

February 6, 2018

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

Dear Secretary Azar:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendations on the need for development and evaluation of team-based care innovations that reduce diagnostic error, and the creation of a process for clinical laboratory standards utilization field studies to advance a more connected, interoperable health information technology (IT) infrastructure.

#### BACKGROUND

During the November 18-19, 2015 CLIAC meeting, the Committee was provided an overview of the Institute of Medicine (IOM) Report: *Improving Diagnosis in Health Care*. At the April 13-14, 2016 CLIAC meeting, the Committee suggested that a workgroup be formed to discuss the issues identified in the IOM report to provide background information and input to CLIAC for its consideration in making recommendations to HHS Agencies. During the November 1-2, 2017 CLIAC meeting, the Committee was provided an update on two workgroup topics: 1) pathologists as integral care team members; and 2) laboratory interoperability with respect to health IT.

With respect to the first topic, the Committee discussed the need to facilitate more effective teamwork in the diagnostic process with the integration of the pathologist into the diagnostic team, especially for the purposes of appropriate test ordering, result interpretation, and communication to caregivers and patients. For the second topic, the Committee discussed the Office of the National Coordinator for Health Information Technology goal of interoperability in healthcare and development of universal standards. It was noted that three recommendations on this topic had previously been sent from CLIAC to HHS. Two recommendations on interoperability were made during the April 13-14, 2016 CLIAC meeting, and another on the communication of test results was made during the November 2-3, 2016 CLIAC meeting.

After deliberation on the issues, the Committee voted to provide the following recommendations to HHS.

CLIA Pathologist as an Integral Team Member Recommendation

HHS should encourage the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error.

- Areas of special interest could include consultations by laboratory professionals e.g. pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients
- Evaluation should include patient and provider outcomes (including satisfaction), and health system outcomes (e.g. costs) including innovation's implementation related challenges and opportunities

CLIA Interoperability Recommendation

CLIA recommends that HHS create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity) to:

1. Better understand the nuances, specificity, and compatibility of sharing LOINC or other standard codes
  - a. on both order-and result-side implementation
  - b. in special cases (radiology, clinical findings, anatomic pathology, molecular diagnostics, etc.)
2. Identify areas in which a combination(s) of standards is needed to realize the level of granularity and semantic interoperability necessary to achieve the IOM goals

CLIA is committed to providing HHS thoughtful advice relating to the development of team-based care innovations, and 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 CLIA's recommendation, please feel free to contact me via email at [arnaout@bidmc.harvard.edu](mailto:arnaout@bidmc.harvard.edu) or by telephone at 617-538-5681.

Sincerely,



Ramy A. Arnaout, M.D, D.Phil  
Chairperson  
Clinical Laboratory Improvement Advisory Committee (CLIA)

cc:

Dr. Anne Schuchat  
Acting Director, CDC

Dr. Reynolds M. Salerno, CLIAC Designated Federal Official  
Director, Division of Laboratory Systems, CDC

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

Dr. Peter Tobin, CLIAC Ex-Officio  
Chemist, Office of In-Vitro Diagnostic and Radiological Health, FDA



THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

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Ramy A. Arnaout, MD, DPhil  
Chairperson  
Clinical Laboratory Improvement Advisory Committee  
2877 Brandywine Road  
Williams Building, Floor 2, Room 2716  
Atlanta, Georgia 30341

Dear Dr. Arnaout:

Thank you for the Clinical Laboratory Improvement Advisory Committee's (CLIAC) recommendations regarding team-based care innovations and interoperable health information technology (IT) infrastructure. Secretary Azar asked that I respond to you on his behalf.

The Department of Health and Human Services (HHS) recognizes the critical role that CLIAC plays in keeping HHS informed of potential issues that affect or could affect clinical laboratories, physicians, and patients. We understand the importance of integrating pathologists into the healthcare team and advancing laboratory interoperability in health IT.

We welcome any additional comments or suggestions that CLIAC may have and appreciate your continued commitment and work to reduce diagnostic error and to implement a more connected health IT infrastructure.

Sincerely,

Eric D. Hargan