Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

June 11, 2015

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. DeSalvo:

At the February 10, 2015 meeting, the following Health IT Standards (HITSC) workgroups were charged with commenting on ONC's Shared Nationwide Interoperability Roadmap. To disperse the work appropriately and avoid overlap, the HITSC workgroups were each assigned specific sections to review.

Workgroup	Assignments	Summary Comments
Transport and Security	**E. Ubiquitous, secure network infrastructure** **F. Verifiable identity and authentication of all participants**	**Section E. Ubiquitous, secure network infrastructure** • Recommend that ONC partner with the NIST, OCR, and other federal agencies, and industry to enable a uniform approach to enforcing cybersecurity in healthcare. • ONC should include a number of considerations to further establish trust across the health IT ecosystem **Section F. Verifiable identity and authentication of all participants** • ONC should acknowledge that because of the sensitivity and criticality of data used in the healthcare industry, and the need for convenient access to data, sometimes in emergency circumstances, healthcare is notably different from banking, social media and email. • ONC (together with OCR, other federal partners, and industry stakeholders) should continue to support the National Strategy for Trusted Identities in Cyberspace (NSTIC) program and draw from existing pilots, where applicable. • ONC should support NIST's effort to update SP 800-63 and help assure its applicability to and utility for healthcare use cases. • ONC should provide guidance on the use of third-party identity proofing services

Workgroup	Assignments	Summary Comments
Transport and Security, continued	**G. Consistent representation of permission to collect, share and use identifiable health information**	**Section G. Consistent representation of permission to collect, share and use identifiable health information** • Today's "standard" for basic choice is a paper document that is hand-signed by the patient. We appreciate ONC's recognition of the limited utility and scalability of this model in electronic exchange, and we share ONC's desire to identify open standards for electronically capturing, representing, exchanging, and interpreting patient consent. • Rather than commit resources to creating new standards, ONC should monitor and, where appropriate, engage in existing efforts to capture consent electronically. • ONC should also provide guidance that defines computable, discrete data fields needed for negotiating patient consent and access to health information. • ONC should continue to monitor SAMHSA pilots and the application of data segmentation for privacy (DS4P) technology, and derive lessons learned from those efforts Attachment: • Appendix_A_HITSC_Interoperability_Roadmap_TSSWG_Comments_2015-04-22_Final
Implementation, Certification and Testing	**I. Stakeholder assurance that health IT is interoperable**	• Testing tools need to be available with adequate lead time for pre-certification testing and should be focused in areas that provide value for end users. Where possible, providers should be involved in development of test tools. • Vendors and SDOs may not have adequate resources to create test tools for certification requirements that do not reflect work already underway. • CCDA Simplification has occurred between Release 1 and Release 2. • Practical, effective, and industry-run tools are needed for post-certification testing in support of interoperability, and evolution of vocabularies, technologies and processes between regulatory cycles. • Testing for interoperability should be ongoing voluntary conformance testing rather than mandatory/compliance driven. Look to HIPAA X12 experience for lessons learned. • "Regular Use" of testing tools needs further definition Attachments: Appendix_B_ICT_Interoperablity_Roadmap_Comments_2015-04-22 Appendix_C_ICTWG_Constraining_CCDA_2015-03-18

Workgroup	Assignments	Summary Comments
Content Standards	**J. Consistent Data Formats and Semantics**	**The workgroup embraced the following key concepts:** • Need for consistency in data formats and semantics • Use of Standards Development Organizations (SDOs) to develop, curate and maintain standards and create implementation specifications / profiles; and need for ongoing collaboration among SDOs • Improve consistency in the implementation of Consolidated CDA through further guidance or constraints • Extension of standards to promote exchange across the care continuum, including new sources of patient generated health data, device/sensor, environmental and other big data • Agreement on a core standardized common clinical data set that is extensible and consistently shared during care transitions • Need for agreement on use cases that each vocabulary supports • Need to exchange information in a more granular form, such as FHIR • Many of the initiatives listed including FHIR, CIMI, DAF (should limit to these three) **Specificity needed to define goals and actions** • Laser focus: achieving national scale with selected standards should be top priority o Consolidated CDA release 2 and Direct Project key first steps o Multi-year cycle time for standards to be absorbed nationally o Broad group of stakeholders that need time to respond to changes o Use all available levers to pursue nationally, encourage aligned adoption of specific named standards o Focus on specifying universal codes and getting data from the source to the provider and others in need of the data o Assure that all federal payers are aligned with common core of standards and incentivize commercial payers to follow • Avoid one hand clapping: greater specificity in standards o Be specific on how the standards support prioritized use cases for each wave of interoperability o Refine those standards over time, but limit structural change o Recommendations include concepts related to improving interoperability between research and clinical domains, stakeholders should consider these and provide input on the use cases in that space that would create the greatest value and subsequent actions o Suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by the US and international agencies and SDOs (e.g., CDISC)

Workgroup	Assignments	Summary Comments

Content Standards, continued	**J. Consistent Data Formats and Semantics, continued**	• Know where we are going: greater specificity in Learning Health System definition
		  o Need to consider the constraints of policy, privacy and security
		  o APIs alone will not open up clinical systems for learning
		  o Great references (e.g., IOM, Learning Community, ESTEL, ONC Query Health)
		  o Use Cases - Select a few use cases that will deliver high return on investment for interoperability instead of the large number included now (56)
		• The important gaps are not in standards, but in policy maker attention to the need to deliver clinical data from the source to the users. Seems not to be on the radar screen
		
		Attachment: Appendix_D_HITSC_CSWG_Roadmap_Comments_2015-04-22

Semantic Standards	**J. Consistent Data Formats and Semantics**	**Additional Focus Areas**
		• Need a shared understanding of the importance of information models and terminology bindings
		• Need agreement on highly granular information models bound to terminologies for information exchange
		• Data standards (e.g., for performance and quality measures, public health) should reflect the semantics implemented in EHR systems and semantics in EHR should be the same across settings
		• Need attention to challenges of data aggregation , for example for resolving duplicates, when data is assembled from multiple sources
		• It is critically important for data provenance to be workable and practical for semantic interoperability
		• Reject usefulness of National Information Exchange Model (NIEM) related to healthcare interoperability
		• The roadmap should include the seamless integration and use of healthcare device information
		Missing Or Misconstrued Items
		• Need to prioritize additional diagnostic studies/reports (e.g. EKG) for patient and provider decision making
		• Need to support semantic web standards including OWL and RDF
		• Recommend minimizing mapping between different standards because mapping is imprecise
		• Support the use of interface terminologies that allow accurate and precise use of target standards
		• Need to support semantic interoperability by multiple mechanisms, including:
		  a) Data exchange - standards for moving copies of data between entities
		  b) Access to data at its source – need shared access to patient centered data sources
		  c) Combinations of a and b including access to aggregated data

Workgroup	Assignments	Summary Comments
Semantic Standards, continued	**J. Consistent Data Formats and Semantics, continued**	**Clarification Needed** • Need a clear plan for achieving the objectives laid out in the Roadmap • Need clarity about how to achieve coordinated governance of semantic standards • The reference to "technical architecture" is too vague • The reference to "translation and adapter services" is unclear • Common data elements are not necessarily standards and a definition needs to be developed, preferably based upon ISO 11179 • The common clinical data set from the roadmap needs more specificity, needs to be vetted broadly, and to be harmonized with other common clinical data sets **ONC Coordination With SDOs** • Need ONC to work more closely with (and within) accredited SDOs • Need closer coordination of US semantic standards with international standards organizations (e.g., via the Joint Initiative Council on SDO Global Health Informatics Standardization) • Reduce overlap and improve coordination • Improve operations (e.g. release schedules) • Suggested vocabularies and code sets do not align well with widely used research and clinical standards Attachment: Appendix_E_HITSC_SSWG_Roadmap_Recommendations_2015-04-22
Architecture, Services and APIs	**K. Standard, secure services** **L. Consistent, secure transport technique(s)**	**Framework Recommendations (see transmittal)** Define a roadmap towards the Health IT Hourglass • To create greatest modularity, move towards parsimony of composables for transport, security and data composables and extend with common orchestration patterns such as pluggable Apps and clinical decision support (CDS) as a service. • Adopt a deliberate policy of "rebalancing" the standards portfolio towards the Health IT Hourglass model • Allow sufficient time to develop, adopt, and use core composables and Orchestration Patterns to allow for demonstrations of success during the rebalancing period • As recommended in the joint Health IT Policy and Health IT Standards Committee recommendations from the JASON Task Force [7], provide flexibility for detailed policy governance of specific use-cases to be performed by Data Sharing Arrangements • Identify critical priorities for 2015–2017 o Create a glide-path to core composables and Orchestration o Reduce "friction" and distraction to adopters and implementers

Workgroup	Assignments	Summary Comments
Architecture, Services and APIs	**K. Standard, secure services** **L. Consistent, secure transport technique(s)**	• Identify roadmap priorities for 2018–2020 o Refine and extend core composable services, profiles, and orchestration patterns o Expand the number of piloted use-cases based on the core composable model o Address needs for national-scale services such as MPI, RLS, Directories, etc. o As Data Sharing Networks emerge, address needs for network-bridging services o Consider mature APIs, orchestrations, and use-cases as candidates for addition to Certified HIT o Begin transition from non-Core/Orchestration standards and APIs • Identify roadmap priorities for 2021–2024 o Address complex data profiles that require more robust data models (as may be needed for the Learning Healthcare System) o Contemplate transition to new Core/Orchestrations based on the current technology directions Appendix: Appendix_F_HITSC_ASA_Roadmap_Comments_Final_2015-04-22

More than twenty public meetings were held across the various workgroups, resulting in the final comments summarized above and included in the detailed attachments from each Health IT Standards Committee (HITSC) workgroup. These comments were approved by the HITSC on April 22, 2015.

We appreciate the opportunity to provide these comments and look forward to engaging the Committee in future discussions to assist in the evolution of the Interoperability Roadmap.

Sincerely yours,

/s/

Jon White
Chair, Health IT Standards Committee

/s/

John Halamka
Vice Chair, Health IT Standards Committee