CLIAC
Clinical Laboratory Improvement Advisory Committee

February 11, 2019

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 the role of the laboratory in improving diagnoses.

BACKGROUND

During the November 7-8, 2018 CLIAC meeting, three presentations were given on current issues surrounding diagnostic errors and the laboratory's contribution to decision-making. The meeting summary can be found at https://www.cdc.gov/cliac/docs/fall-2018/CLIAC_November_2018_Summary.pdf.

After deliberating on the practical ways in which the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) can support team-based diagnostic decision-making to better understand and inform healthcare providers about the complexity of laboratory testing by supporting the laboratory's contribution to diagnostic decision-making, the Committee voted to provide the following recommendations to HHS.

Recommendation 1: CLIAC requests the active participation of laboratory medicine in the workings of the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality. Diagnostic errors related to the total testing process lead to over 50,000 deaths each year. Inspired by the success of the CMS' role in antimicrobial resistance stewardship, CLIAC recommends that healthcare centers be required (for example by CMS, or as suggested by the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality) to have an independent multidisciplinary diagnostic improvement program that includes laboratory professionals as co-equal stakeholders. The program should focus on the total testing process (including but not limited to the traditional pre-analytical, analytical, and post-analytical steps) and emphasize the cognitive elements of test selection and ordering, results interpretation, and

communication (both to the care team and to patients), to promote safety, improve patient outcomes, and decrease diagnostic errors.

Recommendation 2: CLIAC recommends that the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality develop and/or centralize, with an emphasis on the cognitive processes surrounding test ordering, interpretation, and communication and the actions taken as a result thereof:

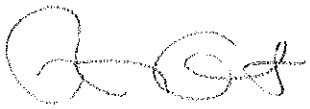
- High-yield approaches to monitoring for diagnostic error
- Effective best practices and research priorities for reducing diagnostic error
- High-impact information-management processes related to decision support for improving diagnostic performance
- Recommendations for incentivizing diagnostic performance improvement
- Develop resources for improving diagnostic performance analogous to those developed for antibiotic stewardship (including through communicating with e.g. the National Quality Forum)

Quantify the "total value" of laboratory diagnostics (including delineating the stakeholders, what budgets, and what units other than dollars, e.g. quality-adjusted life years, are saved or expended based on correct or incorrect decisions involving the total laboratory process)

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
Director, Division of Laboratory Systems, CDC

Ms. Karen Dyer, CLIAC Ex-Officio
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