Health IT Standards Committee

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

May 29, 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:

The Health IT Standards Committee (HITSC) workgroups were charged with reviewing ONC's 2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record Definition, and ONC Health IT Certification Program Modifications (Certification NPRM). To disperse the work appropriately and avoid overlap, the HITSC workgroups were each assigned specific sections to review. Highlights from each workgroup are included below with each of the workgroup's assignments.

Workgroup & Assignments	Summary Comments

Architecture, Services, and APIs
• **§ 170.315(g)(7) Application access to Common Clinical Data Set**
• **VDT - Application Access to Common Clinical Data Set**
• **§ 170.315(b)(6) Data portability**
• **"Create" and Patient Matching Data Quality**
• **XDM Package Processing**
• **§ 170.315(h)(4) Healthcare Provider Directory – Query Request**
• **§ 170.315(h)(5) Healthcare Provider Directory – Query Response**
	A detailed transmittal was provided for this group
	• § 170.315(g)(7) Application access to Common Clinical Data Set
	  ○ Include functional requirements with clear text documenting regulatory intent and signaling in a future regulatory cycle the API requirement will be based on standards-based APIs.
	  ○ Subregulatory flexibility to allow developers to be deemed to achieve certifiable status through participation in a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability
	  ○ Transitional functional certification requirements are too rigid and could serve to limit or constrain achievement of policy goals.
	• § 170.315(b)(6) Data portability
	  ○ Criteria are overly prescriptive in ways that add complexity without addressing the stated policy goals or add functionality that are not clearly tied to the policy goals of portability and data availability
	• "Create" and Patient Matching Data Quality
	  ○ Criteria is generally reasonable
	• XDM Package Processing
	  ○ Confusing and vaguely stated
	• § 170.315(h)(4) and § 170.315(h)(5)
	  ○ No wide scale adoption and production that would be sufficient to understand what relevant certification criteria should be. We therefore found that certification
	Attachments
	• Appendix_A_ASA_Transmittal_NPRM_2015-05-20
	• Appendix_B_ASA_NPRM_2015-05-20.pptx

Workgroup & Assignments	Summary Comments
Content Standards • Medication Allergy List • Computerized Provider Order Entry – Medications • Computerized Provider Order Entry – Laboratory • Computerized Provider Order Entry – Diagnostic imaging • Drug-drug, Drug-allergy Interaction Checks for CPOE • Drug Formulary and Preferred Drug List Checks • Electronic Prescribing • Structured and Codified "Sig" • Incorporate Laboratory Tests and Values/Results • Transmission of Laboratory Test Reports • Pharmacogenomics Data – Request for Comment (first 4 bullets)Decision Support – Knowledge Artifact • Decision Support – Service • Clinical Quality Measures (all sections) • Electronic Submission of Medical Documentation • Transitions of Care • Updated C-CDA Standard • Valid/Invalid C-CDA System Performance • C-CDA Data Provenance • Consolidated CDA Creation Performance • Clinical Information Reconciliation and Incorporation • Incorporation System Performance • Care Plan • Common Clinical Data Set, Updated C-CDA, and Diagnostic Image Reports • Application Access to Common Clinical Data Set	**Overarching Comments** • Getting to interoperability on a national scale requires focus – Focus exclusively on Consolidated CDA 2.0 – Limit set of templates to CDA, discharge, referrals – Do not require CCDA 1.0 <->2.0 exchange – Globally require existing transport standards (Direct Project) • Ensure that the API requirement is consistently implemented • Re-think several standards in light of API/FHIR evolution including clinical decision support, care planning • Areas of benefit within the NPRM: – Including clinical quality measures, common clinical data set, updated SNOMED, quality reporting and the API requirement (For evolutionary standards, use latest versions – not a maturity issue) – Correctly identifies the need for some standards, but refinement needed including identification of food/substance-reactions/intolerances, lab and med order entry • Standards not ready: – Immature: clinical decision support, Data Segmentation for Privacy, Electronic Sending of Medical Document requests, virtual Medical Record, Quality Improvement and Clinical Knowledge data model, electronic Delivery of Service • Should be reconsidered: NCPDP Formulary and Benefit Standard (prefer Real Time Prescription benefit), CCDA Care Plan Template (prefer HL7 Coordination of Care Services Functional Model for dynamic care planning) Attachment: Appendix_C_CSWG_Cert_Rule_2015-05-20_v2

Workgroup & Assignments	Summary Comments
Implementation, Certification and Testing • Costs and Benefits • Applicability • Gap Certification Eligibility Table • Common Clinical Data Set Definition • Consolidated CDA Creation Performance • Open Data Certified Health IT Product List (CHPL) • "Removal" of Meaningful Use Measurement Certification Requirements • The ONC Health IT Certification Program and Health IT Module • Base EHR Definitions • Retesting and Certification • Safety-enhanced design • Web Content Accessibility Guidelines • Design and Performance • Request for Comment on Summative Testing • Encounter Diagnoses • Medication Dosing • Implantable Device List • Pharmacogenomics Data – Request for Comment • Data Portability • Automated Numerator Recording/Calculation	**Overarching Comments** • Intent and spirit of changes proposed is directionally great, but there may be unintended consequences. • Balance is needed between benefits received from lofty goals proposed compared to the cost and time commitments required from implementation. • Be cognizant of time and bandwidth required by developers to support proposed criteria, particularly when criteria are not required by Meaningful Use or other programs. • ONC and ANS should ensure ACBs and ATLs behave consistently to reduce variability and ensure all developers are held to the same level of requirements. Attachment: Appendix_D_ICTWG_Slides_2015-05-20.pptx

Workgroup & Assignments	Summary Comments
Semantic Standards • Pharmacogentics Data – Standards Question • Common Clinical Data Set Definition - vocabulary standards • National Drug Codes for Administered Vaccinations • Transmission to Public Health Agencies – all sections • Immunization History and Forecast • Family health history • "Minimum Standards" Code Sets • Object Identifiers (OIDs) for Certain Code Systems • Demographics • Vital Signs, Body Mass Index (BMI), and Growth Charts • Smoking status • Social, Psychological, and Behavioral Data • Work Information/Industry/Occupation Data • U.S. Uniformed/Military Service Data • Encounter Diagnoses • Medication Dosing	**General Themes** • More attention to the broader range of standards and requirements essential to learning health system objectives. – Many HIT systems that support research and many clinical activities currently use other standards that might not transition or interoperate well. • The Certification Program should allow for versioning of standardized terminologies without changes in regulation. – It is preferable to specify the floor, rather than the ceiling – Specific codes should not be identified in regulation • The NPRM should support methods for combining use of LOINC and SNOMED that are consistent with current published cooperation agreements • The Common Clinical Data Set needs further vetting. • NPRM should avoid regulation that depends on action by entities outside the regulator's control such as specifying "pending" codes. Attachment: Appendix_E_SSWG_Cert_Rule_2015-05-20.pptx

Workgroup & Assignments	Summary Comments

Transport and Security Standards
• Data Segmentation for Privacy - Send/Receive
• CCDA Data Provenance
• Electronic Submission of Medical Documentation
• Auditable Events and Tamper-Resistance
• Automatic Access Time-Out
• End-User Device Encryption
• Integrity
• Privacy and security
	Standards Readiness for Inclusion in Certification – Summary
	• SHA-2 (Secure Hash Algorithm) – Ready - Recommend ONC replace SHA-1 with SHA-2 in 2015 Edition
	• Data Segmentation for Privacy (DS4P) – Not Ready - Has been piloted, and beginning trial implementations in EHR products – resulting in concerns that need to be addressed. Important in that enables data exchange where none has been possible, but not ready to become a standard for certification
	• HL7 IG for CDA Release 2: Data Provenance, Release 1 (US Realm) (DSTU) – Not Ready - Encourage ONC to support continued piloting, use, and refinement of HL7 Provenance IG and FHIR Provenance-Content specification
	• Electronic Submission of Medical Records (esMD) – Not Ready - Applaud significant work since 2013: digital signature standard is consistent with DEA. Encourage ONC to pursue other levers to support further development and piloting
	• NIST 800-92 (Guide to Computer Security Log Management) – Ready - Recommend ONC add this standard to require that certified HIT be capable of recording an audit trail of all security-relevant events
	Revised approach to certifying Health IT Module against Privacy and Security Criteria
	• Agree with new approach to P&S certification
	• Recommend adding P&S criteria:
	  ○ Clinical Module: add Integrity criterion
	  ▪ Involves transmissions (lab order compendium; formulary benefit file)
	• Care Coordination Module: add Amendments criterion
	  ○ Support patient requested amendments
	• Design and Performance Module, API criterion: add (1) authentication, access control, and authorization; (2) Auditable events and tamper-resistance; and (8) Integrity
	Privacy and Security Criteria
	• Auditable Events and Tamper-Resistance
	  ○ All security-relevant events should be auditable. A change in user privileges is security-relevant and therefore auditable
	  ▪ Add certification criterion stating that certified HIT should be capable of recording an audit trail of all security-relevant events
	  ▪ Add NIST SP 800-92, sections 2.1.2 and 2.1.3, as standard for specification of auditable events, in addition to ASTM E2147-01
	  ○ What to audit is a risk management decision
	  ○ Ability to disable audit log? Yes.
	  ▪ Recommend no change from 2014 Final Rule
	• Automatic Access Time-Out
	  ○ Suggested language change: "Automatically terminate access to protected health information after a configurable period of inactivity, and reinitiate session upon re-authentication of the user." *Continued on the next page*

Workgroup & Assignments	Summary Comments

Transport and Security Standards, continued
• Data Segmentation for Privacy - Send/Receive
• CCDA Data Provenance
• Electronic Submission of Medical Documentation
• Auditable Events and Tamper-Resistance
• Automatic Access Time-Out
• End-User Device Encryption
• Integrity
• Privacy and security
	• End-User Device Encryption – Agree with proposed change
	• Integrity
	  ○ Agree with change in testing approach
	  ○ Agree with proposal to move to SHA-2 in the 2015 Edition
	
	Other
	• Data Segmentation for Privacy (DS4P)
	  ○ DS4P implementation is beyond pilot stage, and large vendors are now experimenting with its implementation – reporting needs for further refinement
	  ○ DS4P enables exchange of data that currently are not being exchanged – so important that piloting and implementations continue to progress
	  ○ Recommend that ONC continue to support and encourage trial implementations of DS4P in EHR technology to help accelerate specification refinement and adoption
	• Electronic Submission of Medical Documentation (esMD)
	  ○ Significant progress since August 2013 presentation to HITSC
	  ▪ Digital signature consistent with DEA standard
	  ▪ Capability can be provided by module natively or through external interface
	  ○ Tied to C-CDA Release 2; lacks wide adoption
	  ○ Not ready to become national standard
	  ○ Recommend ONC support pilots to advance refinement, implementability, and adoption to accelerate readiness
	• C-CDA Data Provenance
	• HL7 currently working collaboratively on two different provenance specifications – HL7 Provenance IG and FHIR Provenance-Content specification
	• Neither specification is ready to be adopted as a national standard
	• Data provenance is significant component of data integrity – TSSWG encourages ONC to follow and support the development and piloting of these specifications
	
	Attachments:
	• Appendix_F_TSSWG_Comments_2015-05-20_Final.pptx
	• Appendix_G_TSSWG_NPRM_Comments_2015-05-20_Final_v2

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 HITSC workgroup. These comments were approved by the Health IT Standards Committee on May 20, 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 Certification NPRM.

Sincerely yours,

/s/

Jon White
Chair, Health IT Standards Committee

/s/

John Halamka
Vice Chair, Health IT Standards Committee