May 1, 2015

Dr. Karen DeSalvo
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: Comments on the 2015 Interoperability Standards Advisory [Open Draft]

Dear Coordinator DeSalvo:

I am submitting the below comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the *2015 Interoperability Standards Advisory [Open Draft]* (hereinafter "the Advisory").

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories. Our diverse membership represents a broad array of clinical laboratories, including national independent labs, reference labs, esoteric labs, hospital labs, and nursing home laboratories.

ACLA applauds your leadership in releasing the Advisory in order to further advance health information technology (HIT) interoperability, a critical and vital goal for improving the quality of care for patients. ACLA member laboratories appreciate the opportunity to comment on the Advisory as a living document and hope these comments serve to continue to move interoperability forward.

<u>ACLA Comments</u>

1) Page 4, regarding the use of an advisory versus regulation

The Advisory outlines that the purpose of an advisory is to provide a "non-binding" document that provides "clarity, consistency, and predictability […] regarding ONC's assessment of the best available standards and implementation specifications". ACLA supports this approach as it may provide more responsiveness to HIT interoperability challenges and may receive broader feedback and inclusion than a "Request for Comment" approach.

2) Page 4, regarding "best available" standards or specifications

The Advisory outlines that "when more than one standard or implementation specification is listed as the best available, it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry [can] efficiently interoperate more than one." ACLA supports identifying a single standard wherever possible and practicable. Having more than one standard or specification risks duplicating support requirements for different standards that ultimately are each designed to achieve the same outcome. Further, when there are "administrative" versus "clinical" concepts, ACLA requests that these concepts be clearly labeled as such and additionally associates each one with applicable use cases. For example, "Encounter Diagnosis" indicates SNOMED and ICD, however ICD is widely used in administrative functions (e.g. claims, ADT) and some clinical settings (e.g. pathology reports), while SNOMED is generally just clinical.

3) Page 4, regarding use of "'normative' or 'draft standard for trial use (DSTU)'"

The Advisory indicates that a "'normative' or 'draft standard for trial use (DSTU)'" in a standard or implementation specification that is "in use by a significant number of stakeholders". ACLA recommends providing a more quantitative definition of a "significant number of stakeholders" to clarify if it requires a plurality, a majority, or greater share of stakeholders.

4) Page 6 and 12, Question 5-7, regarding inclusion of SNOMED-CT in "Encounter diagnosis"

The Advisory asks the question, "Should more traditionally considered "administrative" standards (e.g. ICD-10) be removed from this list [Section I] because of its focus on clinical health information interoperability purposes?" ACLA recommends that Section I not include SNOMED-CT as currently listed. SNOMED-CT may be used for the patient Problem List, which is a clinical function, but SNOMED-CT is not typically used in the U.S. realm for administrative diagnosis; therefore we suggest it be removed from Encounter Diagnosis. Conversely, ICD should not be removed because it is used in other mandated implementation guides (e.g. *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface*) and may also be used in pathology reporting.

5) Page 6 and 12, Question 5-6, regarding Ethnicity

Question 5-6 states, "Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?" ACLA notes that some elements, such as "ethnicity", have both administrative and clinical usage. For example, "ethnicity" may be collected and used for administrative purposes, but "ethnicity" may also have clinical significance for some laboratory test results and should be carefully defined as the OMB definition is not adequate for clinical purposes. When clinically significant, the patient's ethnicity is managed using an "Ask on Order Entry" (AOE) question. This process is defined in the eDOS Implementation Guide developed through the ONC Standards & Interoperability Framework, and is designed work in conjunction with the LOI Implementation Guide, also developed through the ONC S&I Framework.

We recommend adopting the additional, more specific race and ethnicity values found in the CDC Race and Ethnicity Code Set (CDCREC) document.[1] The CDC Race and Ethnicity V1.0 terminology has also been recommended by the S&I Framework LRI Vocabulary Work Group.[2] This extended vocabulary is referenced in the eDOS Implementation Guide for use with AOE questions when race or ethnicity is clinically significant for the laboratory test result. ACLA further requests clarification of whether SNOMED-CT is intended to be aligned with Ethnicity or Encounter Diagnosis; ACLA does not believe SNOMED-CT should be used for Ethnicity.

6) Page 7, regarding "Gender Identity"

ACLA requests clarification of the difference between "Gender Identity" and "Sex". In general, Implementation Guide specification discussions through the S&I Framework initiatives have not referred to SNOMED-CT as the source for gender-related vocabulary and doing so in the Advisory might only create unnecessary confusion. Some elements, such as "sex" have both administrative and clinical definitions. For example, HL7 has the concept of "Administrative Sex," used for administrative purposes such as billing, claims, inpatient bed assignments, etc. However, HL7 also has clinical gender, which is used for clinical purposes. These distinctions need to be clear in the Advisory.

7) Page 7 and 12, Question 5-12, regarding "Industry and occupation"

Question 5-12 asks, "Is there a best available standard to represent industry and occupation that should be considered for inclusion in the 2016 Advisory?" The ONC S&I Framework Laboratory Vocabulary Work Group previously considered and concluded the following were viable standards with no preference for either: 1) U.S. Census 2010 Industry/Occupation codes[3], 2) National Institute for Occupational Safety and Health (NIOSH) list (which includes an Industry and Occupation Computerized Coding System (NIOCCS)[4].

8) Page 7, regarding "Lab tests; LOINC"

ACLA requests that ONC clarify if "Lab tests" is for reporting or ordering. The LOINC code is not always the same value for the test and result. LOINC codes used for orders should be referenced as Universal Laboratory Order Codes per the LOINC website.[5] Consider that the S&I Framework aLOINC Order Codes report is incomplete at this time, it is premature to require this coding system as the only vocabulary. Also, when new tests are introduced, there is considerable lag time before a LOINC code is available from Regenstrief, requiring laboratories to use local codes. ACLA supports the following recommendations from the March 9, 2015 draft of the aLOINC Order Code & S&I Framework Initiative Report[6]:

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[1] http://www.cdc.gov/nchs/data/dvs/Race_Ethnicity_CodeSet.pdf
[2] http://wiki.siframework.org/LRI+Vocabulary+WG
[3] http://www.census.gov/people/io/methodology/indexes.html
[4] http://www.cdc.gov/niosh/topics/coding/overview.html#intro
[5] http://loinc.org/usage/orders
[6] http://wiki.siframework.org/a+LOINC+Order+Code+homepage

- "ONC should encourage moving toward the use of LOINC codes, but allow for both a LOINC and local code, or just a local code, to be included in the order and result message";
- "ONC should ensure that Regenstrief has sufficient resources to provide a timely response to the anticipated increased demand for new LOINC codes";
- "ONC should consider asking Regenstrief to convene a panel of experts to determine the best way to code Anatomic Pathology orders and results".

9) Page 7, regarding "Numerical references and values"

ACLA notes that issues with UCUM in the laboratory domain remain unresolved. ACLA recommends ONC convene a UCUM summit to resolve all issues identified by the ONC Charge for Laboratory Work Tiger Team in the document, Recommendation for UCUM as Standard Vocabulary for Units of Measure; Issues for Consideration by Regenstrief. These recommendations include creating a U.S. realm extension.

10) Page 7, regarding "Preferred language"

ACLA supports identifying a single standard whenever and to the extent possible and practicable. If for "Preferred language" ISO 639-2 is recommended, ACLA suggests the other ISO representations be removed.

11) Page 7, regarding "Procedures (medical)" inclusion of CPT-4/HCPCS

In the Scope section on page 2, the Advisory states, "The Advisory does **not** [sic] include within its scope administrative/payment oriented interoperability purposes or administrative transaction requirements that are governed by HIPAA and administered by the [CMS]." CPT codes are used for billing purposes and therefore are out of the scope of the Advisory and should be removed from the "best available" designation for "Procedures (medical)" standards.

12) Page 7, regarding "Race"

ACLA notes that some elements, such as "race", have both administrative and clinical usage. For example, "race" may be collected and used for administrative purposes, but may also have clinical significance for some laboratory test results and should be carefully defined. When clinically significant, the patient's "race" is managed using an AOE question. This process is defined in the eDOS Implementation Guide as noted above in Comment 5.

13) Page 7, regarding "Sex"

ACLA recommends re-labeling, "Sex", to alternatively read, "Administrative Sex" to standardize ONC terminologies. As noted above, certain elements (such as "sex") have both administrative and clinical definitions. HL7, for example, utilizes "Administrative Sex" for administrative purposes such as billing and claims. ACLA further recommends utilizing the HL7 V2 values for "Administrative Sex".

It is critical to harmonize requirements or "best available" recommendations so as not to create conflicts with other mandated standards or implementation guides. Such conflicts have been observed in "Administrative Sex" even from HL7 V2 to V3 value sets where V2 supports the value "Unknown" (which is not interchangeable with the value of "Ambiguous" or "Undifferentiated"); however V3 does not support "Unknown". This type of conflict can increase the cost of developing and deploying terminology standards. To further avoid costs produced by nonmatching or seemingly conflicting standards, ONC could provide mappings between required vocabularies for national use and provide instructions for handling unmapped concepts between HL7 versions. These mappings could be published via the Value Set Authority Center (VSAC).[7]

14) Page 8, regarding "Data element based query for clinical health information"

ACLA requests that ONC clarify the use of the Fast Healthcare Interoperability Resources (FHIR) website under "Data elements based query for clinical health information". It is not clear as written in the Advisory, how use of FHIR will be reconciled with the "Common Clinical Data Set" in the ONC Roadmap.

15) Page 8, regarding "Electronic transmission of lab results to public health agencies"

ACLA suggests additionally name the later version of the HL7 2.5.1 Implementation Guide for "Electronic transmission of lab results to public health agencies", namely, "HL7 Version 2.5.1 IG: Electronic Laboratory Reporting to Public Health, DSTU R2 – U.S. Realm, published November 2013.

16) Page 9 and 12, Question 5-14, regarding "Lab – results (receipt)"

Question 5-14 asks, "Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year's 2016 Advisory once finalized?" In addition to the LRI IG, ACLA strongly recommends including the LOI and eDOS Implementation Guides in the 2016 Advisory. These implementation guides are designed to work collaboratively, and provide cohesive standardization for the laboratory/EHR/provider work flow. ACLA also recommends for "Lab – results (receipt)" that "HL7 V2.5.1" be listed in the "Standard(s)" column and "HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – U.S. Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012" be moved to the "Implementation Specification(s)" column to better conform with the remainder of the table such as with the "Electronic transmission of lab results to public health agencies" and "Immunization registry reporting" entries in the same table.

17) Page 9 and 12, Question 5-14, regarding "Lab – orders"

[7] https://vsac.nlm.nih.gov/

In sequential response to the same Question 5-14 addressed in comment 15, ACLA strongly recommends including LOI and eDOS Implementation Guides in the 2016 Advisory for "Lab – orders". These implementation guides are designed to work collaboratively, and provide cohesive standardization for the laboratory/EHR/provider work flow.

18) Page 9 and 12, Question 5-14, regarding "Lab – Directory of Services"

Following Comments 16 and 17, ACLA strongly recommends including LOI and eDOS Implementation Guides in the 2016 Advisory for "Lab – Directory of Services".

19) Page 12, Question 5-13

Question 5-13 asks, "If a preferred or specific value set exists for a specific purpose and the standard purpose and the standard adopted for that purpose, should it be listed in the "implementation specification" column or should a new column be added for value sets?" ACLA recommends adding a new column for value sets. In some instances (such as with the harmonized Laboratory Implementation Guides), approximately 75 different "value sets" are currently defined.

20) Page 12, Question 5-18

Question 5-18 asks, "Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?" ACLA recommends the preferable approach of listing HL7 messages in the context of the implementation guide which includes use cases, and additional message detail and constraints. For example, the suite of Laboratory Implementation Guides are resolving long standing interoperability issues with this level detail.

Conclusion

ACLA, again, appreciates the opportunity to comment on the Interoperability Advisory. If there are any questions regarding the above comments, please do not hesitate to contact us by phone at (202) 637-9466 or via e-mail at tsparkman@acla.com.

Sincerely,

Thomas B Sparkman, RPh, MPP, JD
Vice President, Government Relations