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Donald Rucker, MD
National Coordinator for Health IT
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the IHE USA we are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the 2017 Interoperability Standards Advisory (ISA). IHE USA appreciates the opportunity to leverage our volunteers' expertise in commenting on the Standards Advisory, and we look forward to continuing our dialogue with ONC on identifying, assessing, and determining the best available interoperability standards and implementation specifications. We feel that this effort will provide the necessary foundation for more rapidly advancing interoperability in our country.

IHE USA (www.iheusa.org) is a 501.c.3 not for profit organization founded in 2010. Its vision is to improve the quality, value, and safety of healthcare by enabling rapid, scalable, and secure access to health information at the point of care. IHE USA operates as a national deployment committee of IHE International in order to advance its mission to improve U.S. healthcare by promoting the adoption and use of IHE and other world-class standards, tools, and services for interoperability. IHE USA engages all levels of public and private sector participants to test, implement, and use standards-based solutions for all health information needs.

IHE USA is committed to supporting and educating all stakeholders to achieve interoperability leading to information exchange that improves the quality and cost effectiveness of healthcare delivery. We will continue to leverage our resources and volunteers to ensure they have access to the tools necessary to share health information in a secure and appropriate manner.

Historically, IHE USA has taken a lead role to support the development and deployment of consensus-based interoperability specifications. IHE USA and our parent organization, IHE International (www.ihe.net), began developing IHE Profiles, or technical specifications leveraging our committee-level interoperability expertise in 1997.

IHE USA has further ensured the proper implementation of IHE Profiles and now hosts the health IT industry's largest, most rigorous interoperability testing events to achieve health information exchange and support widespread adoption and implementation of standards-based interoperable health IT systems.

IHE USA is currently working with its volunteers to review the updates to the new web-based

version of the ISA. In the spirit of the ONC's new ongoing review process for the ISA, IHE USA will continue to review and submit comments on an ongoing basis.

Please find comments below as related to specific questions outlined in the ISA's Section V.

ISA Section V, Question 1: Based on public comment and Health Information Technology Standards Committee recommendations, the ISA is now an interactive web application. What additional functionalities would make the ISA more useful as a resource?

Version Control: IHE USA appreciates the opportunity for timely feedback via the Web version and appreciates the inclusion of a Reference Edition as stated in the 2017 ISA:

> "In December of each year, ONC will publish a static "Reference Edition" of the ISA that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change. For example, in December 2016, ONC will publish the 2017 ISA Reference Edition."

IHE USA finds that it would be beneficial if ONC defines a plan for version control for web-based content. For example, how often will ONC update the web version of the document? IHE USA is concerned that important updates will not be communicated to implementers, and use of the Reference Edition will overshadow use of the more dynamic web version. ONC should share regular summaries of the changes made between versions to help the industry better understand the differences from the Reference Edition.

Clarification of "Federally Required": IHE USA suggests it is valuable to include hyperlinks, when applicable, to the regulation associated with a federally required standard/implementation specification. However, based on the scope it is unclear as to whether the "Federally Required" characteristic is obligatory for federal agencies only or should be applied to commercial implementers as well. IHE USA suggests clarification on requirements for commercial uses.

Updates to Webpage Navigation: Currently the "Home" button navigates to Section I of the 2017 ISA. IHE USA suggests that the button should navigate to the Introduction section to the ISA.

Maintenance of User Comments: IHE USA is pleased with the opportunity to register and comment directly within the ISA. However, we want to ensure that these comments will be clearly marked as User Comments, rather than official ISA content. Our organization is also curious as to whether users are notified when an additional comment or update is added following his/her comment. Also, with the new Web-based version, one needs to make sure the list of comments by stakeholders is maintained. One may use the comments for education, direction, or even for strategy in institutions, and being able to retrieve past comments will be important. ONC may want to consider adding search features for comments. ONC may also want to capture more demographics from users leaving comments to better sort through feedback. For example, filters and queries of comments by topic, keyword, author, or institution/organization type may be valuable for users. For commenters not interested in disclosing this information, an anonymous option should be considered.

Use Cases: Links to use cases would be helpful information to include with Interoperability Needs to highlight their value. A standardized Use Case format would be helpful to the industry. The current hyperlinks to the Interoperability Proving Ground (IPG) can be expanded to better

serve these needs. This resource has room for improvement in its organization and query functions. The IPG is broad in the resources listed and can benefit from improved categorization.

ISA Section V, Question 2: In what ways has the ISA been helpful? What are ways in which the ISA could be improved to add value to nationwide standards adoption and use?

Leveraging Others to Highlight ISA Value: ISA is only useful to the extent that it has actual "usage" (being read and followed). Driving of usage could be increased if ONC participates in targeted outreach to other organizations to link "into" the ISA. IHE USA suggests that ONC should work in collaboration with other organizations to further align standards to better highlight the ISA tool within their communities. HIMSS, HL7, IHE, ASTM, CDISC, NLM, IHTSDO and other organizations that have standards referenced by ISA are a few of the organizations that ONC should target to help with ISA promotion. Partnerships with other federal agencies (CDC, OCR, OIG, FDA) would also help to highlight the value that ISA adds to improved healthcare interoperability.

Promoting Case Studies and Success Stories: ONC can better demonstrate the ISA's value by providing examples of the uses of the different standards and the benefits of implementation. IHE USA suggests adding a resource page to highlight these examples or adding an open comment area focused on sharing the value of the ISA. White papers and blog posts can be leveraged to highlight the value as well. Key industry initiatives for standards and interoperability testing, such as the IHE North American Connectathon, would also be helpful to highlight.

Marketing the ISA: As the ISA expands, ONC may need to consider the intended audience. New stakeholders may be less technical than the current audience and may not have the bandwidth to interpret the document appropriately for implementation. ONC may want to consider using a marketing consultant to better reach these audiences.

Removal of "Best Available": As stated in earlier comments, IHE USA believes that the removal of "best available" is detrimental to the nationwide adoption and use of interoperability standards. Adding language that indicates these are current and emerging standards for serious consideration would help highlight the role of these standards and specifications in reaching interoperability objectives.

Expansion on the Security Appendix: The Security Appendix lacks any categories or explanation for the resources listed, and is large and overwhelming to navigate. This list needs to be vetted and better organized. IHE USA plans to review the Appendix in future ISA reviews with a focus on how this Appendix can be improved, and will offer further comment.

Mobile Health: IHE USA suggests that ONC explore the addition of mobile health as a specific section including standards that may differ for the mobile health environment. It may be beneficial to add a section on gaps or differences in standards unique to the mobile space.

ISA Section V, Question 8: Are there additional Social Determinant Interoperability Needs with corresponding standards that should be included in the ISA?

IHE USA supports the inclusion of Social Determinants of Health (SDOHs) as valuable data elements that should be captured and integrated to not only improve the care provided but also

help improve and address healthcare costs. In a comparison of SDOHs outlined by the National Academy of Sciences to SDOHs currently listed in the ISA, we noted a few gaps that could be addressed within the ISA.

- **Country of Origin/Birth**: Currently there are no Interoperability Needs capturing this information, and IHE USA believes this SDOH may be relevant for a number of scenarios. For instance, inclusion of this information can assist in identifying potential cultural or language considerations in treatment or care. Such data may be pertinent in outbreak situations. This information can also be applicable to those serving overseas.
- **Dietary Patterns**: ISA currently does not include an Interoperability Need to capture SDOH data for dietary behaviors, including but not limited to diet, nutrition, obesity and eating disorders. Exploration and inclusion of standards related to this topic would be valuable.
- **Neighborhood and Community Compositional Characteristics**: More granular location information beyond zip codes should be explored to assist in the capture of social determinants related to community and neighborhood demographics. Geocoding, census tracts, carrier-route codes, and zip+4 are all potential data sets that should be considered to capture more granular patient information.
- **Substance Abuse and Behavioral Health**: IHE USA commends ISA on the inclusion of specific Interoperability Needs for alcohol and tobacco use, but feels that an Interoperability Need for Substance Abuse would be beneficial to capture other substances' use/abuse (illicit or otherwise). IHE USA would like to highlight the importance of standards related to Behavioral Health issues (including Substance Abuse). We understand the challenges around these sensitive data elements and we support ONC's continued collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) to further advance these standards.

Some of the Interoperability Needs in the ISA are relevant but could be expanded to capture more granular information.

- **Employment**: It is important that the ISA capture Industry and Occupation standards (Section I-H). However, no data set within this Interoperability Need is available for employment status (i.e. full time, part time, unemployed), which could be pertinent data to the individual's care.
- **Negative Mood/Affect**: We commend ISA for including an SDOH Interoperability Need for Depression (Section I-S), but feel that this Need can be expanded to include the capture of individual anxiety issues.
- **Tobacco Use/Exposure**: The current SNOMED CT codes used for this Interoperability Need are interpretative and ambiguous. LOINC may offer some more granular options to use: (LOINC codes 64572-1; 64570-5; 68536-2; 68535-4; 82769-1; 81228-9)
- **Exposure to Violence**: IHE USA commends ONC on the inclusion of Violence within the SDOHs listed in the ISA, but suggests expanding the title of the Interoperability Need to include "Exposure to Violence and Abuse". Inclusion of abuse is more encompassing of patient exposures that may relate to their health, including emotional and sexual abuse. The current LOINC codes for this Interoperability Need also use the term "abuse".

We appreciate the opportunity to submit comments on the 2017 ISA. Our comments are

intended to recognize the importance of each stakeholder's role in advancing standards-based interoperability and health information exchange, and ensuring that each domain is invested in overcoming the inherent challenges, while further enhancing health IT's pivotal role in enabling healthcare transformation.

We welcome the opportunity to meet with you and your team to discuss our comments in more detail. Please feel free to contact Joyce Sensmeier, President, IHE USA at 312-915-9281, or Celina Roth, Sr. Manager, IHE USA, at 312-915-9213, with questions or for more information.

Thank you for your consideration.

Sincerely,

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President, IHE USA

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