

May 9, 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

Since 2012, CLIAC has provided three recommendations to HHS to improve laboratory data interoperability. The Committee firmly believes that laboratory data interoperability is essential to providing timely and accurate laboratory results that support patient-centered health care, reducing care delivery redundancy and costs, and real-time case reporting to enhance response by public health.

During the April 13-14, 2016 CLIAC meeting, the Committee was provided an update on laboratory interoperability and ONC policies and engagement with clinical laboratories. The Committee discussed the challenges and steps towards widespread exchange of laboratory data in electronic health records (EHRs). The majority of information found on EHRs emanates from laboratories. Representation of laboratories is thus essential for developing comprehensive national health information technology standards and policies. The Committee voted to provide the following recommendations to HHS and ONC.

RECOMMENDATIONS

1) To facilitate wider uptake of standards for laboratory interoperability, HHS should endorse and stimulate adoption of an implementation guide/s for laboratory results reporting (e.g., The EHR-Lab Interoperability and Connectivity Specification (ELINCS) for orders available at: <http://www.chcf.org/projects/2009/elincs>); and successful pilots that arise from

the S&I framework effort

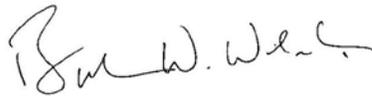
(<http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative>)

2) CLIAC requests that the Office of the National Coordinator for Health Information Technology (ONC) Standards and Policy Committees each include a pathology informatician (pathologist with expertise in clinical informatics) as a committee member.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to develop 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 email at burton.wilcke@med.uvm.edu or by telephone at 802-656-0525.

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, Center for Surveillance, Epidemiology, and Laboratory Services

Dr. Reynolds M. Salerno, CLIAC Ex-Officio

Director, 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



JUN 15 2016

Burton W. Wilcke Jr., PhD
Chairperson
Clinical Laboratory Improvement Advisory Committee
2877 Brandywine Road
Williams Building, Floor 2, Room 2716
Atlanta, Georgia 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 infrastructure. Secretary Burwell asked that I respond directly to you on her behalf.

The Department of Health and Human Services recognizes that the interoperability of laboratory data is a key component of providing patient-centered health care, reducing care delivery costs, and supporting public health. Organized action will be important in advancing the interoperability of laboratory data.

The Office of the National Coordinator for Health Information Technology (ONC) continues to work towards establishing widespread electronic laboratory interoperability. ONC recently launched a funding opportunity around Laboratory data exchange known as the Lab US Realm Project. Please visit the following link: <http://wiki.siframework.org/Lab+US+Realm+Pilot+Project>. The Lab US Realm Project is accepting proposals until June 20, 2016 that focus on production of cost-savings studies that can be used to promote the adoption of the suite of Lab US Realm Implementation Guides (HL7). ONC also has two other funding opportunities, High Impact Pilots and the Standards Exploration Awards. They are intended to support health IT standards testing and implementation, building on federal and private efforts to ensure health information can flow where it is needed.

ONC has been supporting standards and implementation guides (IGs) central to the Electronic Health Record-Lab Interoperability and Connectivity Specification. In particular, ONC continues to support efforts for the refinement and adoption of the Health Level Seven (HL7) Laboratory Orders Interface, HL7 Laboratory Results Interface, and HL7 Electronic Directory of Services IGs. These IGs are identified in ONC's 2016 Interoperability Standards Advisory (see <https://www.healthit.gov/sites/default/files/2016-interoperability-standards-advisory-final-508.pdf>) and continue to be considered for the ONC Health IT Certification Program to complement the use of other standards that support lab interoperability such as Logical Observation Identifiers Names and Codes. Further, consistent with CLIAC's recommendations, we have recently appointed a pathologist who is also a medical informatician to the Health IT Standards Committee. ONC will consider a similar appointment to the Health IT Policy Committee during the next nomination cycle.

I would also like to take this opportunity to thank you for serving as a CLIAC member for the past four years, and as Chairperson for the past three. We welcome any additional comments or suggestions CLIAC may have.

Sincerely,

A handwritten signature in black ink that reads "Mary Wakefield". The signature is written in a cursive style with a large initial "M" and a decorative flourish at the end.

Mary K. Wakefield, Ph.D., R.N.
Acting Deputy Secretary