The Office of the National Coordinator for Health Information Technology

PROPOSED INTEROPERABILITY STANDARDS MEASUREMENT FRAMEWORK

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Introduction

In 2015, the Office of the National Coordinator for Health Information Technology (ONC) released *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* (the Roadmap). The Roadmap lays out a series of "calls to action" and "commitments" aimed at focusing public and private efforts toward the Roadmap's 2024 end-state where nationwide interoperability enables a learning health system. The Roadmap identified the importance of measuring different aspects of interoperability to inform how much progress towards achieving an interoperable learning health system. Moving towards a set of uniform and trackable nationwide interoperability measures is essential to demonstrate progress towards achieving the Roadmap's goals (see pages 48-51 of the Roadmap). Measuring interoperability is also essential to monitoring progress towards a goal set by Congress. In the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress declared a national objective to achieve widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide by December 31, 2018. If this objective is determined to have not been met, then a report will be issued that identifies barriers to achieving widespread interoperability and recommends actions that the federal government can take to achieve the stated objective.

The purpose of the Proposed Interoperability Standards Measurement Framework (the Framework) is to determine the nation's progress in implementing interoperability standards in health information technology (health IT) and the use of the standards as a way to measure progress towards nationwide interoperability. Additionally, the Framework will help identify specific barriers to standards implementation and use that need to be addressed. Given that standards play a critical role in interoperability, it is essential that ONC measures the implementation and use of standards when exchanging health information. This document outlines ONC's proposed approach to measuring standards supporting interoperability. Key measurement areas that ONC has identified include: tracking whether interoperability standards are contained in health IT products and services; and the subsequent use of standards by end users[1] (e.g., providers), including whether end users are customizing their use of the standards.

The potential industry benefits from pursuing this measurement framework would be three-fold: 1) to inform the evolution of the Interoperability Standards Advisory (ISA)[2]; 2) to inform updates to the ONC Health IT Certification Program[3]; and 3) to inform stakeholder decision-making. For example, such information could help industry and policymakers better understand a standard's readiness to be referenced in procurements or regulatory requirements, as well as implemented into products. Exchange networks will be able to identify trends in the implementation and use of standards in order to make informed decisions about future strategic direction. Measuring standards customization/conformance will provide insights into the variability in how standards are implemented in the field including where this variability is occurring and potentially impeding interoperability.

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[1] An end user is a person actually using the health IT product. The types of end users who have access to a health IT product will vary by product. For instance, care managers, in addition to other clinical providers, may be users of health IT products focused on supporting care coordination.

[2] The ISA is maintained by ONC and is a coordinated catalog of standards and implementation specifications that are available for use by the health IT industry to meet interoperability needs.

[3] The ONC Health IT Certification Program is a voluntary program for the certification of health IT standards, implementation specifications, and certification criteria adopted by the U.S. Department of Health and Human Services (HHS).

Feedback Requested

ONC is seeking public comments on its proposed interoperability standards measurement framework and how to best engage data holders and other relevant stakeholders in implementing the proposed framework. In the standards measurement framework, the term "standards" is used to refer to both standards and accompanying implementation specifications. By engaging with various health stakeholders, such as health care providers, payers, health IT software developers, health information exchange organizations, medical associations, and consumers/patient groups among others, ONC hopes to develop a measurement framework that is realistic to implement while providing an accurate assessment. While reviewing the proposed measurement framework, please consider the questions posed at the end of this document and submit your responses during the public comment period.

Measurement: Current State

Stakeholders' current capabilities to measure interoperability standards vary significantly across the health IT ecosystem. This variability presents significant challenges to tracking national interoperability progress on the implementation and use of standards. The variability of current capabilities in the ecosystem is based on a number of factors discussed below.

Standards Implementation

An analysis was conducted on behalf of ONC to determine the best sources for obtaining standards implementation and use measures and entailed having discussions with a variety of key health IT stakeholders. Based on this analysis, health IT developers and exchange services appear to be the most reliable data holders of this information. Most health IT developers and exchange networks have similar capabilities to track the implementation of standards in their products and services. They usually track which versions of their products have a specific standard implemented and the number of users that have a version of a product with a standard implemented in it. However, the following factors can affect a developer's ability to accurately measure implementation:

- *Lack of information*: Developers may lack up-to-date information on which version of their product a client has implemented. Locally-deployed/client-server products, for instance, often give control to users to determine if and when to upgrade to a new version. Users sometimes skip versions if they do not see sufficient value in the latest upgrade. While developers often receive information that an upgrade has been completed, the information appears to be imperfect.

- *Indirect sales*: Sales partner relationships also factor into the accuracy of information available to the developer. For example, resellers may not notify the health IT developer when the reseller's clients upgrade product versions.

Standards Use

The most significant variability in the capabilities of health IT developers and exchange services relates to tracking the use of standards when electronic health information is exchanged. The differences are based on a number of factors, including, but not limited to*:*

- *Architecture*: The architecture (i.e., cloud versus client-based, federated versus centralized, exchange networks provided by developer or a partner organization) of the product or network can impact how and what information can be tracked. System or network architecture can drive what is able to be electronically tracked centrally and the level of flexibility to track new items. For instance, some federated architectures do not have

the capability to directly track the volume of transactions or other use-related statistics. (Note, the term "transaction" does not refer to a HIPAA transaction; instead, it more specifically refers to the electronic exchange of health information between two parties.) However, such federated networks can gather the data from individual nodes through surveys or other mechanisms. Networks with centralized infrastructures often are able to centrally track certain electronic measures. Networks that centrally store data have a greater ability to provide information about the content and vocabulary standards that are utilized, while networks that provide central routing services usually do not "look inside" the package/payload and will not be able to provide information on the content and vocabulary standards.

- *Development decisions*: Health IT developers have made differing decisions about the comprehensiveness and level of granularity to build into their measurement capabilities.

- *Access to the data*: Where capabilities have been built into a product to measure end user utilization of the standards, sometimes only the end user or health IT developer can access the information. In other instances, the health IT developer has created a mechanism to centrally track the information. For example, some health IT developers obtain data from end users for areas the health IT developer prioritized for measurement (often those focused on meeting national program requirements such as the Medicare and Medicaid Electronic Health Record Incentive Programs or various quality measurement programs).

- *Variability in standard implementation*: Variability in how a standard is used in the field can also cause one developer's health IT system to not be interoperable with another health IT developer's system that has implemented the same version of the standard. This lack of interoperability is driven by multiple factors, including, but not limited to: 1) optionality in standards and 2) customizations made by developers in their product, including those made during implementation at provider sites. However, there is limited experience to date in tracking the conformance and customization of standards implemented in the field. A number of existing national surveys touch on standards, but no existing source or combination of sources provides the full spectrum of data required to develop national measures of uptake and use of key and emerging standards.

Proposed Interoperability Standards Measurement Framework Overview

The framework includes two measurement objectives, describes goals for each objective, defines measurement areas for each objective, and lists the audiences for each measure.

ONC has identified, through discussions with various key stakeholders, two key measurement areas where moving towards uniform implementation and use measures as outlined in the framework will support the ability to measure nationwide interoperability progress:

1) Implementation of standards in a health IT product;
2) Use of standards, including customization of the standards, by end users to meet specific interoperability needs.

Objective 1: Interoperability Standards Implementation in a Health IT Product

The objective to measure interoperability standards implementation of a product focuses on understanding a standard's lifecycle, which refers to the process by which standards are developed, implemented, and then subsequently used. This also includes understanding how a standard enters a health IT developer's product development plan to the standard becoming part of a product deployed to end users. Identifying and tracking the measures within the following measurement areas will allow stakeholders to understand the progress related to standards implementation across the health IT ecosystem.

To measure the implementation of interoperability standards across the steps in the implementation life cycle, the following components should be captured nationally on an annual basis:

a. *Standards in development plans*: Health IT developers and exchange networks should publicly report what standards are in their development plans and for what purposes. This will allow the tracking of emerging standards as health IT developers and exchange networks update their development plans to reflect their future activities.

b. *Standard implemented in health IT product or service*: Health IT developers and exchange networks should publicly report what standards have been implemented into particular versions of their products or services that are not already derivable from the <u>ONC Certified Health IT Product List</u> (CHPL)[4]. Tracking the progress of a standard from being listed in development plans to being implemented into products and services is an important step for following the emergence of a standard into the health IT ecosystem.

c. *Product version with standard implemented deployed to end users*: Health IT developers should publicly report how many end users have deployed a product version or subscribed to a service with a standard implemented.

Objective 2: Use of Standards by End Users to Meet Specific Interoperability Needs

Measuring the use of interoperability standards moves beyond understanding what standards are implemented in products and services that are theoretically available to end users, to knowing what standards are actually being used by end users in deployed systems. The focus on use will allow the identification of instances where a deployed standard is not being used by end users. This could result from a number of factors, including, but not limited to, insufficient education on how to use the functionality enabled by the standard, difficulty finding or using the functionality, or lack of other users with whom to exchange. Tracking the use of standards will provide a window to where interoperability is and is not occurring and allow stakeholders to investigate the reasons behind the success or failure of using standards.

Consideration also has to be given to the type of standard being tracked (transport, content, vocabulary), the particular standard being used, and the interoperability need it is addressing. For instance, to measure vocabulary standards used in an exchange transaction, the health IT developer or exchange network would need access to the message content, which may not be available. The particulars of the standards being used can impact what can be measured at what point in the transaction chain.[5]

In addition, stakeholders occasionally experience interoperability issues among products that have implemented the same version of a standard or implementation specification. Tracking interoperability issues that occur after a standard is implemented in the field and being used will help stakeholders identify where variability and optionality are creating issues and determine how to resolve their differences.

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[4] The CHPL is an online interactive listing of certified health IT that allows users to search certified products and see product attributes.

[5] For example, Health Information Service Providers (HISPs), which use the Direct protocol to exchange messages, are not able to look at the content of messages because they are encrypted, preventing HISPs from tracking the content and vocabulary standards being used. The point of origin or receipt of the Direct message would have to be targeted to understand what content and vocabulary standards were used in the message.

As Standards Developing Organizations (SDOs) develop and modify existing standards, ONC encourages them to consider this measurement framework, as relevant, to help enable better standards implementation and use measure tracking. In the near term, the significant variability in health IT developers' and exchange networks' measurement capabilities determines what can be feasibly measured. Recognizing this, the best strategy is an approach that accommodates the fact that some organizations will have more robust capabilities while others will only be able to report on a subset of measures or provide partial data.

Measurement Areas

To measure the interoperability standards used, the following components should be reported nationally on an annual basis:

a. *Standard used by end user*: Health IT developers and exchange networks should publicly report what percentage of end users (who have access to a product version with a standard implemented) have actually used a particular standard. This will enable stakeholders to identify standards that have been deployed widely but not used by end users. It will also provide insights for standards where tracking the volume of use is not informative.[6] Clearly establishing what counts as "use" will be a vital step, and ONC will coordinate with health IT developers and exchange networks to help establish measures that are both meaningful and capable of being tracked.

b. *Volume of transactions by standard*: Health IT developers and exchange networks should publicly report the volume of transactions by standard. Tracking trends in the volume of transactions by standard will allow stakeholders to identify the trajectory of growth or decline of a standard's use, which standards are most heavily used, changes in usage patterns over time, and the identification of outliers. Today, organizations have varying definitions of what constitutes a transaction. ONC plans to coordinate efforts among various stakeholders who are data holders to help establish what counts as a transaction, as well as the measurement frequency, as an essential step for all measures that track the volume of transactions. For transactions that include multiple steps, measurement should focus only on the most pertinent piece of the transaction that allows tracking if information was sent, received, found, and integrated. For instance, in a query using the Integrating the Healthcare Enterprise (IHE) profiles, the focus could be on the number of documents successfully returned and not on other steps in the process, such as how many systems were queried to find a matching patient.

c. *Level of conformance/customization of interoperability standards*: Stakeholders have limited experience to date in measuring this area. As a result, additional foundational work is essential to identify the best approach(es) to track the conformance and customization of standards after implementation in the field. ONC requests stakeholder feedback on the best methods to measure this area.

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[6] For example, knowing that 50 percent of providers used a particular provider directory standard may have more value than understanding the raw number of times a provider directory was queried using a particular standard.

Table 1: Proposed Standards Implementation and Use Measurement Framework

Objective	Goal	Measurement Types	Measurement Areas	Data Holders
1. Understand if specific standards are built into health IT products and available to end users (i.e., the implementation lifecycle)	Improve knowledge of implementation level of standards within health IT products and services (i.e., which standards are most commonly available)	Implementation specification measures	a. Standard on development plan	• Health IT and Health Information Exchange (HIE) Developers • Health Information Organizations (HIOs) and other exchange networks (e.g., Surescripts)
			b. Standard implemented in health IT product	• Health IT and HIE Developers • Exchange Networks
			c. Product version with standard implemented deployed to end users	• Health IT and HIE Developers • Exchange Networks
2. Understand the use of standards and how they are deployed into production systems to meet specific interoperability needs as well as the level of conformance or customization of standards during implementation	Track the use of standards by end users in deployed systems (i.e., which standards are most commonly being used and understand how often and in what manner standards are customized during implementation)	Use measures	a. Standard used by end users in deployed systems	• Health IT and HIE Developers • HIOs • Exchange Networks • Healthcare Organizations
			b. Volume of transactions by standard	• Health IT and HIE Developers • HIOs and other Exchange Networks • Healthcare Organizations
			c. Level of conformance/ customization of standards (to be developed)	• HIOs and Exchange Networks • Healthcare Organizations • Standards Developing Organizations (SDOs)

Data Collection Sources and Mechanisms

Accurately measuring the implementation and use of interoperability standards in health care will require a multi-pronged approach and data from multiple industry stakeholders. Stakeholder support and strong participation across the ecosystem will be vital to this measurement framework's success. ONC will work with stakeholders who are data holders to promote the creation and use of the measures outlined in the framework as well as the public reporting of the results. We are soliciting input regarding how best to work together to achieve these goals.

One existing reference source about interoperability standards utilization in products is captured by the ONC Health IT Certification Program through the CHPL . However, as the CHPL's information is not a complete picture of the industry, use of this proposed measurement framework can enable stakeholders to focus on measuring areas of interoperability standards implementation into health IT products and services that are not currently accessible through the CHPL.

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.

In the next couple of years, the best path to collect data regarding the implementation and use of interoperability standards appears to be from surveys of health IT developers and exchange networks in addition to self-reporting by stakeholders who are data holders. ONC will work with stakeholders fielding surveys to promote implementation and alignment with this proposed measurement framework. ONC intends to enter into and continue partnerships with organizations fielding existing or developing new surveys to add relevant implementation and use questions to the survey instrument. This survey approach will be modeled after the successful partnerships ONC has developed with industry/external stakeholders. ONC encourages stakeholders to adopt and use the proposed measurement framework and to publicly report on the measures. Additional foundational work is needed to establish the measurement approach for tracking the conformance and customization of standards implemented in the field, and ONC encourages stakeholder feedback on how best to track this important area.

In three to five years, ONC seeks to coordinate with stakeholders to define uniform electronic measures of the implementation and use of standards that can be built into health IT developers' products. This approach will provide more accurate information compared to self-reported survey data, and automating the process will ease the burden of capturing and reporting the data.

Questions

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?

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

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?

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

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

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?

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?

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?

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?

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