



California Association of Public Health Laboratory Directors  
CAPHLD



October 30, 2018

Attention: CLIAC Secretariat  
1600 Clifton Road NE  
Mailstop V24-3  
Atlanta, GA 30333

**RE: Public Comment on Educational Requirements for High Complexity Laboratory Directors, 42 CFR §493.1443(b)(3)**

Submitted for the November 2018 CLIAC Meeting via [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov)

The California Association of Public Health Laboratory Directors (CAPHLD) wishes to comment on the interpretive guidelines for 42 CFR 493.1443(b)(3). These interpretive guidelines state that “An acceptable doctoral degree is a Doctor of Philosophy – Ph.D., Doctor of Science – D.Sc. *If acceptable to the board, a Doctor of Dental Surgery – D.D.S., Doctor of Veterinary Medicine – D.V.M., Doctor of Public Health – Dr.P.H.*”.

The California Association of Public Health Laboratory Directors agrees with the American Board of Bioanalysis (ABB) recommendation as stated in a written comment to CLIAC dated October 24, 2018, that CLIA-approved boards be allowed to determine the acceptability of Ph.D. and D.Sc. degrees.

We further agree with the ABB recommended amendment to the CLIA interpretive guidelines 42 CFR 493.1443(b)(3) as follows: “An acceptable doctoral degree is a Doctor of Philosophy - Ph.D., Doctor of Science – D. Sc., Doctor of Dental Surgery – D.D.S., Doctor of Veterinary Medicine – D.V.M., or Doctor of Public Health – Dr.P.H. acceptable to a CLIA-approved certifying board for a director of high complexity testing” or the alternative recommended amendment of 493.1443(b) CLIA regulation to read “Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution that is acceptable to a certifying board approved by HHS.”

We request that CMS allow CLIA-approved board organizations to have the latitude to determine which board applicant candidates have the appropriate laboratory-related

educational background based on their level of coursework content and type of doctoral education. We agree with ABB's contention that a critical issue is not the title of a degree but the review of content for the field of study, referred to as "essential education content", when determining acceptability of degrees.

If CMS policy for acceptable earned doctoral degrees is not consistent across all doctoral degrees, this could lead to issues with inconsistent surveyor judgement for personnel qualifications during inspection compliance and jeopardize current board approved laboratory directors or future potential laboratory directors who are currently completing doctoral degrees. This includes less traditional doctoral study programs which are online or encompass new areas of study.

The California Association of Public Health Laboratory Directors and the LabAspire program are willing to work with ABB, CMS, CLIAC, and the Association of Public Health Laboratories (APHL) in developing language for interpretive CLIA guidelines, essential educational content for doctoral degrees, and defining what is meant by an earned doctoral degree, so that board exam applicants can move forward with confidence that they have satisfied the requirements to take an examination administered by an approved board and qualify as a CLIA high-complexity laboratory director.

Nationwide, and notably in California, Public Health Laboratories are facing a severe shortage of CLIA-qualified, high-complexity directors. Due to the challenges of meeting CLIA requirements, certifying board eligibility, and specific state regulatory requirements, many California Public Health Laboratories do not have a full-time laboratory director or a laboratory director succession plan. To address this urgent need for laboratory directors, the California Department of Public Health and the California Association of Public Health Laboratory Directors have partnered to develop a training program for new Public Health Laboratory Directors called LabAspire. The LabAspire program began in 2008 and has since developed several high-complexity laboratory directors who are working at state and local public health laboratory levels.

The current LabAspire program accepts Ph.D. level as well as graduate level, public health laboratory managers seeking a doctoral degree. LabAspire fellows seeking a doctoral degree (Dr.P.H.) to meet CLIA high-complexity laboratory director educational requirements have enrolled in a new on-line program offered by the University of South Florida (USF). The USF Doctorate in Public Health Laboratory Science and Practice was established in 2015 through collaboration with the Association of Public Health Laboratories to develop new Public Health Laboratory Directors. We believe that the LabAspire training program and the USF Dr.P.H. program are important steps in developing strong workforce development plans for Public Health Laboratories.

We appreciate the opportunity to provide oral and written comment to CLIAC on this issue.

Respectfully,



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Member, LabAspire Executive Committee

cc: Dr. Paul Kimsey, California Department of Public Health  
Mr. Robert Thomas, California Department of Public Health  
Mr. Peter Kyriacopoulos, Association of Public Health Laboratories  
Dr. Mark Birenbaum, American Board of Bioanalysis