33 W Monroe, Suite 1700
Chicago, IL 60603
swillis@himss.org
Phone: 312-915-9518
Twitter: @EHRAssociation

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Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013

Dear Administrator Verma,

On behalf of the members of the Electronic Health Record (EHR) Association, we are pleased to submit the comments below 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 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. The EHR Association's 30 member companies serve the majority of hospitals and ambulatory care providers using EHRs across the United States.

Our comments focus on reducing administrative burden in the Medicare Shared Saving Program, offering recommendations and seeking clarification for the appropriate use criteria, as well as offering expertise to ensure that future approaches on E/M codes align with EHR capabilities and do not introduce additional burdens on usability.

Medicare Shared Savings Program

The EHR Association is supportive of proposals that aim to reduce the administrative burden associated with participation in the Medicare Shared Savings (Shared Savings) Program, including those that are associated with beneficiary assignment methodology and the definition of primary care as it relates to beneficiary assignment. We agree with CMS' belief that by assigning a beneficiary to the accountable care organization (ACO), regardless of who furnished the primary care service in a rural health clinic (RHC) and federally qualified health center (FQHC), will help promote RHC and FQHC participation under the program.

Also, the EHR Association is supportive of the proposal to allow CMS to re-designate a measure under the Shared Savings Program, from pay-for-performance to pay-for-reporting, when substantive changes are made to the measure specifications under the Quality Payment Program. This proposal ensures participating ACOs will not be negatively impacted when substantive measure changes occur during the course of the organization's participation in the program.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The EHR Association understands the challenges that the appropriate use criteria (AUC) initiative poses for all stakeholders and appreciates the proposed delay of the AUC roll-out by one year, as not all essential capabilities exist to facilitate communication of the necessary AUC data onto the claim.

As we have identified in earlier feedback on the proposed AUC initiative, the program requires many parts to come together, specifically:

- Clarity on provider-led entities (PLEs) and the AUC Method they use (including the mapping of their specific scoring system to the CMS proposed three-part categorization)
- Interaction between the clinical decision support mechanism (CDSM) and the ordering system and ensuring the relevant data is provided by the CDSM to the ordering system, preferably in an industry standard format, considering both data necessary for the claim and data relevant for other purposes
- Communication of the relevant data from the ordering provider to the furnishing provider, including any information about potential exemptions to be supplied in a newly proposed modifier
- Communication of the relevant data from the furnishing provider to the claims/billing system that in turn generates the appropriate claim

Ensuring smooth and easy workflow for all parties involved, particularly the ordering provider, is essential as it is actually the furnishing provider that stands to benefit while being dependent on the ordering provider to communicate the essential data for the claim. In that context, we seek the following clarification and offer suggestions.

- **Adoption Timeline**

  We support the general consideration to start with early adoption in 2018 and further adoption in 2019 before penalties go into effect in 2020. Considering the many moving parts, we suggest that implementing focused pilots during 2018 and 2019 involving providers, vendors, and CMS would help ensure all communications can be achieved before penalties are applicable in 2020.

  We are concerned that nationwide deployment, where the claims systems can communicate the data but necessary interoperability among the other components is not yet widely adopted, will only yield further inefficiencies in provider organizations and distract from their main mission to care for patients.

The proposed early adoption timeframe can be used to this end, with focused pilots in 2018 and 2019, and full adoption in 2020.

We must caution that this approach requires coordination among a critical set of stakeholders, on a voluntary basis, to participate in early adoption with a limited time window. We encourage CMS to engage as quickly as possible to establish this early adopter community, in order to set up the AUC roll-out program for success.

With such an approach, we believe that CMS should maintain its revised plans for deployment as proposed, with an educational and operations testing year in 2019, followed by full deployment in 2020. Further uncertainty or delays in CMS' implementation schedule would risk waste of provider and vendor time and resources. We suggest that the roll-out of AUCs be harmonized with the roll-out of QPP, as it includes the use of AUCs for performance attestation.

- **Provider Obligations**
  Considering the multiple parties involved in providing and communicating AUC data, we seek clarification on the respective obligations of the ordering provider and the furnishing provider in terms of the accuracy and completeness of data collection, data retention, and forwarding data to be included on the claim. We specifically ask that CMS clarify its intentions regarding ordering provider obligations and any associated auditing plans for the 2019 testing year. What are the requirements for ordering providers in 2019, and what are the consequences if an ordering provider does not obtain the intended AUC data in 2019 or beyond?

- **Create Transparency of AUC Method Score to CMS Adherence Modifier**
  We request that CMS include in the authorization of the PLE's AUC Method the mapping of the AUC Method's scoring system to CMS' Adherence Modifier that indicates whether the ordered service did or did not adhere to the applicable AUC(s), or no criterion were available. Such mapping can then be consistently used by varying CDSM supporting that PLE's AUC Method to communicate to the ordering system, or in the absence of (standard) integration be consistently applied by a downstream system prior to generating a claim.

- **Encourage Use of Standard Interoperability Capabilities**
  While CMS appropriately does not call out specific standards to enable communication between a PLE and CDSM, CDSM to ordering system, ordering system to furnishing provider's HIT, and finally from the furnishing provider's system to a billing/claims management system, the proposed rule does call out the potential use of HL7 FHIR® based services in this flow. We would like to clarify HL7 FHIR-based services alone would not be able to support the full workflow. FHIR would be focused on the interaction between the ordering system and the CDSM and perhaps the communication between the PLE and the CDSM regarding updates to the AUC Methods supported. Subsequent communications are typically using HL7 V2 order and charge messages, not normally considered CDS although critical to the success of enabling data

exchange from the ordering provider to the claim.

HL7 and IHE are working on creating and updating the necessary HL7 FHIR and HL7 V2 based standards/implementation guides/profiles to enable consistent access and exchange to the relevant data, as soon as CMS finalizes the requirements and definitions of the data that must be provided on the claim. We understand that X12's standards already can support the claims data considering the use of HCPCS G-codes and associated modifiers. We encourage CMS to work with ONC and these standards organizations to finalize, publish, and promote the resulting standards for wide adoption across the workflow.

In the absence of agreed-upon standards, organizations will provide variant, potentially proprietary interpretations and solutions to support their clients' data access/exchange requirements. Such methods should be considered reasonable and necessary until such time that sufficiently mature AUC-relevant interoperability and workflow standards have been developed. ONC could play a useful facilitation role in this process.

- **Data Corrections**
  We are not clear on the mechanism available to provide updates to the AUC data submitted through the claim if data corrections are identified by any of the communication partners in the flow of data. We ask CMS to clarify such data correction mechanisms.

- **Clarify Data Used for Validation of the CDSM Consultation**
  We seek clarification on what data is used to relate the AUC data on the claim with what the CDSM actually provided to establish best practice to retain such data for potential audit, e.g., retaining the AUC Decision Support number (as issued by the CDSM to identify the specific AUC consultation) by the Ordering Provider's system, particularly when such data is not required on the claim. In this context, it would help to clarify who bears responsibility in case such data is not available during an audit, considering that the furnishing provider submits the claim while the ordering provider interacted with the CDSM. In particular, understanding the obligations of the ordering provider would benefit from this clarification.

- **Clarify Hardship Application Process**
  We seek clarification on which HCPCS G-code and modifier values are to be communicated when a provider is in the process of applying for a hardship but has not yet received such hardship exemption, while having to submit the claim for an imaging service subject to AUC.

Comments on Evaluation and Management (E/M) Documentation

The EHR Association supports this initiative as a key component in addressing physician dissatisfaction with excessive data entry and perceived usability issues with their EHRs, recognizing that there are other regulatory requirements driving documentation.

We at EHRA volunteer our expertise as EHR developers to CMS as they undertake this initiative. We can offer advice to aid CMS in ensuring that whatever future approaches are considered would align well

with the capabilities of EHRs and do not introduce unintended additional burdens on EHR usability. Fundamentally, the documentation guidelines reflect the structure of the E/M codes and we are concerned that addressing the guidelines alone could lead to physician and reviewer uncertainty in regard to appropriate coding.

We agree that the history and physical (H&P) documentation should be the driven by clinical relevance, and that reducing or eliminating the H&P requirements for billing purposes should not be seen as implying that this information is not critically important and that these clinical tasks should not be completed or documented consistent with actual clinical circumstances.

We recognize that variations in physician documentation practices, office/hospital processes, and non-clinical factors would pose significant challenges to using time as the sole or most important factor for reimbursement. It should also be noted that there is not a linear relationship between clinical complexity and encounter time. Re-evaluation of the E/M CPT codes should be able to account for both intellectual complexity and non-intellectual complexity (time could potentially be a proxy here).

We note that increased utilization of telehealth services will, by necessity, require re-evaluation of the Physical Exam component of physician documentation and should be included in this initiative.

Finally, it is important to acknowledge that CMS is not the only payer to use CPTs, DGs and RVUs to determine payment levels. These concepts are deeply embedded within existing EHRs and changes will require significant effort on the part of developers and payers in conjunction with a massive education effort for providers, coders and auditors. Having said that, the initiative is long overdue, but the scope and ramifications should not be underestimated and all stakeholders should be involved in the process.

Physician Quality Reporting System (PQRS)

The EHR Association is supportive of the proposal to retroactively reduce the number of reported measures required under PQRS from nine measures to six measures. We also support efforts to align data submission requirements across quality payment programs, and this proposal is consistent with that approach as it aligns previous program requirements with existing requirements for providers under the Merit-based Incentive Payment System (MIPS).

Moving forward, we believe the most appropriate approach to ensure a smooth transition under MIPS is for CMS to provide clear and consistent program requirements and deadlines, with as much advance notice as possible. Clearly communicating these requirements to providers and vendors will ensure stakeholders are given adequate time to develop, prepare, and adapt the necessary changes to meet program requirements.

We look forward to working with CMS to ensure an appropriate balance is achieved that rewards stakeholders who make proactive effort to comply with quality payment program requirements, while simultaneously providing flexibility to improve the success of the program and its participants.

Thank you for this opportunity to comment. We look forward to continuing to offer our expertise and experience to CMS.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Richard Loomis, MD
Vice Chair, EHR Association
Practice Fusion

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Nadeem Dhanani, MD, MPH
Modernizing Medicine

David Heller
Greenway Health

Cherie Holmes-Henry
NextGen Healthcare

Joseph M. Ganley
McKesson Corporation

Rick Reeves, RPh
Evident

About the EHR Association
Established in 2004, the Electronic Health Record (EHR) Association is comprised of 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.ehra.org.