



CLIAC

Clinical Laboratory Improvement Advisory Committee

February 20, 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 antimicrobial resistance.

BACKGROUND

During the November 7-8, 2018 CLIAC meeting, two presentations were given on current issues surrounding antimicrobial resistance and an update on activities of the Antimicrobial Resistance Surveillance Task Force (ARSTF) established by the Council of State and Territorial Epidemiologists (CSTE), the Centers for Disease Control and Prevention (CDC), and the Association of Public Health Laboratories. The meeting summary can be found at [https://www.cdc.gov/cliac/docs/fall-2018/CLIAC November 2018 Summary.pdf](https://www.cdc.gov/cliac/docs/fall-2018/CLIAC_November_2018_Summary.pdf).

After deliberating on the topic, the Committee voted to provide the following recommendations to HHS.

Recommendation 1: In support of antibiotic stewardship efforts by the president's advisory council and others, CLIAC recommends that CMS require that clinical laboratories, in a timely fashion (e.g. within at most one year) and using reasonable effort, convert to contemporary antimicrobial resistance breakpoints in accordance with manufacturer's instructions.

Recommendation 2: Recognizing the urgency imposed by the pace of emerging antimicrobial resistance, CLIAC recommends that the FDA update existing guidance to prioritize manufacturers' timely integration of updated antimicrobial susceptibility breakpoints.

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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