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September 6, 2016

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8016
Baltimore, MD 21244-8016

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Washington, DC 20201

On behalf of the Electronic Health Record Association (EHRA), we submit the following comments on the Centers for Medicare and Medicaid Services (CMS) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model. These comments are based on the collective perspectives and experiences of more than 30 member companies who serve the majority of hospitals and ambulatory care providers using EHRs across the United States.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The EHRA commends CMS for their review of previous AUC efforts, and understands the challenges of building a program that meets the goals of improving patient health outcomes and reducing inappropriate and costly imaging services, while reducing the instances of alert fatigue and excessive burden on providers. We appreciate that CMS recognizes the importance of integrating AUC into EHR workflows and general clinical decision support (CDS) workflows, instead of creating a separate set of imaging CDS workflows. We agree with CMS's decision to extend the timeline to support quality and less disruptive implementation of this program and commend the step-wise approach as the best way to meet the goals as stated above.

We think that in order to achieve the important goals of this program efficiently and effectively, the process flow from ordering provider to filling/furnishing professional to claims submission needs to be appropriately addressed in order to avoid an implementation that introduces manual effort and potential for error.

While the timeline has been extended, we want to reiterate previous statements the Association has made to CMS regarding timelines. With a likely publication date of the final rule in November, applications for CDS are currently due in January of 2017. It is unlikely that those who develop clinical decision support mechanisms (CDSMs) will have time to make adjustments between November and January, especially given the large volume of final rules set to be published in that same timeframe.

Similarly, no guidance on how to enter required information on a claim to CMS was shared in this rule and won't be available until next year's PFS rule cycle. This timing translates to finalized regulatory changes to claims in November 2017, with claims being affected starting in January 2018. We know from experience that this is not enough time to implement wide-sweeping regulatory changes, and we encourage CMS to clarify changes to claims as part of another cycle earlier than next year's PFS. Therefore, in response to CMS's request for comments, the EHRA supports an off-cycle regulatory schedule (i.e., sooner than the CY 2018 PFS rulemaking) to address claims requirements.

While we support many of the definitions laid out in the PFS, including the prior decisions on multiple types of Provider-Led Entities (PLEs), we have concerns about what is not included in the PFS. Specifically, the PFS lacks information and consideration regarding the process of communication between the ordering professional and the furnishing professional. The most critical element to a successful program will be a well-defined workflow for the imaging order and referral process. In many cases, ordering providers and furnishing providers might use different health IT tools; standards to communicate information about the AUC consulted by the ordering provider to the furnishing provider along with the order will be necessary. Thoughtful design of the workflow and accompanying standards will facilitate a simple, usable workflow and efficient implementation that is necessary to meet the proposed timeline.

The EHR Association asks CMS to carefully think through how the workflow should take place, and we offer suggestions as developers of technology who have worked through similar challenges in the past. Currently, the furnishing professional is the entity who would be penalized for lack of compliance, but the responsibility of completing the AUC lies with the ordering professional. The only recourse for the furnishing professional to stay compliant is to reject an unqualified order. The communication between these two professionals needs to be seamless, and a rejected imaging order provides too little opportunity too late for corrections needed to lead to a successful transaction. For electronic referrals, we recommend there be a profile for including a standardized or codified field within the referral as well as within the claims form. We note that the pilot-stage standards referenced in the 2016 Interoperability Standards Advisory (ISA) and the 2017 draft ISA address some of these issues, and urge that work be accelerated to refine these profiles while avoiding mandating premature use of immature standards.

The EHRA recommends that CMS consider an alternative and simpler workflow that would achieve the same goal of reduced inappropriate imaging services. Such a workflow could be modeled on the workflows currently in place with lab partners. These workflows include “ask on entry” (AOE) questions, which are specific to the test ordered and provided by the lab vendors, combined with medical necessity checking that evaluates whether the diagnosis code and test CPT code are approved for insurance coverage. Such an approach, similar to that used for the “Advanced Beneficiary Notice” (ABN), would leverage what vendors and physicians are already doing and would not require disruptive modifications to CDS, claims, and referrals. Radiology vendors or CDS providers could create the AOE questions for the advanced imaging studies targeted. If the AOE responses were not satisfactory and the provider wished to proceed with ordering the test, an ABN could be generated requiring the patient to agree to pay for an imaging study not medically indicated based on the criteria. This would remove the financial liability a radiology provider faces when performing a test requested by another physician, which does not meet criteria. The burden of ordering appropriate tests then falls upon the ordering physician where it rightly belongs.

We have previously commented on the standards in relation to claims submission, and we summarize those comments in Attachment A to these comments. The EHRA notes that, relative to the proposed requirements to support AUCs, efforts are underway to establish the appropriate standards to support interactions with AUC service providers. Such efforts include communicating the resulting AUC along with the order for an image service; providing it to a patient accounting application; and, moving it along on a claim. We suggest recognition of these current efforts, based primarily on HL7 V2 and FHIR, as emerging implementation specifications to provide an early indication how these requirements can be consistently supported.

The EHRA is concerned about the potential for future standards development that is based on an onerous process between the imaging order and referral. Such standards may not be mature enough to implement or may cause substantial burden for providers and developers without achieving the desired benefit. Instead, we recommend that CMS first simplify any required workflow and communication between ordering and furnishing professional and ensure that a complementary standard is selected for testing. In addition, we request that CMS avoid new or specialized certification criteria for AUC-related functionality and, instead, focus on having tests available around applicable standards.

In addition, we would like to raise a potential issue for an entity that develops CDSMs, whether as a stand-alone capability or as part of an EHR or other health IT. If CDSMs need to cover all of the finalized priority areas, then this required scope may be broader than that needed by specialties some vendors serve.

Further, we ask that CMS clarify the relationship between the designated priority clinical areas and associated requirements for CDSMs and the more general CMS-specified clinician obligation to consult with an AUC for applicable imaging services. In particular, it will be important to clarify and communicate how the “not applicable” indication for a query against a CDSM that does not have an applicable AUC meets the responsibilities of the ordering and furnishing clinician.

Lastly, the requirement to assign a unique identifier to the CDSM lookup and save such an identifier in an audit log for six years seems unusually burdensome. We ask that CMS clarify how the value of such a requirement to save the data for six years would outweigh the technical implementation effort.

We would like to point out that though CDSMs can be standalone applications that require direct entry of patient information, as CMS rightly observes, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from EHRs and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow. Another critically important piece of information is the patient's imaging history and if similar imaging studies and reports exist. Access to this data via standards-based information exchange would result in reduced duplicative scanning.

Quality Payment Program (QPP)

To align the Medicare Shared Savings Program (MSSP) with the Advanced APM requirements of the QPP, CMS has proposed to modify the Accountable Care Organization (ACO) #11 quality measure to assess the degree of CEHRT use by all eligible clinicians participating as providers or suppliers to an ACO. CMS has further proposed to make ACO #11 a pay-for-reporting measure for Shared Savings ACO assessment for the first two years following this change, in line with the existing process for introducing new measures. Per the proposal, the degree of use would be based on eligible clinician (EC)-reported EHR data that is required and collected for the Advancing Care Information (ACI) QPP performance category. In the pay-for-reporting phase, at least one EC must meet the reporting requirements for ACI; and, in the pay-for-performance years, the EHR adoption as an ACO quality measure will be based on a sliding-scale evaluation.

- In our [response](#) to the MACRA proposed rule, we supported the simple approach proposed for Advanced APMs and other APMs to meet the CEHRT requirements of the QPP program. In the MACRA proposed rule, CMS did not propose to assess the level of use of each APM entity or individual EC participating in the APM, but whether the APM requirements meet the standard set forth in the proposed rule. The EHRA continues to support this approach, and we encourage CMS to apply the same criteria to the MSSP program participants in Tracks 2 and 3 and to drop measure ACO #11 for Track 2 and 3 participants. Doing so will significantly reduce the complexity and reporting burden for Qualified Professionals who are already demonstrating their commitment to the goals of delivery system reform through their participation as an ACO and the financial risk associated with Tracks 2 and 3.
- Should CMS move forward with the proposed modifications to ACO #11, we seek clarification that providers would only need to submit data for the ACI MIPS performance category and not for all of MIPS. As we stated in our response to the MACRA proposed rule, we encourage CMS to determine an EC's QP status before the MIPS performance period to avoid the burden of MIPS reporting. If MSSP ACO Tracks 2 and 3 participants are unable to avoid MIPS reporting because of the ACO #11 quality measure, we believe their reporting burden should be minimized to only the ACI category.

As always, the Association looks forward to working with CMS and ONC toward refining these regulations as they move forward.

Sincerely,



Sasha TerMaat
Chair, EHR Association
Epic

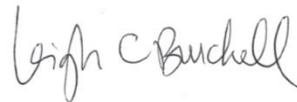


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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

Attachment: Attachment A – Summary of Previously Submitted Comments on Standards in Relation to Appropriate Use Criteria Claims Submission

Attachment A

Summary of Previously Submitted Comments on Standards in Relation to Appropriate Use Criteria Claims Submission

ONC Draft 2016 Interoperability Standards Advisory

Submitted November 6, 2015, [View Comments](#)

Additionally, the EHRA suggests that considering the anticipated requirements to support Appropriate Use Criteria (AUC), efforts are underway to establish the appropriate standards to support the interaction with an AUC service provider, communicating the resulting AUC along with the order for an image service, provide it to a patient accounting application, and to move it along on a claim. We suggest recognition of these current efforts, based primarily on HL7 V2 and FHIR, as emerging implementation specifications to provide an early indication how these requirements can be consistently supported. The following are two proposed additional entries:

Interoperability Need: Provide access to appropriate use criteria Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Emerging Implementation Specification	IHE: Guideline Appropriate Ordering (GAO)	Draft	Pre-Pilot	None	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
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Interoperability Need: Communicate AUCs with the order and charge to the filling provider and billing system for inclusion on claims. Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Emerging Implementation Specification	IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)	Draft	Pre-Pilot	None	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
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The 2016 ISA included both in the Projected Content section. Both are under CDS, whereas only one should be.

CY 2016 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B

Submitted September 8, 2015, [View Comments](#)

Appropriate Use Criteria

We note that the schedule and process proposed for appropriate use criteria (AUC) is focused on the content of the criteria, and not on the technical standards that may be used, nor the method in which the content would be delivered. Given the timelines for implementation of the content, we urge that options for technical standards and how content is delivered be left open. In particular, we do not see the HealthDecisions standard as proposed in ONC 2015 edition certification earlier this year as sufficiently mature for this use case.

The Protect Access to Medicare Act (PAMA) outlines milestone dates that are key in the development of the provider-led entities as well as dates that lay out the timeline for software developers to adopt and providers to implement the necessary capabilities to support the adoption of appropriate use criteria by January 1, 2017. These dates dictate an initial list of CDS mechanisms are provided by April 1, 2016. CMS has indicated in this 2016 Physician Fee Schedule proposed rule their intentions to release the initial list of specified applicable CDS mechanisms after the CY 2017 PFS final rule. This rule is scheduled to be released in November 2016. The proposed schedule allows less than two months for software developers and health IT implementers to understand the applicable CDS mechanisms, update their software to include the initial list, and implement the information across the industry for the start date of January 1, 2017. We are significantly concerned that the timeline that CMS proposes to follow leaves insufficient time for physicians to be in a position to comply by January 1, 2017. Certification of health IT used to support the adoption of AUC for ordering of diagnostic imaging is especially impractical on such a timeline, and the 2014 edition CDS criteria and associated interoperability standards are not well suited to support the necessary workflow.

We also urge CMS to consider the time needed to successfully implement the program, inclusive of finalizing the necessary interoperability standards and guidance, as well as vendor efforts to enter into business agreements for having access to the clinical content that will be required for CDS for presenting the AUC guidelines within clinical workflows for the ordering of advanced diagnostic imaging procedures. This also includes the need to develop or modify health IT products as needed, to make updates available to clients, and to allow sufficient time for clients to adopt these updates. Additionally, CMS will presumably have to specify how the evidence of the use of given AUC guidelines for specific diagnostic imaging procedures need to be documented on the healthcare claim. There will be development work to enable communication of the AUC guideline reference from the system responsible for the ordering of the procedure through to the billing system.

We do applaud CMS in their intention to spend the appropriate time with the program to define the process by which organizations are recognized for the development of AUC guidelines. We appreciate that CMS is faced with a short amount of time from PAMA becoming law to when information could have first been released. We urge CMS to do what they can to accelerate the timeframe by which requirements may be known for health IT to support AUC implementation and adoption, or to delay the

program effective date to a more reasonable timeframe. We also urge CMS to develop an approach that serves to expedite the recognition of AUC developers and the promulgation of implementation guidance for vendors and their provider clients that best supports industry readiness by the statutory dates.

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications
Submitted May 29, 2015, [View Comments](#)

General Comment

We are also surprised not to see any reference to imaging appropriate use criteria (AUCs), particularly in the decision support sections, as we expect that the standards used to support an AUC service, or to obtain AUC knowledge to incorporate into an approved method, are consistent across the 2015 Edition and the AUCs. We urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the 2015 Edition.

§ 170.315(a)(22) Decision support – knowledge artifact

EHRA suggests removing this criterion from the 2015 Edition. We do not recommend use of the HealthDecisions standards proposed for clinical decision support knowledge artifacts or services for the purpose of appropriate use criteria (AUC); these standards are immature and not ready for widespread implementation as described in our feedback on those criteria. However, we urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the choices made for clinical decision support (CDS). In our view, the HealthDecisions standards proposed in the 2015 Edition are not appropriate for either. Such functionality should not be driven by certification.

The EHRA would also like to highlight that HHS will have milestones later this year and next year to release the appropriate definitions and services for imaging AUCs, and the EHRA would like to ensure alignment with this and other government programs. The current proposed standards are not appropriate for adoption for AUC.

§ 170.315(a)(23) Decision support – service

EHRA suggests removing this criterion from the 2015 Edition. We do not recommend use of the HealthDecisions standards proposed for clinical decision support knowledge artifacts or services for the purpose of appropriate use criteria (AUC); these standards are immature and not ready for widespread implementation as described in our feedback on those criteria. However, we urge ONC to work closely with CMS to ensure that CMS adopts a standard for AUC services and knowledge artifacts that are consistent with the choices made for clinical decision support (CDS). In our view, the HealthDecisions standards proposed in the 2015 Edition are not appropriate for either. Such functionality should not be driven by certification.

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