that furnishing professionals may begin reporting as early as January 1, 2018. While there will be further rulemaking next year, CMS is announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. CMS will adopt procedures for capturing this information on claims forms and the timing of the reporting requirement through PFS rulemaking for CY 2018. CMS is interested in receiving feedback from the public to include a discussion of specific operational considerations that it should take into account and include in such rulemaking. CMS also seeks information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether separate rulemaking outside of the payment rule cycle would be preferred.

AMIA Recommendation: AMIA reiterates its concern for this proposed implementation date. The implementation of CDSM is a major undertaking for health care organizations. Our members typically allow 12-18 months to implement a system of that scope, to allow for budget request, vendor selection, procurement, project planning, implementation, testing, training, and go live. Key

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decisions on how to interpret and record AUC ratings for ordering professionals, as well as how such ratings should be transmitted on the claims have not been made. These will be vital components to any qualified CDSM, and we simply do not agree that such work can be carried out on the proposed timeline.

AMIA strongly recommends CMS initiate separate rulemaking for the next component of AUC policymaking (especially billing issues) outside the payment rule cycle, if there is to be any chance of meeting the January 1, 2018 deadline. Specifically, CMS must propose a consistent way to interpret and record AUC ratings and propose ways such information can be rendered on claims.

C.6.f. – Exceptions to Consulting and Reporting Requirements

CMS proposes an exception for an applicable imaging service ordered for an individual with an emergency medical condition. CMS also proposes an exception for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. Finally, CMS proposes a third exception for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. CMS specifies that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment would also be granted a significant hardship exception for purposes of the AUC consultation requirement.

AMIA Recommendation: AMIA supports these proposed exceptions for ordering professionals, and believe they are reasonable. However, we do not see adequate protection for furnishing professionals who must report on claims in this proposal. As mentioned previously, we are concerned that some portion of furnishing professionals' referrers will not participate, and we believe this unjustly impacts furnishing professionals, given the penalty schema.