BCBSA RESPONSE TO REQUEST FOR COMMENTS ON THE PROPOSED INTEROPERABILITY STANDARDS MEASUREMENT FRAMEWORK

The Office of the National Coordinator for Health Information Technology (ONC) solicited responses to ten (10) specific questions regarding the Proposed Measurement Framework. Below are the Blue Cross Blue Shield Association's (BCBSA) responses to those questions. BCBSA is a national federation of 36 independent, community-based and locally-operated Blue Cross and Blue Shield companies (Plans) that collectively provide healthcare coverage for one-in-three Americans

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?**

   Comment: A voluntary reporting approach to standards measurement may not provide statistically valid, reliable data to inform policy decisions and the resulting administrative and operational actions to address presumably identified deficiencies, especially if limited to reports from Health IT developers and exchange networks.   Instead, ONC should develop an annual statistically valid survey. Reported data should be drawn from the end user points, to include providers, payers, health information exchanges (HIEs), health information service providers (HISPs), and clearinghouses.

   In addition, ONC should take advantage of the lessons learned from the implementation of the Health Insurance Portability and Accountability Act (HIPAA) Administrative Transactions; e.g., adopted standards and implementation specifications. Bench testing-based certification conducted in a laboratory only narrowly measures the quality of the proffered "floor model" system or application. A more accurate measurement of interoperability would result from the end user's implementation on site, which can and should be validated as part of the onboarding process and daily at run-time.

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

   Comment: The proposed measurement framework is a good starting point but is too broad as presented to identify gaps contributing to the lack of interoperability in a given system. In order to encourage user confidence in the interoperability of a given system, ONC could encourage a "system interoperability certification" labeling schema for vendor's products. Payers, population health vendors, and HIEs could then rely upon the product certification when selecting their services and software. ONC and a consortium of participants should be responsible for oversight of the certification schema to ensure objectivity and, should take advantage of the approach and the success of HIPAA Administrative Transaction implementation, i.e., effective validation testing at point of use by providers, payers, clearinghouses, and practice management system vendors.

   In the Proposed Framework document on Page 6, ONC has identified components it believes should be captured nationally on an annual basis to measure standards implementation across the implementation life cycle. These components include *Standards in development plans* (i.e., what standards the vendor / product developer is planning

to use in future products)*; Standards implemented in Health IT products or services* (i.e., standards that are not included in the testing for ONC Certified Health IT Products)*; and Product version with Standard implemented and deployed to end users* (i.e., vendor reports on the volume of products that have been deployed and to how many end users)*.

We believe that using a voluntary reporting schema to gather data of the effectiveness of the implementation of interoperability standards may result in misleading conclusions where the standard may have been deployed but is otherwise still in development. The same misleading conclusion may occur where use of the standard is voluntary, or is only a "standard" for the purpose of bench testing a product for certification.

Results and conclusions can be rendered moot when measuring the use of standards that are otherwise still under development. There are times in a standard development organization's (SDO) processes when a standard does not make it out of development. Subsequently, a different direction than the one measured may be chosen for the final standard. That now un-measured approach does make it through the SDO's consensus-based adoption process and on to industry-wide implementation. And only mandated standards are consistently implemented industry-wide.

Voluntary standards may not be implemented consistently. When drawing conclusions from measuring the application of voluntary standards, ONC should consider including information on the scope and context of the implementation measured and appropriate warnings regarding the reported measurements of their effectiveness.

Lastly, regarding vendor-reported product uptake as a measure of standards' effectiveness, providers and EHR vendors might have limited conformance experience; that is to say, limited experience with implementation issues around usability issues, multi-party communication reliability and system integration of the EHR products. Payers and the practice management system vendor have plenty of product-to-standard conformance experience, via HIPAA validation and run-time data quality checks.

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?**

Comment: The usage of standards should be reported by survey of the end users – providers and payers – not by the vendor. Also, a measure of the volume of a standard is helpful, but inadequate. Transaction trends are a valuable measure, however standards need to be in a state of conformance compliance so that end users will be reporting outcomes on the same standards. Today a supposed standard can be implemented differently between EHRs.

In order to determine the effectiveness of the use of the standard ONC should consider measuring:

- The quality of the data, in the context of conformance criteria published by the SDO.
- The percentage of structured data, in contrast to PDF, fax and paper shared by the source with exchange trading partners.

Regarding using the volume of transactions by standard as a "use measure," the number of trading partners participating with a given stakeholder's implemented standard is more suggestive to success than volume. The

number of partners should be measured to assess interoperability. A stakeholder may successfully implement a standard and exchange high volume of data with one trading partner, but this situation is a less useful indicator of true interoperability. Also, while volume can be helpful, especially as a percentage of overall business, it is useless without quality measures along with it.

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

Comment: The framework should take advantage of the effectiveness measurement tools used by existing entities with standards development and implementation experience involving multi-stakeholder input, i.e., the SDOs and e.g., the HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 (Attachment Guide). (This "Attachment Guide" for C-CDA based exchange includes explicit conformance criterion that can be the basis for automated real-time validation at point of exchange.)

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

Comment: We do not believe all the appropriate stakeholders who can support collection of needed data have been identified in the Proposed Framework. ONC should, at a minimum, add BCBSA, the AHIP Innovation Lab, Strategic HIE Collaborative (SHIEC), Cooperative Exchange, and WEDI.

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?**

Comment: [No comments]

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?**

Comment: Regarding reporting on the implementation and/or use of interoperability standards on an annual basis feasible, BCBSA believes it is feasible, if done in the context of an annual survey to key end-user stakeholders and not the vendor developers / manufactures. The key stakeholders are providers, payers, HIEs, and clearinghouses.

Regarding what potential challenges exist to reporting annually, we offer that annually may not be adequate to track and measure progress to identify a problem area or to identify area of success/progress as the basis for best practices sharing. ONC should consider issuing reports on a more frequent basis, e.g., twice per year. ONC could get a cross-section of volunteers to conduct more frequent reporting and then do a broad, statistically valid survey of the data users, not the product developers. The developer role should be to identify what products are delivered, who has them and to verify the test-bed validation work conducted using their base product. Interoperability is about what the product does in the field, not in the lab.

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?**

Comment: BCBSA recommends following the process from the implementation of the HIPAA Administrative Transaction Standards: i.e., focus on standards with conformance standards and those standards for which vendors in the marketplace have existing products to test and validate compliance to the standard at the various points of data exchange (i.e. provider to provider, provider to payer, provider to HIE, payer to provider, HIE to consumer/member, etc.)

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?**

Comment: ONC should create a representative team of stakeholders – either independently or under the auspicies of the new HIT Advisory Committee – that would include payers, providers, HIEs, Labs, EHR vendors and Population Health vendors, and the SDOs (HL7, WEDI, and X12). The charge to the team would be to reach consensus on recommendations to ONC regarding the questions ONC identifies in this project, e.g., the criteria for selecting standards for measurement; and how measures will be specified so that there are consistency-promoting common reporting definitions.

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

Comment: An effort to measure customization is questionable on its face; standards should not be customized as that defeats the purpose of standards and can affect interoperability. If ONC is set on attempting to measure the customized standards implementation conformance with the base standard, some considerations for the selection of measures used to track the level of "conformance" might include:

- Validation and testing as required of HIPAA Administrative Transactions.
- A qualitative ranking scale, similar to CMS ranking of health plans – a four star rating for best in class, and scale down to one or no stars as a poor performer. Provider and payer users need a measure of the software product interoperability, and software vendors need a ranking for which they can seek to raise the bar from two stars to four, while users should be encouraged to avoid software ranking as zero or one.

Measuring the level of conformance or customization could be expressed as a percentage. However in the context of quality, even if an end-user (provider/payer/ other user) is 90% compliant with a standard, the 10% not in compliance could be related to the data/processes and operations that are most important to achieving interoperability. The capacity for data harmonization is one example.