Lantana
CONSULTING GROUP

Date: March 18, 2016

To: The Office of the National Coordinator for Health Information Technology (ONC)

Subject: Draft 2017 Interoperability Standards Advisory

These comments follow ONC's request for feedback on the 2016 Interoperability Standards Advisory (2016 Advisory). Lantana Consulting Group (Lantana) appreciates the opportunity to offer opinion and participate in the development of the 2017 Advisory.

General Recommendations

- Change "Draft Standard for Trial Use (DSTU)" to "Standard for Trial Use (STU)".
- The Standards Process Maturity characteristic conveys a standard or implementation specification's maturity in terms of its stage within a particular organization's approval/voting process. We recommend a three-level definition for the status of the Standards Process Maturity:
    - Final
    - Standard for Trial Use (STU)
    - Ballot in Development
- The advisory includes both emerging and mature standards. We recommend the Advisory focus on including promising standards for adoption, and publish mature standards in a separate document.

Best Available Vocabulary, Code Sets, Terminology Standards, and Implementation Specifications

Information models, such as OpenEHR, Health Level Seven (HL7) V2, CDA, or FHIR, must be expressive and complete to convey the complex clinical care concepts The information required by a lab or radiological system differs from the information required when documenting a CDA template for another type of clinical report. To ensure models are expressive and complete, we recommend ONC develop separate clinical and technical review processes.

Information models describe the semantic context for clinical use cases. Semantics convey meaning through structured terminologies, ontologies, and code systems. Terminology models define concepts through attributes, relationships, and rules. For example, a coded allergy to penicillin is incomplete without context. When you place this codified concept in a CDA where you know the patient, author, date/time this provides a rich clinical context to accompany the term. We recommend ONC integrate clinical context into the vocabulary standards as described by the information model.

Section I-F: Functional Status/Disability

We suggest that ONC adopt:

- Value sets that standardize the functional and mental status concepts within the HL7 *Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1* (C-CDA R2)

- An information model similar to the one that underlies CDA that represents functional status and disability concepts within standard code systems, such as SNOMED-CT and the International Classification of Functioning, Disability, and Health (ICF)

Section II-B: Care Plan

Currently, C-CDA can exchange static care plans for simple use cases, where coordination is less complex. We suggest the 2017 Advisory include both simple and complex coordination of care activities. Regulation should point to the specific document type best suited for each use case, preventing over-use of the generic C-CDA summary document.

Section II-C: Clinical Decision Support

There is considerable work in progress to harmonize standards for CDS and Quality Measures with the focus moving towards FHIR. We recommend ONC highlight emerging standards such as HL7 Clinical Decision Support and the Clinical Quality Improvement Framework FHIR Implementation Guide. This indicates that work is in progress towards changing future standards.

We recommend Standards attain a minimum low adoption level to be considered during rule making. Furthermore, we suggest ONC share their vision of how the use cases will be implemented to increase adoption.

Section II-K: Public Health Reporting Interoperability

The implementation specifications listed in II-K adequately address the basic framework for patient and provider information exchange. If more detail is needed (e.g., disease info with symptoms, diagnoses, lab results), please consider the PHER working group case report.

To ensure the 2017 Advisory adequately addresses real world "Interoperability Needs," ONC should consider the following use cases:

- **Reporting antimicrobial use and resistance information to public health agencies**: Electronic data are reported to the Centers for Disease Control and Prevention (CDC) through the National Healthcare Safety Network (NHSN). An additional step is required for the hospital to agree to share data with any additional group (e.g., state public health agency) through NHSN.
- **Case reporting to public health agencies:** We support a structured format, which is in early stages. The HL7 Public Health and Emergency Response (PHER) work group balloted a draft standard for a specific case report form to collect the necessary variables for reporting nationally notifiable conditions to the CDC and state health departments.

Section II-L: Quality Reporting

Quality measure and quality reporting definitions are aligned, but with separate standards. We recommend that ONC create an overarching category for Quality with two sub-groups: (1) Quality Measurement Standards and (2) Quality Reporting Standards.

Starting with the 2017 reporting period, we recommend that Federal programs require QRDA Category III Release 1.1 STU – Balloted (March 2016). We also recommend that ONC add the following as an emerging alternative: FHIR-Based Clinical Quality Framework (CQF on FHIR) – Balloted (May 2016).

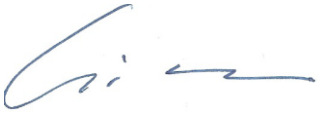
Section II-T: HL7 Privacy and Security Healthcare Classification System [HCS]

We recommend that the 2017 Advisory include the normative HL7 Privacy and Security Healthcare Classification System (HCS), because it covers vocabulary for the confidentiality code required in:

- CDA R2 Implementation Guides in the Document Header and optionally at the section level
- IHE XDS Soap Headers required by Meaningful Use

Thank you for the opportunity to respond to this draft of the 2017 Interoperability Standards Advisory (2017 Advisory). Please let us know if you have questions regarding our suggestions.

Sincerely,



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