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American
Clinical Laboratory
Association

March 15, 2010

Secretary Kathleen Sebelius
Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave., S.W.
Washington, DC 20201

Re: **Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (RIN 0991-AB58)**

Dear Secretary Sebelius:

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit our comments on the *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (the "Interim Final Rule").*[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As the primary providers of clinical laboratory services throughout the country, our members commend the Office of the National Coordinator ("ONC") on its efforts to facilitate the adoption of electronic health records ("EHRs") in accordance with the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), enacted as part of the American Recovery and Reinvestment Act of 2009 ("ARRA").[2]

ACLA's member companies provide laboratory testing for a countless number of the nation's physicians and hospitals for their Medicare beneficiaries. As such, laboratories interact with physicians and hospitals on a daily basis with respect to the electronic transmission of laboratory test results and orders. Therefore, although clinical laboratories are not eligible for incentive funds under the EHR Incentive Programs, laboratory information is an integral component of an EHR. To the extent that the Interim Final Rule addresses how, and if, laboratory information is transmitted, stored, or managed by the certified EHR, laboratories that supply this information to eligible professionals ("EPs") and eligible hospitals, as well as laboratories that develop their own EHRs, will be impacted by the Interim Final Rule. That is, laboratories will need to ensure that laboratory orders and results are compliant with the criteria, standards, and specifications adopted by ONC to facilitate the adoption of certified EHRs by the EPs and eligible hospitals to which we provide services. Accordingly, our comments herein will focus on these aspects of the Interim Final Rule.

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[1] *75 Fed. Reg.* 2014 (Jan. 13, 2010).

[2] For purposes of our comments, any reference to "EHRs" or "EHR technology" includes both Complete EHRs and EHR Modules, as defined in the Interim Final Rule, unless otherwise specified.

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I. Comments on the Interim Final Rule

The Interim Final Rule sets forth the initial set of certification criteria, standards and implementation specifications to support the achievement of meaningful use by EPs and eligible hospitals. This first iteration of criteria, standards, and implementation specifications is intended to ensure that an EP's or eligible hospital's EHR technology has the capacity to facilitate the meaningful use of EHR technology in connection with Stage 1 of the EHR Incentive Programs. As such, this Interim Final Rule is inextricably linked to the Proposed Rule issued by the Centers for Medicare & Medicaid Services ("CMS") on the Medicare and Medicaid EHR Incentive Programs. Given this connection, some of our comments may require changes to the meaningful use measure itself, which, in our view, will impact the criteria, standards, and implementation specifications ultimately adopted by ONC. However, where possible, we have made our best effort to limit our comments to the adopted criteria, standards, and implementation specifications presented in the Interim Final Rule.

A. Certification Criteria

1. Use of Computerized Order Entry ("CPOE")

ONC requires that EHR technology enable a user to electronically record, store, retrieve, and manage, at a minimum, certain order types including laboratory orders.[3] Before commenting on this criterion, ACLA notes its strong support of the inclusion of CPOE as an adopted certification criteria for EHR technology. The benefits of CPOE are several. CPOE is able to decrease delay in order completion, reduce errors related to handwriting or transcription, allow order entry at point-of-care or off-site, provide error-checking for duplicate or incorrect doses or tests, and simplify inventory and posting of charges. As such, CPOE is a notable benefit of using EHR technology and, therefore, should be a required component of any certified EHR technology.

However, we ask that ONC clarify the CPOE measure as well as make some additional modifications to the measure as it relates to the EP. First, we do not think it is appropriate for the use of CPOE to be exclusively used by the physician. As we understand it, the "P" in "CPOE" refers to the physician and does not clearly include the support staff in the physician's office. However, it is the experience of our member laboratories that, in most cases, it is the support staff in the physician's office that conducts the order entry.[4] Accordingly, we are seeking additional clarification with respect to what is meant by "CPOE." Although it is of great importance that the data that laboratories receive is as accurate as possible, it is equally important that not only the physician be permitted to use CPOE for purposes of meaningful use. As such, the CPOE certification criteria should be structured to capture the use of CPOE by other authorized persons, such as support staff. We suggest that ONC clarify that the user of the CPOE includes the EP and any authorized user in the office of the EP who typically enters information into electronic systems. In the alternative, ONC should clarify that the use of CPOE include situations where the EP enters

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[3] 75 *Fed. Reg.* at 2025.

[4] While we realize that based on certain state scope of practice laws that non-EPs may not have the authority to sign orders, for purposes of satisfying the CPOE meaningful use objective non-EPs should count towards satisfying the objective.

only the orders, and the additional demographic and billing information is entered by other authorized users in the EP's office or even by others (*e.g.*, laboratory personnel in the patient service center of a laboratory that collects specimens from the patient). Under such circumstances, the use of CPOE should be considered meaningful use.

Second, the CPOE certification criterion addresses the recording, storing, and managing of orders. The criterion does not include the transmission of the order, a decision that seems incorrect. Specifically, with respect to laboratory orders, CPOE should have the ability to record, store, manage, and transmit order information for laboratory testing to enhance and spur the adoption of the electronic exchange of data. This would increase the reliability of the laboratory results by avoiding errors related to manual order entry and would help to ensure proper testing and billing. The ability to transmit laboratory order information should include the requirement to have standardized bi-directional laboratory interfaces and the functionality to obtain and transmit all laboratory order data necessary for the laboratory to conduct proper testing, patient matching, and billing (including limited coverage rules and printing Advance Beneficiary Notices of Noncoverage ("ABNs")).

Lastly, the CPOE certification criterion should include a prompt for the authorized user of the CPOE to include diagnosis codes at order entry. As indirect providers of care, laboratories rely on the ordering physician to supply the diagnosis codes on the order or requisition. However, it is often the case that the diagnosis code is not included on the order or requisition, which requires laboratories to reach out to the ordering physician to obtain the necessary information for the valid order, as Medicare and other payers require the laboratory to include diagnosis codes. Given the additional time and resources that laboratories expend on this effort, the use of CPOE as part of certified EHRs is an ideal opportunity to incorporate information and prompts that would be helpful to providers, such as laboratories in receipt of the EP's order. Moreover, during the initial stages of the transition from ICD-9 to ICD-10 diagnosis codes physicians will likely find it even more difficult to include the appropriate diagnosis codes, if any at all, as they try to navigate through the new ICD-10 system. As such, we ask that ONC require that as part of the CPOE requirement a prompt notify the ordering EP to include the appropriate diagnosis code on a laboratory order or requisition.

2. *Incorporate Clinical Laboratory Test Results*

The incorporation of clinical lab test results into an EHR as structured data is another adopted certification criterion in the Interim Final Rule.[5] The criterion has four separate components on which we have commented. First, with respect to the receipt of results (42 CFR 170.302(g)(1)), we recommend that ONC specify that HL7 version 2.3.1 be used. In terms of adoption, version 2.3.1 has been widely adopted by vendors and vendors understand the meaning of a structured format in those terms. We are concerned that if ONC does not specify a version with respect to this requirement, there may be confusion as to which version of the standard should be used, and laboratories will have to continue to support multiple standards.

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[5] 75 *Fed. Reg.* at 2026.

Second, with respect to the display of codes in a readable format (42 CFR 170.302(g)(2)), ONC should clarify what is meant by "human readable format." Particularly, we recommend that the name of the test be determined by the laboratory. Specifying another test name, for example, a standard test name that might be applicable to a LOINC code would be confusing to physicians as the standard test name, in many cases, will not match the name of the test in the laboratory's systems or its Directory of Services.

Third, with respect to the display of test report information (42 CFR 170.302(g)(3)), we recommend that this criterion require not only that the certified EHR has the capability of displaying the Clinical Laboratory Improvement Amendments ("CLIA") required report elements at 42 CFR 493.1291(c)(1) through (7), but that the certified EHR be required to display these report elements. This recommendation is of great importance to laboratories because CLIA requires that laboratories ensure that test results are accurately and reliably sent from the laboratory to its final destination. Specifically, section 42 CFR 493.1291(c)(1) through (7) enumerates the required elements (*e.g.*, the test report date, the test performed, etc.) to be included in test reports. Because only the laboratory is subject to the requirements under CLIA, and in turn any liability thereunder, it is critical that certified EHR be required to display the required CLIA test report components so laboratories will not be responsible for any subsequent removal or modification of the test report's content that may occur once the information is transmitted to the EHR vendor before reaching the physician.[6] In other words, by requiring that the CLIA required report elements be displayed in the certified EHR, laboratories will not be unfairly held accountable for any elements that may be removed or altered by other parties from the test report before received by the physician.

Lastly, with respect to the update of a patient's record (42 CFR 170.302(g)(4)), it is unclear as to who is the "user" who will be updating the patient's record and we recommend that ONC make this clear. Is the "user" the physician or anyone in the physician's office? This is important because we are concerned that "user" updates of the patient's record could result in differences between the patient's record in the EHR and the laboratory's report of record. As such, an alternative to this criterion is to require that the user create an additional record, rather than permitting a user to change the original record. This would ensure that the laboratory's record would be the same as the record maintained in the EHR.

3. *Implement 5 Clinical Decision Support Rules*

The Interim Final Rule requires that certified EHR implement five clinical decision support rules.[7] ACLA strongly supports the implementation of clinical decision support rules as part of certified EHR. As noted in our discussion of CPOE, clinical decision support allows providers to make more informed patient care decisions, which will only improve quality of care, efficiency, and

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6 Based on the recently issued CLIA Interpretative Guidelines (S&C-1-12-CLIA), it appears that the EHR vendor, acting as an agent of the physician, may be interpreted as the final destination. However, at this point, it is not clear how these guidelines will be applied in practice and, therefore, we are still concerned that laboratories would be responsible for test report content until it reaches the authorized person or physician. *See* Letter to State Survey Agency Directors, CLIA – Issuance of Revised Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual to Facilitate the Electronic Exchange of Laboratory Information (March 1, 2010).

7 75 *Fed. Reg.* at 2027.

reduce medical errors. With respect to laboratory testing, clinical decision support rules can prompt providers to order medically necessary diagnostic tests for their patients. Of course, however, the decision to order such testing would ultimately be made by the provider.

However, we do seek clarification regarding this criterion and its relation to the clinical quality measures. It is unclear as to which clinical quality measures the clinical decision support rules must relate. Thus, we recommend that ONC make clear whether the clinical decision support rules may be used to support any or all the clinical quality measures set forth in CMS' Proposed Rule for the EHR Incentive Programs.

4. Capability to Exchange Key Clinical Information

Certified EHR is required to have the capability to exchange key clinical information among providers of care and patient authorized entities electronically.[8] Our primary concern with respect to this criterion is that the electronic infrastructure necessary to support this broad level of exchange of information is not universally available throughout the country. As the criterion is written, the exchange of the patient's summary record among providers of care and "patient authorized entities" could include other EHRs, laboratory information systems ("LISs"), health information exchanges ("HIEs"), and possibly personal health records ("PHRs"). Given the range of possibilities for recipients of this information, we request that ONC clarify the scope of this exchange and the term "patient authorized entities."

Additionally, the transmission of a patient summary record that includes diagnostic test results raises serious concerns for laboratories. As discussed above, laboratories are obligated under CLIA to ensure that laboratory test results include certain key elements as part of the test report.[9] As such, in the transmission of test results, the laboratory is accountable for ensuring that the test report includes these CLIA-required test result elements. Accordingly, it is critical that ONC clearly specify the extent to which such key clinical information will be exchanged. Moreover, from the perspective of the laboratory's compliance with CLIA, the laboratory should not be responsible for the test report's content beyond the transmission of such information to the physician. Laboratories should not be indefinitely responsible for exchanges between multiple EHR systems once the initial test report is delivered to the end user. As such, we strongly encourage ONC to work with CMS to ensure that to the extent that the certified EHR transmits laboratory information to an other EHR, HIE, or LIS, the laboratory is relieved of any further regulatory responsibility under CLIA for the display of the required report information in the recipient EHR, HIE, or LIS or for any failure of the original EHR system to be or remain in full compliance with this certification criterion.

5. Capability to Provide Electronic Submission of Reportable Laboratory Results

In accordance with the Interim Final Rule, certified EHR is required to have the ability to provide the electronic submission of reportable laboratory results to public health agencies, and

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[8] *Id.* at 2028.
[9] *See* 42 CFR 1291(c)(1) – (7).

actual transmission where it can be received.[10] As part of this certification requirement, the adopted content exchange standard is Health Level Seven ("HL7") version 2.5.1. However, as discussed in greater detail in the standards portion of these comments, we are concerned that many public health agencies cannot comply with HL7 version 2.5.1 or receive such information electronically at all. Based on our member companies' experience with public health agencies, many of these agencies have not yet adopted version 2.5.1. Thus, we recommend that the content exchange standard be solely HL7 2.3.1 or permit the adoption of either versions 2.3.1 or 2.5.1.

6. Capability to Provide Electronic Syndromic Surveillance Data

ONC requires that certified EHR have the capability of providing electronic syndromic surveillance data to public health agencies, and actual transmission according to applicable law and practice.[11] As part of this criterion, the adopted content exchange standard is HL7 versions 2.3.1 or 2.5.1. Similar to the above criterion relating to public health agencies, our concern here is that some public health agencies do not have capability to receive public health surveillance information in electronic format. In fact, ONC and CMS seem to acknowledge that all public health agencies do not have the ability to receive this information electronically in the meaningful use measure above relating to the electronic submission of laboratory results to public health agencies because for that measure submission seems only to be required if the information can be received. As such, we recommend that ONC clarify that this certification criterion simply requires the ability of the system to record, retrieve, and transmit such information based on at least one test of these capabilities, rather than the *actual* transmission of surveillance data to the public health agency, unless it can be received by the public health agency.

B. Initial Standards

1. Transport Standards

ONC has adopted Simple Object Access Protocol ("SOAP") version 1.2 and Representational State Transfer Rest ("REST") as transport standards for certified EHR technology.[12] We believe, however, that ONC should adopt the SOAP standard, as the sole transport standard for purposes of certified EHR technology for a few reasons. First, the REST protocol is not as widely accepted as SOAP and, therefore, ONC should adopt the standard with the most utility and acceptability. Second, the National Health Information Network ("NHIN") supports the adoption of SOAP and, therefore, we see no reason why ONC should not follow NHIN's lead and adopt yet another standard. Lastly, it is our member companies' experience that the SOAP protocol has better mechanisms related to Quality of Service ("QoS") and interoperable security, which are both critical to the proper functioning of EHRs. Thus, ACLA supports the SOAP method as the sole transport standard.

Additionally, ONC should clarify that the transport standard, regardless of which one, will apply strictly to communications external to the EHR. The transport standard should not be

[10] 75 *Fed. Reg.* at 2028.
[11] *Id.*
[12] *Id.* at 2030.

intended for internal communications within private networks. We ask that ONC make this clear in its final rule.

2. Content Exchange and Vocabulary Standards

As set forth in the Interim Final Rule, the adopted content exchange and vocabulary standards are based on the purpose of the information exchange.[13] Addressing first the content exchange standards, the standard for the submission of laboratory results to public health agencies is HL7 version 2.5.1 and the standard for the submission of surveillance data to public health agencies is HL7 versions 2.3.1 or 2.5.1. While we support the adoption of HL7, we encourage ONC to either adopt only version 2.3.1 or permit the use of either 2.3.1 or 2.5.1 as ONC has allowed for the submission of surveillance data. Based on our member companies' experience, public health agencies are not yet equipped with the technology to accept HL7 version 2.5.1. It is our understanding that, at present, more interfaces make use of version 2.3.1 than version 2.5.1 as it is a relatively new version that has yet to be promoted. In fact, the Centers for Disease Control and Prevention ("CDC") is actively promoting the use of version 2.3.1 for public health reporting when interfacing with state public health agencies. As such, we see little reason to require the adoption of a standard that cannot be used by the receiving public health agency. Moreover, we see no reason for ONC to adopt versions 2.3.1 or 2.5.1 for the submission of surveillance data, but only 2.5.1 for the submission of laboratory results to the same public health agencies. Thus, we strongly recommend that with respect to the content exchange standards for both purposes, ONC either adopt only HL7 version 2.3.1 or permit the use of 2.5.1 as an alternative, to the extent that both the EP and the public health agency have agreed to use the newer standard.

With the respect to the vocabulary standard, ONC has adopted the use of Logical Observation Identifiers Name and Codes ("LOINC") to populate information in a patient summary record related to laboratory orders and results and for the submission of laboratory results to public health agencies when LOINC codes have been received from a laboratory. We, however, have some concerns with respect to the adoption of LOINC. First, ONC adopts LOINC for both laboratory orders and results. However, LOINC is a vocabulary standard that is primarily used for results, and not for orders. ACLA is not aware of any laboratory that uses or accepts LOINC codes for laboratory orders at this time, which suggests the need for thorough testing before the adoption of LOINC for orders. While there are ongoing efforts by the National Library of Medicine and the Health Information Technology Standards Panel ("HITSP") to develop a set of standard order codes using LOINC for a limited number of tests, and for certain tests LOINC may work as an order code, that is not the case for all laboratory orders. Indeed, most laboratories have developed and require their own laboratory-specific order codes that reflect differences relevant to their tests and test menus. Accordingly, the adoption of LOINC for laboratory orders would allow only a limited number of tests to be ordered through the certified EHR. As such, ONC should clarify that LOINC is a vocabulary standard only for laboratory results, and not for laboratory orders. In lieu of this approach, we strongly urge ONC to permit the use of laboratory-specific order codes in addition to LOINC to ensure that certified EHRs cannot only process laboratory orders using LOINC.

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13 *Id.* at 2033.

Second, the adoption of LOINC also raises the issue of what other elements of the LOINC vocabulary will be required of certified EHRs. Each LOINC code has a name associated with the code as well as a variety of other properties. Thus, it is unclear as to whether ONC is requiring the adoption of these other LOINC elements in addition to the LOINC code itself. While we would support the adoption of LOINC codes to the extent that it makes sense to use such codes and as one of the possible vocabulary standards, we would not support the adoption of the other LOINC elements, such as the LOINC description. Specifically, for example, the LOINC name is often a scientific one (*i.e.*, the name of the analyte being tested) rather than the name commonly used by the laboratory and the ordering physician, which, at the very least, will be confusing to the physician or, at worst, will result in physicians ordering the incorrect test. In fact, from a compliance perspective, it is important that the ordering entity be clear on the laboratory test that is being ordered, which would not be the case if LOINC code descriptions were used in lieu of the commonly reported test name. Thus, we ask that ONC make clear that certified EHRs be only required to adopt the LOINC codes as part of the LOINC database.

Lastly, as part of our comments on the adopted standards, ACLA would like to propose the adoption of another standard as part of ONC's Final Rule that has been developed by ACLA member companies. The ACLA Laboratory Test Compendium[14] is intended to streamline the exchange of laboratory orders and results between laboratories and physicians. The industry standard will enable one or more clinical laboratories to automatically and remotely load, update, and maintain their electronic Directory of Services ("eDOS") electronically within the physician's EMR system of choice. The framework is based on the HL7 messaging protocol to maximize industry acceptance and adherence to existing standards. It is not designed to be a "universal" Test Compendium in the sense of a single standardized common set of order codes but, rather, is intended to provide a simple and low-cost template so all clinical laboratories can share their eDOS with their clients and enable EMR systems to support all order codes used by the laboratories that the physician selects and uses. We urge ONC to adopt ACLA's Laboratory Test Compendium Framework as part of its final rule.

3. Privacy and Security Standards

The Interim Final Rule outlines six adopted privacy and security standards for certified EHRs.[15] First, with respect to general encryption and decryption of electronic health information (42 CFR 170.210(a)(1)) and the encryption and decryption of electronic health information for exchange (42 CFR 170.210(a)(2)), we ask ONC to clarify that data encryption is required only for communications to external systems or networks. We ask that the required encryption not be for internal communications over private networks or for "data at rest."

Second, with respect to verification that electronic health information has not been altered in transit (42 CFR 170.210(b)), we are concerned that laboratories would be required to use the hashing algorithm in tandem with each EHR to verify that data has not been altered in transit. There are a number of ways to comply with this standard and each EHR may have its own hashing

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14 A draft of the ACLA Laboratory Test Compendium is available on ACLA's website *at* http://www.clinical-labs.org/issues/technology/edos.shtml.

15 75 *Fed. Reg.* at 2035.

algorithm to satisfy the standard. This, of course, could prove burdensome and expensive to the laboratory if each EHR utilizes a different approach. As such, this seems to be beyond the scope of the EHR certification criteria as it will require the sender of the information and the recipient of the information to comply with this standard, even if the sender does not have an EHR.

Third, with respect to cross-enterprise authentication (42 CFR 170.210(d)), we are concerned that this requirement will be extremely burdensome for laboratories. As laboratories, we often send results to the ordering physician to the extent that the physician has questions. However, not everyone would appear within the enterprise within HITSP, which will require the authentication of physicians for which the laboratory provides no services. Our ability to send results to physicians is based on their having an account number or some other type of identifier on file with the laboratory that allows the laboratory to validate that the information can be sent to the physician. If the physician does not have an account with the laboratory, the laboratory is unable to validate the physician's right to receive the requested tests results. As such, it will be extremely burdensome for laboratories to authenticate physicians with which the laboratory has no relationship. Thus, certification based on this requirement should be deferred for the present, and an alternative and a less burdensome approach to authentication should be considered for future certification requirements subject to notice and public comment.

II. Conclusion

In closing, we appreciate the opportunity to submit our comments on the Interim Final Rule. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Alan Mertz