

To Whom It May Concern:

I have been personally affected by the subjective interpretation of the CLIA regulation 493.1443 (b)(3) and would like to offer my experience as a discussion comment for the meeting segment on the Clinical Laboratory Improvement Amendments personnel requirements. I am unable to attend the meeting in person and must present my comment in writing. I respectfully ask for representation and inclusion of my statement during the aforementioned meeting segment.

Taking into consideration the CLIA regulation 493.1443 (b)(3), which states that a laboratory director must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and planning to apply for HCLD certification in order to direct an Assisted Reproduction Technology (ART) Laboratory, I completed a doctoral program and earned a Doctor of Health Science degree from Nova Southeastern University. This endeavor was not only time consuming, but also very costly.

The **Doctor of Health Science (D.H.S. or D.H.Sc.)** program is a post-professional doctoral program for those who intend to pursue or advance a professional practice career in healthcare. This degree leads to a career in high-level administration, teaching, applied research, or practice, where advanced analytical and conceptual capabilities are required.

In addition to this degree, I hold a Master of Science degree in Biomedical Sciences with a focus in Clinical Embryology and Andrology, have a Technical Supervisor (T.S.) certification and state license, and have 19 years of experience supervising/co-directing ART laboratories.

Despite this extensive experience and what I believed, at the time, to be an adequate doctoral degree under CLIA regulations, I applied for HCLD certification through the American Board of Bioanalysis (ABB) and was denied. This created for me, an enormous professional setback.

Notwithstanding, CLIA regulations allow physicians to be licensed as laboratory directors. These physicians are usually not experienced on the minutiae of running ART laboratories and must employ skilled laboratory supervisors to serve as their designated directors. The fact that these skilled supervisors cannot be licensed as directors is both illogical and unfair. I respectfully urge regulatory committees to reflect on the information presented in this letter and to consider broader, more holistic standards for laboratory director qualifications, allowing truly competent individuals to pursue HCLD certification in their areas of expertise.

Respectfully yours,



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