July 31, 2017

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

Dear Dr. Rucker,

The Alliance for Nursing Informatics (ANI) advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. ANI, in collaboration with the American Nurses Association (ANA), has reviewed the Office of the National Coordinator for Health IT (ONC) Proposed Interoperability Standards Measurement Framework. In that spirit we offer our comments as nursing stakeholders.

ANI and ANA fully endorse the objective of this proposed framework 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 and identify barriers to nationwide interoperability.

ANI and ANA commend ONC for the evaluation efforts put forth in the “Proposed Interoperability Standards Measurement Framework” (the Framework) 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.” Measuring the progress of nationwide interoperability is critical to achieving a learning health system as we move towards a person-centered, connected health/connected care ecosystem. The Framework also proposes to “help identify barriers to standards implementation and use that need to be addressed.” The identification of barriers and challenges that need to be addressed lends itself to the development of an interoperability “toolkit” which is one of the several recommendations proposed in the following comments to ONC’s Proposed Interoperability Standards Measurement Framework.
The recently released ONC report, *Standard Nursing Terminologies: A Landscape Analysis* (May 15, 2017), is an illustrative example of the challenges and complexities associated with achieving the Framework’s goals. Although the *Standard Nursing Terminologies: A Landscape Analysis* report provides an excellent and comprehensive “landscape assessment to better understand the current state and challenges associated with using terminologies and classifications to support nursing practice within health information technology (health IT) solutions”, there is no precise assessment or quantification of the use of nursing terminologies by vendors and healthcare settings. While the report quantifies this information by indicating that “through a literature review and interviews with terminology owners, this assessment examines the current state of development and usage within the 12 Standard Nursing Terminologies (SNT) recognized by the American Nurses Association (ANA)” (Page 4)¹, there is not an emphasis on the benefits or limitations of interoperability, including the patient at the center, for shareable, comparable data across the connected care ecosystem. Therefore, ANI supports the proposed Framework’s objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability. ANI is able to support collaborative engagement amongst the appropriate stakeholders in the development and reporting of these measurement areas.

ANI and ANA would also like to kindly request feedback regarding the synergy between the ONC Framework to measure the progress towards nationwide interoperability and the recent draft report from the National Quality Forum (NQF), *A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy, Environmental Scan Report* (March 31, 2017). According to the NQF draft report, “NQF has taken on a project at the request of the Department of Health and Human Services (HHS) to develop a measurement framework that reflects the potential impact of interoperability” (NQF, page 2).² The important and interrelated work of both ONC and NQF provides a holistic view of interoperability. ANI and ANA encourage a collaborative approach between all stakeholders (inclusive of the healthcare consumer and care givers) to leverage and bridge these two efforts as a mechanism to achieve the “vision for how interoperability is necessary for a ‘learning health system’ in which health information flows seamlessly and is available to the right people, at the right place, at the right time. Our vision: to better inform decision making to improve individual health, community health, and population health” as

cited in *Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure* (ONC’s 10-Year Interoperability Concept Paper).  

**Objective 1: Interoperability Standards Implementation in a Health IT Product**

We concur with the emphasis and level of specificity for the measurement areas outlined in objective 1, such as the transparency of reporting how many end users have deployed a product version. We believe it is crucial to measure variability in the implementation of standards supporting interoperability, both in planned and actual development. Obtaining a baseline and central tracking with transparency to all is key.

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

As stakeholders, we believe it is important to track interoperability issues across organizations and between and among health data sharing networks to trend results and investigate lessons learned for improvement and transparency.

Towards that goal, we recommend the development of an interoperability toolkit to assist organizations in measuring and testing the level of conformance/customization used by vendors or others to meet specific interoperability needs. This would include a list of available standards for comparison to functionality used by a particular vendor and activities required to implement key and emerging standards. Such information can also assist in purchasing decisions. Variation in Health Information Exchanges (HIEs) impacts the robustness of interoperability as an artifact of the population needs. This variation should be considered as a reason to require testing of interoperability regardless of the specific needs of a particular HIE.

**Please see our responses below addressing the specific questions provided 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?**

Yes, voluntary reporting system is best but it may only achieve selective input and insight. The mechanism for reporting should also include other means to collect data beyond Health Information Exchanges (HIEs) and other data sharing networks and platforms. Since the value for interoperability is

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ultimately defined by the patient, it might also be helpful to obtain reporting from individuals and families. This would also support individual empowerment in healthcare.

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

The Interoperability Standards Advisory could seek feedback from professional groups such as ANI. ANI recommends a collective representative group to act as a steward for understanding and evaluating level of maturity and adoption and would be willing to participate in the collective. In addition, these professional groups could assist in conducting formal evaluations that may perhaps include site visits.

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?

For this initial period, we believe that the proposed measurement framework does include the correct set of objectives, goals and measurement areas.

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

One noted gap is the omission of tracking the ‘non-use’ of standards. It would be helpful to understand why there is a conscious choice to not use standards and if the choice is due to barriers.

In addition, we encourage that future versions of this measurement framework emphasize improved patient outcomes in a connected health and care ecosystem as its ultimate goal. The framework should include key care activities where nurses and other clinical providers depend on HIT interoperability to support effective longitudinal care planning, care coordination and learning health activities.

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

The stakeholders listed in Table 1: Proposed Standards Implementation and Use Measurement Framework are sufficient to support collection of needed data for the Objectives and Measures as currently defined. We also encourage this work to be expanded to include the broader stakeholders defined in the ONC document, A Shared Nationwide Interoperability Roadmap version 1.0 available at https://www.healthit.gov/policy-researchers-implementers/roadmap-calls-action-and-commitments-organized-participant-group.

We encourage the ONC to consider methods to obtain balancing feedback for Objective 1 by adding healthcare organizations as a stakeholder. As we collectively improve knowledge of the level of
implementation for standards within health IT products and services, end-users, including nurses who are selecting and evaluating health IT products and services, will offer valuable feedback regarding the utility of these standards on outcomes, including advancing connected health, learning health system activities and the quadruple aim.

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?

We encourage ONC to recognize the kind of support data holders, especially healthcare delivery organizations, may need to effectively monitor progress of interoperability standards. We recommend ongoing education and/or toolkit development to support education for the impact of the adoption of interoperability standards, including the type of standard being tracked (transport, content, vocabulary), the interoperability need it is addressing, and the magnitude of adoption impact on the connected care ecosystem. Specific use cases (as outlined in the Interoperability Roadmap) may be helpful to articulate the value for interoperability for multiple stakeholders, including the person at the center of care.

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?

We appreciate the recommended sequence of measuring the implementation and use of interoperability standards and its relationship to the annual ISA, and believe a more explicit linkage to national progress will reinforce the value of the ISA to a variety of stakeholders. Building on our comment to Question 4, there is significant value in understanding the volume and barriers of “non-use” of standards.

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?

We agree that measurement should focus only on the most pertinent piece of the transaction and recommend focusing on downstream activities in the transaction chain, such as responses to requests for data or receipt and use of data, rather than tracking only data sent without confirmation of the effectiveness and success of that transaction. Quantifiable criteria should be established that can be
used to include or exclude standards that should be monitored. These criteria should focus on variables such as maturity and anticipated impact of the standard. The RE-AIM framework (Reach, Efficacy, Adoption, Implementation, and Maintenance) may provide a useful conceptual foundation for the definition of important criteria when selecting standards that should be monitored (http://re-aim.org/about/applying-the-re-aim-framework/).⁴

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?**

As noted above, we recommend the use of a framework with transparent, measurable criteria to select standards for measurement. For example, these criteria may include that a standard needs to target at least 2 types of clinical settings for it to be *selected* for monitoring. Reporting requirements should then be derived from these established criteria to drive consistency. For instance, in the example above, monitoring should require *reporting* from at least 2 types of clinical settings.

We also encourage ONC to produce a clear definition of the phrase “end-user” with specifications for calculating measures such as “percent of end-users” to increase consistency in reporting. “End-user” may be interpreted differently (e.g., individual clinician, patient, analyst, or organization) depending on the standard being used or data being exchanged. We suggest the term “end-user” be clarified, possibly in relation to the definitions of stakeholders being used.

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

We recommend the RE-AIM framework or another appropriate framework be used to guide the development of measures and the toolkit. For example, the implementation and maintenance concepts from the RE-AIM framework could serve as a useful foundation to establish measures of conformance or customization. A RE-AIM checklist and a RE-AIM Scoring Instrument which could be adapted for establishing interoperability standards measures are available here: https://rtips.cancer.gov/rtips/reAimCriteria.do and here: http://re-aim.org/wp-content/uploads/2016/09/checklistdimensions.pdf.

ANI and ANA commend the ONC’s focus on interoperability standards and a measurement framework to monitor and evaluate our nation’s progress in this important domain. We appreciate the opportunity

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to contribute to the conversation on this framework, particularly as it relates to impacts on patients for improved systems that promote coordinated patient care.

Sincerely,

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