July 20, 2017

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services

Submitted electronically to: https://www.healthit.gov/policy-researchers-implementers/interoperability/Proposed_Interoperability_Standards_Measurement_Framework_Public_Comments

Re: Proposed Interoperability Standards Measurement Framework Public Comments

Dear Dr. Rucker:

The American Medical Informatics Association (AMIA) welcomes the opportunity to submit comments regarding the Office of the National Coordinator for Health Information Technology's (ONC) Proposed Interoperability Standards Measurement Framework.

AMIA is the professional home for more than 5,400 informatics professionals, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA members play a leading role in moving basic research findings from bench to bedside; evaluating interventions across communities; assessing the impact of health innovations on health policy; and advancing the field of informatics.

AMIA supports the development of a Measurement Framework for Interoperability Standards. This draft framework was thoughtful and rightly identified current gaps, challenges, and opportunities. We believe that various important policy questions would be informed by data collected as part of such a Measurement Framework, as well as provide a window into our progress toward nationwide interoperability. For example, as the industry moves from local coding for laboratory results to LOINC, away from a legacy set of standards based on the Consolidated Clinical Document Architecture (CCDA) towards a Fast Health Interoperability Resources (FHIR)-based ecosystem, it will be important to understand the details of this transition.

At the same time, we strongly recommend that Measurement Areas have a positive benefit/burden ratio for those being measured, either by delivering high value for the data collected or by making measures easy to report. Conceptually, AMIA further recommends that measurement and measure reporting:

1) Be automated wherever possible;
2) Initially, target high-value standards/use cases; and
3) Deliver value to those stakeholders being measured.

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We underscore the need to have the benefits of measurement outweigh the costs, and that there is sufficient effort to develop and implement automated measurement solutions. As the work moves forward, we urge ONC to be very mindful of the potential burdens associated with additional measurement and to carefully balance the burdens of measurement with expected benefits. As the field moves from surveys to more automated reporting, we urge ONC to focus on guidance to industry on what may be used in voluntary and optional automated data collection before there is any definitive shift from surveys to automated collection. It is essential that measurement not become an end in and of itself and that we recognize the costs to clinicians, developers and others in developing and implementing automated solutions.

Objective One Measurement Areas

AMIA supports the proposed measures outlined in Objective 1. We anticipate that individual developers and the wider industry would benefit from data obtained from reporting on Objective 1 Measurement Areas, and we anticipate that reporting on those measures would place minimal burdens on health IT developers and exchange networks.

Objective Two Measurement Areas

Objective 2, which focuses on the "use of standards, including customization of the standards, by end users to meet specific interoperability needs," will require substantial examination, broad stakeholder input, and – potentially – much work to realize a positive benefit/burden ratio. As a general observation, we anticipate Objective 2 Measurement Areas will rely more heavily on clinical end-user reporting then is envisioned by the proposed Framework to provide valuable, actionable data.

AMIA recommends ONC develop both quantitative and qualitative measures for Objective 2 Measurement Areas. As an initial step, ONC must understand which standards are used to facilitate interoperability for clinical use cases that are widely considered to have high-value for patients. Focusing on high-value use cases and associated standards will constrain the measurement options and limit the reporting burden. An example is (1) RxNorm for e-prescribing and sharing information across organizations, and (2) LOINC for moving lab orders and results information between EHRs and lab systems, as well as sharing across institutions. We see these two examples as high-value scenarios, especially given that standards for diagnoses and procedures are nicely adopted across the industry.

We note that quantitative measures should be automated to assess the use of controlled medical terminologies (i.e., Section I of the Interoperability Standards Advisory). This may require software that can execute over a given sample of data using built-in measure logic, rather than leaving it to individual assessments that could lead to varying interpretations.

Automated measurement may also require changes to the standards themselves. To have an accurate understanding of how different standards are used, we anticipate that ONC will need to work directly with Standards Development Organizations (SDOs) to ensure that pertinent artifacts,

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sent or received, include the identifiers of the standards used to create it as associated meta-data. Automated measurement and reporting is necessary because while clinician end-users and their health IT support are likely to be a better focus point of measurement, they are likely to have limits in what they can report, especially for Objective 2, given their variable and uneven knowledge of standards, versioning, etc.

In addition to automated measures, AMIA sees an opportunity to glean valuable information on the level of conformance/customization of standards by conducting retrospective reviews using valid and reliable quantitative and qualitative data collection methods. These reviews would enable ONC to contextualize transaction-level and other quantitative data to better understand (1) if clinically relevant data were available to the clinician when and where they were needed, and (2) which standards were used to facilitate specific instances of interoperability (or not). Rather than try to develop measures for the myriad of ways interoperability may be occurring, we recommend an approach that looks to understand where interoperability is needed, and then assess whether it is occurring.

Such an approach, described in more detail in Appendix B, would rely on claims data to identify referral partners/patterns of providers who share large numbers of patients, and statistical samples to target retrospective reviews. These reviews would then examine whether expected interoperable data sharing, using specified standards, occurred for patients with health conditions that necessitated receiving care from multiple providers. Using a retrospective review would also enable an assessment of why expected interoperable data sharing did not occur. If the sampling is representative, such an approach should offer insight into the level of interoperability across the nation, and address whether interoperability was in place among providers who share a high volume of patients. This approach would help ONC assess the use of standards to facilitate the availability of data and the impact of interoperability where it is likely to influence the care of patients most – among the clinicians and organizations that treat them routinely.

Below we outline our recommendations in more detail, and we address ONC's specific questions related to this RFI. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC for the opportunity to comment and look forward to continued dialogue.

Sincerely,

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President and CEO
AMIA

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Appendix A: AMIA Response to RFI Questions

Questions for Feedback	AMIA Response
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?	Whether a strong or weak incentive structure is necessary, we do not anticipate that participation will occur widely across industry participants on a strictly volunteer basis. Ideally, the reporting system creates a high ratio of value/burden. Further, if reporting is easy, then we expect higher rates of participation with a decreased need for strong incentives. However, if the accumulation of value is not shared among those being measured, or reporting is not easy, we anticipate that incentives will be necessary to encourage participation in the reporting system and we suggest a focus on positive incentives. At one end of the incentive spectrum, ONC could consider reporting industry-based measures as part of its Conditions of Certification, especially for Objective 1; at the other end, ONC could provide a public acknowledgement for those reporting system participants who do so voluntarily.
2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?	As discussed in the transmittal letter, AMIA sees value in a quantitative and qualitative approach to standards measurement. We see an opportunity to glean valuable information, pertinent to both Objective measurement areas, by conducting retrospective reviews.

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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?	Yes, we anticipate that if properly designed and implemented, ONC could help coordinate an "Interoperability Index" to better understand whether the technical requirements are in place to support interoperability.
4) What, if any gaps, exist in the proposed measurement framework?	We anticipate that a stronger emphasis on clinical data holders and clinically valuable scenarios would improve the utility of the framework. Additionally, ONC should be mindful of various scenarios when data is derived from systems outside the purview of Certification, and therefore not subject to consistent standardization.
5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?	AMIA recommends Standards development organizations (SDOs) be included as stakeholders. As noted, we anticipate that SDOs will need to adjust their standards (and their development process) to accommodate automatic reporting envisioned by ONC.
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?	AMIA agrees with the ONC's assessment of limitations regarding the current state of measurement, and we anticipate that those limitations are important factors in determining where to focus energies. We reiterate the need to engage with SDOs who will need to modify existing and future standards to ensure that every artifact sent or received includes the identifiers of the standards that were used to create it.
7) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the	We agree with the goal of annual reporting. Reporting on a more frequent basis should be feasible for automated measures.

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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?	See answer to question 9.
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?	We recommend ONC host a series of roundtables with specific stakeholders to garner input on the prioritization of standards. These roundtables should identify the relative feasibility of reporting on certain standards over others, (i.e. the "low hanging fruit") as well as those standards needed to execute specific use cases that have high clinical value initially.
10) What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?	We anticipate that this exercise will require substantial effort, with little return on investment if "conformance to standards is the sole objective." Rather, we recommend ONC use a retrospective review to glean additional data and information that could help policymakers and other stakeholders understand which standards were used (or not used)

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	towards a more comprehensive view of the state of interoperability "in the field." See Appendix B under Methodology.

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Appendix B: Retrospective Review for Interoperability Standards

Below is a proposed strategy meant to help ONC measure standards use in the service of interoperability. Our approach uses a retrospective review to accomplish the following aims:

- Enable measurement that could determine whether, and to what extent, nationwide interoperability is occurring;
- Develop measures of interoperability without creating burdens on providers and healthcare organizations;
- Prioritize measures that reflect the patient and clinician experience; and
- Focus on care / referral patterns that share high-volumes of patients.

Rather than focus on volume-based measures, such as how many messages were exchanged or what % of patients participated in information exchange, we believe a better approach would seek to understand if the outcomes enabled through interoperability had occurred. Such an approach would include a retrospective review to answer questions, such as: Were clinically relevant data available when and where needed? If not, why not? Which standards supported this data availability?

Our proposed strategy would work as follows:

- Target Population for the Review
    - Using current, publicly available CMS claims data, select a set of patients with clinical conditions that would be expected to benefit from well-coordinated care, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, as well as mental and behavioral health conditions and patients with multiple conditions. These conditions could span chronic care, acute care, long-term / post-acute care and mental/behavioral healthcare use cases.
    - Another population that could be targeted, and may be easier to pursue from a measurement perspective, is provider dyads or provider networks with a high volume of shared patients. Again, currently available CMS claims data could be used to identify providers that have the highest volume of shared patients, under the assumption that it is important to understand the kinds of interoperability that exists between entities sharing, for example 10,000 patients as opposed to only a handful of patients.

- Methodology: Determine Desired Data Flows
    - For each of those identified conditions/providers, define key expected data flows – including expected standards – that would likely improve care. The goal is to identify what data should be available to optimize the patient's care, identify which standards were used to make the data available, as well as reasons for its unavailability / absence. For example:
        - Were outside lab results available in a timely manner?

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        - If so, how were they made available? (e.g. fax, Direct, via HIE, "other")
        - If not, why not? (e.g. lab refused, patient not in HIE, MPI match failure, "other")
    - Were outside images and reports available, using what standards?
    - Were outside summary records (CCDs) available?
    - Were other providers' notes available?
    - How many records were requested by the Emergency Department and how were they were obtained?
    - Are all codes valid?
        - Check against current version plus all deprecated codes; Invalid codes might inform customization practices, handling of old codes, other issues (like the practice of removing "." from all ICD codes)
    - Number of distinct codes in use
        - This will help to ascertain whether a standard is being used to its full extent or only partially
    - Top 50 or 100 most frequently occurring observations (e.g. most frequently ordered labs or prescribed medications) should be relatively consistent across sites/vendors
    - Create a graph with individual codes (or "chapters" of a standard) on x-axis and volume of coded observations on y-axis (This will be similar to top 50 or 100 but more comprehensive). When compared across sites/vendors, resulting pattern of peaks and valleys should be relatively consistent.
    - Graph volume of coded observations over time (say monthly or quarterly). Time is x-axis and number of observations is y-axis. The expectation is that of relatively steady volume of observations over time. Look for unexplained slopes, peaks, valleys, other abnormalities.
  - For each of these data flows, it would be important to capture the relevant entities and vendors that were involved. For example, if outside labs were available, who was the lab, and who was the EHR vendor. Likewise, if data were not available.

- Methodology: Fielding
  - Select a statistically large enough sample of patients whose care covers the desired measurement domains (e.g., chronic care, acute care LTPAC care) and/or select a statistically representative number of providers with high volumes of shared patients.
  - Distribute a set of questionnaires, administered by trained auditors to get meaningful data at a modest cost.
  - Reviews could be conducted by CMS or third-party organizations, such as the Joint Commission, or be included as part of ONC-Authorized Certification Bodies in-the-field surveillance activities.

Results from this kind of review, could then be aggregated to inform policymakers and stakeholders on the current state of interoperable data sharing, and which aspects of the Interoperability Roadmap need enhancement, including standards, governance and best practices. This review could also supplement what we know about the general performance of certified health IT, the interactions between certified and non-certified health IT, and help clarify the incidence of information blocking.