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October 24, 2016

Vindell Washington, MD, MHCM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Dr. Washington,

On behalf of the members of the Electronic Health Record Association (EHRA), we offer the following comments and suggestions on the Office of the National Coordinator for Health IT's (ONC's) 2017 Interoperability Standards Advisory (ISA). We appreciate the ongoing improvements applied to the Interoperability Standards Advisory. Having a single place for those interested in available interoperability standards and implementation guidance is valuable. This response was developed through a collaborative effort by member company representatives with deep experience in supporting the interoperability needs of hospitals and ambulatory care organizations across the country that are using EHRs to provide safer, more effective, and efficient care to their patients. We offer the following overall considerations, while providing more detailed feedback in the attached document.

- **Purpose and Focus**
  - ***Clarify the purpose and focus of the ISA, including its relationship to the certification program.*** Understanding the purpose of the ISA remains a challenge, as it does not set a clear expectation regarding how entries in the ISA may progress to inclusion in a future certification edition (e.g., maturity and adoption level thresholds). However, it does include a new paragraph in the *Purpose* section inviting agencies to consider using standards in this ISA (*"Stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components are encouraged to look first to the ISA in order to more fully inform their goals"*), rather than referencing the most current certification edition first. This may lead to interoperability requirements that are aspirational, but not yet practical to achieve; or worse, may conflict with capabilities already provided through the certification edition, albeit it an earlier version or alternate standard.

- ***Clarify the applicability of the ISA to health IT in general and capabilities such as electronic health record technology (EHRT), lab information systems (LIS), radiology information systems (RIS), etc., in particular.*** With the inclusion of many new standards (e.g., around research), the existing impression with prior ISAs that the full set of standards is generally applicable to all EHRT seems further amplified. We suggest that the ISA introduction clearly indicate that the scope includes interoperability across all of health IT supporting clinical and healthcare processes (e.g., EHRT, LIS, RIS, health information management (HIM), registries, research, etc.), but cannot be considered to be applicable to all categories of such health IT. Individual programs focusing on specific areas of clinical health IT support would identify which interoperability requirements apply. For example, research-focused standards likely would not apply to EHRT in general, or LIS-EHRT interoperability, but rather to health IT involved in the collection of research data that is to be communicated with other research parties. Such clarification will further help communicate that not all health IT currently supports all standards listed, nor they are expected to implement all standards.

- ***Clarify considerations for health IT developers regarding when to focus on standards requiring further development vs. those ready for initial implementation vs. those that are widely deployed.*** Focusing particularly on health IT developers, the expectation should be further clarified that these developers are not expected to implement and pursue all standards referenced, particularly emerging standards. Most emerging standards, such as FHIR, are not ready for wide deployment and endorsement, primarily due to a lack of well-defined and widely agreed-upon implementation guides and profiles. FHIR in its current state is subject to varying interpretations, akin to the initial rollout of HL7 V2, V3, and CDA. Early efforts to deploy such standards beyond individual provider/healthcare organizations into, for example, the inter-provider and provider-patient space has resulted in many variations, making such interoperability still challenging. We recognize that we do want to promote activity in those areas to accelerate adoption, but health IT developers must recognize that early adoption of not "fully-baked" standards will likely result in updates or re-writes as more mature versions are adopted. Early adoption is not for everybody, thus cannot be set as an expectation or requirement.

- ***Clarify the focus of the federal program requirement to identify ISA candidates.*** It is unclear what a "federal program requirement" represents in the table. Programs established through regulations are clear, but it is unclear whether there are any other programs that are tied to regulations that should introduce requirements for the ISA. The EHRA is concerned that when federal procurement and contract requirements are included, such requirements get equal weight as a federal regulation, while private contracts do not have that weight. A federal contract is, in effect, no different than a private contract, where certain standards may or may not be a prerequisite for being able to qualify for that contract. We, therefore, suggest that federal contracts, similar to private contracts,

should not be considered a source for the ISA and request that this section be changed from *"Federally Required"* to *"Regulatory Requirement"* to clarify that is to be restricted to federal regulations.

- **Use Case Clarity**
  - ***The question "the best standard for what?" remains a challenge***. Single use case titles do not create the necessary clarity to always understand whether the proposed standard is best suited for the purpose. We suggest that each "interoperability need" would be better described by including a paragraph clarifying the context. This is equally valuable in the vocabulary section as in the other sections. Such a paragraph may also help the authors consider the adoption level more appropriately. For example, in a number of instances LOINC is marked with a high adoption level (five bullets); but, while LOINC is generally widely adopted, for a particular vocabulary and a particular use case, it is not necessarily accurate and a far lower adoption level should be identified. We will further clarify this concern in the individual sections below.

- **Semantic Interoperability**
  - ***Continue facilitation of terminology harmonization across standards and implementation guides.*** Various standards references use terminology for similar purposes, but different values. Convergence to general vocabulary standards such as LOINC, SNOMED, RxNorm, etc., is making major strides to the necessary harmonization to achieve semantic interoperability. However, more efforts are required to ensure that provider organizations, public agencies, and registries are aligned. We suggest that this be recognized as an area of ongoing focus, requesting critical stakeholders to move this important work forward.

  - ***Establish clear criteria regarding when to include a value set.*** We suggest that terminology should only be included where a value set authority center object identifier (VSAC OID) is available.

  - ***Focus additional facilitation to align common data definitions across standards development organizations.*** The wide variety of standards starts to further emphasis the need for harmonization across standards to consistently express common data. For example, patient demographic data is included in most of the standards, yet have varying rules and guidance on lengths, data types, and vocabulary. We suggest that the Office of the National Coordinator for Health IT (ONC) work with the respective standards development organization (SDOs) to initiate the necessary efforts to harmonize such overlapping data sets to ensure that data can be consistently exchanged.

- **ISA Response Process**
  - ***Provide feedback on inclusion/exclusion rationale for comments submitted.*** We strongly recommend that rationale for not including suggestions be provided to those who provided them, perhaps through a companion document. The EHRA provided a number of suggestions in response to the follow-up request when the 2016 ISA was published, but

many of those suggestions were not included without a clear explanation as to why not. Consequently, we determined that it would be best to re-submit most of those suggestions. To further clarify this concern, we suggested that projected items for the 2017 ISA should only be included if enough support was expressed through the feedback process, not simply because there was no feedback and/or support from the SDOs. It is not clear whether all additions clearly received such support from health IT developers and user communities (e.g., providers, registries, agencies, etc.).

We look forward to ongoing collaboration with ONC and other stakeholders to move forward on this important initiative.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Richard Loomis, MD
Vice Chair, EHR Association
Practice Fusion

**HIMSS EHR Association Executive Committee**

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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:
Protect Access to Medicare Act Provisions for AUC for Advanced Diagnostic Imaging [Referenced on page 11 of our comments]