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July 31, 2017

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to submit comments regarding the proposed Interoperability Standards Measurement Framework published this spring by your office. We welcome the chance to lend our voice to the topic of standards as this issue continues to be one of paramount concern for our members.

CHIME is an executive organization serving nearly 2,400 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation.

Background

ONC outlines its stated purpose for the proposed Interoperability Standards Measurement Framework as being one which "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." It furthermore aims "to determine the nation's progress in implementing interoperability standards as a way to measure progress towards nationwide interoperability."

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) makes clear that Congress "declares it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018." The law is clear that Congress' intent was to not only foster data exchange among disparate systems but also "to use the information that has been exchanged using

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common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes."

CHIME understands that Congress has mandated that ONC establish metrics no later than July 1, 2016 to determine if interoperability is being met. Recognizing this is a statutory requirement, CHIME appreciates ONC's work to inform the state of interoperability. We agree with ONC that this needs to be a multi-pronged approach. Nonetheless, we unfortunately know that this goal will not be achieved by December 31, 2018, given the current state of interoperability and the lack of a uniform set of standards, not the least of which is a way to accurately match patients to their records. This issue alone represents one of the biggest hurdles around interoperability. CHIME is pleased to offer our ideas for beginning to measure interoperability in a more robust manner. Below we outline how we believe this can be accomplished in response to the questions posed by ONC

Responses to Questions Posted by ONC

Q1. 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?

A1. We believe if standards are going to be measured that it makes sense to begin with a voluntary approach, acknowledging though that a voluntary reporting process may not elicit the requisite sample size to draw accurate conclusions. But, we also are unclear how a mandatory process would be operationalized. Would this occur as a requirement on vendors as a requisite for obtaining certification? It would seem to us that measurement needs to involve the providers and we are leery of any mandates on providers. If providers could obtain credit under a reporting program – so long as this was not compulsory – this may be an avenue to explore. This could be considered under the Medicare Incentive-based Program (MIPS) for clinicians but we don't believe another requirement under Meaningful Use would be welcomed so long as the program remains in a pass / fail state as is the case for hospitals. It's also not clear to us how data might be collected from providers since they generally rely on their vendors to incorporate the requisite standards into their products. A survey of providers to offer their perspective on interoperability (what's working well and what is not) – while not specific to the use of standards – may offer additional insight into the overall state of interoperability.

Further, while we have concerns with just measuring standards (as detailed further below), we believe to the degree that the measurement of the use of standards is done so in a manner that facilitates "apples to apples" comparisons will be more helpful. For instance, LOINC lab results using different test equipment and reagents will elicit different results and thus measuring the use of standards for data exchanged by different providers may not provide meaningful comparison.

Recognizing that ONC must by law help ascertain the state of interoperability, we do not believe the use of standards has evolved to the point that they are worth measuring because they are used broadly across multiple use cases and measuring their use will not elicit a clear picture of interoperability. For example, the CCD-A used for communicating the admission of a patient to the hospital following a visit to the emergency department is not the same as one that is used to communicate a visit to a primary care practitioner, which also varies from a visit to a specialist. As one member depicted their present-day challenge, his institution is trying to move a CCD-A from one system to another but is continuously bumping into challenges. They must verify each piece of data coming from ambulatory vendor A coming into inpatient vendor B. This CIO has resigned themselves to the fact that – in his own words – "they are better off keying in the data rather than having to sit there for every single CCD-A for every patient whether they want this data or that to come into the system." From a measurement standpoint, it paints a complicated picture of how the use of an HL7 standard would be measured to elicit a true comparison across providers as enabled by their respective products.

<u>Should ONC move ahead with their standards measurement strategy, we first recommend they work collaboratively with the healthcare industry to prioritize use cases and then work their way through those to determine the way standards are used in each setting by identifying a more granular set of standards used which could be measured.</u>

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Second, we recommend that before ONC embarks on any wide scale measurement activities, they test this out in the form of a pilot first to better understand the utility of the data collected. Specifically, ONC should examine the impact of user customizations and how this affects interoperability and the measurement of it.

Third, we recommend ONC explore the practicality of surveying providers (and other stakeholders) on their biggest challenges around interoperability and the biggest successes to help better understand where the most significant challenges remain. CMS credit should be given for participation where possible.

Q2. What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

A2. We appreciate the need to measure the use of different standards and agree this can be helpful, but only to a limited degree. ONC proposes to measure interoperability using the following three components and report results annually:

1. Standard used by end user – this would involve what percentage of end users have actually used a particular standard;
2. Volume of transactions by standard – this would involve vendors and exchange networks publicly reporting the volume of transactions by standard;
3. Level of conformance/customization of interoperability standards – this would address how much variability there is among standards used.

We outline our ideas further under A4.

Q3. 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?

A3. We believe the proposal ONC has laid out only addresses a subset of the overall landscape that is needed to render a more complete picture on the state of interoperability. The language in the statute defines interoperability to mean, "the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes."

We recognize that Congress has outlined their definition to focus on standards used to "exchange" information, however, we believe the Congressional intent encapsulates not only standards for the way data is presented, but also other key ingredients essential for facilitating a coordinated care experience. From our perspective, this includes but is not limited to; focusing on communications standards and the way data is exchanged; how patients are identified; how we handle consent to share information; and how trust is established when sharing information. Taken together, we think measuring just standards is thus premature.

Q4. What, if any gaps, exist in the proposed measurement framework?

Q4. As noted above, we believe just focusing on standards will offer an insufficient picture of the state of interoperability. We believe that interoperability involves: 1) getting relevant patient information to the clinician who needs it; 2) moving the right information between providers, health systems, and patients; 3) and includes data, context, communication, trust, permissions, and usability. We furthermore believe that there are several key principles needed to be in place before national interoperability can be realized These include a need for:

- Open standards: Optional extensions allow for innovation in a standardized way.
- Universality: For EHRs, implementations of a transaction and use case must work universally: with any trading partner; using any brand/version of a certified system; and without further implementation costs. For networks, any health information exchange (HIE) must be able to participate and interconnect fully without unreasonable barriers to entry for core functions.
- Context: Use cases (scenarios) drive what data is needed and data requirements for each use case are standardized.

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- Trust: This consists of: securely identifying patients with 100% certainty; employing non-repudiation so the data can be trusted and employing validation for the sender and receiver; facilitating authorizations for sharing patient information; and indemnification in the case of situations that are outside an entity's control (i.e. cyberattack).
- Seamless communication: For EHRs, each new trading partner should require: no new interface mapping by technical IT staff; no compendiums; no new implementation fees by EMR or interface providers; and no new costs for each trading partner added, or each new scenario or document exchanged with existing trading partners. HIEs must seamlessly interconnect.
- Usability: EHRs should be capable of: sending and receiving all core documents and data fields defined for each supported scenario; ignoring optional data if it cannot be used; selecting and presenting needed information in context for the clinician; automatically processing/analyzing received data for clinical alerts and related purposes; and users should not have to read through a formatted summary of care to find the nuggets of information they seek.
- Affordability: Since cost can be a significant barrier that is sometimes interpreted as data blocking, each new scenario, document, or trading partner combination must not cost thousands to implement, it should be as simple as adding a new email address (like DIRECT), and it should support robustness of multiple scenarios (like HIEs).

We recommend ONC consider the key principles outlined above and factor these into the overall assessment on the state of interoperability.

Q5. Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

A5. As we have already noted, it may be hard to elicit the type of information you are looking for from providers, given how dependent they are on their vendors. We are also unclear as to whether HIEs would be able to dictate which standards are used.

Q6. 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?

A6. See response to A5.

Q7. 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?

A7. Before this can be determined, as noted above, we believe a pilot test to determine the feasibility and utility of measuring standards interoperability is warranted first.

8Q. 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?

A8. See response to A7.

Q9. 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?

A9. As noted above, we believe standards measurement should revolve around use cases and will vary by setting; even then we worry this will not offer the most complete picture of the state of interoperability.

Q10. What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?

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A10. This should be determined in conjunction with stakeholders once the use cases have been defined.

Conclusion

CHIME is pleased offer our ideas on measuring interoperability. We look forward to remaining an engaged stakeholder as ONC operationalizes the interoperability provisions stemming from the MACRA, as well as, those contained in the 21st Century Cures Act.

Sincerely,

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Russell Branzell, FCHIME, CHCIO CEO & President, CHIME

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