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June 20, 2017

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 729-D
Washington, DC 20201

Submitted Electronically

RE: Public Comment on ONC 2017 Measurement Framework

Dear Office of the National Coordinator for Health IT:

On behalf of the American Immunization Registry Association (AIRA) we are pleased to submit comments on ONC's **Proposed Interoperability Standards Measurement Framework** dated April 2017. These comments are a compilation of the collective input of our members which include over 75 organizations representing public health Immunization Information Systems (IIS), IIS implementers and vendors, non-profit organizations and partners.

AIRA's general comments are presented on the following pages, called out by page number and section within the Measurement Framework as appropriate. We also made every effort to respond to the questions posed by ONC at the end of the document. Please contact Rebecca Coyle, AIRA's Executive Director, with any questions: coyler@immregistries.org.

AIRA greatly appreciates the efforts of ONC to coordinate the adoption of standards across agencies, and we look forward to supporting our members and partners in similar measurement efforts.

Sincerely,

A handwritten signature in blue ink, appearing to be "R. Coyle", is located below the "Sincerely," text.

Rebecca Coyle MEd, Executive Director
American Immunization Registry Association (AIRA)

Comments on the ONC Proposed Interoperability Standards Measurement Framework

By: AIRA

General Comments:

The title of this document might over represent what it includes. It reads as less of a measurement framework and more as a proposed survey of EHR/health IT practices. Some sections of the document point to a future state that addresses more of a true framework. For example, the following is found on page 9:

To implement this proposed measurement framework, ONC plans to coordinate efforts among various stakeholders who are data holders to help define pertinent terms (implementation, use, and transaction); establish which interoperability standards to focus on; determine how to measure; and track the implementation and use of interoperability standards. Health IT developers and exchange networks are best positioned to provide the needed data to create measures. End users such as providers are not well positioned to capture (or even know about) this data nor are they necessarily the most accurate sources for these data.

Also, there may be inconsistent use of the term "end user". When first mentioned, it indicates that an "end user" is a person, but is that really what the authors want represented when capturing data? For example, for software deployment, do they want to measure provider organization deployment data or actually individual person user data? If the latter, the variability in defining "end user" may introduce such variation between stakeholder that the data becomes useless. It seems unlikely that individuals at the same organization (using the same instance of a product) will be different in their ability to use the functionality.

Responses to select questions posed at end of document:

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?

Although it may represent a needed starting point, the data returned in the proposed data collection approach is essentially inferred self-report data, where an end-user's use is inferred by a health IT developer, and self-reported by this developer. This method may not ultimately prove to be accurate or comprehensive. It is difficult to know what would incentivize health IT developers to do the work to gather and report these data. The document would be stronger

if it articulated the value to health IT developers as well as providers/end users. Typically, health IT developers are primarily driven to enhance the usefulness of their software for their customer base. Emphasizing the tangible benefits for provider end users may help motivate health IT developers to report this data.

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

It may be better time spent to develop an automated measurement process to actually test implementation and use (as well as accurate use) of a standard. This would vary depending on what standard was being measured, but ideally, there should be a way to capture this information in a valid, testable, repeatable, universally comparable way.

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?

Overall, the approach is nicely structured and separates implementation of standards from use of standards.

The definition under Objective 1 sounds a bit like what could be gleaned from CHPL, but maybe the intent is something slightly different. This difference or overlap may need to be explored a bit more. Maybe CHPL could be enhanced to accommodate the current gap this is designed to fill so that comprehensive data is located in a single location.

The Use Measures, specifically suggested measure 2.c, may be difficult to discern consistently across organizations and implementations. For example, an upstream configuration change may result in the underlying exchange standard to be impacted when that was not the intent. The end result to a health IT system expecting to receive the data is what appears to be a customization change to the standard or a non-conformant implementation.

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

There are two major gaps in this measurement framework.

First, IT development organizations can only be expected to see at most half of the interoperability picture, and in many cases less than this. The other partner (e.g. public health) provides a critical perspective on the conversation that will not be captured. Furthermore, many IT development organizations do not have full control over how the software is deployed, upgraded, configured or used. As it is typical for IT to only actively engage when problems are reported by users, they often assume that no feedback from their users means the interfaces they developed are working correctly.

Second, we have found self-reported data to differ from direct-measured data when asking system administrators how well their software meets technical standards. This problem stems from the lack of definitive technical measures, difficulty in framing questions that can accurately capture meaning of the measure, the challenge of placing these questions in front of the right people, and the problem of responders answering questions that they don't really know the answer to. Direct measuring forces consistent definition of what exactly is to be measured, allows for third party verification, and ensures consistency across responses.

Closing both of these gaps are major challenges. Engaging both sides of these interfaces would require a large expansion in scope, and direct-measurement requires dedicated resources and costs that far exceed those of a survey.

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

ONC may want to consider adding Public Health as a stakeholder, given that Public Health is a recipient of these data and may have insights into how well a standard is implemented.

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?

Ideally, standards that are cited in existing rule and regulation, such as Meaningful Use Stage 3, should be prioritized for early measurement. Accurate and broad implementation of these standards has immediate and practical implications for providers and health IT.

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?

This will vary substantially by domain, but maintaining ONC's current transparent process, convening diverse groups of stakeholders for input, providing documents that allow for public comment, and integrating comments as they are received will help the measures to 1) measure the most important aspects of interoperability, and 2) build investment across stakeholders to actually participate.

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

Unfortunately, "conformance" is difficult to define in the field. Fundamentally, any existing exchange of data that is live in a production setting can be considered "conformant" to the requirements of the trading partners. In some cases, we know that exchanges may not

actually be able to conform to national standards due to local variability in policy, regulation or law. For example, a national specification may call for the exchange of Social Security Number as a patient identifier, but some jurisdictions may be legally bound to not exchange the SSN. We think it's important that existing integrations which meet the needs of both trading partners should not be penalized if they don't meet the letter of a national standard. This is particularly critical for long standing integrations that have been optimized for trading partners but yet may not meet a national specification. End users and the patients they serve may be better served by preserving existing integrations rather than promoting the implementation of a new national standard which doesn't come with a defined beneficial increase in functionality.

A better question may be to ask if an integration is utilizing the most robust standard available to all trading partners involved. For example, if a public health agency supports multiple versions of a standard it may be more important to ask in the most advanced version aligns with the national standard (keeping in mind some local variation may be required) and whether or not a particular integration is using the most advanced version available to all trading partners (regardless of whether it worked "out of the box" or required some local customization).

We must also keep in mind that resource limitations may prevent a timely adoption of standards. Particularly for existing integrations, a lack of resources at one or multiple trading partner sites may result in a delay in implementation. When faced with limited resources, an organization will often prioritize the development of new integrations over upgrading existing integrations which meet their current needs. We would not like to see this fact adversely affect the conclusions drawn from data captured. As in Meaningful Use, it may be important to define a concept like "active engagement" to also capture the number of integrations "queued" to migrate to new standards as soon as resources are available.

It should be noted that "customization" is itself an ambiguous term. Is this document looking to capture information about where an integration has extended a standard (i.e. More data is flowing that is covered by the national specification) or contradicts or incompletely implements a national standard? Clarification would be appreciated.