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May 7, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Attention: Health Information Technology; Implementation Specifications, and Certification Criteria: 2014 Edition EHR Standards and Certification Criteria Proposed Rule

Dear Mr. Posnack:

Lantana Consulting Group (Lantana) welcomes the opportunity to comment on the Office of the National Coordinator (ONC) for Health Information Technology's notice of proposed rulemaking (NPRM) for the 2014 Edition EHR Standards and Certification Criteria Proposed Rule as published in the March 7, 2012 *Federal Register* [77 FR 13832]. Our comments focus on those areas of particular relevance to our HL7 Clinical Document Architecture (Consolidated CDA, Quality Reporting Document Architecture (QRDA)) and National Quality Forum Quality Data Model expertise.

First and foremost, Lantana congratulates ONC for such a thoughtful document. This is not easy, and the careful consideration that has gone in to each criterion, each sentence, is apparent. Overall, this is a solid document that will move the country forward. Please interpret our comments in the constructive manner intended.

Lantana's work focuses largely around interoperability specifications, although we see interoperability specifications not so much as an end in and of themselves, but as a means to an end; that end being a more data-driven healthcare system. Lantana's mission is to transform healthcare through health information. Lantana principals and employees have served as primary authors for CDA, CCD, Consolidation, QRDA, and eMeasure. Bob Dolin, President and Chief Medical Officer at Lantana, is Past Chair of HL7, and prior co-chair of HITSP Foundations Committee.

Our detailed comments and rationale on the NPRM are outlined below. We are commenting on those areas that will have significant impact on the use, collection, and reporting of health information and where we can lend our knowledge in these areas.

If Lantana can provide further information or if there are any questions regarding our recommendations, please contact Liora Alschuler, Lantana CEO, or Bob Dolin.

Sincerely,

Liora Alschuler — Chief Executive Officer

Bob Dolin, MD — President and Chief Medical Officer

Proposed 2014 Edition EHR Certification Criteria

New Certification Criteria

Ambulatory and Inpatient Setting

§ 170.314(a)(12) - Imaging

The Consolidated CDA Diagnostic Imaging Report standard was developed jointly between HL7 and DICOM and is starting to get traction in the industry. We suggest that ONC communicates that this standard complements the DICOM image standard for exchanging images and their interpretations.

§ 170.314(a)(13) - Family health history

The Consolidated CDA Family History templates meet the minimum goal of capturing "the health history of a patient's first-degree relatives." It is compatible with the more detailed Pedigree specification which is cited in the NPRM. We suggest that the Final Rule cite both sources.

§ 170.314(e)(1) - View, download, and transmit to 3rd party

1. We suggest SNOMED as the standard vocabulary for Encounter Diagnosis rather than ICD-10-CM.
2. The Final Rule should reference the most recent version of the Consolidated CDA guide. The latest published version is December 2011. A new version is in ballot now, addressing some minor gaps with the NPRM.
3. The CDA Consolidation guide is a compilation of 9 document types (CCD, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note, Unstructured Document), and in general, when referencing Consolidated CDA, it is not clear if the reference is strictly to Consolidated CDA's CCD and/or to other document types. In some cases, such as where a criterion requires inclusion of an encounter diagnosis, it might be inferred that the NPRM is referencing some other document type, since CCD doesn't contain an encounter diagnosis template. (Note – we are putting Consolidated CDA back through ballot, in order to ensure that, at a minimum, CCD does have CDA templates for all data elements required within the MU2 NPRM, including the encounter diagnosis. We thank the S&I group for formulating this list.)

Ambulatory Setting

§ 170.314(f)(7) - Cancer case information; and (f)(8) - Transmission to cancer registries

The proposed implementation guide is not harmonized with the Consolidated CDA guide. The proposed guide should be harmonized first and then incorporated by reference in the next edition of MU.

Revised Certification Criteria

Ambulatory and Inpatient Setting

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record

1. The CDA Consolidation guide is a compilation of 9 document types (CCD, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note, Unstructured Document), and in general, when referencing Consolidated CDA, it is not clear if the reference is strictly to Consolidated CDA's CCD and/or to other document types. In some cases, such as where a criterion requires inclusion of an encounter diagnosis, it might be inferred that the NPRM is referencing some other document type, since CCD doesn't contain an encounter diagnosis template. (Note – we are putting Consolidated CDA back through ballot, in order to ensure that, at a minimum, CCD does have CDA templates for all data elements required within the MU2 NPRM, including the encounter diagnosis. We thank the S&I group for formulating this list).
2. We request clarification on the intended use of "incorporate" provided in the rule. Incorporation for laboratory results received through messages, specifically those using the Laboratory Results Interface, is distinct from data elements received as part of a document. Some challenges with incorporation of data elements from a Consolidated CDA include: [1] many EHRs require that a term be in their Problem List Master File before it is incorporated into the Problem List; [2] local terms are mapped to SNOMED in a many-to-one relationship, so we cannot assume that two CCDs, each having a Problem mapped to the same SNOMED code, are both referring to exactly the same thing.

§ 170.314(c) - Clinical quality measures: (c)(1) - Capture and export; (c)(2) - Incorporate and calculate; and (c)(3) - Reporting

The NPRM states that "we expect that exported quality data would be formatted according to the standard vocabularies in the QDM…". We must point out, however, that the QDM is not an interoperability specification; it is a Domain Analysis Model. As such, it is not testable or implementable as a wire format. Interoperability specifications specify export formats. QDM will support consistency in the definition of clinical quality measures through QDM-based interoperability specifications.

HL7 is currently balloting a revision to QRDA Category 1 which includes a QDM-based QRDA. We recommend the adoption of the QDM-based QRDA Category I for 170.314(c)(1) Clinical Quality Measures – capture and export: (ii) Export. QRDA Category I is the ***only*** interoperability specification based on the QDM.

If QRDA is not cited, we suggest that the criterion remove the requirement to export the data for clinical quality measures. Inclusion of a criterion without a standard would only result in promotion of a wide variety of exchange methods that would lead to more effort to reconcile.

Ambulatory Setting

§ 170.314(e)(2) - Clinical summaries

1. We suggest SNOMED as the standard vocabulary for Encounter Diagnosis rather than ICD-10-CM.
2. The CDA Consolidation guide is a compilation of 9 document types (CCD, Consultation Note,

§ 170.314(e)(2) - Clinical summaries
Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note, Unstructured Document), and in general, when referencing Consolidated CDA, it is not clear if the reference is strictly to Consolidated CDA's CCD and/or to other document types. In some cases, such as where a criterion requires inclusion of an encounter diagnosis, it might be inferred that the NPRM is referencing some other document type, since CCD doesn't contain an encounter diagnosis template. (Note – we are putting Consolidated CDA back through ballot, in order to ensure that, at a minimum, CCD does have CDA templates for all data elements required within the MU2 NPRM, including the encounter diagnosis. We thank the S&I group for formulating this list).

Unchanged Certification Criteria

Refinements to Unchanged Certification Criteria

§ 170.314(a)(4) - Vital signs, body mass index, and growth charts
A potentially ambiguous situation arises where the NPRM promotes a functional requirement without a corresponding interoperability specification. Here, we would suggest the use of LOINC or SNOMED codes for height/weight, BMI, etc., and encourage transmission of this data as discrete, structured values (value + uom).

§ 170.314(a)(11) - Smoking status
In response to S&I recommendations, HL7 is reballoting the Consolidated CDA IG, with the addition of a Smoking Status template, including a SNOMED CT value set that we feel most closely aligns with the intent of the NPRM. Alternately, we suggest that a request be made to IHTSDO to extend SNOMED to address smoking status vocabulary, rather than perpetuating communication of text strings.

Unchanged Certification Criteria Without Refinements

§ 170.314(a)(7) - Medication allergy list
We note vocabulary discrepancies between MU2 NPRM referenced artifacts – Consolidated CDA references RxNorm along with UNII and NDF-RT for substance-based allergies, whereas the NQF QDM references RxNorm along with SNOMED CT for substance-based allergies. These conflicts are understandable, given that value sets are often nested within MU cited artifacts. We recommend that ONC either (work with HL7 to) proactively identify and resolve discrepancies and/or designate a "source of truth" that can be pointed to in the case of discrepancies. Given this finding, we performed a systematic terminology comparison between the HITSC Vocabulary Task Force Transmittal Letter, the 2011 QDM, the MU2 NPRM, and Consolidated CDA. We would be happy to share our detailed findings with HITSC. At a high level, we found the following discrepancies which will require reconciliation: • Payor: Consolidated CDA references X12 Health Insurance Types; QDM references Payer Typology

§ 170.314(a)(7) - Medication allergy list

- Encounter diagnosis and cause of death: MU2 NPRM recommends ICD10; Consolidation and QDM reference SNOMED
- Procedures: MU2 NPRM cites ICD10 only, (not SNOMED); Consolidation and QDM reference SNOMED
- Discharge Disposition: Consolidated CDA uses an HL7 code system; QDM references SNOMED

Lantana will submit ballot comments on the open Consolidated CDA ballot to address these discrepancies. We suggest that an interoperability specification should be that source of truth – an interoperability specification provides formal and testable criteria, and is the focal point for harmonization across functional criteria, quality criteria, and interoperability. Here for instance, ONC might consider Consolidated CDA as the source of truth.

Request for Additional Comments

In addition to the comments provided in the template, we offer the following feedback:

- **Care Plans:** We suggest the Consolidated CDA Care Plan section as an initial step to support communication across providers. The S&I Framework Longitudinal Care Coordination initiative should review appropriate messaging/service formats to support dynamic care plan coordination as part of the EHR Incentive Program.
- **Disability Status:** Consolidated CDA, in collaboration with S&I Long Term Care group, has made various revisions to accommodate the CCD Functional Status section. This does not address all aspects relevant to Disability Status, but provides a sound stepping stone to move this criterion forward.