April 3, 2015

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

DELIVERED ELECTRONICALLY

RE: Comments in response to "Connecting Health and Care for the Nation: A Shared Nationwide Roadmap; DRAFT Version 1.0"

Dear Coordinator DeSalvo:

I am submitting the below comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the Office of the National Coordinator for Health Information Technology's (ONCHIT) "Connecting Health and Care for the Nation: A Shared Nationwide Roadmap; DRAFT Version 1.0" (hereinafter "Roadmap").

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 Roadmap 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 Roadmap as a living document and hope these comments serve to continue to move interoperability forward.

ACLA Comments

1) Page 4, Paragraph 3, "3 critical pathways"

Paragraph 3 of page 4 identifies "3 critical pathways" for HIT interoperability to ultimately "better health for all". ACLA notes that while the second pathway is "motivating […] through use of appropriate incentives", laboratories do not currently receive any direct incentives for implementing, maintaining, or improving interoperability. ACLA further suggests adding a fourth critical pathway, "4) Evaluate outcome of efforts to establish

improved interoperability (e.g. evaluate the outcomes of the Draft Standard for Trial use (DSTU) implementations."

2) Page 6, General Question 2, "What, if any, gaps need to be addressed?"

Many standards referenced are not ready for implementation. Specifically the HL7 standards that are DSTU are designed solely for early adopters who understand the specification is fluid, and changes are likely to occur prior to the standard becoming normative. Can ONCHIT investigate an approach to facilitate faster evolution of HL7 normative standards? For example, ONCHIT could fund two-year pilots for proof of concept of a DSTU implementation guide and, further, compensate pilot participants to offset the risk of implementing the evolving standards.

3) Page 6, General Question 3, "Is the timing of the specific actions appropriate?"

For any given set of referenced standards, the standards need to move beyond draft versions before the given standard is required for use.

4) Page 6, Question 3 regarding "Governance"

Standard Development Organizations (SDOs) should continue to manage projects around coordinated governance processes for nationwide interoperability to ensure that stakeholders continue to view these as a priority.

5) Page 6, Question 4 regarding "Supportive Business, Cultural, Clinical and Regulatory"

It will be essential for federal, state, and private health plans and purchasers to implement the same data exchange formats required for EHR interoperability and accept the common clinical data set for the entity's business practice. Once the common clinical data set is established and utilized for implementation, these third party entities will need to adopt and accept this information for their business transactions.

6) Page 6, Question 5 regarding "Privacy and Security Protections for Health Information"

The Roadmap on page 125 notes that "[a]s all of these health IT systems become connected to each other, the cyber threats increase at a significant rate, as an intrusion in one system could allow intrusions in multiple other systems." This concern echoes similar concerns with consumers allowing their data to be used across multiple entities. Interoperability must carry strong assurance that the healthcare data will not be exposed to a greater risk of cyber threats.

7) Page 6, Question 6 regarding "Core Technical Standards and Functions"

    a. Question 1, "Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

Not all systems are easily defined by vocabularies and national coding systems. There remains a need for local coding systems as well as uncoded values to continue to be supported. Further the datasets including "lab test(s)", "lab value(s)", or "lab result(s)" are large and varied. ONCHIT needs to clarify in the roadmap or point to a specific standard that clarifies what elements these datasets contain (i.e. is either the C-CDA representation or the S&I Framework Laboratory Implementation Guides the appropriate standard?).

In regards to secure and standard service, the most prevalent interface today, especially between high volume trading partners, remains TCP/IP data exchange over a secure tunnel. The TCP/IP exchange removes the need for encryption, provides instantaneous delivery, and enables delivery of results without waiting for a request to send. While this solution is not advantageous for all clients, it should not be overlooked for high volume trading partners.

In regards to modularity, modularity has certain risks, such as result segments being interpreted out of context to the rest of the result data. Attempts to use SOA and API to work with data at a granular level need to take into account the level of granularity necessary to preserve data integrity.

b. Question 2, "Do you believe the approach proposed by the Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?

In lieu of a national identification, the matching criteria appear to be as accurate as possible at this time. Special attention needs to be placed on managing patient records where multiple patients fraudulently present as a single patient.

8) Page 6, Question 7 regarding "Certification Testing"

In addition to the standards work done by SDOs, entities exist that work to establish guidelines and constraints in the use of standards developed by SDOs. The S&I Framework, in particular, has worked to prioritize new standard initiatives and identify needs for constraining implementation guides. In most cases, the newly developed or constrained standards have then been picked up by SDOs and managed per their normal processes. The S&I Framework, however, needs to maintain a project list so that the priority of each project is not lost or overridden by other projects.

9) Page 7, Question 8 regarding "Measurement"

a. Question 1, "Does the measurement and evaluation framework cover key areas? What concepts are missing?

Validation and usability testing should drive the needs to support framework initiatives. Additionally, there needs to be clear definitions of each type of provider and an entity must chose a category within which they belong.

b. Question 2, "Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?

ACLA believes valuable lessons were learned in the initial phases of the EHR Incentive program regarding adoption and usage. While many providers were able to take advantage by establishing a certified EHR in their workflow, there have been unknown successes regarding the actual usage in the end-to-end flow. There needs to be some consideration on the best ways to monitor the usage as intended without creating additional resource burdens (i.e. cost, personnel, time) on the affected users.

c. Question 3, "Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g. encounter, patient, provider, organization)?

While this does appear to be the most soluble approach, ACLA requests the adoption of measurements is simplified and does not provide unnecessary flows for the provider's practice.

d. Question 5, "What measurement gaps should be prioritized and addressed quickly?"

Patient identification is the most impactful concern. A pilot program should be implemented with the Common Clinical Data Set to quickly ensure it would help resolve patient identification issues.

10) Page 12-13, "Common Clinical Data Set"

The Roadmap identifies "Critical Actions for Near Term Wins" on pages 11 through 14, including "2) Improve technical standards and implementation guidance for sharing and using a *common clinical data set*" (emphasis added). ACLA notes that some elements, such as "sex" have both administrative and clinical definitions. For example, HL7 has the concept of "Administrative Sex" – used for administrative purposes such as billing/claims, inpatient bed assignments, etc., but they also have the concept of (clinical) gender, used for clinical purposes. These distinctions need to be clear in the Common Clinical Data Set definition. Additionally, Patient's date of birth, weight, height, race and ethnicity have clinical significance for some laboratory tests results and should be carefully defined. ACLA is willing to assist in the definition of clinically significant data, as well as defining data elements that are clinically significant.

The Common Clinical Data Set discussion in the Roadmap continues onto page 13 proposing that "[t]hese standards should enable sharing a common clinical data set, further constrain implementations of the C-CDA and define standards for data provenance at the document and data element levels and implement standards in a manner that makes sharing and receiving electronic health information easy for users. See the Core Technical Standards and Functions building block for more detail on technical standards actions." ACLA suggests that Data Provenance at the Data Element level must be consistent with

regulatory requirements; for example, laboratories must ensure their IT systems comply with requirements under the *Clinical Laboratory Improvement Amendments of 1988* (CLIA).

11) Page 17, Paragraph 3 regarding secure access to health data for patients, authorized family and care providers

Discussing, "Interoperability Vision for the Future", on page 17, the Roadmap outlines the goal of allowing "appropriate, secure, timely and reliable" access to health data for "individuals, their families, and health care providers". ACLA recommends standards associated with "Blue Button" (i.e. Direct, HTTP, and FHIR) be named as the standards to provide health care information to patients and other authorized family and care providers.

12) Page 20, "Guiding Principles for Nationwide Interoperability", "1. Build upon the existing health IT infrastructure"

ACLA strongly endorses the first Guiding Principle for Nationwide Interoperability on page 20 to "[b]uild upon the existing health IT infrastructure", especially for laboratories who have been working through the ONC S&I Framework on various laboratory interoperability implementation guides since 2011.

13) Page 24, "Core technical standards and functions", Item J, "Consistent Data Formats and semantics (sic)"

Item J of "Core technical standards and functions" on page 20 discusses that some HIT systems "may rely on translation services" in an attempt to achieve common formats. ACLA strongly recommends *against* the concept of translation being applied to clinical laboratory results; results should not be translated into any form other than what was reported by the laboratory as unvalidated changes or manipulation of laboratory data could result in misinterpretation of clinical data that could ultimately result in patient harm. If data is being mapped into a new value, for example such as patient weight changed from U.S. Pounds to Kilograms, both should be stored with mapping provided either after or before the U.S. Pounds. Any results that need to be recalibrated to Kilograms also must be repeated for both the original result based on US Pounds and Kilograms.

14) Page 33, "Governance Principles", "Policy", "Individual Access and Correction"

The Roadmap, on page 33, proposes a policy of allowing individual access and action to update or correct the patient's own data. ACLA recommends that "Individual Access and Correction" be removed from the roadmap at this time. ACLA acknowledges that much of the patient demographic data has no clinical significance on laboratory testing; however, a patient's date of birth, weight, height, race and ethnicity will have clinical significance for some laboratory tests. If the patient modifies his/her data and such modifications are not authenticated by an authorized provider, the change could have a negative impact on the patient's outcome if the modified data is not accurate. For example, if a patient decreased his or her documented weight to the point at which the weight change impacts what might be reported as an abnormal laboratory result, this could potentially have a detrimental effect on the patient's outcome. ACLA continues to support patient access, generally, to the

patient's individual health data while ensuring for the data's security and accuracy to best ensure the safety and highest quality of care for the individual patient.

15) Page 33, "Governance Principles", "Operations", "Inclusive Governance"

The Roadmap's Governance Principles recommend inclusiveness and "adequate stakeholder representation […] in the development of data policies and operations policies". ACLA agrees with this principles and recommends that ONCHIT's Federal Advisory Committees (HITPC/HITSC) be more inclusive, to include representation from the clinical laboratory industry.

16) Page 38, Paragraph 1, regarding reducing potentially duplicative diagnostic testing

The Roadmap discusses, as background, that "economic gains" could be achieved through interoperability through reducing duplication "for instance" of "laboratory and imaging tests". While ACLA concurs that reuse of prior lab results is appropriate in certain scenarios, there are clinical situations where repeating of tests is necessary. Clear guidelines need to be in place to define when reuse of test results is applicable. For example, genetic test results are generally static, but glucose test results are variable and would need to be performed in compliance with American Diabetes Association (ADA) guidelines.

17) Page 43, "Table 2", Column 2, Item 4 regarding transmission, availability, and usability of a "common clinical data set"

On page 43 within "Table 2: Critical Actions for a Supportive Business and Regulatory Environment that Encourages Interoperability" under column 2, "2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality", item 4 states, "ONC will reinforce the ability of individuals and providers across the care continuum to send, receive, find and use a common clinical data set through its funding program." ACLA suggests that ONCHIT provide targeted funding to laboratory related entities to resolve interoperability issues, for example:

- More adequately fund LOINC code issuance so that LOINC codes are issued in a more timely fashion;
- Fund the UCUM summit to resolve all issues identified by the ONCHIT Charge for Laboratory Work Tiger Team in the document "Recommendation for UCUM as Standard Vocabulary for Units of Measure; Issues for Consideration by Regenstrief." These recommendations include creating a U.S. Realm Extension;
- If needed, fund UCUM creation of U.S. Realm Extension to increase and enhance mapping to support interoperability;
- As needed, fund laboratory development to implement UCUM. Laboratories do not receive Meaningful Use Incentive funding. Targeted funding would advance structured data for laboratory results.
- Pilot testing of standards through grants to all participants to offset the development expenses.

18) Page 48, "Table 3", "C2. Providers and technology developers supporting individual empowerment", column 2, item 2

"C2" of "Table 3" on page 48 discusses "enabling patients" to "transmit [the patient's health information] to a destination of the patient's choice." ACLA requests that ONCHIT clarify or provide more granular definition for "destination of the patient's choice". Laboratories are currently required to validate appropriate content and transport standards and security protocols for transmitting health information and without appropriate clarity on the destination for the electronic data, content and security could be compromised and result in negative implications for the patient.

19) Page 76, "Table 9", "I2. Certification programs", column 2, items 1 and 2

"Table 9: Critical Actions for Stakeholder Assurance that Health IT is Interoperable", "I2. Certification programs", column 2, "2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality" discusses identifying for ONCHIT certification criteria that should be added to the ONCHIT Certification Program and having "other existing industry certification programs" continue to "complement ONC's certification program." As required under CLIA, the laboratory industry is inspected every two years to validate that systems and processes meet requirements under the law. This is a no-notice inspection, so the laboratory must be ready at all times. The Centers for Medicare and Medicaid Services (CMS) has licensed the College of American Pathologists (CAP) for this CLIA Certification process that includes an inspection of the procedures that a laboratory follows to validate electronic interfaces between the Lab system and the system used by the physician and/or the hospital. This includes periodic follow-up review of these interfaces that is more precisely defined by the CAP lab accreditation requirements (a more in-depth certification than standard CLIA-certification) by stating it should be accomplished every two years. With this level of inspection already in place, ACLA asserts that there is no need for further certifications in the lab industry. ACLA *does* agree that CLIA needs to be expanded to support electronic formats and encourage ONC to work with CAP, CMS and other accrediting agencies to appropriately address overlapping certification requirements.

20) Page 80, paragraph 2 regarding Standards Development Organizations

Continuing in the "Background" section on page 80, the Roadmap lists a number of SDOs which "are primarily responsible for developing, curating and maintaining all of the standards mentioned above as well as any accompanying information models." ACLA notes that some of the listed SDOs are accredited by the American National Standards Institute (ANSI) and are therefore required to comply with ANSI "best practice"[1]. ACLA recommends that ONCHIT focus on ANSI accredited standards development organizations or only those which adhere to the ANSI Essential Requirements guidelines.

[1] As defined in ANSI Essential Requirements: Due process requirements for American National Standards (2015

21) Page 82, paragraph 3, regarding moving from document-centric information exchange to data element-centric exchange

The Roadmap notes on page 82 that over time the electronic exchange of health care information may shift from the current document-centric model to a more data element-centric model which requires additional interoperability standards for the granular data elements. Given the criticality of secure and accurate transmission, accessibility and usability of laboratory results and the patient-specific data that may affect the actual value or clinical usability of the result from a given clinical laboratory test service, ACLA strongly recommends and requests that the laboratory industry be involved and represented in any effort to develop element-centric standards as HIT and interoperability continue to evolve.

22) Page 82-83, regarding list of standards activities

Pages 82 to 83 of the Roadmap list a "non-exhaustive set of standards activities that are being worked on actively by various standards communities and SDOs" and requests that commenters "recommend additions." ACLA recommends adding the following:

- ONC S&I Initiatives – Laboratory Implementation Guides (Orders [LOI], Results [LRI], electronic Directory of Service [eDOS] and Electronic Laboratory Reporting [ELR]), until the Normative editions of these Implementation Guides are published at the completion of the draft standard for trial use period.
- Anatomic Pathology has complex ordering and reporting requirements that necessitate additional development, beyond currently defined Laboratory Order Implementation Guides [LOI] and Lab Result Interface (LRI) Implementation Guides. These include the following examples:
    - Pap reports include results from Cytology (Pap), Molecular (HPV), Chlamydia) and charts of historical information
    - Specialized Biopsy Reports include organ diagrams showing placement of each biopsy usually color-coded based on severity of diagnoses, and multiple photomicrographs of diseased cells
    - Hematopathology incudes comprehensive integration of results from multiple departments: Histology (marrow biopsy), Hematology (CBC), Molecular, Genetics, Flow Cytometry
    - Telepathology
    - Specimen Identification & 2D barcodes (CLSI/HL7 standard)

23) Page 85, "Table 10", "J4. Vocabulary Approach", column 2, item 1

"J4" of "Table 10" on page 85 states, "1. Through coordinated governance, public and private stakeholders will work with SDOs to define a standard approach to federated distribution of centrally maintained code sets." ACLA suggests utilizing subject matter experts (SMEs) to perform cross-mapping between code set vocabularies. In the case of laboratory terminologies, laboratory SMEs must be involved.

24) Page 85, "Table 10", "J4. Vocabulary Approach", column 2, item 2

"J4" of "Table 10" on page 85 states, "2. Health IT developers will provide accurate translation and adapter services where needed in order to support priority learning health system use cases (see Appendix H for Priority Interoperability Use Cases)." ACLA suggests amending this language to read, "Health IT developers will provide tools to support translation and adapter services. The accuracy of translation and adapter services should be completed by cross functional subject matter experts in order to support priority learning health system use cases (see Appendix H for Priority Interoperability Use Cases)."

25) Page 90, "Table 12", "L3. Receive and Find", column 2

Within "L3. Receive and Find" of "Table 12: Critical Actions for Consistent, Secure Transport Techniques", the Roadmap outlines six recommendations for the 2015-2017 timeframe. ACLA recommends adding the following elements within this timeframe:

- SDOs should pilot, assess and refine standards for SOAP and RESTful web services;
- Health IT developers should implement national standards for SOAP and RESTful web services as they are available.

26) Page 93, paragraph 1, regarding data elements listed as "a starting point for standardization"

Page 93 lists a number of data elements as "a starting point for standardization". ACLA comments include the following:

- Requests that ONCHIT clarifies the meaning of "historical" for the elements "historical address" and "historical phone number" (i.e. is "historical" equivalent to "prior"?);
- Requests that "gender" be clarified to be the equivalent of (or replaced by) "sex" so as to utilize terms already existing and endorsed by ONCHIT in prior final rules;
- Suggests synching the patient matching data elements to existing Meaningful Use standards already named by ONC and, if needed, work with SDOs to support and harmonize data (e.g. validated address fields are handled identically in HL7 V2 (Lab IGs), V3 (C-CDA) and FHIR Resources);
- Recommends harmonizing patient matching data quality proposed elements with the same elements required in the ONC S&C Framework Laboratory Implementation Guides (i.e. LRI, LOI, eDOS, ELR);
- Requests ONCHIT clarify the expectation by vendors that laboratories store and "echo back" data the vendors already have in their system as EHR vendors maintain "historical" data but ambulatory laboratories focus on "current" data. For example, "Previous Last/Family Name, Historical Address, Historical Phone Number, and multiple patient identifiers not applicable to the laboratory." This issue is critical as laboratory data exchange must comply with CLIA requirements. ;
- Recommends that patient identifiers be distributed only as necessary to meet the requirements of the receiving service provider. The ordering provider and the service provider should agree on the identifier(s) for requester and receiver;
- Recommends that data accuracy should be linked to the creator of the data (e.g. the laboratory is responsible for the accuracy of the laboratory data it creates);
- Recommends adding the following additional elements for matching:
  - Gender change

- Place of birth
- E-mail (if more than one is present in the patient record, all should be sent)
- If the patient is part of a set of twins or multiple birth
- Biometric identifiers/processes.

27) Page 97, paragraphs 2-3, regarding EHR | HIE Interoperability Work Group

On page 97, the Roadmap outlines work conducted through the EHR | HIE Interoperability Work Group (IWG) and the ModSpec project. ACLA reiterates Comment 20 (above) and recommends that ONCHIT focus on ANSI accredited standards development organizations or only those which adhere to the ANSI Essential Requirements guidelines.

28) Page 107, "Exchange Activity"

Under "Measuring the Flow and Use of Interoperable Information", the Roadmap outlines measuring "exchange activity" to assess interoperability. ACLA requests that ONCHIT clarify methodology used to measure each component of the Exchange Activity described in this section. ACLA further recommends that the laboratory industry be involved with identifying these methodologies which are related to the laboratory services and industry.

29) Page 107, "Availability and Use of Information from Outside Sources"

The Roadmap on page 107 discusses the potential need for including "information from outside sources at the point of care or the availability of essential electronic health information with online health records for consumers." ACLA requests that ONCHIT clarify what information would be defined as "information from outside sources" and which entities would be considered "outside sources."

30) General Comment regarding Roadmap terminology

At various points within the Roadmap, the Roadmap utilizes the term "lab" generally to identify the clinical laboratory industry. ACLA requests that this terminology be amended throughout the Roadmap to the term "laboratory" or "clinical laboratory" to ensure complete accuracy. (Examples occur on pages 38, 77, 80, 85, and 116.)

31) Pages 163 - 166, "Appendix H"

a. Item 6: Please clarify whether this Use Case is just for order transmissions or tracking of the samples and in the state of the order.

b. Item 8: ACLA recommends this item involve practice changes, physician moves and patient record moves

c. Item 21: In regards to patient access, please clarify whether this means "access" within a patient health record (PHR) or within the healthcare entity.

d. Item 22: True interoperability will require that third party payers adopt and accept the same standardized transactions for the payer's business transactions.

e. Item 41: Item 41 on page 165 reads, "Providers and patients receive electronic laboratory results from laboratory information systems (LISs) inside and outside their organization." ACLA suggests amending to read: "Authorized providers, patients, and/or the patient's authorized custodian(s) receive electronic laboratory results from the laboratory information systems (LISs) inside and outside their organization."

f. ACLA recommends adding the following "Use Case" to "Appendix H" to support anatomic pathology reporting:
   - Anatomic Pathology has complex ordering and reporting requirements that necessitate additional development, beyond currently defined Laboratory Order Implementation Guides [LOI] and Lab Result Interface (LRI) Implementation Guides. These include the following examples:
     - Pap reports include results from Cytology (Pap), Molecular (HPV), Chlamydia) and charts of historical information
     - Specialized Biopsy Reports include organ diagrams showing placement of each biopsy usually color-coded based on severity of diagnoses, and multiple photomicrographs of diseased cells
     - Hematopathology incudes comprehensive integration of results from multiple departments: Histology (marrow biopsy), Hematology (CBC), Molecular, Genetics, Flow Cytometry
     - Telepathology
     - Specimen Identification & 2D barcodes (CLSI/HL7 standard)

Conclusion

ACLA, again, appreciates the opportunity to comment on the Roadmap. 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