January 4, 2016

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 to advance 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 1988 (CLIA) which includes technological advances affecting general clinical laboratory quality and laboratory medicine. The Committee has had an ongoing interest in the need for laboratory data interoperability as a way to provide timely and accurate laboratory results that support 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. After the April 15-16, 2015 CLIAC meeting on laboratory information exchange in health IT, the Committee recommended that HHS convene a multidisciplinary stakeholder group to propose a framework for achieving safe and effective laboratory interoperability, including goals with measureable actions, and robust strategies for achieving the goals. During the November 18-19, 2015 CLIAC meeting, the Committee was provided an update on the FDA/CDC/NLM public workshop on "Promoting Semantic Interoperability of Laboratory Data" held on September 28, 2015, followed by an update on information related to laboratory interoperability that had been incorporated in The Office of the National Coordinator for Health Information Technology (ONC) roadmap, Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap.

After deliberating on the interoperability challenges and the need for bringing about widespread exchange of laboratory data in electronic health records

(EHRs) and other health IT systems, the Committee voted to provide the following recommendation to HHS.

RECOMMENDATION

HHS should ensure the following next steps:

*EHR content display related to laboratory data (including graphs) should be standardized such that all CLIA-required test report elements are on every laboratory display/graph.

*National Institute of Standards and Technology (NIST) should create use cases for testing transmission and display of laboratory data in the pre- and post-implementation stages of EHR use to maintain semantic interoperability in various laboratory (clinical/anatomic pathology) settings. Use cases should start at the laboratory system and involve sending data across the interface for display in multiple EHRs. This would test the interoperability of comments, units, reference ranges, etc. (sometimes the reference ranges in the EHR are different than in the laboratory information system).

*Consider the incorporation of CLIA use cases in next certification cycle.

*CMS should consider identifying activities considered as 'information blocking' and place multifaceted strategies to discourage such activities. For example, incentives could be built for offsetting the current high fees for laboratory/EHR interfaces.

In addition to the recommendation above, HHS should consider following next steps to drive interoperability:

*Drive semantic interoperability through incentives (perhaps from CMS) and establish some measure thereof and leverage existing standards in CLIA.

*Engage laboratory professionals and consumers in a discussion regarding global issues of interoperability and its related outcomes.

*Use information from Standards & Interoperability guides to address patient identification issues. For example, HHS should require laboratories to collect and send key patient identifying characteristics such as first name, last name, date of birth, and gender, and optional items such as cell phone number, email address, and physical address. This would help ensure accurate patient matching across systems.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory interoperability in health IT, and 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 802-233-9753.

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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, Division of Laboratory Services, CMS

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington DC 20201

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Burton W. Wilcke Jr., PhD
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 to advance a more connected, interoperable health information technology (IT) infrastructure. Secretary Burwell asked that I respond to you on her behalf.

The Department of Health and Human Services (HHS) recognizes the important role that CLIAC plays in keeping HHS informed of potential issues that affect or could affect clinical laboratories, physicians, and patients. The advancement of laboratory interoperability in health IT has critical implications for medical decision making and for stakeholders in the testing process. I will discuss your recommendations among HHS agencies and follow up accordingly.

We will carefully consider CLIAC's recommendations regarding interoperable health IT and welcome any additional comments or suggestions that CLIAC may have.

Sincerely,

Mary Wakefield

Mary K. Wakefield
Acting Deputy Secretary