November 6, 2015

Dr. Karen DeSalvo
Acting Assistant Secretary for Health
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 2016 Interoperability Standards Advisory [Draft for Comment]

Dear Secretary DeSalvo:

I am submitting the attached comments on behalf of the American Clinical Laboratory
Association (ACLA) in response to the *2016 Interoperability Standards Advisory [Draft for
Comment]* (hereinafter "the Draft").

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 Draft 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.

Sincerely,

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

ATTACHMENT

ATTACHMENT: ACLA Comments on the 2016 Interoperability Standards Advisory [Draft for Comment]

General Comments:

1. ACLA appreciates the Draft's new format; it is much clearer and simplifies the comment process.

2. While many of the standards cited are identified as "Free" (see inset), there is still a significant resource cost to implement in systems and test interoperability between trading partners. Inset (from Draft page 7):

   #5: Cost
   This characteristic conveys whether a standard or implementation specification costs money to obtain.
   - "$" – when this designation is assigned, it signifies that some type of payment needs to be made in order to obtain the standard or implementation specification.
   - "Free" – when this designation is assigned, it signifies that the standard or implementation specification can be obtained without cost. This designation applies even if a user account or license agreement is required to obtain the standard at no cost.

Specific Comments:

Page #	Comment
9	**I-B: Care Team Member**
	Interoperability Need: Representing care team member (health care provider)
	<table><tr><td>Type</td><td>Standard/Implementation Specification</td><td>Standards Process Maturity</td><td>Implementation Maturity</td><td>Adoption Level</td><td>Regulated</td><td>Cost</td><td>Test Tool Availability</td></tr><tr><td>Standard</td><td>National Provider Identifier (NPI)</td><td>Final</td><td>Production</td><td>●●○○○</td><td>No</td><td>Free</td><td>N/A</td></tr></table>
	Limitations, Dependencies, and Preconditions for Consideration: • For the purpose of recording a care team member, it should be noted that NPI permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of 'person'. • There is a SNOMED-CT value set for a "subjects role in the care setting" that could also be used in addition to NPI for care team members. **Applicable Security Patterns for Consideration:** • Feedback requested
	Comment: ACLA agrees with the usage of NPI but would like to recognize a concern with adopting SNOMED-CT for this subject role without a formal pilot and assessment determining its possible usage and adoption.
9	**Text:** I-C: Encounter Diagnosis: Interoperability Need: Documenting patient encounter diagnosis

Page #	Comment
	Interoperability Need: Documenting patient encounter diagnosis | Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
---	---	---	---	---	---	---	---
Standard	SNOMED-CT	Final	Production	●●●●○	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●○	Yes	Free	N/A | | Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested | **Comment:** The definition for "Encounter Diagnosis" needs clarification in order to determine which standard(s) are appropriate. For example, SNOMED-CT may be used for patient "Problem" list but not the actual patient diagnosis, which is a clinical function, but is not typically used in the US Realm for administrative diagnosis. ICD-10 was required for adoption October 1, 2015.
10	**Text:** I-D: Race and Ethnicity: Interoperability Need: Representing patient race and ethnicity **Interoperability Need: Representing patient race and ethnicity** | Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
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Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Production	●●●●●	Yes	Free	N/A | | Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. • The HIT Standards Committee noted that the high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions.	• Feedback requested	

Page #	Comment
	Comment: **Race** 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 tests results and should be carefully defined. When clinically significant, the patient's "race" should be managed using an "Ask on Order Entry" question (AOE). 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. As a clinical example, Glomerular Filtration Rate, Estimated (eGFR) results reference ranges vary based on race. **Ethnicity** 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 tests results and should be carefully defined because the OMB definition is not adequate for clinical purposes. When clinically significant, the patient's "ethnicity" should be managed using an "Ask on Order Entry" question (AOE). 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. ACLA feels the adoption of OMB values for race and ethnicity is overstated; while some values in the OMB value set are commonly used, we do not concur there is widespread adoption of the OMB standard.
14	**Text:** I-J: Lab tests: Interoperability Need: Representing laboratory tests and observations **Interoperability Need: Representing laboratory tests and observations** | Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
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Standard	LOINC	Final	Production	●●●●○	Yes	Free	N/A	 **Limitations, Dependencies, and Preconditions for Consideration:** • The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology. • The HIT Standards Committee recommended that organizations not using LOINC codes should maintain and publish a mapping of their codes to the LOINC equivalent until migration to LOINC has occurred. **Applicable Security Patterns for Consideration:** • Feedback requested

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	Comment: It can sometimes take several months to obtain a LOINC, thus it is impossible to provide a mapping while awaiting a number from Regenstrief. Additionally, some very specialized laboratory tests may never receive a LOINC code assignment. ACLA does not view SNOMED cited in the "Standard" section, therefore it is unclear how to interpret the HITSC recommendation; further we don't believe that SNOMED adoption is level 4.
14	**Text:** I-I Industry and Occupation: Interoperability Need: Representing patient industry and occupation **Interoperability Need: Representing patient industry and occupation** <table><tr><td>Type</td><td>Standard/Implementation Specification</td><td>Standards Process Maturity</td><td>Implementation Maturity</td><td>Adoption Level</td><td>Regulated</td><td>Cost</td><td>Test Tool Availability</td></tr><tr><td>Standard</td><td>[See Question 4-5]</td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> Limitations, Dependencies, and Preconditions for Consideration: Applicable Security Patterns for Consideration: • Feedback requested • Feedback requested **Section I: Vocabulary/Code Set** 4-5. Based on public feedback and HIT Standards Committee review, there does not appear to be a best available standard for several "interoperability needs" expressed in this section of the draft Advisory. Please provide feedback on whether this is correct or recommend a standard (and your accompanying rationale). **Comment:** The ONC S&I Framework Laboratory Vocabulary Work Group previously considered two options, and felt the following were viable candidates with no preference given to either: • US Census 2010 Industry/Occupation codes: http://www.census.gov/people/io/methodology/indexes.html • National Institute for Occupational Safety and Health (NIOSH) list, which includes an Industry and Occupation Computerized Coding System (NIOCCS), available on the CDC website: http://www.cdc.gov/niosh/topics/coding/overview.html#intro[1]
15	**Text:** I-L: Numerical References & Values: Interoperability Need: Representing numerical references and values

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[1] The NIOSH Industry and Occupation Computerized Coding System (NIOCCS) is a web-based software tool designed to translate industry and occupation (I&O) text to standardized I&O codes. It is used by occupational researchers, federal government agencies, state health departments and other organizations that collect and/or evaluate information using I&O. Its purpose is to provide a tool that reduces the high cost of manually coding I&O information while simultaneously improving uniformity of the codes.

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	Interoperability Need: Representing numerical references and values <table><tr><td>Type</td><td>Standard/Implementation Specification</td><td>Standards Process Maturity</td><td>Implementation Maturity</td><td>Adoption Level</td><td>Regulated</td><td>Cost</td><td>Test Tool Availability</td></tr><tr><td>Standard</td><td>The Unified Code of Units of Measure</td><td>Final</td><td>Production</td><td>●●●○○</td><td>No</td><td>Free</td><td>N/A</td></tr></table> **Limitations, Dependencies, and Preconditions for Consideration:** / **Applicable Security Patterns for Consideration:** • The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations. / • Feedback requested **Comment:** Some 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 <u>Recommendation for UCUM as Standard Vocabulary for Units of Measure; Issues for Consideration by Regenstrief</u>; these recommendations include creating a US Realm Extension. Or, another workshop similar to the recent FDA/CDC/NLM Semantic Lab Interoperability. ACLA believes the adoption level is overstated; while the UCUM values may coincidentally be used by labs, widespread adoption of the UCUM standard is minimal at best.
23	**Text:** II-H: Laboratory: Interoperability Need: Receive electronic laboratory test results

Interoperability Need: Receive electronic laboratory test results

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm* [no hyperlink available yet]	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:

- HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.

Applicable Security Patterns for Consideration:

- Feedback requested

Page #	Comment
	Comment: • While HL7 2.x is widely adopted, ACLA believes the adoption level for HL7.2.5.1 is overstated. • Standards in other entries are marked as Regulated; should HL7 2.5.1 be marked as regulated? • ACLA believes the adoption level for the LRI IG is overstated; while EHRs certified to the LRI standard, they did not actually implement the LRI IG. • The Companion Guide has been added to the HL7 Master Grid of Standards at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=413
23	**Text:** II-H: Laboratory: Interoperability Need: Ordering labs for a patient **Interoperability Need: Ordering labs for a patient** | Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
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Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm *[no hyperlink available yet]*	Draft	Pilot	●○○○○	No	Free	No	 **Limitations, Dependencies, and Preconditions for Consideration:** • HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. **Applicable Security Patterns for Consideration:** • Feedback requested **Comment:** • While HL7 2.x is widely adopted, ACLA believes the adoption level for HL7.2.5.1 is overstated. • Standards in other entries are marked as Regulated; should HL7 2.5.1 be marked as regulated? • The Companion Guide has been added to the HL7 Master Grid of Standards at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=413
24	**Text:** II-H: Laboratory: Interoperability Need: Support the transmission of a laboratory's directory of services to health IT

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	Interoperability Need: Support the transmission of a laboratory's directory of services to health IT.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Standard	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 *[no hyperlink available yet]*	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• Feedback requested

Comment:
- While HL7 2.x is widely adopted, ACLA believes the adoption level for HL7.2.5.1 is overstated.
- Standards in other entries are marked as Regulated; should HL7 2.5.1 be marked as regulated?
- The eDOS IG is Final and has been added to the HL7 Master Grid of Standards at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=151
- eDOS IG final title is: HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Realm; change first Release 2 to R2 (recent update in HL7 naming conventions
- The Companion Guide has been added to the HL7 Master Grid of Standards at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=413

25

Text:

II-K: Public Health Reporting: Interoperability Need: reporting antimicrobial use and resistance information to public health agencies

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●●○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to implementation guide for additional details and contract information for enrolling in the program.	• Feedback requested

Page #	Comment
	Comment: ACLA recommends continued coordination between standards bodies and implementation guides so there are not downstream requirements (i.e. public health) that are not supported by the upstream feeder system (such as the lab reporting to EHR system).
26	**Text:** II-K: Public Health Reporting: Interoperability Need: Reporting cancer cases to public health agencies **Interoperability Need: Reporting cancer cases to public health agencies** *(see table below)* **Comment:** ACLA recommends continued coordination between standards bodies and implementation guides so there are not downstream requirements (i.e. public health) that are not supported by the upstream feeder system (such as the lab reporting to EHR system).
27	**Text:** II-K: Public Health Reporting: Interoperability Need: Electronic transmission of reportable lab results to public health agencies

Interoperability Need: Reporting cancer cases to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm	Draft	Production	●●●○○	Yes	Free	Yes
Emerging Alternative Implementation Specification	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:
- Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements.

Applicable Security Patterns for Consideration:
- Feedback requested

Page #	Comment
	Interoperability Need: Electronic transmission of reportable lab results to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation specification	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1*	*Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements.	• Feedback requested

Comment:
- While HL7 2.x is widely adopted, ACLA believes the adoption level for HL7.2.5.1 is overstated.
- ACLA recommends continued coordination between standards bodies and implementation guides so there are not downstream requirements (i.e. public health) that are not supported by the upstream feeder system (such as the lab reporting to EHR system).
- ACLA does not believe that the adoption level of the named Implementation Specification is as widespread as indicated. It is marked 'Final' but is not a normative document.
- ACLA suggests citing the later version of the electronic lab reporting implementation guide: HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm) Draft Standard for Trial Use, Release 1.1, published May 2014, in lieu of the older Informative implementation guide which does not address gaps resolved by the May 2014 Implementation Guide.

| 28 | **Text:** |
| | II-K: Public Health Reporting: Interoperability Need: Reporting administered immunizations to immunization registry |

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	Interoperability Need: Reporting administered immunizations to immunization registry

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements.	• Feedback requested

Comment:
ACLA recommends continued coordination between standards bodies and implementation guides so there are not downstream requirements (i.e. public health) that are not supported by the upstream feeder system (such as the lab reporting to EHR system).

Text:
III-A: An unsolicited "push" of clinical health information to a known destination

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Interoperability Need: An unsolicited "push" of clinical health information to a known destination between individuals

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*
Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes
Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	No	Free	No
Emerging Alternative Standard	*Fast Healthcare Interoperability Resources (FHIR)*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **Recipient Encryption** - the message and health information are encrypted for the intended user • **Sender Signature** – details that are necessary to identity of the individual sending the message

Comment:
ACLA believes that the adoption level of the "Direct" standard is overstated and not as widespread as indicated.