April 20, 2016

Karen DeSalvo, MD
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
RE: *Comments on 2016 Interoperability Standards Advisory*
<Submitted Electronically>

Dear Dr. DeSalvo,

On behalf of Cerner, I am writing to provide input to the upcoming 2017 Interoperability Standards Advisory (2017 ISA). We appreciate the efforts of you and your team to improve on the ISA to help make this a valuable document for the industry to the best available interoperability standards and implementation specifications.

Cerner associates have participated in the collaborative efforts led by the Electronic Health Record Association (EHRA) as well as with HL7 to provide input to the draft 2017 ISA. We largely support and endorse those comments 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 concerns.

We appreciate the enhancements made to the interoperability characteristics. We are working with the EHRA to identify opportunities to improve on the statistics that can better measure the extent to which interoperability has taken hold to go beyond estimated adoption levels.

While we recognize many improvements in the ISA and can see some value in having a compendium of best available standards and implementation specifications, particularly around well curated and coordinated vocabularies, the overall value and purpose of the ISA remains a challenge.

- It is not clear what role the ISA will play as a predictor for an upcoming certification edition regulations. Currently, standards and implementation guides with varying levels of maturity characteristics already appear in a certification edition, e.g., C-CDA R2.1, while others do not, e.g., XDS, XCA. We understand that the ISA is intended to provide "sub-regulatory" guidance, but we are concerned that ambiguity about the role of the ISA with regard to future regulatory activity creates potential confusion that could cloud the value of the ISA.

- During HIMSS it was suggested that the ISA can serve as a "to-do" list for where to fill in standards gaps, which might be helpful for certain use cases, but not necessary for others. For example, standards and implementation specifications needed to connect larger data sharing networks, it is likely that those networks will have resources and experts to be the primary drivers to identify any standards gaps and to fill them with support directly from the SDOs and other profiling organizations. On the other hand, smaller groups attempting ad-hoc integration won't be able to find sufficient information in the ISA to satisfy their needs. In other words, the ISA is probably not needed for larger networks, but is not sufficiently specific for smaller networks. This will be a consistent challenge. We have some suggestions below that may help address this.

- The challenge remains that without regulatory pressure to adopt specific standards and implementation specifications as "minimum required" to support basic out-of-the-box interoperability, while leaving opportunity for advanced interoperability and innovation between tightly collaborating partners and networks without penalty, many organizations will not have the bandwidth or wherewithal to adopt the emerging and not yet mandatory standards and implementation specifications.

- A number of new standards are being proposed in the research space raising concern not with the potential value of the use case, but with the need to arrive at a consistent library of vocabulary standards that are used across all structural standards that enable the industry to achieve "document once, use everywhere" and further emphasize the need for secondary uses to be as fully derivable as possible from data relevant in primary use. We suggest that you seek to include standards emerging from researchers, where those standards overlap with clinical activities.

- For those not as familiar with the origins of the recommended standards and implementation guides, or with ongoing debates about the merits of competing standards, it would be very helpful to provide links to the fora where previous decisions/recommendations were made, e.g., HITSC meetings, Task Force recommendations, etc. This is of particular interest for vocabularies and value sets, but would be helpful for all other standards and implementation guides as well.

To address these challenges, we offer the following suggestions that could help increase the usefulness of the ISA:

- Enhance the focus and documentation of real-world use cases where promising work is in progress. One way to do this might be to merge the content of ONC's Interoperability Proving Ground into the ISA, by providing lists of known use-cases and pilots, linked to each of the standards described in the ISA. That way, implementers will have additional opportunities to identify who to contact to explore use of specific standards.

- Similarly, tighter coordination with the NLM Value Set Authority and/or CDC PHIN VADs would be useful to surface and remove overlaps in value set authority and thus establishing a clear "gold standard" reference point for locating appropriate vocabulary and value set documentation.

- If the ISA is to be linked to these rapidly-changing domains (value sets, Interoperability Proving Ground), then it may be necessary to find a faster and more flexible way to keep the ISA up to date. The current once-a-year approach is not likely to be sufficient. We suggest considering a more wiki-like approach, where end-users and non-ONC experts could submit updated data to be included in the ISA on a continual basis. A wiki-like platform would also enable linking to sources where recommendations were made to use particular standards, e.g., HITPC/SC meetings, Task Force efforts, etc.

- Careful curation will be important if a wiki-like approach is adopted to ensure that accurate information is displayed, and to avoid "flame-wars" among standards partisans. The contributors to the ISA need not be limited to ONC staff, but could be extended to SDO or other

qualified experts. It might be possible to solicit updates via the ISA web page itself, and then let ONC staff vet the additions and approve the suggestions that are contributory.

The challenges notwithstanding, 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
Senior Strategist