May 29, 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 Proposed Rule, "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications", RIN 0991-AB93, 45 CFR Part 170, March 30, 2015 (80 FR 16804)

Dear Secretary DeSalvo:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the Proposed Rule, "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications", RIN 0991-AB93, 45 CFR Part 170, March 30, 2015 (80 FR 16804).

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, again, appreciates the opportunity to comment on this proposed rule. 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

ATTACHMENT: ACLA Comments

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Comments by the American Clinical Laboratory Association (ACLA) on the Proposed Rule, "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications", RIN 0991-AB93, 45 CFR Part 170, March 30, 2015 (80 FR 16804)

<table>
<tr><th>Page</th><th>ACLA Comment</th></tr>
<tr><td>16871

16905</td><td>FR Section or Text:
"3. Common Clinical Data Set Definition
"…
"Vocabulary Standards
"We propose to include HL7 Version 3 (''AdministrativeGender'' and a nullFlavor value) for sex

ACLA Comment:
ACLA suggests you re-label as "Administrative Sex" to standardize your terminologies; this could be handled as a mapping of term names, e.g. HL7 V2 "Administrative Sex" maps to HL7 V3 "Administrative Gender"

Some data elements, such as "sex" have both administrative and clinical usage. For example, HL7 V2 has the concept of "Administrative Sex" – used for administrative purposes such as billing/claims, inpatient bed assignments, etc., but they also have the concept of "clinical" gender, used for clinical purposes. These distinctions need to be clearly defined in the Common Clinical Data Set.

We suggest using HL7 V2 "Administrative Sex" values; this concept is used in "[R] HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm DSTU," as well as the S&I Framework LOI, eDOS, and ELR Implementation Guides. Please harmonize requirements so they are not in conflict with currently mandated Standards/Implementation Guides. We too wish to avoid "sunk costs" by re-developing terminology standards.

At minimum, 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) https://vsac.nlm.nih.gov/

Example Mapping for V2 Administrative Sex/V3 Administrative Gender
<table>
<tr><th>HL7 V2.5.1</th><th>HL7 V3</th></tr>
<tr><td>F-Female (HL7 Table 0001)</td><td>F-Female (AdministrativeGender)</td></tr>
<tr><td>M-Male (HL7 Table 0001)</td><td>M-Male (AdministrativeGender)</td></tr>
<tr><td>A-Ambiguous (HL7 Table 0001)</td><td>UN-Undifferentiated (AdministrativeGender)</td></tr>
<tr><td>N-Not Applicable (HL7 Table 0001)</td><td></td></tr>
<tr><td>O-Other (HL7 Table 0001)</td><td></td></tr>
<tr><td>U-Unknown (HL7 Table 0001)</td><td>UNK (NullFlavor)</td></tr>
</table>
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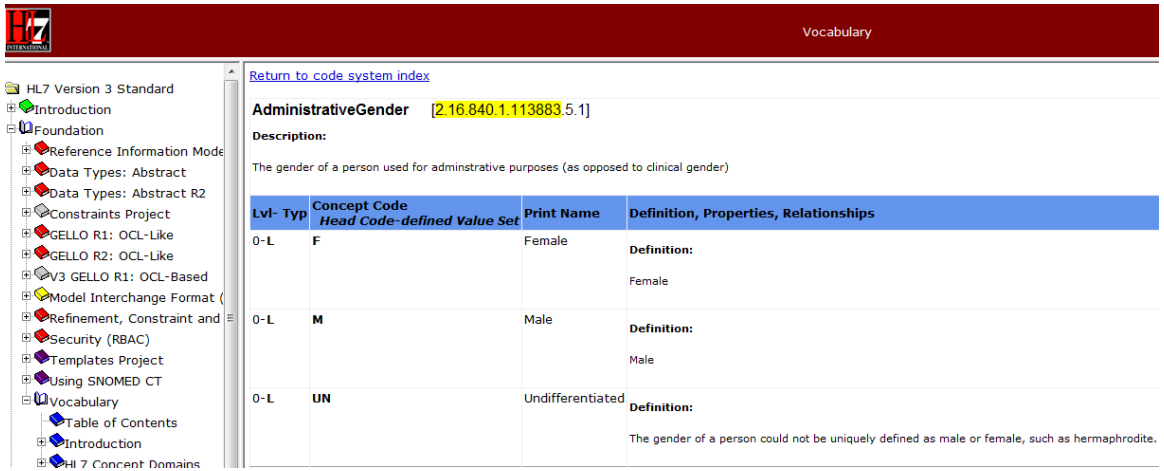
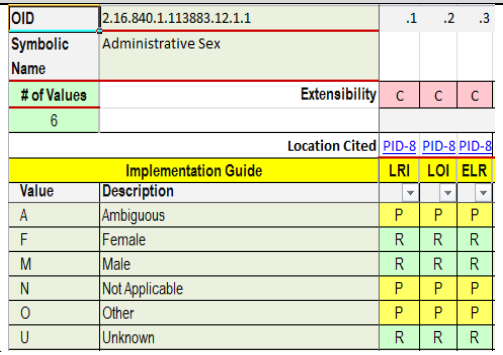
Page	ACLA Comment
	HL7 V3 Value Set: Note: V3 Definition for "Undifferentiated" is defined as "The gender of a person could not be uniquely defined as male or female, such as hermaphrodite." This is not equivalent to "Unknown" and appears you excluded, but should be included for mapping of "Ambiguous". HL7 V3 AdministrativeGender  HL7 V2.5.1 Administrative Sex | Type	Table	Name	Value	Description
---	---	---	---	---
User		Administrative Sex		
	0001		A	Ambiguous
	0001		F	Female
	0001		M	Male
	0001		N	Not applicable
	0001		O	Other
	0001		U	Unknown	 The table below from the HL7 September 2014 LRI/LOI ballot Value Set (HL7 V2.5.1 values). NIST requires each value set, in the context of each "Location Cited" be defined as "P-Permitted, R-Required, or E-Excluded". PID-8 is HL7 V2.5.1 "Administrative Sex". Reconciliation and implementing this level of detail definition is extremely time consuming, thus represents enormous "sunk costs" if replaced by different vocabularies in the ONC 2015 Edition HIT Certification.

Page	ACLA Comment
	Criteria 

OID	2.16.840.1.113883.12.1.1		.1	.2	.3
Symbolic Name	Administrative Sex				
# of Values		Extensibility	C	C	C
6					
		Location Cited	PID-8	PID-8	PID-8
	Implementation Guide		LRI	LOI	ELR
Value	Description				
A	Ambiguous		P	P	P
F	Female		R	R	R
M	Male		R	R	R
N	Not Applicable		P	P	P
O	Other		P	P	P
U	Unknown		R	R	R

Additional Comment for consideration:
Overall, ACLA has concerns with the rules citing specific values and tables as these are dynamic and may change in the future. For example, HL7 table values and LOINC value reference. We recommend these types of actual values be leveraged in a flexible document, like an FAQ, Implementation Guide or non-regulatory artifact.

We would strongly recommend removing the language "nullFlavor value attributed as follows: M (Male), F (Female), and UNK (Unknown)" and only referencing the standard itself.

16904	**FR Section or Text:** "(g) *Preferred language*—(1) *Standard.* "As specified by the Library of Congress, ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1 (incorporated by reference in § 170.299). "(2) *Standard.* Request for Comments (RFC) 5646." **ACLA Comment:** ACLA supports identifying a single standard as much as possible; ISO 639-2 was marked as [R[1]] in the ONC Interoperability Standards Advisory, suggest the other ISO representations be removed.

[1] *A superscript [R] is noted before a standard or implementation specification if it meets the first "best available" characteristic – adopted in regulation by HHS or required by another federal agency*

Page	ACLA Comment
16905	**FR Section or Text:** "(m) *Numerical references*—(1) *Standard.* The Unified Code of Units of Measure, Revision 1.9." **Comment:** 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 US Realm Extension. UCUM version 1.9 does not contain the usable list of common UCUM measures as referenced on page 16818. If the "Table of Example UCUM Codes for Electronic Messaging 1.3"[2] is to be referenced, then it needs to be incorporated into the UCUM, Revision 1.9, at a minimum, as an Appendix to the document. References posted on the LOINC website at: http://loinc.org/usage/units.
16905	**FR Section or Text:** "(n) *Sex*—(1) *Standard.* Birth sex must be coded in accordance with HL7 Version 3 attributed as follows: "(i) *Male.* M "(ii) *Female.* F "(iii) *Unknown.* UNK" **ACLA Comment:** Please clarify the meaning of "Birth sex" in this context, for example, does use of this terminology only apply to information exchange for newborns or is this referring to biological or chromosomal sex? If so, please clarify or rename the concept. These "clinical" gender concepts are usually messaged as an "Observation" in HL7 messaging. We strongly disagree with introducing a value set that is in conflict with the S&I Framework Laboratory Implementation Guide standards you have already named. The S&I Framework Laboratory Implementation Guides use the following HL7 V2 table which does completely map to the table values identified above. The value of "U" for Unknown has been in use for over 20 years in the lab industry; why does it need to be changed to "UNK"? Version 3 has had very limited adoption in the laboratory industry in the US Realm. If you intended to reference V3 nullFlavor to represent unknown, please clarify (for example *Unknown* refers to nullFlavor UNK); otherwise, the current verbiage mixes and potentially confuses values from two V3 value sets. In a newborn, unknown (V2 or V3), ambiguous (V2), or undifferentiated (V3) could potentially impact laboratory results/genetic testing.

[2] http://loinc.org/usage/units for consistency

Page	ACLA Comment
16904	**FR Section or Text:** "§ 170.205(l)(2) "(2) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, Version 1.2." **ACLA Comment:** There is no Version 1.2. The last published version of the implementation guide (March 2014) was titled, "HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 1.1 - US Realm." The first "R2" in the title indicates this version is an update to the R1 S&I Framework sponsored implementation guide, published in 2011. The version balloted in January 2015 was titled Release 2, instead of 1.2 due to HL7 naming conventions; it contained sufficient revisions to warrant a new ballot, making it a new "Release." The version currently being reconciled will be titled as follows when published, "HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Realm"
16815	**FR Section or Text:** "We also propose, for the purposes of certification, to require a Health IT Module to be able to use, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC®) adopted at § 170.207(c)(3) (version 2.50) as the vocabulary standard for laboratory orders. This is the most recent version of LOINC®." **ACLA Comment:** LOINC codes used for orders should be referenced as Universal Laboratory Order Codes per the LOINC website: http://loinc.org/usage/orders. Considering that the S&I Framework a LOINC Order Codes report[3] 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 a considerable lag time before a LOINC code is available from Regenstrief, requiring laboratories to use local codes. ACLA supports the following recommendations from the April 30, 2015 draft report of the aLOINC[4] Order Code S&I Framework Initiative Report (page 5). • We support the use of LOINC as the universal code system for laboratory orders. The best practice in messaging is to exchange both the local and the standard code. Further, we recognize that there will be some cases where an appropriate LOINC code does not exist for the test (such as a brand new test). ONC will need to keep this fact in mind on future efforts to standardize coding. • ONC should ensure that the Regenstrief Institute has sufficient resources to provide a timely response to the anticipated increased demand for new LOINC codes.

[3] http://wiki.siframework.org/a+LOINC+Order+Code+Homepage

[4] *a*LOINC refers to agreed upon LOINC code

Page	ACLA Comment
	• A model should be developed for coding anatomic pathology and cytology tests, where a test may include several codes (specimen collection, processing, and interpretation) for orders and results. We recognize the test is for one analyte, therefore it is not a panel. However, if several codes are necessary, there may need to be a way to link all the codes for one test together. ONC and the Regenstrief Institute will need to consider how multiple codes for one analyte are recorded in a structured format which typically has one code per analyte.
	FR Section or Text: "§ 170.315(b)(4) Incorporate laboratory tests and values/results "**(1)** Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (1) Receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2); and, at a minimum, the version of the standard specified in § 170.207(c)(3). (2) Display the tests and values/results received in human readable format. (B) Inpatient setting only. Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format. (ii) Display the test report information: (A) Specified in 42 CFR 493.1291(a)(1) through (3) and (c)(1) through (7); (B) Related to reference intervals or normal values as specified in 42 CFR 493.1291(d); (C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and (D) For corrected reports as specified in 42 CFR 493.1291(k)(2). "Attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record." **ACLA Comment:** This certification criterion specifies meeting requirements for the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI IG), LOINC, and CLIA requirements. Utilizing LOINC may, in some cases, be in conflict with CLIA reporting requirements for test description. In some cases a textual description from the lab must be displayed for CLIA reporting, instead of the related LOINC code description. We encourage ONC to harmonize requirements with CMS and CDC for CLIA reporting so conflicting requirements can be eliminated. A potential area of conflict revolves around the concept of "Reference Report" found in the Functional Requirements Guide, and the CLIA concept of "Report of Record". We seek clarification if these are viewed as equivalent concepts. While the document is clear on the requirement for certified EHRs in the ambulatory setting to be able to support use of the LRI/IG, some certified vendors are requesting changes be made to the existing proprietary laboratory interfaces which deviates from the intended purpose of a common interface across vendors and labs. This has the potential to create a great deal of pressure on the labs to modify

Page	ACLA Comment
	numerous non-standard interfaces when labs would rather leverage the time and resources that have been dedicated to support the LRI/IG. EHRs should be strongly encouraged to utilize the LRI/IG with laboratory systems whenever available.
16838	**FR Section or Text:** "EHR–S Functional Requirements LRI IG/Testing and Certification Requirements "We seek comment on the HL7 EHR–S Functional Requirements for the V2.5.1 Implementation Guide: S&I Framework Lab Results Interface R2, Release 1, US Realm, Draft Standard for Trial Use, Release 1 (''EHR–S IG''). The EHR–S IG is currently under ballot reconciliation with HL7.105 The focus of the EHR–S IG is the definition of EHR system functional requirements related to the receipt of laboratory results that are compliant with the LRI Release 2. The EHR–S IG also includes additional requirements as set forth in CLIA as well as clinical best practices beyond the scope of LRI Release 2. "We specifically seek comment on the clarity and completeness of the EHR–S IG in describing the requirements related to the receipt and incorporation of laboratory results for measuring conformance of a Health IT Module to LRI Release 2. In addition, we seek comment on how a Health IT Module should be tested and certified consistently and uniformly for the incorporation of laboratory results data. For example, should testing and certification require the Health IT Module to demonstration the ability to associate the laboratory result with an order or patient, to recall the result for display or for submission to another technology, and/or to use the result for automated clinical decision support interventions? Further, what, if any, specific capabilities currently included in the EHR–S IG should be part of testing and certification for this criterion?" **ACLA Comment:** When the EHR-S Functional Requirements LRI IG was balloted through HL7 in January 2015, several sections were not yet completed and it received 454 comments, with an additional 9 "found items" added. It is still undergoing intensive ballot reconciliation; as of April 20, 2015 the ballot reconciliation was 65.9 % complete with 130 open negative comments. Since this document still requires extensive work, and the method to test is not yet defined, it is premature to include in the Final Rule at this time.
16814 - 16815	**FR Section or Text:** **"2015 Edition Health IT Certification Criterion** "§ 170.315(a)(2) (Computerized provider order entry—laboratory) "We propose to adopt and include in this criterion, for the *ambulatory setting,* the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders (LOI) from EHR, Draft Standard for Trial Use, Release 2—US Realm (''Release 2''). […] • "Incorporate US Lab Realm value sets developed for clarity and consistency across all laboratory IGs; and • "Use a new publication method for value sets that allows for precision usage at point of use and provides ''at a glance'' comprehensive usage at the field and component-level across all laboratory IGs; and synced with value set activities (HL7, VSAC, etc.)."

Page	ACLA Comment
	ACLA Comment: Please clarify the last two bullets in this section. ACLA Suggests changing "US Lab Realm value sets" to "US_Lab_Value_Set" as named when balloted through HL7. Lab is not a "realm". ACLA further suggests changing "across all laboratory IGs" to "across all laboratory IGs subject to ONC Certification" and spelling out Value Set Authority Center (VSAC) since it is not in the acronym list.
16812	**FR Section or Text:** **"III. Provisions of the Proposed Rule** "b. Compliance With Adopted Standards and Implementation Specifications In accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards and/or implementation specifications in any subsequent final rule, the entire standard or implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and implementation specification includes the entire document unless we specify otherwise. For example, if we adopted the HL7 Laboratory Orders Interface (LOI) implementation guide (IG) proposed in this proposed rule, health IT certified to certification criteria referencing this IG would need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it would remain that way for testing and certification unless we specified otherwise in regulation. In such cases, the regulatory text would preempt the permissiveness of the IG." **ACLA Comment:** The permissiveness in the Implementation Guide is necessary in some cases, for example, ONC intends to require LOINC for order/test codes related to the Laboratory Orders Interface (LOI) implementation guide (IG). However, when a lab creates a new test, there is a time lag to obtain a new LOINC code from Regenstrief. Also, the LOINC for the order/test code should be assigned by the laboratory, not the EHR Systems, to assure proper encoding. We are concerned that patient safety may be compromised in haste to meet regulatory requirements.
16812	**FR Section or Text:** "….this approach supports our goal to make the ONC Health IT Certification Program more agnostic to health care settings and accessible to health IT that supports care and practice settings beyond the ambulatory and inpatient settings." **ACLA Comment:** The LOI and LRI Implementation Guides named in the rules are specifically targeted for "ambulatory setting" only and do not address distinct differences in laboratory data transmission that exist within the inpatient setting. While these guides are intended to eventually encompass all patient care settings, this has not yet been accomplished. ACLA supports this direction, but gaps remain. **Additional ACLA Comment:** As Clinical laboratory tests have an immeasurable impact on diagnostic and treatment decisions made by clinicians, ACLA agrees with this statement but would recommend an expansion to include anyone exchanging lab results with an external entity should support the

Page	ACLA Comment
	LRI format, regardless of whether they are inpatient or ambulatory. We encourage anyone sending inpatient results to follow the HL7 process for any considerations which may be needed to support that data.
16819	**FR Section or Text:** • "Support for or against the proposal to require attribution of vital sign values using specific LOINC codes and associated metadata;" **ACLA Comment:** Specific LOINC codes should not be referenced in the regulation for vital sign values and other values as it is changing. Overall, ACLA has concerns with the rules citing specific values and tables as these are dynamic and may change in the future. For example, HL7 table values and LOINC value reference. We recommend these types of actual values be leveraged in a flexible document, like an FAQ, Implementation Guide or non-regulatory artifact.
16827	**FR Section or Text:** "What is the highest level of school you have completed or the highest degree you have received? LOINC Codes for question-answer list combination is 63504-5" **ACLA Comment:** Referencing LOINC codes that are designated for specific surveys (i.e. PhenX) in the LOINC database should be excluded from the regulations as they were intended for a different purpose and may be overly restrictive. Overall, ACLA has concerns with the rules citing specific values and tables as these are dynamic and may change in the future. For example, HL7 table values and LOINC value reference. We recommend these types of actual values be leveraged in a flexible document, like an FAQ, Implementation Guide or non-regulatory artifact.
16833 16839	**FR Section or Text:** "Encounter Diagnoses "For encounter diagnoses, we are carrying over the requirement from the 2014 Edition ''ToC'' certification criterion that a Health IT Module must enable a user to create a transition of care/referral summary that also includes encounter diagnoses using either SNOMED CT (September 2014 Release of the U.S. Edition as a baseline for the 2015 Edition) or ICD–10 codes." "Encounter diagnoses (according to the standard specified in § 170.207(i) (ICD–10–CM) or, at a minimum, the version of the standard at § 170.207(a)(4) (September 2014 Release of the U.S. Edition of SNOMED CT)" **ACLA Comment:** The use of two standards for diagnosis codes creates great risk of confusion. ICD-10 is the current standard for diagnosis codes and ACLA recommends ICD-10 should be the only standard referenced here. SNOMED should only be referenced as the standard for the Problem List.

Page	ACLA Comment
16837	**FR Section or Text:** "We propose to adopt a 2015 Edition ''incorporate laboratory tests and values/results'' certification criterion that is revised in comparison to the 2014 Edition ''incorporate laboratory tests and values/results'' criterion (§ 170.314(b)(5))." **ACLA Comment:** The April 15, 2015 CMS NPRM for certification criteria has removed this as a requirement for EP attestation. ACLA requests that ONC clarify the purpose of an EHR certifying this criterion if the EPs do not have any obligation to use it and 2017 is the first time they are attesting? EPs should have to continue to attest to the "incorporate laboratory tests and values/results criterion" in the 2017 MU3 regulations. See CMS comment regarding Incorporate Laboratory Results.
16838	**FR Section or Text:** "In addition, we seek comment on how a Health IT Module should be tested and certified consistently and uniformly for the incorporation of laboratory results data." "As also discussed in the 2015 Edition ''incorporate laboratory tests and values/results'' above, the LRI Release 2 IG requires the information for a test report as specified at 42 CFR 493.1291(a)(1) through (3), (c)(1) through (c)(7), (d), (g), (h) and (k)(2) to be included in the content message. Therefore, inclusion of this standard for certification should not only facilitate improved interoperability of electronically sent laboratory test reports (as discussed in more detail in the 2015 Edition ''incorporate laboratory tests and values/results'' criterion), but also facilitate laboratory compliance with CLIA as it relates to the incorporation and display of test results in a receiving system." **ACLA Comment:** ACLA strongly encourages clarification on what constitutes "display of test results in a receiving system." EHRs can display laboratory results in multiple formats (spreadsheet, flow charts, mobile apps) and stakeholder discussions have not provided agreement as to what information is required to be displayed in each of these formats. CLIA has not yet provided further clarification on this issue, so it is imperative for it to be more clearly defined in these rules.
16838 /16839	**FR Section or Text:** "We also propose, for the purposes of certification, to require a Health IT Module to be able to use, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC) adopted at § 170.207(c)(3) (version 2.50) as the vocabulary standard for laboratory orders."

Page	ACLA Comment
	ACLA Comment: ACLA strongly encourages ONC to include a reference in this section regarding the use of LOINC codes for laboratory orders as specified in the LOI implementation guide (i.e. LOINC codes identified for laboratory orders must be designated by the performing laboratory and not by the EHR).
16898	FYI Typo: Table 8, Item 2 CFR text § 170.315(a)(2) CPOE – laboratory; Average low ($) 508,1300 **ACLA Comment:** $508,1300 is not a valid dollar amount and should be corrected in the final publication.
16901	FYI Typo: Table 9, Item 12 § 170.315(b)(9) Care Plan; Average high ($) 488000 **ACLA Comment :** $488000 should be written as 488,000 to be consistent with the other dollar figures in the tables
16907	**FR Section or Text:** "(A)Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINCcode 8287–5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1);" **ACLA Comment:** Since LOINC is a dynamic and changing database, requirements in regulations to use specific LOINC codes for vital signs will be unnecessarily restrictive and should not be included. In addition, Regenstrief Institute has strongly recommended the use of "methodless" LOINC codes for maximum interoperability. LOINC code 8287-5 specifies "tape measure" as the only method that providers can use to obtain this measurement. In the future, a more optimal LOINC code may be identified, so restricting providers to using specific LOINC codes should be removed from the regulations. Overall, ACLA has concerns with the rules citing specific values and tables as these are dynamic and may change in the future. For example, HL7 table values and LOINC value reference. We recommend these types of actual values be leveraged in a flexible document, like an FAQ, Implementation Guide or non-regulatory artifact. **Additional Comment:** LOINCcode should be two words (LOINC code).
16812	**FR Section or Text:** In accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards and/or implementation specifications in any subsequent final rule, the entire standard or

Page	ACLA Comment
	implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and implementation specification includes otherwise. For example, if we adopted the HL7 Laboratory Orders Interface (LOI) implementation guide (IG) proposed in this proposed rule, health IT certified to certification criteria referencing this IG would need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it would remain that way for testing and certification unless we specified otherwise in regulation. *In such cases, the regulatory text would preempt the permissiveness of the IG.*" (*emphasis added*) **ACLA Comment:** The statement that regulatory text could preempt an IG creates concern. Technical specifications and Implementation Guides are used as guidelines for the software development community. If there are details referenced in the regulation that supersede the published guides they are likely to cause interoperability issues. ACLA recommends that proper protocol be leveraged to request changes through change requests.
16862	**FR Section or Text:** "Based on CMS guidance, the use of the Delivery Notification IG can be used to provide the necessary level of assurance that sent laboratory results are received by a provider.184 Additionally, we note that the Delivery Notification IG could be generally useful for any transmission that requires a high level of assurance." **ACLA Comment:** ACLA recommends this be further clarified for intended use and when necessary leverage the current work completed by the laboratory workgroups in HL7 and the S&I Framework.
16854	**FR Section or Text:** **"**§ 170.315(f)(4) Transmission to cancer registries" **ACLA Comment:** ACLA laboratories follow the Standards for cancer data reporting as provided by NAACCR (North American Association of Central Cancer Registries (www.naaccr.org)). CDC supports laboratories efforts to conform to the *NAACCR HL7 E-Path Version 2.3.1 Specification and Implementation Guide*. Laboratories can include the required LOINC and SNOMED codes in the current HL7 format. ACLA suggests CMS/ONC publish mappings from the currently used NAACCR format to any new cited standards, e.g. the proposed rule referenced Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 and Implementation specifications. HL7 Implementation Guide for CDA © Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1. This approach may enable EHR Systems to support the proposed new standards using existing NAACCR formatted messages from laboratories.