

**NEW YORK STATE EDUCATION DEPARTMENT
STATE BOARD for CLINICAL LABORATORY TECHNOLOGY**

**Meeting Minutes
Friday, October 3, 2025
12:00pm – 2:00pm**

**80 Wolf Road
3rd Floor, Rooms A & B
Albany, NY
And via WebEx**

Members present: Nader Okby, MD, Chair; Kathleen Crowley, Vice Chair; Adrienne Boyd; Mary Ellen Clerkin; Jeninne Wright; Sumanta Goswami; Eloise Aita

Members via WebEx: Heidi De Mesa; Maria Friedlander; Alyson Rutigliano

Members Excused: Melissa Stemmer; Adam Tegnander

Extended members present: Angela Tomei-Robinson

Board office staff present: Suzanne Sullivan, Executive Secretary; Renée Gecsedí, Associate in Nursing Education; Heidi Weinman, Secretary

Guest observers: Amy Kellogg, Harter, Secrest & Emery Law for NYS Clinical Laboratory Association

Guest speaker: Beverly Rauch, Director, Clinical Laboratory Evaluation Program (CLEP)

Call to Order and Approval of Prior Meeting Minutes: The meeting was called to order at 12:01pm. Minutes of the April 4, 2025, were tabled due to needed clarification.

News:

Ms. Sullivan welcomed new board member, Eloise Aita. This was Ms. Aita's first board meeting since being appointed to the board.

Ms. Sullivan briefly described a lawsuit that the American Clinical Laboratory Association (ACLA) was involved with. The lawsuit had enormous impact under CLIA for laboratory developed tests. ACLA challenged some new FDA regulations related to laboratory developed tests to treat them like other developed tests. The court ruled that laboratory developed tests are a laboratory service and are not considered a medical device under FDA laws/rules and as such, the FDA does not need to approve them as those services are governed by CLIA.

Presentation by Beverly Rauch:

Ms. Rauch discussed two recent CMS memos. The first one, issued June 2025, is related to enforcement discretion for personnel qualifications, specifically for persons with nursing degrees to perform high complexity glucometry tests. The second one, issued September 2025, is related to enforcement discretion to allow cytologists or cytopathologists to be able to perform remote review of slides will cease effective March 2026. This is due to federal statutes which state that testing for cytopathology must be performed at

the site where the certificate is issued. It does not affect other areas of testing. There will continue to be an allowance for remote review of data, slides, images and digital images in other disciplines in the clinical laboratory. Letters will be sent by the DOH/CLEP out once approved.

Ms. Rauch then described the CLIA exemption evaluation that was completed in March 2021. CLIA gave NYS a conditional evaluation due to NY having less stringent board Certificate of Qualifications (CQ) than CLIA's. Specifically, NY was issuing CQs to those persons with earned doctoral degrees or not board certified. Federal regulations require board certification. NY will change the process and statute. The law was changed in February 2025, and they are working on the regulatory package. This must be completed prior to the March 2027 CLIA evaluation.

Discussion of Proposed Clinical Laboratory Technology Board Guidance for Provisional Permit Evaluation Guidance:

Ms. Sullivan sought input from the Board members related to the four pathways for obtaining a provisional permit. There was no discussion related to pathways 1 & 2. The 3rd pathway requires clinical training, but the amount of the training is not defined. The Board members recommend that an applicant choosing this pathway should have a minimum of 500 clinical training hours covering the areas of hematology, hemostasis, clinical chemistry, immunology, immunohematology, urinalysis/body fluids and clinical microbiology.

For the 4th pathway, the applicant must demonstrate work as a research assistant. Clarity was needed for "research laboratory." The Board members agreed that a clinical laboratory must be a laboratory that conducts research and develops new or improved clinical laboratory tests or procedures and is operated by the federal government, a medical device company or a pharmaceutical company; conducts biomedical research; holds a federal CLIA certificate that authorizes high complexity testing; or holds a NYS DOH clinical laboratory permit.

Board members further agreed that the research assistant work should be no less than 750 hours, and that the applicant must describe the research in a 350-word summary of the research.

New Business:

Ms. Sullivan asked the Board members for their input as to what new projects they should look at. Scope of practice and restricted licenses were brought up.

No further business was brought forth.

Meeting adjourned at 1:52pm.