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July 24, 2017

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

Dear Dr. Rucker,

On behalf of the more than 30 member companies of the Electronic Health Record Association (EHRA), we are pleased to offer our comments on the Office of the National Coordinator for Health Information Technology's proposed Interoperability Standards Measurement Framework (Framework). We appreciate this opportunity to provide input to establishing a framework for measuring interoperability and the use of standards.

EHRA has been working to identify opportunities for EHRA members to contribute to providing insight on the value and benefit of interoperability. Two initiatives are in progress:

1. **The impact of interoperability**

   EHRA supports efforts to further analyze the impact of interoperability through comprehensive research initiatives. Certainly, volume metrics alone do not paint the full picture (e.g., more is not always better, such as the requirement to send more data rather than the right data through documents). Moreover, interoperability is just one of the contributing factors that drive outcomes, cost, and other measures.

   Rather than waiting for such analytics to become available from independent organizations, EHRA asked its members to share success stories where the introduction of interoperability made a positive difference to their clients. EHRA is pleased to share Interoperability Success Stories: The Journey Continues, which is available online. We look forward to adding additional success stories in future versions.

2. **Interoperability volumes**

   Alongside other approaches, EHRA supports efforts to provide insight into interoperability volumes. Such insights can help clarify when standards are ready for national adoption and to be included in a widely-supported standards floor for sentinel use cases. This research may also identify areas where interoperability has shown to be effective but uptake has been limited. EHRA is exploring what types of volume data may be provided or supported by its members.

General Comments

This draft Framework is thoughtful and effectively reviews gaps, challenges, and opportunities. Although insight on standards-based interoperability volumes is important, in the context of the 21st Century Cures law and generally the need to access and exchange data across stakeholders, the primary focus of this measurement framework should be on data availability. We suggest that it will be essential to perform in-depth, in-the-field research to truly understand the impact of interoperability.

We also recognize that interoperability is not always achieved using standards. Having an unstructured PDF is better than not having the data at all. That reality does not mean that we prefer non-standard methods. To the contrary. As we migrate toward an interoperability environment where the norm is access and exchange of structured, codified, clear narrative, rich data (including images) that is right-sized to the stakeholder's needs using an appropriate mix of transport and methods (messages, documents, services) enabled for both push and pull of information, the use of rich narrative which may include some non-standard, non-structured, non-codified formats should be recognized as having value.

Consequently, we suggest that a framework of measuring exchanges using standards should also address non-standard interoperability. This broader approach can help identify areas of focus to aid transition to a more standard approach that is both human and computer-readable across all systems involved and to get a fuller picture of how widespread interoperability truly is.

Having such a comprehensive view also contributes to the understanding of information blocking, particularly where information blocking may really occur and where, in fact, other factors affect the ability to interoperate. We support using a voluntary reporting approach that, based on a jointly agreed-to set of measure definitions, can provide further measurement of adoption and readiness.

We note that the measure definitions need to consider the scope of a "standard." A focus on "what standard is used" is not as helpful as "what profile or implementation guide is used" where more specific guidance is available (whether required for certification, generally available, or developed for very specific purposes). Considering this, we suggest that an approach that starts with use cases for data access and exchange, identifies access and exchange volumes for those use cases, and is then stratified by standard specifications used (inclusive of profiles, implementation guides, and/or proprietary) will yield the desired insight into the use of standards in interoperability.

As with any government or private sector initiative, we must prioritize and focus, or we run the risk of disjointed efforts and unrealistic expectations. We therefore urge ONC to work with the new Health IT Advisory Committee and the industry to identify the most critical, sentinel use case on which to focus our attention in terms of measurement, research, and action. For example, clinical decision support (CDS) as a use case is too broad, but transitions to Long-term Care or Lab Orders and Lab Results between ambulatory providers and an independent lab are more focused use cases. Taking a use case approach will also start to put any measures in context as more in-depth analysis of impact becomes available over time, such as envisioned through the NQF Interoperability Measurement Framework being developed.

As the work moves forward, we urge ONC to carefully consider and take into account the potential burdens and opportunity costs on providers and developers associated with additional measurement; it will be important to carefully balance the burdens of measurement with expected benefits. In addition, as we are able to move from surveys to more automated reporting, we ask that ONC focus on guidance to the industry on voluntary and optional automated data collection well ahead of any definitive shift from surveys to automated collection.

With these thoughts to provide general context, we provide our responses to the specific questions posed by ONC:

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?*

   EHRA Response:
   Yes, voluntary initiatives are preferred.

   At the same time, using consistent measure definitions is essential to enable comparisons. We recognize providing an incentive to contribute the reports may be a challenge. However, as we believe that the provider community sees value in reporting on this topic as part of improving interoperability, similar to other quality reports, that they will in turn encourage their health IT suppliers to provide the necessary support. Also, the engagement of the provider community can then drive participation by all technology vendors, including non-EHR health IT and non-certified EHR technology, as interoperability involves many forms of health IT beyond EHR technology.

   We note that we do not suggest that individual providers are to report on the measures, rather that the healthcare organization they work for or are part of (healthcare system, hospitals, multi-provider practices, individual practices) submit the reports.

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Another challenge will be the roll-out of the ability to support measurement reporting, as not all users will have the needed tools available at the same time. Consequently, we must accept variations in reporting, particularly in the early stages.

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

EHRA Response:
We suggest that any volume measurements should be meaningful and easily obtainable from metadata already available on the transactions, rather than involving separate surveys collecting these or other data. Surveys without supporting tools would be onerous and unlikely to be answered, while collating appropriate reports from existing data should be easier to achieve.

A uniform measurement approach is essential to ensure data is collected consistently and is thus comparable. Independent industry initiatives would have a high probability to yield different definitions, methods, data requirements, and so on, which are unreasonable for software developers to support on behalf of their clients.

Reporting on interoperability capabilities from a software developer perspective (including interoperability created by healthcare organizations themselves) can be done at the time of the software release or, for those solutions subject to certification, through concurrent reporting (although not as a prerequisite to certification) at the time of the certification process. Then reports published through mechanisms such as CHPL.

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?*

EHRA Response:
We believe that the measurement framework includes various measures that are not essential, and that it should be further focused through identification of critical, sentinel use cases. We recognize that achieving this focus may be challenging; but, without focus, we run substantial risk of not being able to develop, implement, and deploy all desired interoperability.

Of the proposed six measures, we suggest that the following two measures are essential to understand whether standards are ready for national adoption into a certification program as part of a standards floor, or to assess areas of focus to encourage adoption where the impact of interoperability is clearly established.

   a. **Objective 1, Measure B - Standard implemented in health IT product -** We support reporting by the IT developer regarding the standards it supports (specific implementation guides and versions) for all use cases involving inter-healthcare

organization interoperability. This information can be published as part of release documentation and perhaps included on CHPL. However, it should be done separately from certification, as standards-based interoperability by non-certified technologies that provide interoperability are of interest as well.

Additionally we suggest that this measure include the networks the IT developer supports (e.g., eHealth Exchange, Carequality, CommonWell, HIE, etc.), including the applicable standards. There should also be a flexible process for updating standards used to enable product evolution.

b. **Objective 2, Measure B - Volume of transactions by standard -** We support enabling IT, in a voluntary manner over a reasonable time period, and using standardized guidance supplied by ONC or applicable industry organization(s) to report on transaction volumes that are inclusive of standards used (down to implementation guides, profiles, versions) to transport across disparate organizations and are categorized by type of destination and/or intermediary system (e.g., same vendor system, through network such HIE, CommonWell, eHealth Exchange, Carequality, etc., or point-to-point different vendor system).

We note that the focus should be on the use case selected for data access and exchange, the volume of transactions (number of transactions), and the standard (implementation guide, version, proprietary) used. It is important to clearly define the unit of measure; e.g., number of documents, number of order transactions, or number of tests ordered, including or excluding acknowledgements, etc. To provide context, and begin to put the volumes in perspective, we suggest to report on the number of users and/or patients involved in these transaction volumes.

Also, we note that most standards do have a place on the transaction to include this information, but it may not always be valued or sufficiently utilized to fully provide this information.

Lastly, we suggest that the healthcare organizations are in the best position to provide reporting on this measure, using technology vendors' reporting mechanisms to extract the data from their systems. The rationale is that healthcare organizations own the operational data being extracted; and, larger organizations increasingly use multiple systems to support their needs where not one system has all the information, or there is overlap in reporting that would not reflect the intention of the measurement.

Again, as suggested in the draft framework, we need to allow sufficient time for developers to add such reporting capabilities, mindful of other priorities to support client needs including work to enhance usability.

We have reservations with the following measures:

c. **Objective 1, Measure A - Standard on development plan -** We suggest that ONC not include this measure as plans may change over time due to changing client requirements and priorities.

   Communication of that information is best done in the context of vendor/client relationships to set appropriate expectations. Note that while some vendors communicate target delivery dates early, others will not do so until the product is formally announced as generally available.

d. **Objective 1, Measure C - Product version with standard implemented deployed to end users -** We are concerned with sharing client information at the suggested level of detail. Providing annual information on the percentage of clients that have certain interoperability capabilities could be considered. However, for healthcare organizations to report on what capabilities they have available, including self-developed capabilities on, for example, their website, would enable other stakeholders to understand potential interoperability opportunities with that healthcare organization. Our concern is that healthcare organizations own that information; as developers we are not comfortable sharing it ourselves, but we support healthcare organizations including this information as part of reporting their capabilities.

   We also suggest that similar to Objective 1 Measure B, that healthcare organizations report/publish the network(s) in which they participate.

e. **Objective 2, Measure A - Standard used by end users in deployed systems -** We suggest that if Objective 2, Measure B is pursued through instrumenting software, then Measure A is not necessary. However, if reported by the healthcare organization on the standard capabilities they have deployed and available to connect, to both inform other healthcare organizations about their capabilities and inform availability at a national level, that would be helpful.

f. **Objective 2, Measure C - Level of conformance/customization of standards (to be developed) -** We suggest that this measure is too complex for instrumentation or national surveys. Rather we suggest that this type of measure is best pursued through targeted research of specific use cases that explore the impact of interoperability using reasonable samples. Within such research there is a better opportunity to explore the contribution of the level of standards conformance to the impact of interoperability, e.g., is availability of data, regardless of format, more important than fully conformant, standardized data.

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

   EHRA Response:
   As part of our response to Question 3, we identified a number of gaps that would be helpful to address.

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

   EHRA Response:
   We suggest clarifying the role of standards development organizations (SDOs):
   a. Help assess/adjudicate where variations involve non-conformance
   b. Include new requirements to reduce ambiguity based on conformance assessments

   We also suggest clarifying that healthcare organizations can be IT developers, thus where the Framework applies to IT developers, it applies to those healthcare organizations that develop interoperability capabilities, not just configure and implement them.

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?*

   EHRA Response:
   We suggest that in general, volumes can be metered by the software providing the interoperability capabilities using transactions' metadata already available. However, we should not assume that EHRs are the best source for this, as integration engines or other capabilities are better suited to collect this information, particularly in larger organizations with multiple systems. We also note that the relevant metadata is not always populated accurately, or at all, considering historical (non-)use of this data.

   Some systems can already provide this type of data, while others may need to expand on their reporting capabilities or put these in place. We therefore suggest that a two-step approach should be considered: (1) measuring general volumes first, listing standards used; and (2) break volumes down by standard/implementation guide/profile or other format used, enabling sufficient time for capabilities to be put in place, and, in general, done on a voluntary basis.

   Regardless of approach, there will be a challenge to recognize double counting as both healthcare organizations and networks report on essentially the same transactions. Since networks do not necessarily cover all transactions, we tend to lean toward focusing on healthcare organizations to submit the reporting, while network data can be used for general context as to what flows through networks versus otherwise.

Even where IT developers do operate their clients' IT operations, IT developers are not the owners of the data, hence the need to obtain this information from healthcare organizations; IT developers would provide the necessary reporting tools to enable healthcare organizations to do so.

On the other hand, reporting of interoperability capabilities in generally available software versions should be done by the IT developers of that software, while healthcare organizations should report on deployed/implemented capabilities, effectively contributing to a directory of electronic contact points and associated capabilities.

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?*

   EHRA Response:
   We suggest that for new versions, reporting on capabilities can be done as the versions become available. Where support for newer standards is made available to older versions as well, annual reporting is reasonable. Although it could be reported along with documentation necessary for certification, the reporting should not be a prerequisite to certification since non-certified software should be encouraged to participate as well. Furthermore, having information available on all interoperability capabilities, particularly those that support critical, sentinel use cases, is relevant and should be encouraged, whether certified capabilities are used or not.

   Regarding reporting on agreed to volume measures, we suggest that yearly is reasonable, but that a breakdown on a quarterly basis would be helpful to get better insight considering the rapidly changing environment. We note that receiving data from various stakeholders is reasonable, but clearly can yield overlaps (e.g., provider organizations submitting data would overlap in part with networks submitting data). We suggest that data from provider organizations can provide the total context, while networks provide a different segmentation of a subset of that data.

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?*

   EHRA Response:
   We suggest developing measures around critical, sentinel use cases and, as standards evolve, focus over time on addressing additional use cases, rather than establishing and implementing measures across the full spectrum of interoperability.

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?*

   EHRA Response:
   We suggest that working in a public, open setting with involvement of all relevant stakeholders, including the newly formed Health IT Advisory Committee, is important. Establishing a dynamic roadmap that evolves over time, of the critical, sentinel use cases with associated interoperability capabilities/standards would be helpful, particularly to avoid too many priority-one initiatives in year one. EHRA is very interested in working with ONC to contribute to this discussion to identify reasonable, practical use cases to be addressed over time to establish such a roadmap.

   We note that the sample question of "How will standards be selected for measurement?" should be effectively flipped around. The focus should be on the interoperability use case/workflow and understanding what standards (versions, IGs, proprietary, etc.) enable data availability.

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

    EHRA Response:
    We believe that quantifying non-conformance is very difficult using general survey tools. To understand non-conformance, use of robust testing tools and properly sampled transactions are essential but not necessarily sufficient, as expert manual review would still be required, particularly as testing tools are maturing. Surveys may provide insight into where standards did not support use cases in general, based on anecdotal reports, but they cannot provide in-depth insight into the root causes of why there is non-conformance.

    The testing tools used in certification, while not necessarily comprehensive to all aspects of standards in use, would be a reasonable starting point to also measure consistency of what is in operational use, even if the health IT used was not subject to certification. Sampling as part of in-the-field research would allow for lower impact data capture as running every transaction through a recognized conformance test would not be practical and of limited benefit.

    The One-Click C-CDA Scorecard highlights that challenge as interpretation of its scores always requires review to understand the cause for any unexpected scores. Scores alone would not tell the story and could be misleading if such tools were deployed to monitor every transaction without focused analysis and interpretation.

Conclusion

Interoperable electronic health records are essential. Robust standards and implementation guidance

provide the foundation to enable consistent and predictable data exchange, but measurement of interoperability capabilities, with reporting by the owners of the data, must recognize that meaningful data exchange also occurs beyond certified, standards-based technology.

We look forward to continuing to work with ONC and other stakeholders to advance interoperability and support patient care through the best use of electronic health records.

Sincerely,

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.