NEW YORK STATE EDUCATION DEPARTMENT STATE BOARD for CLINICAL LABORATORY TECHNOLOGY

Meeting Minutes Friday, April 4, 2025 11:00am – 1:00pm

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; Heidi De Mesa; Maria Friedlander; Sumanta Goswami; Alyson Rutigliano; Melissa Stemmer

Members via WebEx: Kelly Cwikla; Adam Tegnander; Jeninne Wright

Extended members present: Angela Tomei-Robinson

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

Guest observers: Eloise Aita, past president of the NYS Clinical Laboratory Association; Amy Kellogg, Harter, Secrest & Emery Law for NYS Clinical Laboratory Association; Nadia Rajsz, Chair, Medical Laboratory Technician program at SUNY Orange County Community College

Call to Order and Approval of Prior Meeting Minutes: The meeting was called to order at 11:01am. Minutes of the January 31, 2025, June 14, 2024, and February 23, 2024, Clinical Laboratory Board meetings were approved.

News:

Ms. Sullivan thanked Kelly Cwikla for her invaluable service as a member of Clinical Laboratory Technology Board, as this was her final board meeting. Ms. Cwikla was first appointed in March 2015, and served two terms. On behalf of the Board, Ms. Sullivan wished Ms. Cwikla success in her future endeavors.

Ms. Sullivan briefly described the New York State Assembly's and Senate's responses to the Governor's proposed New York State budget, noting that none of the bills in the budget currently under consideration directly impact the Clinical Laboratory Technology professions. She also described a New York bill that would license genetic counselors.

Ms. Sullivan described new Federal Executive Orders that could adversely impact public health programs that rely on laboratory testing. She noted that one Executive Order required the United States to withdraw from the World Health Organization (WHO). This could adversely affect the United States' readiness to manage a future epidemic (including laboratory testing of persons at risk of infection. Ms. Sullivan stated that the American Clinical Laboratory Association (ACLA) and Johns Hopkins University developed a proposal to establish a public private partnership model to improve the United States' response to a future pandemic or epidemic. The proposal addressed the need for laboratory testing. Ms. Sullivan also noted

that federal funding cuts to the Veteran's Administration could impact the federal clinical laboratory workforce.

Ms. Sullivan described a New York State law, enacted on February 14, 2025, which made the requirements for qualifying as a clinical laboratory director consistent with CLIA regulatory requirements and allowed for additional New York State requirements. (Chapter 46 of the Laws of 2025) Ms. Sullivan stated that she was not aware of how this new law would Impact Department of Health's (DOH) efforts to update their regulations governing Certificate of Qualifications requirements for the clinical laboratory director. Ms. Sullivan indicated that she would invite a DOH representative to the next scheduled Clinical Laboratory Technology Board meeting to describe the changes to the Certificate of Qualifications requirements for the clinical laboratory directors. She also noted that the State Education Department, in consultation with the Clinical Laboratory Technology Board, may need to harmonize the Department's current clinical supervision policies with updated DOH regulations.

Discussion of Proposed Clinical Laboratory Technology Board Guidance for Stem Cell Processes Training Programs:

Ms. Sullivan and Clinical Laboratory Technology Board Members discussed a document entitled, "New York State Clinical Laboratory Technology Board Guidance for Stem Cell Processes Training Programs." The Guidelines describe minimum criteria for stem cell processing training programs that applicants must complete to qualify for a Clinical Laboratory Technologist Restricted License in Stem Cell Processes. The Clinical Laboratory Technology Board voted to approve the Guidelines with one minor change.

Discussion of Supervision Requirements for Clinical Laboratory Personnel:

Ms. Sullivan sought input from the Clinical Laboratory Technology Board members regarding supervision requirements for provisional permit holders, limited permit holders and persons participating in Restricted License Training Programs clinical laboratories and in DOH approved "remote testing sites".

Ms. Sullivan described a CMS policy that allows clinical laboratories to conduct testing (authorized by their CLIA certificates) in "remote testing sites" that are not "certified" by CMS. The CMS policy requires the clinical laboratories to comply with all other applicable federal and state laws, including HIPAA. Ms. Sullivan stated that CLIA regulations generally require on-site supervision of high complexity test performance by testing personnel. She also noted that DOH regulations generally require the laboratory director or supervisor to be on the laboratory premises during all hours in which tests are performed.

A discussion ensued. Clinical Laboratory Technology Board members generally agreed that provisional permit holders and limited permit holders must provide laboratory services in a clinical laboratory or at "remote testing locations" authorized by DOH under the on-premises supervision of the clinical laboratory director or a qualified clinical laboratory supervisor designated by the laboratory director to supervise the permit holder. Ms. Sullivan noted that persons participating in Restricted License Training Programs authorized to provide laboratory services only at the clinical laboratory facility identified on their Training Program Certificate (permit), and not at any "remote testing locations." Clinical Laboratory Technology Board members generally agreed that persons participating in Restricted License Training Programs must provide laboratory services under on-site supervision of a clinical laboratory director or a qualified clinical laboratory supervisor designated by the director to supervise the trainee.

New Business:

Ms. Rutigliano asked about recent changes to New York State Education Department Regulations that set forth minimum requirements for registered, license qualifying Clinical Laboratory Technologist and Clinical Laboratory Technician programs. Ms. Sullivan confirmed that although the new regulations require Clinical Laboratory Technologist programs to offer at least 500 hours of supervised clinical education many such programs continue to offer 720 hours of clinical education. Ms. Sullivan confirmed that programs may offer clinical education at more than one clinical laboratory facility, such as a hospital clinical laboratory and a reference laboratory. Ms. Sullivan responded to several questions regarding simulation, noting that there is no blanket prohibition on the use of simulation in Clinical Laboratory Technologist or Clinical Laboratory Technician programs. She cautioned that such programs may need to obtain State Education Department approval to reduce the number of clinical education hours or substitute clinical education hours with simulation. She also noted that education programs remain responsible for ensuring that their graduates are prepared for entry level clinical laboratory practitioner practice.

No further business was brough forth.

Meeting adjourned at 12:24pm.