

July 24, 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 regarding laboratory interoperability.

BACKGROUND

During the April 10-11, 2018 CLIAC meeting, the Committee was provided an overview on past CLIAC discussions and recommendations related to the laboratory interoperability topic. Three presentations were then given on current issues surrounding the standardization of laboratory data. The meeting summary can be found at

https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/CLIAC_Summary/cliac_0418_summary.pdf.

After deliberating on the interoperability challenges and the need for bringing about widespread exchange of laboratory data in electronic health records and other health information technology systems, the Committee voted to provide the following recommendations to HHS.

Recommendation 1:

CLIAC recommends that FDA and CMS create and implement guidelines for in vitro diagnostic device and laboratory information system manufacturers which describe specifications for interoperability, and require use of emerging standards such as Laboratory Analytical Workflow Profile and Logical Observation Identifiers Names and Codes for In Vitro Diagnostics .

Recommendation 2:

The committee recommends that the CDC consult with the Office of the National Coordinator for Health Information Technology to identify the appropriate agency to develop a report to

1. quantitatively define "interoperability" at each of the following levels: device, department, institution, health-care system, and nationally (e.g. "the U.S. is 12% interoperable"),
2. Determine the yearly dollar spend on interoperability is, and who pays for it (manufacturers, hospitals, insurers),
3. Determine the costs in terms of adverse outcomes of a lack of interoperability, which is presumably related to the appreciable cost of diagnostic error,
4. Determine the return-on-investment for achieving (degrees of) interoperability; e.g., how much in terms of health, lives, and/or money is saved by a device/department/institution/system/the country achieving a certain level of interoperability,
5. Delineate the barriers to achieving interoperability (in terms of regulation, financial resources, human capital, conflicting values/incentives among stakeholders, access to data, and adoption).

CLIAC is committed to providing HHS thoughtful advice related to clinical laboratory quality improvement and laboratory medicine practice. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via email at rarnaout@bidmc.harvard.edu or by telephone at 617-538-5681.

Sincerely,



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

cc:

Dr. Robert R. Redfield
Director, CDC

Dr. Reynolds M. Salerno, CLIAC Designated Federal Official
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Ms. Karen Dyer, CLIAC Ex-Officio
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