May 6, 2015

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to advancing a more connected, interoperable health information technology (IT) infrastructure.

BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1998 (CLIA), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. The Committee has been highly interested in the need for laboratory data interoperability as a way to provide patient-centered health care, reduce care delivery redundancy and costs, support analyses that pinpoint waste and identify best practices, and support public health with real-time case reporting, disease surveillance and disaster response. The Office of the National Coordinator for Health Information Technology (ONC) developed a roadmap, Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0, as a proposal to deliver better care and result in healthier people through the safe and secure exchange and use of electronic health information. After hearing presentations at the April 15-16, 2015 CLIAC meeting on laboratory information exchange in health IT [posted at http://wwwn.cdc.gov/cliac/Meetings/MeetingDetails.aspx (presentation 5, 6 and 7)] and deliberating on the matter, the Committee desires to promptly communicate its recommendation to HHS in response to their concerns regarding the ONC Roadmap.

The committee agrees with the following principles:

*A more connected, interoperable health IT infrastructure will require safe and effective integration of laboratory data

*Actions are needed to advance interoperability by

-making laboratory data more available for interoperability through

-coding and standardization of nomenclature

-ensuring data integrity/accuracy as data transfers

-ensuring data is displayed to maximize interpretation

-ensuring data confidentiality and security

RECOMMENDATION

HHS should convene a multidisciplinary stakeholder group that

* Includes, but is not limited to, representatives from: ONC, Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), industry representatives, health IT developers/vendors, all CLIA-approved accrediting organizations, informaticians, laboratory directors/professionals, provider end-users, patient/consumer representatives, and other relevant professional organizations
* Proposes a framework for achieving safe and effective laboratory interoperability (both system and patient facing) that encourages innovation and defines how to operationalize interoperability (and related deliverables) with detailed use cases
* Provides both short term next steps and long term goals with definable measurable actions and outlines who is responsible for these actions
* Puts into place robust measurement and evaluation strategies for goal achievement

The Committee would like HHS to also consider these points:
Illustrative components that should be addressed by the framework include those described in:

*The CDC White paper: The Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems
http://www.cdc.gov/labhit/paper/Laboratory_Data_in_EHRs_2014.pdf

*A 2012 letter from CLIAC to HHS

https://wwwn.cdc.gov/CLIAC/pdf/2012_Oct_CLIAC_%20to_Secretary_re_EHR.pdf

*Aim to create conditions that promote safe/effective laboratory data interoperability

*Consider incentives and other levers for actions such as new regulation, existing regulation (e.g. CMS Conditions of Participation), evidence-based recommended practices (e.g. ONC SAFER Guides), accreditation (e.g. College of American Pathologists, The Joint Commission) and certification

*Framework would also need to consider creation of new incentives, funding and/or revenue streams to support laboratory data interoperability

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory interoperability in health IT. CLIAC is committed to providing HHS thoughtful advice in support of developing a more connected, interoperable health IT infrastructure. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via my personal email at burton.wilcke@med.uvm.edu or by telephone at 802-860-2925.

Sincerely,

Burton W. Wilcke, Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:
Dr. Thomas Frieden
Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official
Deputy Director for Science, Division of Laboratory Programs, Standards, and Services

Dr. Barbara Zehnbauer, CLIAC Ex-Officio
Director (Acting), Division of Laboratory Systems, CDC

Ms. Karen Dyer, CLIAC Ex-Officio
Director (Acting), Division of Laboratory Services, CMS

Dr. Alberto Gutierrez, CLIAC Ex-Officio
Director, Office of In Vitro Diagnostic Devices, FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington DC 20201

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Burton W. Wilcke, Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)
2877 Brandywine Road
Williams Building, 2nd Floor, Room 2716
Atlanta, GA 30341

Dear Dr. Wilcke:

Thank you for the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommendations on advancing a more connected, interoperable health information technology (HIT) infrastructure. Secretary Burwell asked that I respond directly to you on her behalf. The Department of Health and Human Services (HHS) recognizes CLIAC's important role in advising us on technological advances affecting clinical laboratory quality and laboratory medicine, and on issues related to the Clinical Laboratory Improvement Amendments of 1998. I believe collaborative and structured action will be important in advancing the interoperability of clinical laboratory data. I will discuss your recommendations with the HHS agencies you have identified in your letter, and will follow up accordingly.

I understand that the Committee is highly interested in the need for laboratory data interoperability as a way to provide patient-centered health care, reduce care delivery costs, identify best practices, and support public health. Please accept my personal thanks for your continued collaboration. I welcome your input and feedback on additional ways to successfully propose a framework for achieving safe and effective laboratory interoperability.

Sincerely,

Mary Wakefield

Mary K. Wakefield
Acting Deputy Secretary

May 6, 2015

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to clinical laboratory biosafety, especially with regards to emerging infections in the United States (US).

BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1998 (CLIA), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. This includes issues of clinical laboratory safety that fall under the overarching umbrella of laboratory quality. During the November 5-6, 2014 CLIAC meeting, the Committee deliberated on laboratory biosafety in the United States. The topic of laboratory safety and quality, with lessons learned through the Ebola response, was again presented to the Committee for consideration during the April 15-16, 2015 CLIAC meeting. Background information was given from the clinical and public health laboratory perspectives, as well as a presentation on the importance of safety assessments from a NIOSH industrial hygienist. After deliberating on the issues, the Committee voted to provide the following recommendation to HHS.

RECOMMENDATION

With regard to emerging infections, HHS should:

1. Provide oversight that ensures assessment of the safety and decontamination of laboratory instrumentation by manufacturers.
2. Ensure that biosafety training and assessment is required of all CLIA-certified laboratories, including personnel responsible for the preanalytical, analytical, and postanalytical phases of testing.

3. Ensure oversight, input, and resources into studies evaluating the safety of all laboratory practices, instrument testing, etc., so that studies are sound, robust, evidence-based, and applicable.
4. Develop a process for investigating and reporting laboratory acquired infections.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory safety and quality in the US. CLIAC is committed to providing HHS thoughtful advice in support of this effort. Thank you for your consideration of this recommendation.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via my personal email at burton.wilcke@med.uvm.edu or by telephone at 802-860-2925.

Sincerely,

Burton W. Wilcke, Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:
Dr. Thomas Frieden
Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official
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Burton W. Wilcke Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee
2877 Brandywine Road
Williams Building, Floor 2, Room 2716
Atlanta, GA 30341

Dear Dr. Wilcke:

Thank you for the Clinical Laboratory Improvement Advisory Committee's (CLIAC) recommendations regarding biosafety in clinical laboratories. Secretary Burwell asked that I respond directly to you on her behalf.

The Department of Health and Human Services (HHS) recognizes the important role that the CLIAC plays in keeping HHS informed of potential issues that affect or could affect clinical laboratories, including CLIA-certified laboratories. Emerging infections such as Ebola present serious challenges to the safety of laboratory personnel, and it is important to ensure that these personnel have the oversight, resources, and training to manage potential exposures to such infections. The evaluation of the safety of current laboratory practices and the proper procedures for the decontamination of laboratory instrumentation also play extremely important roles in protecting laboratory employees.

We will carefully consider the CLIAC's recommendations regarding clinical laboratory biosafety and will welcome any additional comments or suggestions that the CLIAC may have.

Sincerely,

Mary Wakefield

Mary K. Wakefield
Acting Deputy Secretary