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July 20, 2017

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Rucker:

Cerner Corporation appreciates the opportunity to provide comment on the Office of the National Coordinator's Request for Information regarding an Interoperability Standards Measurement Framework posted April 26, 2017 on ONC's HeathITBuzz blog ("ONC RFI").

Cerner's health information technologies connect people, information and systems at more than 18,000 facilities worldwide. Recognized for innovation, Cerner solutions assist clinicians in making care decisions and enable organizations to manage the health of populations. Cerner's mission is to contribute to the improvement of health care delivery and the health of communities.

Cerner's support and leadership in health IT interoperability have been well documented. We believe that every individual has a right to access their complete health record, regardless of where it's located or what system contains the data. It is immoral and unethical for any organization to block the flow of information that could help individuals — and their providers — make better-informed decisions about their care.

Many of the nation's greatest thought leaders in health IT will provide comment to the ONC RFI. In fact, Cerner associates participated in efforts of other organizations, such as the Electronic Health Record Association (EHRA), to provide a common perspective on the framework being considered. Cerner's individual response is intended not only to emphasize our support of your work and outstanding leadership, but also to outline what we believe is a necessary component to the foundation of measuring interoperability and specifically the role of measuring the use of interoperability within that.

On June 3, 2016, Cerner submitted a response letter to ONC's RFI regarding Assessing Interoperability for MACRA. We believe that the principles we outlined in that response also apply to a framework that focuses specifically on the use of interoperability standards. These principles help illuminate the potential value of proposed measures and the context within which their collection creates that value, thus clarify our perspective when responding to the detailed questions.

1. Interoperability measurements should be outcomes focused.
2. Measurement should center on clinical use cases that reflect transactions of value to the provider and the patient, focusing on the specific information needed for the relevant use

case, which must be normalized and adhere to standards that allow integration. Volume statistics do not provide a satisfactory answer to the question, "Did the provider have access to the actual data needed to deliver optimal care?"
    a. Measurement should be patient-centric, as patients receive care in very unpredictable patterns, not limited by organization or provider.
    b. Measurement should be disease and condition-centric, driven by real-world data needs.
3. Measurement definitions must be developed in a process transparent to the industry that includes all essential stakeholders.
    a. At a minimum, this includes: ambulatory providers (general, specialists, behavioral health, LTPAC), acute care facilities, health plans, public health and consumers.
4. The measurement must utilize a strong, sound methodology that would pass muster in an academic audience - and be readily understood by a consumer - and must be defined specifically to reduce the possibility of multiple interpretations of data.
5. The measurement definition process should be approached as an iterative, learning process.
6. Measurements should encompass not only data access activities (transactions between providers) but also structural aspects, including costs and difficulty of implementation.
7. The measurements should include heterogeneous systems on either end of these transactions; vendor-proprietary transactions and transactions between the same vendor's products do not reflect real-world needs, and must not be the sole source of the measurements.
8. To the greatest degree possible, measurement must be a byproduct of use; minimal effort should be required to collect data, assuring minimal disruptions to user EHR workflow.
9. When surveys are used, survey questions must be objective, both in practice and in perception, and must be blinded to reduce bias.
10. Any third party entities that perform surveys must have no conflicts of interests, including "pay to play" business models where the surveying agency receives money from the vendors being surveyed.

Of these principles, particularly the first and second principle need to be considered carefully as the questions remain when attempting to understand the impact of standards based interoperability whether outcomes were improved and whether the provider did or did not have access to the actual data needed to deliver optimal care.

In general, we believe and support that standards based interoperability does contribute to improved outcomes, and is essential to certain downstream uses, e.g., CDS. However, we are concerned that focusing too much or too soon on standards based interoperability only can make perfect the enemy of the good. For example, use of unstructured PDFs can get at least the data to the right provider in an easy to read format, while a standards-based C-CDA lacks some of the readability although is more structured and codified, i.e., despite the availability of structured data formats, unstructured exchange is still very prevalent to allow for data access. Such data availability should not be ignored. Consequently, we need to be considerate of defining and using interoperability standards measures that support a growth path to our ultimate goals of full semantic interoperability (well structured, codified where needed to enable clinical decision support, rich in content, e.g., images, yet can still be presented in a format that is easy to read by a human as well), while accepting the short-term realities of both syntactic

and semantic interoperability not being fully standardized. We suggest that a focus on sentinel use cases can provide the necessary, minimum context to perform measurements, in lieu of full impact analyses, that will provide insight into data availability for those use cases, as well as an understanding of the methods used to enable the data availability.

Recognizing that having some capability and volume metrics, as suggested in the framework, to begin the process while working towards understanding impact over time through targeted research, we suggest in general to focus on:

- Interoperability **use/impact** measures on the effect of presence/absence of data from other sources.
    - Address a dozen sentinel use cases to focus research/grants to understand the real impact/value of interoperability (e.g., cost, quality, patient engagement), including data availability and standards (implementation guide/profile, version) used. Examples may be in the cost savings around image sharing, quality of care/readmission rates of transitions of care to long-term care.
- Interoperability **access/exchange** measures on data availability:
    - Use the sentinel use cases identified above to focus volume and capabilities measures rather than selecting standards to assess their use. I.e., focus on data availability and what, if any, standards were used to make data available in support of the selected use cases. Context of the volumes is important to understand the level of interoperability that has been achieved and the trends of where we are heading. Is the access/exchange inter or intra healthcare organizations. Distinguishing between APIs by consumers is different than APIs used by providers within an organization, and different from APIs used across independent organizations (IDNs, healthcare systems, individual practices). These examples indicate a different perspective of interoperability, each relevant in their own right, that provides a collective understanding of interoperability in general. Therefore, we suggest to measure volumes of data exchanged/accessed by any means, any format, any semantics, whether part of a certification edition or referenced in the standards advisory or not, related to the sentinel use cases, stratified by:
        - Volumes sent/requested vs. received/responded.
        - Distribution of standard/implementation guide/profile or proprietary specification used to format the transactions.
        - Distribution of exchange/access affiliation or method used:
            - Access/exchanges through vendor-neutral networks (e.g., CommonWell, Carequality, Direct, eHealth Exchange, etc.)
            - Access/exchange through state HIEs
            - Peer-to-peer transactions that do not fit in either of the above (e.g., vendor-specific networks, dedicated connections, etc.)
            - Consumer mediated portal access.
            - APIs – Smart Apps
            - Venue of care

      We note that definition of reporting buckets must be simple while allowing for apples to apples comparison. Only measuring at the core standard level is not helpful as too many variant interpretations can exist. If we measure, we need to measure at the profile/implementation guide level where the core standard is effectively part of an “other” bucket.

- We suggest to include measurement of active, operational participation in networks that enable data sharing supporting the sentinel use cases, as well as measuring the percentage of external partners (those who have responsibility for a user's patient but are not part of the user's organization, e.g., across IDNs, from private practice to hospital or laboratory) engaged in electronic access/exchange for the sentinel use cases.

- Interoperability **standards** measures on readiness for endorsement or as consensus standards for an evolving standards floor (minimum set of standards that all HIT must support to be certified for specific use cases/interoperability needs) focusing on the essentials.
  - Volume measures stratified as suggested above can provide input whether there is sufficient adoption of emerging standards to include in the evolving standards floor.
  - We support a request to IT developers to make publicly available:
    - SDO-developed standards/implementation guides/profiles versions supported in their GA versions (including test results against agreed to test harnesses where available) for both format and vocabulary/terminology.
    - Non-standard capabilities that are publicly available as well for other IT developers to use.

    However, we note that this information cannot be used as an approximation of volume of adoption, rather only availability of certain interoperability capabilities as of a certain point in time.
  - We suggest to also request healthcare organizations to make publicly available the interoperability capabilities they have deployed to provide transparency into what interoperability capabilities are available and emerging from both an IT developer and healthcare organization perspective.

We believe that only the combination of these essential use/impact and exchange/access measures can inform which interoperability standards need to be adopted at a national level and in combination of an agreed to standards floor can practically create important clarity on whether IT developers are engaged in information blocking or not.

Cerner appreciates the hard work of you and your staff to advance true interoperability. As always, we stand ready to offer our insights and experience. Please feel free to contact me if you have any questions or if we can be of further assistance.

Sincerely,

John Travis MA, CPA, FHFMA
Vice President, Regulatory Research and Strategy
Cerner Corporation

Responses to 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?

   Cerner: Yes. As interoperability standards measures focused on volumes are particularly important to determine whether a standard is ready for national adoption (maturity) and in combination with an understanding of impact/value (e.g., to assess whether a standard should remain part of a national program) can put the volumes data in context, a voluntary approach should be feasible. It is critical though this be use case driven to provide focus on data availability and how it is achieved, while avoiding a limited perspective on which standards are adopted, Any reporting must be based on a commonly agreed to definition to ensure the ability to compare apples to apples. Such definitions need to be clear on the unit of measure and the granularity of information. We suggest that it is important to be able to stratify volume measures based on:

   a. Access/exchanges through vendor-neutral networks (e.g., CommonWell, Carequality, Direct, eHealth Exchange, etc.)
   b. Access/exchange through state HIEs
   c. Peer-to-peer transactions that do not fit in either of the above.
   d. Consumer mediated portal access.
   e. APIs – Smart Apps
   f. Venue of care

   We suggest this must be at the level of implementation guides/profiles that are tailored to specific use cases rather than the highly flexible underlying standards such as HL7 V2, V3, FHIR.

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

   Cerner: We believe that any efforts to collect these measures should be based on the software managing the interoperability at hand for volumes and one time reporting by the IT developer on the standards (implementation guides, profiles) it supports in respective solutions and versions). We suggest that the actual volume reporting should be done by the users of the solutions, e.g., healthcare organizations or networks, as they would know which of their interoperability capabilities can provide the best reporting on their aggregate volumes. Additionally, understanding network participation is equally important as it shows capabilities from a provider perspective.

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?

   Cerner: We want to suggest that the main focus should be on use cases and then what standards/implementation guides/profiles/proprietary specifications are used to support interoperability for that use case, rather than the other way around that the proposed framework seems to suggest focusing on the standard first and measure

where an identified set of standards is used. Focusing on specific use cases first can enable both an understanding of data availability and what is used to make it available.
Within that context, we do not believe that all proposed measures are essential to achieve the main objectives for measuring the use of interoperability standards/implementation guides/profiles as well as proprietary specifications in support of the use cases identified. We suggest that the following measures are helpful and essential for the sentinel use cases:

i. *Standard implemented in health IT product.*
We suggest this should not only be specific about the base standard supported, but the specific version, implementation guide, or profile, while it should include other publicly available proprietary specification as applicable.
We suggest this documents the product version as of when the interoperability capability was enabled.
ii. *Volume of transactions by standard.*
We suggest that this must be stratified as clarified in our response to Question 1.

We do not believe the other measures are helpful or essential for the following reasons:

i. *Standard on development plan.*
This measure does not create any more insight into adoption and maturity of standards. When reporting on the standards (and publicly available proprietary methods) that are Generally Available this would be sufficient.
ii. *Product version with standard implemented deployed to end users*
We are not convinced that the value obtained from this information, whether a percentage from HIT developers or numbers of users that have it available, is worth the measure.
While it would be feasible to get general statistics on percentage of users to whom support for a particular standard/implementation guide/profile was deployed, we believe that to obtain actual numbers of users who have the ability to operationalize a particular should be obtained from the users, perhaps including reasons why it was not deployed yet. However, having volume information on actual use, which can be enabled through software more easily, in combination with use/impact measures from research/grants would provide the relevant information to make the necessary decisions.
iii. *Standards used by end users in deployed systems*
We suggest that the volume of transactions by standard covers this measure already, thus not necessary to ask separately.
iv. *Level of conformance/customization of interoperability standards*
We believe that this is too complicated to measure through surveys or "metering" at a level that is providing value considering the anticipated investment. It is unclear what the scale/unit of measure would be and how a partial use of standard vocabulary would compare with either the absence or addition of certain fields/vocabulary/etc. We also note that a transaction may be conformant to the standard (e.g., NCPDP Script 10.6)

but not to an implementation guide (e.g., Surescripts' Script 10.6 Implementation Guide). We therefore believe that this may be better addressed as part of targeted research to understand the impact of conformance and/or customization, as well as improvements in testing tools. Not economical feasible: exceptions, etc. configuration variations.

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

Cerner: Other than our suggestions in questions 1 and 3, we do not see further gaps to this standards focused framework, rather that we do not believe the need to pursue certain measures, as identified in question 3, to support the benefits outlined in the Introduction.

As the definition of standards measures progresses, there must be clarity on the level of granularity that is desired. We do not believe that measuring at the "standard" level is necessarily helpful (e.g., HL7 V2, HL7 V3, of HL7 FHIR). It must go down to the version, implementation guide, or profile to understand how interoperable we are relative to syntactic and semantic interoperability, where even that may be a challenge depending on tightly either of these is bound to specific vocabulary.

Understanding of the sender vs. receiver perspective is important to distinguish. While a sender may support a particular standard/implementation guide/profile, if the receiver does not then access/exchange may not occur, or not according to a desired standard. We also suggest that both volumes on how much one sends/requests vs. receives (unsolicited) should be addressed. We note that the overall access/exchange communication is relevant, not necessarily the individual communications to ask, acknowledge, receive, handshakes, etc. Thus, including every HL7 V2 acknowledgement message is not relevant for the big picture understanding of interoperability, although may be of interest in targeted research settings. The measurement definition should be very clear on what exactly is counted and relevant.

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

Cerner: It is unclear how SDOs can contribute measurement data. Already most if not all standards include a version and specific guide/profile being used. It is more up to the implementers to actually value that. On the other hand, there must be clarity that Health IT Developers include Healthcare Organizations that self-develop and/or implement 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?

Cerner: Software can be enabled to measure the essential volume measurements, but may require time for everybody to have their software enabled accordingly. We suggest that healthcare organizations should report on these volumes, while they can turn to their HIT developer to assist to run or submit reports as the healthcare organization already must authorize disclosure of this data. This would be akin to

quality measure reporting.

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?

   Cerner: Annual reporting is reasonable for a product's ability to support standards/implementation guides/profiles and publicly available proprietary specifications, but consideration should be given to report the volume based measures on a quarterly basis to better see the trend to inform annual review of updates to the standards floor. We suggest that an annual report with a quarterly break-down would provide a reasonable starting point.

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?

   Cerner: We believe that the focus should be on sentinel use cases to focus the combination of use/impact, access/exchange, and standards measures. However, it is reasonable for volume measures and publication of interoperability standards to collect those measures across all access/exchanges. I.e., report for each data access/exchange the volume sent, received, and what standard/implementation guide/profile/proprietary transport and format was used. Reinforce that most important measures are on data flows that cross organizational boundaries, which will then capture all standards in play.

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?

   Cerner: We suggest that collaborative groups such as CommonWell, Carequality, EHRA, Direct Trust, Argonaut provide appropriate representation to validate completeness, practicality, and appropriateness of proposed measure definitions. We suggest that the EHRA in particular would provide an appropriate forum on how to report on IT developer specific measures. These organizations supplemented with provider representatives could provide input how to roll-out the ability to report on volumes.

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

   Cerner: We are concerned that this will be very difficult to measure. Measuring conformance on sample transactions during validation processes, e.g., certification, are more manageable, while conformance testing of all transactions in production settings will quickly get in the way of data availability goals. We also must recognize that different implementations against the same standard/implementation guide/profile may yield different, but equally valid interpretations. This is more significant for foundational standards and less true for specific, nationally adopted implementation guides/profiles. Considering that complexity, we are not convinced

that this measure is worth pursuing through national surveys or volume measures. We believe that the other measures can provide sufficient insight into interoperability adoption and conformance in combination with robust test tools available during the early validation phases of the solution roll-out.