May 4, 2012

American Clinical Laboratory Association

Dr. Farzad Mostashari, National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attn: 2014 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Ste. 729D
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0991-AB82: Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

Dear Dr. Mostashari:

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the proposed rule on the Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries and Medicaid recipients each year, ACLA member companies will be impacted directly by the Proposed Rule.

I. Summary of ACLA's Comments

We urge the Office of the National Coordinator for Health Information Technology ("ONC") to make efforts to ensure that the 2014 certification criteria are consistent with regulations implementing the Electronic Health Record Incentive Program for Stage 2 and with other regulations and guidance that affect laboratories and other health care providers, such as those implementing Clinical Laboratory Improvement Amendments ("CLIA"). ONC should permit some flexibility in the versions of standards for transport, content exchange, and vocabulary so that CEHRTs can take advantage of the most recent versions that feature the functionality best suited for the clinical setting. Finally, we urge ONC to consider the practical impact of certain proposed criteria on laboratories and laboratory tests and to provide exceptions or flexibility, when warranted, to accommodate current laboratory practices.

We note at the outset that we have declined to use ONC's Proposed Rule Public Comment Template.[2] Most of ACLA's comments – and, most likely, many other stakeholders' comments – do not fit neatly into boxes. Several of our comments span several standards, specifications, and criteria; they relate to ONC's general approach, rather than to a particular EHR capability; or they

[1] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, 77 Fed. Reg. 13,832 (Mar. 7, 2012).
[2] http://www.healthit.gov/sites/default/files/pdf/PublicCommentTemplate_3-13-12.pdf.

respond to questions posed in the preamble. The comment format ONC provided in the template cannot accommodate our comments.

II. Substantive Comments

A. ONC and CMS must align their rules on "EHR Standards and Certification Criteria" and "Meaningful Use Stage 2" and each must be consistent with other regulatory requirements.

We urge ONC and the Centers for Medicare & Medicaid Services ("CMS") to coordinate closely as each promulgates final rules on the EHR Certification Criteria, 2014 Edition and on the EHR Incentive Program for Stage 2. (ACLA has submitted comments on CMS's proposed rule separately.) ONC has made efforts to align its certification criteria with CMS's Stage 2 meaningful use objectives, which is encouraging, but it also raises the possibility of unintended inconsistencies between the two rules, based on comments each agency receives and responds to. We hope that, prior to release of the final rules, the agencies thoroughly review the final rules to identify and address both inconsistencies in the rules and any ambiguities that are likely to be confusing to stakeholders. Additionally, the final rules must be consistent with other regulatory requirements, such as CLIA and implementing regulations.

B. ONC must be mindful of the programming burdens laboratories already face.

ONC, along with other agencies, must be mindful of the myriad regulatory initiatives being implemented within a very short two-to-three year window and the programming burdens faced by laboratories and other health care providers. In addition to the "meaningful use" requirements embodied in CMS's companion Proposed Rule, providers are facing the conversion to ICD-10 diagnosis codes in 2014 and the Version 5010 standard for electronic health care transactions, among other major changes. Each of these initiatives requires a tremendous resource commitment to design a compliant program, test it, possibly redesign the system, implement it across an enterprise, and conduct training on how to use it properly. It would be helpful for ONC to work with other entities issuing mandates and deadlines that require significant programming overhauls and re-trainings to prioritize the changes and to stagger them such that providers can manage the cascade of requirements. Doing so would allow all providers to implement the directives more efficiently and effectively and to obtain the intended objectives.

C. ONC should not be overly prescriptive about the exact version and release of vocabulary and messaging protocols.

Throughout the proposed regulations on standards for transport, content exchange, and vocabulary, ONC specifies the version of the standard and sometimes the release, as well. ACLA is concerned that some standards could be outdated within just a few months of the final rule's implementation and that some standards may not be CLIA-compliant. We recommend that rules related to the EHR Incentive Program (from both CMS and ONC) adjust the references to specific standards and versions within the objectives, measures, and certification. ONC should identify version releases as the *minimum versions* that CEHRTs must support, but CEHRTs should not be precluded from adopting newer, more recent codes that have value to patient care. A good example of the kind of verbiage ONC should adopt throughout the rule can be found in proposed 45 C.F.R. §

170.314(f)(8) relating to cancer case information.[3] It says a user must be able to "electronically create cancer case information for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(i); and (ii) At a minimum, the versions of the standards specified in §170.207(a)(3) and (g)." Additionally, while version releases are indicated as a minimum requirement, 2014 Edition CEHRT also should be allowed to support future releases as they become available and proven in the industry. ONC also should consider how to ensure that the most current versions are supported for certification for future adoption and that obsolete versions are phased-out. For example, molecular diagnostic technology evolves constantly, leading to a steady stream of requests for new codes to support the technological advances.

ONC asks for comment on its proposed approach for adopting additional transport standards through interim final rulemaking with comment.[4] ACLA supports this approach. Although we encourage ONC to be mindful of the many programming requirements facing laboratories and other providers – and to permit ample time between deadlines so that providers can implement new systems properly – we would welcome so-called "off-cycle rulemaking" regarding a transport standard if the proposed transport standard would be less expensive and more flexible for providers.

D. The vocabulary standards pertaining to race and ethnicity could be problematic for laboratories in some instances.

ONC's proposed vocabulary standards for race and ethnicity can be problematic for laboratories when conducting laboratory testing for diseases for which an individual's race has clinical significance. ONC proposes that certified EHR technology enable a user to record patient demographic data electronically, including race and ethnicity.[5] It proposes the use of the Office of Management and Budget ("OMB") Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised October 30, 1997, which states, "When self-identification is used, a method for reporting more than one race should be adopted."[6] One problem with the OMB standards is that they allow for text entries, which competes with the imperative to have demographic information entered as structured data.

ACLA notes that there are some laboratory tests for which an individual's race has clinical relevance in determining a normal range, but the proposed standards, which permit selection of more than one race, do not allow for selection of a predominant race. Selection of a predominant race is necessary for the appropriate interpretation of some tests. For example, the normal value for an estimated Glomerular Filtration Rate ("eGFR") test, which measures an aspect of kidney function, is different for African-Americans than for other racial groups.[7] Another such test is maternal serum alpha-fetoprotein concentration, which typically is higher in African-American

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[3] *Id.* at 13,884.
[4] *Id*. at 13,849.
[5] *Id*. at 13,881.
[6] *Id.* at 13,880; *see also* Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, *available at*: http://www.whitehouse.gov/omb/fedreg_1997standards.
[7] *See* GFR MDRD Calculator for Adults, *available at*: http://nkdep.nih.gov/lab-evaluation/gfr-calculators/adults-conventional-unit.shtml.

women than in other women.[8] The OMB standards do not provide a mechanism for determining which of multiple selected races dominates a patient's racial make-up so that the appropriate reference range may be applied.

A patient's race should be an "ask at order entry" question when a health care provider is using Computerized Provider Order Entry ("CPOE") to order laboratory testing. Additionally, ONC should amend this proposed certification criterion by requiring some notation about an individual's predominant race when multiple races are identified.

E. ONC should clarify certain aspects of its public health certification criteria.

As proposed, 2014 EHR certification criteria for the inpatient setting would include the capability to enable a user to electronically record, change, and access reportable clinical laboratory tests and values/results and to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with standards set forth at 45 C.F.R. §170.205.[9] ACLA requests that ONC clarify that the certification criteria relating to the capability to submit information to public health registries applies to certified EHRs, not to laboratory information systems. ONC also should clarify that "reportable laboratory tests" mean only those whose transmission is required under state and local law.

F. SNOMED-CT terminology is not used widely enough for inclusion in EHRs.

ONC asks for comment on the use of SNOMED-CT terms for familial conditions and their inclusion, where appropriate, on a patient's problem list.[10] We believe the requirement for SNOMED-CT vocabulary for diagnostic codes contradicts the current practice of utilizing ICD-9 codes for billing and could cause significant confusion and potential billing discrepancies if required without adequate preparation time. While we agree that certified EHRs should be allowed to support SNOMED-CT, it should not be required at this time. This should be deferred until after the implementation of ICD-10.

In addition, in the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule, released in July 2010, in response to a suggestion that SNOMED-CT be used for reportable lab results, ONC said, "We do not believe that the industry and public health departments are currently able to support the use of SNOMED–CT…for reporting on a widespread basis."[11] ACLA believes this is still true today. ACLA urges ONC to consider the use of SNOMED-CT technology only for the purposes for which it is well-suited, such as reporting laboratory results to public health entities. We also recommend that ONC defer piloting the use of SNOMED-CT for other functions until the next iteration of EHR certification criteria in order to give health care providers additional time to become familiar with it.

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[8] Barbara F. Crandall, Thomas B. Lebherz, Phillip C. Schroth, and Myles Matsumoto, *Alpha-Fetoprotein Concentrations in Maternal Serum: Relation to Race and Body Weight*, CLIN. CHEM. 29/3, 531-533 (1983).
[9] 77 Fed. Reg. 13,884.
[10] *Id.* at 13,838.
[11] Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590, 44,641 (July 28, 2010).

G. Certification criteria relating to incorporating lab test results would be difficult to achieve currently in the inpatient setting and the result display criterion may be inconsistent with CLIA requirements.

ONC proposes that 2014 Certification Criteria include in the inpatient setting "transmission of electronic laboratory tests and values/results to ambulatory providers."[12] ONC says it is proposing to adopt this certification criterion "to further reduce costs and improve the electronic exchange of laboratory tests and values/results."[13] ACLA certainly supports these goals and the electronic exchange of laboratory information in general. However, we are concerned that the application of this criterion to the inpatient setting may be premature. Development of the implementation guide for the ambulatory setting was an extremely involved effort, and it cannot be applied effortlessly to the inpatient setting because of the number of additional complexities associated with the types of laboratory tests ordered for hospitalized patients. The Laboratory Results Interface Implementation Guide was developed for the types of tests commonly ordered in the ambulatory setting and does not address electronic messaging of complex test results such as molecular genetics, anatomic pathology, and cytology. These need further development and testing before they can be included in routine electronic transmission of laboratory results from hospitals to ambulatory providers. ACLA recommends that ONC begin the planning process now for implementation in the next iteration of EHR certification criteria.

ONC also proposes that a certified EHR have the *capability* in both inpatient and ambulatory settings to "electronically display all the information for a test report specified at 42 C.F.R. §493.1291(1) through (7)."[14] As written, this criterion would allow vendors and end users to shut down display of one or more of the test report data elements that CLIA requires laboratories to transmit. This provision should be revised to add the following sentence: "The capability specified in this paragraph must be enabled by default (*i.e.*, turned on), and test report information must be displayed in all instances." Other criteria are qualified by similar language,[15] and given the CLIA requirements that are involved, the same should apply to the test report display criterion.

III. Conclusion

Thank you for your consideration of ACLA's comments and suggestions.

Sincerely,

Alan Mertz, President
ACLA

[12] 77 Fed. Reg. 13,845.
[13] *Id*.
[14] *Id*. at 13,882.
[15] *See*, *e.g.*, proposed 45 C.F.R. § 170.314(d)(2), (3).