September 26, 2012

The Honorable Kathleen Sebelius
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 the implementation of electronic health records (EHRs), as directed by the EHR Certification and Meaningful Use regulations and as overseen by the Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS).

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), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. The Committee has been highly interested in the impact of EHR implementation on the use of laboratory information, spending much time and consideration to understand the implications of CMS' Meaningful Use regulations and ONC's EHR Certification requirements [as implemented in collaboration with the National Institute of Standards and Technology (NIST)]. Upon the recommendation of CLIAC, a Communication in Informatics workgroup was convened to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC. After hearing a report from this workgroup at the August 29-30, 2012 CLIAC meeting and deliberating on the matter, the Committee desires to promptly communicate its recommendation to HHS in recognition and support of the agency's anticipated response to the November 8, 2011 Institute of Medicine report: Health IT and Patient Safety: Building Safer Systems for Better Care.

RECOMMENDATION

At the August 29-30, 2012 meeting, CLIAC made the following statement and four-part recommendation:

CLIAC recognizes that serious patient safety risks can arise from errors in the order entry, transmission, display and interpretation of laboratory data in electronic health records. Display and use of non-numerical laboratory information is an under-appreciated critical issue. Interoperability with laboratory information systems (LIS) as well as correct transmission of data across multiple interfaces is also critical. The laboratory community can provide important input and solutions to these challenging problems.

Recommendation, Part 1: *Laboratory experts with experience in hospital, ambulatory or public health settings should be members of key Office of the National Coordinator (ONC) advisory committees and other agency groups that are setting standards and policies for laboratory information in electronic health records.*
Recommendation, Part 2: *Provider usability is an important strategy for mitigation of these patient safety risks. Further work in this area should be supported.*
Recommendation, Part 3: *A national system for reporting EHR laboratory related safety events and near misses should be established to clearly define their prevalence, understand the underlying causes and stimulate the design of broad-based solutions.*
Recommendation, Part 4: *A catalogue of various solutions for laboratory data should be created using work that has already been done and considering areas of expertise [e.g., human factors] that may not have been previously engaged.*

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance nationwide implementation of EHRs. CLIAC is committed to providing HHS thoughtful advice in support of Meaningful Use and assuring laboratory information in the EHR is safe and effective for use by healthcare providers, public health and individuals. 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 [redacted] or by telephone at [redacted].

Sincerely,

Paula Santrach, M.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:
Dr. Farzad Mostashari
National Coordinator for Health Information Technology, ONC

Dr. Thomas Frieden
Director, CDC

Dr. May Chu, CLIAC Designated Federal Official
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Ms. Judith Yost, CLIAC Ex-Officio
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