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July 31, 2017

Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Rucker:

On behalf of [IHE USA](http://www.iheusa.org), we are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the [ONC Proposed Interoperability Standards Measurement Framework](#) (the Framework). IHE USA appreciates the opportunity to leverage our members' expertise in commenting on the ONC Framework, and we look forward to continuing our dialogue with ONC on identifying, assessing, and determining the best available tools and resources to measure the state of interoperability within the health IT community. We feel that this effort will provide important information on the status of our healthcare system's ability to share and use secure electronic information and inform the community on how to continue to advance interoperability to improve care delivery.

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, called IHE Connectathons, to achieve health information exchange and support widespread adoption and implementation of standards-based interoperable health IT systems.

Overall, IHE USA agrees with the value that this proposed framework could provide in advancing the implementation and use of interoperability standards in the health IT community. Measurement is critical to understanding how to improve efforts in this space. Our comments below highlight our responses to the questions posed by ONC and touch on the following three themes:

- **Limiting undue burden**

IHE USA would like to highlight the importance of pursuing a measurement framework that will not produce undue burden on the industry. Existing reporting frameworks should be leveraged wherever possible.

- **Standards as the means, not the end goal**

IHE USA stresses the importance of capturing measurement for Objective 2, which focuses on measuring the “Use of Standards by End Users to Meet Specific Interoperability Needs,” specifically understanding the outcomes related to the use of those standards. The standards measured should align with relevant use cases that are critical to the advancement of interoperability and improved information exchange. Furthermore, identifying measurements to capture the use of standards in implementation versus production will be essential to capturing a realistic picture of interoperability.

- **Inclusion of all relevant stakeholders**

Successful creation and deployment of the Framework will depend on the inclusion of all relevant stakeholders. Proper representation across the health IT ecosystem will be critical to identifying and avoiding undue burden in reporting, and aid in overcoming potential industry apathy in the adoption and ongoing use of this framework.

Included below are IHE USA’s responses to the ten questions posed by ONC (included in italics) to aid in the development of this framework.

1) Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system’s value to stakeholders?

IHE USA agrees that this is a reasonable approach to implementing the framework. The health IT community as a whole is interested in improving interoperability, and measurement is needed to help guide improvement. Even with a voluntary approach, governmental guidance and incentive may still be important in this effort, and how that may take shape should be explored.

Some barriers that exist to a voluntary, industry-based reporting system include:

- Inertia that will likely occur with the absence of “mandated” or regulatory action.

- Lack of participation from smaller organizations/systems with limited or no resources to contribute voluntarily.
- Potential issues with reporting bias that ONC will have to consider how to manage.

Collaborating with large consortia (including IHE USA) and national, state or regional Health Information Exchange (HIE) networks can help with the promotion and outreach for this framework, and possibly alleviate some inertia. Many of these organizations tend to be more representative of large organizations, so special effort should be made to ensure engagement of smaller organizations.

2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

Leveraging existing reporting systems should be the priority to maximize (re-)utilization of the existing wealth of data in which the community has invested. ONC may consider conducting a review of other federal agencies and data already collected by these agencies as potential data that can be leveraged for this measurement framework. For example, the Centers for Disease Control and Prevention (CDC) may have statistics on provider use of standards to report data for programs such as National Health Surveys or National Program of Cancer Registries (NPCR).

Another reporting system currently exists in the form of the [IHE Product Registry](#), a web-based database of IHE Integration Statements. The IHE Product Registry enables developers to create, manage and publish Integration Statements for their commercial and open source healthcare IT systems. It allows users to browse for these systems based on their conformance with specific IHE Actors and Profiles or implementation specifications. The system is open for use by developers and users and can be leveraged for the purposes of this measurement framework.

IHE USA suggests that leveraging the sector in executing this framework will be critical to its adoption. A number of health IT organizations beyond IHE USA should be considered in collaboration for reporting. These include, but are not limited to, Standards Development Organizations, Health IT non-profits, and EHR vendors. Physician-based groups including, but not limited to, the American Medical Informatics Association (AMIA), the American Medical Directors of Information Systems (AMDIS), the Physicians' EHR Coalition (PEHRC) and the HIMSS Physician Committee should all be engaged to understand the use of this framework and potential reporting options.

3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

For the framework objectives, IHE USA agrees that it is important to capture information about the implementation of standards, and to understand the level of consistency of use of these standards. Beyond use, it would also be valuable to understand the outcomes related to the use of these standards in how they improve aspects of care (i.e. preventing duplicative tests, incorporation/reconciliation of data).

In addition, we are concerned the current measurement areas maybe too vague, such as whether standards have been built into products and/or deployed. Specific interoperability needs, similar to the Interoperability Standards Advisory (ISA), should be leveraged and measures should be selected for those needs. The interoperability needs considered should be limited to begin this framework but should represent a balance of clinical scenarios that occur across the care continuum. Some examples to consider may be:

- 1) Care Coordination: Support a Transition of Care or Referral to Another Health Care Provider (C-CDA content standard, Direct transport standard, IHE and HL7 FHIR[®] query standards)
- 2) Public Health: Reporting Administered Immunization to Registry (HL7[®] 2.5.1 IG for Immunization Messaging)
- 3) Operational Efficiency: Receive Electronic Lab Test Results (HL7[®] 2.5.1 LRI IG)
- 4) Patient Engagement: View/Download/Transmit clinical summaries (C-CDA content standard), use of patient generated content

4) What, if any gaps, exist in the proposed measurement framework?

The proposed framework currently addresses standards adoption and use, but would provide greater value if the measures also addressed the quality of the data and its usability to improve outcomes.

To measure the quality of implemented standards, ONC should look to leverage and aggregate information from existing validation tools, such as SMART Scorecard and other C-CDA validators. IHE USA suggests ONC explore the feasibility of employing such scoring mechanisms on a large scale for the purpose of the framework.

5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

In addition to the stakeholders identified to support data collection, IHE USA recommends adding the Centers for Medicare and Medicaid Services (CMS) as they are collectors of metrics from the Meaningful Use and the Quality Payment Program, which may be leveraged by the framework. Specifically to Objective 2, IHE USA suggests adding federal and state public health agencies, including but not limited to CDC, as their registries may be a source of data for measuring interoperability.

6) Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?

Data holders listed are likely already collecting some of the data around these measures but are not likely doing so in a consistent way across all groups. A major challenge will be defining a normalized, common core of measurements and data definitions for these data holders to collect. Harmonization of a uniform set of metrics with clear definitions on what data holders will need to support is necessary. ONC mentions the use of surveys as the best

approach of their data collection for the next few years. While this will be additional work for data holders to complete, IHE USA suggests this approach is reasonable as it provides both the best vehicle to include stakeholder input, and to allow for uniformity in the type of data collected across these stakeholders.

Challenges may also arise if the measures identified are too rigid in regards to the versions of standards measured. When new versions of a standard are released, ONC should consider measuring the old and new versions concurrently, with the ability to consider these metrics in aggregate where necessary (e.g. C-CDA 1.1 or C-CDA 2.1).

7) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

Reporting on an annual basis sounds both reasonable and feasible. If reporting occurred less frequently, too much of a gap would exist to allow for meaningful interpretation of the status of interoperability standards in the healthcare community. More frequent reporting could create undue burden. Furthermore, to help alleviate any potential burden, IHE USA recommends ONC provide an efficient and simple vehicle for submitting measurements within the framework.

8) Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?

To determine standards to include in the measurement framework, IHE USA recommends a process of exploring the top use cases/categories for information exchange and identifying standards based on these use cases. As a first step, some categorization of the use cases could be explored before refining to the standards within these use cases. Use cases can be gleaned from the existing ISA Interoperability Needs, or determined by soliciting stakeholder input. To help begin the consideration of use cases, IHE USA suggests exploring use cases in the categories listed under our response to Question 3. There are already common categories that exist within Meaningful Use.

Once the categories are established, ONC can serve as the convener of stakeholders for that category to refine measurements related to a specific use case category. These groups need to be specific to the use cases and care settings in which exchange occurs.

ONC should also explore processes to understand, identify, and align data sources that are already in place in EHRs with the use cases. While this may not be the only source of data collection for these measures, it may serve as a starting point in understanding the current capabilities of data holders to report on the standards to be monitored.

9) How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

To ensure the sustainability of this framework, IHE USA suggests a public-private collaborative with ONC serving as the conduit for these efforts. IHE USA recommends ONC set up a collaborative environment similar to that of the Standards & Interoperability (S&I) Framework to collaborate on standards for measurement and common definitions for reporting. This collaboration will be necessary to determine how data holders organize their data in their respective systems. This will inform requirements for how to collect data for this framework.

The previously mentioned processes (in Question 8) should be leveraged to guide the selection of standards for measurement. By conducting a use case review, ONC may identify standards that are used frequently and have overall clinical relevance. In determining the measurements for the standards, both quantity and quality should be considered for areas of measurement. IHE USA recommends exploring a maturity model to define the levels of progress for an interoperability standard related to the integration and use of the data for clinical purposes; we suggest ONC consider the [Continuity of Care Maturity Model](#) as a foundational model to build from, or using a scorecard approach (i.e. [C-CDA Scorecard](#)).

10) What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?

First, IHE USA recommends defining conformance and the levels of conformance measures. We suggest conformance to mean a system’s ability to meet all of the “SHALL” requirements associated with a standard or specification. Any exclusion of these SHALL requirements would be non-conformance. Customizations including additional optional fields but also meeting the SHALL requirements should also be considered as conformance.

Validator tools, such as the C-CDA scorecard, can serve as a mechanism to measure conformance of standards in production. With other standards having fewer complexities than C-CDA, it may be feasible to create similar validators for other interoperability standards, such as registry reporting. The [HIMSS Immunization Integration Program](#) may provide guidance on how to validate immunization registry reporting or query standards.

Another mechanism for tracking the level of conformance with standards is through the [ConCert by HIMSS™](#) interoperability certification program. ConCert by HIMSS™ tests and certifies health IT products from vendors committed to advancing interoperability and enabling secure, reliable transfer of data within and across organizational and state boundaries. This automated testing and certification program verifies that, once certified, a product is capable of exchanging health information securely and reliably with other certified products. ConCert by HIMSS™ relies on tightly constrained interoperability specifications based on national standards including relevant profiles developed for the IHE Technical Framework specifications, and the ONC Health IT Certification Program criteria. ConCert certification supports both query-based exchange and DIRECT exchange with the addition

of the provider directory. The ConCert by HIMSS™ program is currently exploring the implementation of surveillance to ensure the deployed certified products continue to support the interoperability standards that the products were tested and certified against. Additionally, the vendor systems that have achieved ConCert by HIMSS certification could be used to further analyze standards implementation and conformance.

IHE USA recommends some level of surveillance or audit would be necessary to best measure the customization and conformance of standards in production. While validation tools can automate some aspects of conformance, audits on certified products would further verify conformance of standards in production.

We appreciate the opportunity to submit comments on the 2017 ONC Proposed Interoperability Standards Measurement Framework. 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 depth. 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.

Thank you for your consideration.

Sincerely,



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President, IHE USA



David S. Mendelson, MD
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Michael J. McCoy, MD
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