HIMSS Electronic Health Record Association

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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Docket No. FDA-2016-D-1224

On behalf of the members of the Electronic Health Record Association (EHRA), we appreciate the further guidance and clarification provided by the Food and Drug Administration (FDA) on the role of electronic health record technology (EHRT) in providing data to electronic data collection (EDC) systems and other clinical study-related systems.

We suggest that this guidance should not be limited to EHR-to-EDC interoperability, as clinical study data may be sourced from other health IT, which should be considered in the same context. Therefore, replacing references to EHRT with (Certified) HIT would seem appropriate for the guidance being considered.

We also suggest that most data exchanges are best supported by document-based exchange. The Office of the National Coordinator for Health IT's (ONC's) 2016 Interoperability Standards Advisory includes references to Integrating the Healthcare Enterprise (IHE) profiles that provide a potential starting point for such documents, although we note that adoption of these profiles is limited and may soon be superseded by the emerging FHIR standard for Structured Data Capture (SDC).

The current reference to ONC's Health IT Certification Program on line 155 creates the impression that interoperability between EHRT and EDC systems are already available through certified health information technology. However, that is not the case, as the 2015 Certification Edition does not include any of these standards/profiles. We suggest clarification in the guidance as to whether it references the best available standards and implementation specifications per the 2016 Interoperability Standards Advisory, subject to further review and updates, or the most current Certification Edition.

Lines 136 – 143 suggest that EDC capabilities may be supported directly by (C)EHRT. While that is certainly possible, we urge the FDA not to create a requirement that EDC capabilities must be included directly in (C)EHRT. Depending on provider needs, separate EDC capabilities with appropriate interoperability may be sufficient to accommodate certain user communities, while in other cases it may be more appropriately supported by combined (C)EHRT and EDC capabilities. Such dynamics are best addressed through market needs rather than implied by government direction statements.

Lines 257 – 261 under the "Data Modifications" section propose that any modifications to data made by healthcare professionals in the EHR who are not part of the clinical investigation must be done without obscuring previous entries. We ask FDA to clarify why professionals who are not part of the clinical investigation are specifically referenced. A typical CEHRT provides the capability to record access and actions related to electronic health information by all users as specified in the auditing requirements in the 2015 Certification Edition. We suggest that FDA clarifies that this capability is adequate to meet this requirement. We also ask FDA to clarify the meaning of making modifications "*without obscuring previous entries.*" Does this require audit trail information regarding any modifications, including before/after data? This requirement is divergent from the current certification requirements for auditing where only the identification of the user who performed the change and the date/time is required, but not the actual data that was changed. We suggest that FDA clarify that the audit and access control requirements specified in the 2015 Certification Edition provides adequate support to enable the use of clinical documentation source systems to electronically provide data to EDC systems. The EHRA also suggests further consideration of this requirement, since storing PHI in audit logs significantly increases the risk of breach and would require additional controls to be implemented for its protection.

An area of concern with the interoperability of clinical data in support of clinical studies is the potential need to communicate <u>all</u> the relevant data, which would include provenance and audit data as the data is collected and modified before it is submitted. Further guidance on the ability to collect and transmit, as well as clarification on whether to include such data in the data exchange protocols, is essential to understand whether CEHRT/health IT data streams are sufficient or whether duplicative/augmented data collection downstream in an EDC is required.

Lines 279 – 280, in the section "Informed Consent," propose listing in the consent form all entities who may gain access to the patient's health record relating to clinical investigations. We ask the FDA to provide additional guidance on capturing and transmitting consent and to clarify whether the term "entities" refers to organizations, individuals, or both. Capturing consent for every individual who may gain access to the patient's record would be significantly challenging to implement, both technically and operationally. We suggest that FDA clarify that consent captured at the organizational level would be sufficient. There are multiple standards that exist for consent, each designed for use within a specific ecosystem. However, there is a justifiable need for a harmonized standard as the boundaries between ecosystems dissolve. Some of the standards, such as FHIR consent directive, are still in the draft stage and efforts to develop implementation guidance for basic choice and granular choice consent are currently active, most notably in the ONC Patient Choice Technical Project. We ask that

the FDA clarify its intention that the requirement is to support basic choice (i.e., opt-in/opt-out) as a baseline, and support for granular choice is to be implemented over time in a phased manner.

For the section "Privacy and Security of Data," we ask the FDA to indicate that the privacy and security safeguards in accordance with current HIPAA security rule requirements for health IT systems, and the healthcare practice and the requirements in the 2015 Certification Edition for CEHRT, are sufficient.

The EHRA supports the agency's efforts to facilitate the use of EHR data to modernize and streamline clinical investigations in general. As noted in our comments, there are open questions on interoperability, privacy, and security that need to be carefully reviewed and clarified in order to ensure that the larger goals of this guidance are achieved.

Sincerely,

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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.