****

February 27, 2015

National Coordinator for Health Information Technology

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Standards and Interoperability Framework Initiative – Task Force
200 Independence Avenue, S.W.
Suite 729-D
Washington, D.C. 20201

Dear Task Force:

On behalf of the American Clinical Laboratory Association (ACLA), we wish to express our continued support of the Meaningful Use rules and the ONC EHR Meaningful Use Certification program, and thank you for allowing us to speak to the task force today. ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories, in addition to esoteric labs, hospital labs, and nursing home labs. As providers of millions of clinical laboratory testing services each year, ACLA member companies are actively engaged in the secure and standards-based electronic exchange of health information, and are supportive of appropriate efforts to accelerate the advancement of interoperable health information exchange through such programs as Meaningful Use. Given their central role in providing laboratory diagnostic testing, ACLA members are on the front-line of these work efforts to ultimately increase the quality of care available to patients.

As you are well aware, clinical laboratory results impact a majority of patient diagnostic and therapeutic decisions and the member ACLA laboratories continue to work closely with Standards Development Organizations (SDO) and with vendors providing systems to our clients that help drive their diagnostic evaluations. ACLA members were engaged early in the Standards and Interoperability Framework Initiatives (S&I Framework) taking leadership roles to help move critical solutions forward.

For the first time, the healthcare industry has introduced a single laboratory results interface guide, the Laboratory Results Interface Implementation Guide (LRI IG), to support interoperability across all laboratories and EHRs. This was done as a Draft Standards for Trial Use (DSTU). The significance of this first time effort within the U.S. market – where healthcare is not managed by a centralized structure, but is uniquely distributed across organizations – should not be overlooked. Before this particular effort, interfaces were uniquely defined and implemented point-to-point even when the interface was consistent between vendors, however, due to unique business requirements, adjustments were made even in “Standards Interfaces” to accommodate local issues. While many laboratories had single interfaces with a single EHR vendor, often unique local modifications had to be developed. With the establishment of LRI IG across the industry, this requires re-evaluation of those unique local business rules to determine how relevant those rules may be considering the larger context of consistent patient care across the continuum of care.

Laboratories focus on providing services that help physicians better understand the health issues of their patients by providing laboratory results as quickly as possible. This has been achieved, in part, by providing connectivity in this space for over 30 years. For example, when EHR vendors are not able to capture data in a structured digital record it has been the practice of the community to move vast pieces of data into “comment records” trailing the result segments (HL7 term is Observation Segments known as OBXs).

For the first time, attempts are being made to model consistent behaviors through the LRI IG effort. The lab experience so far, is that several vendors are struggling and have asked the labs to alter the LRI IG. The labs believe these alternations put the ordering providers at risk of attestation failure and this will not be known until a few of these interfaces are validated. In some cases, the EHR vendors could not make the timely changes to their systems before needing to deliver the updated software to their clients.

Understanding these issues helps explain our next statements.

* **National Priorities** should drive improved patient care across different healthcare providers through the successful exchange of data through highly interoperable systems. This can only be done with deliberate piloting of DSTU implementation guides that are driving interoperability. Such an effort will require additional initiatives to help facilitate expanded implementation guidance on areas in the lab space where expanded structure can be developed and standardized. There is no incentive to pilot DSTUs because of the threat of having to abandon development if it is not adopted by the community. Laboratories have an additional burden as their interfaces need to be verified with College of American Pathologists (CAP) to validate that the changes meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories need support from other government agencies to have reduced penalties or burdens for those providers (including labs) piloting new S&I Framework Initiatives to validate proposed solutions for a prescribed timeframe.
* **Facilitating Federal Participation in SDOs** is not as critical as the support of the community to facilitate changes to SDOs to resolve issues encountered during the pilot of DSTUs. ONC's support through the S&I Framework has been successful in engaging broader participation from a core team of dedicated initiative participants, including representation from the Office of National Coordinator (ONC), National Institute of Standards and Technology (NIST), National Library of Medicine (NLM), and The Centers for Medicare and Medicaid Services (CMS). Many of these agencies are already involved in applicable SDOs.
* **Balanced Representation** is critical for the success of these initiatives. Balanced representation among participants needs to be focused on those providers that create, use and/or make use of the data to ensure sure clinical issues are driven by the subject matter experts (SMEs) with direct knowledge. In some cases, this means the balance will tip to the providers, but no single provider should have a significant vote based on head count within the initiative. While limiting votes to one per organization is helpful to the process; we also recommend equally weighted voting by provider-type to allow each the opportunity to be involved and represented.
* **Measureable, meaningful real-world results –** initiatives focusing on simple solutions to resolve long standing, complex, implementation issues to improve national interoperability is key. In order to achieve wide spread adoption, stakeholders should be involved both in identifying and assessing real-world opportunities, and at key points in the policy and program development towards implementation. For example:
	+ Defining additional universal order codes for laboratory tests, and standardizing short and long test names;
	+ Producing a single, national, implementation guide for clearly defined use case with minimal deviations will reduce health care implementation costs.
* **Reasonable implementation path –** ONC's roadmap defines a guiding principle to "Build upon the existing health IT infrastructure." We strongly endorse this Guiding Principle, especially for laboratories who have been working through the ONC S&I Framework on various laboratory interoperability implementation guides since 2011.
* **Interim and Long Term Goals or Outcomes** should be driven by the community of provider SMEs with knowledge of the critical patient care issues that need to be addressed short term so that longer term goals can be achieved through incremental immediate outcomes that have successfully been adopted by the community. For example: the incremental, scaled adoption of result level LOINC codes starting with voluntary usage in the early adoption phase, followed by expansion to a target adoption rate for Meaningful Use Stage 1, and, ultimately being required for Stage 2, represents a reasonable approach.
* **Rapid Cycle Implementations** is a great concept, but requires consideration of patient impacts based on the critical nature of the data. We recommend that this be a low priority looking first at Balanced Representation and Interim/Long Term Goals/Outcomes and letting the provider SMEs determine if an initiative has low risk for Rapid Implementation. Alternatively, the scope of the initiatives could be narrowed but aimed to resolve critical interoperability challenges. For example, there is a major initiative to clarify usage and harmonize value sets across the four S&I Framework sponsored laboratory implementation guides. Perhaps this initiative could be restructured as a separate "mini-initiative" subject to rapid definition/implementation to pilot a new "Rapid Cycle" approach.

Thank you, again, for the opportunity to present. ACLA looks forward to our continued collaboration with the S&I Framework Taskforce.

Sincerely,

Thomas Sparkman

Vice President, Government Relations