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National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
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Submitted electronically to: <http://www.healthit.gov/isa>

Dear Dr. Rucker:

On behalf of Cerner, I am writing to provide input to the 2019 Interoperability Standards Advisory Reference Edition (2019 ISA Reference Edition). Over the course of 2018 various updates have been made in response to 2018 ISA Reference Edition feedback, which has increased the value and relevance of the ISA. We appreciate these efforts of you and your team maintain an index of currently available and relevant interoperability standards and implementation specifications for healthcare information technology.

Cerner associates have participated in the collaborative efforts led by the Electronic Health Record Association (EHRA) as well as with HL7 Int'l to provide input to the 2019 ISA Reference Edition. We largely support and endorse the comments of those organizations and refer to their response for more detailed considerations; however, we are also responding individually to urge you and your team to consider the following general comments.

We suggest that clarity on Implementation Maturity and Adoption Levels are essential to enable stakeholders to make informed decisions on early adoptions, inclusion in regulatory programs, or inclusion into contracts. We do recognize the challenges with these measures, but urge ONC to document and reference the sources that lead to the ratings, e.g., actual use of standards by networks, suggestions by expert panel(s), or actual statistical analyses. While the introduction clearly indicates that the intent of the Adoption Level is as a measure of actual use by end users, this is not as evident in the individual interoperability needs. Various specifications are marked as "Pilot" but have a two or higher Adoption Level rating, which seems contradictory to the nature of a "Pilot", e.g., IHE Document Metadata Subscription for the Publish and Subscribe Message Exchange in the Publish and Subscribe Message Exchange interoperability need.

We note that understanding the purpose and scope of various use cases and interoperability continues to be challenge, thus understand the applicability of the various ratings on maturity and adoption levels. An example may be the *Representing Patient Sex (at Birth)* interoperability need compared with the other interoperability needs for the *Sex at Birth, Sexual Orientation and Gender Identity* use

case. Improved clarification of who is to provide the data and in what context would help implementors and HIT vendors better assess the appropriateness of the values sets. The availability of practical operational reference guidance for concepts that are at best confusing as they are new to a healthcare applied use for semantic interoperability would also be of great value. While the Limitations, Dependencies, and Preconditions for Considerations hint at it, in combination with the title, a brief description would help remove ambiguities. Such guidance would further clarify whether one should suggest that the value set for *Representing Patient Sex (at Birth)* would benefit from adding “intersex” as a valid value at time of birth as assessed by the clinician. Analogous ambiguities of purpose are found with other use cases/interoperability needs. We recommend adding a summary paragraph to each interoperability need that clarifies the essence and scope of the need. Such introductions would not only help the user of the ISA better assess the ratings, but also determine whether additional information for support of interoperability may need to be suggested.

We suggest that inclusion of the Functional Models, Functional Profiles, and Information Models can provide a good introduction into the components involved in healthcare IT. However, we caution that these models are often used as-is by both regulators and standards developers or profile developers to specify capabilities (e.g., functional profiles) or representations (e.g., information models). Depending on the intent and purpose of the healthcare IT, appropriate sub- or super-sets of functions may be necessary, while data may need to be represented and managed differently depending on purpose and use. The models and profiles referenced do not do justice to the richness of these variations. We recommend that the models are introduced as references for understanding concepts and capabilities only, while clarifying they are not expected to be used as-is, unlike the interoperability standards and implementation specifications referenced elsewhere, as different use cases will require varying capabilities and implementation approaches.

We will continue to work ONC and various industry stakeholders to find the right constructs that can provide the necessary insight into the state of interoperability, establish a nationally endorsed set of standards and implementation specifications, and generally advance the level of interoperability necessary to enable full access to the electronic medical record for patients, providers, and other stakeholders to ensure the right data is available to the right person at the right time.

Please do not hesitate to contact me if we can be of further assistance.

Sincerely,



Hans J. Buitendijk, M.Sc., FHL7
Director, Interoperability Strategy