



NEW YORK STATE SOCIETY OF DERMATOLOGY
AND DERMATOLOGIC SURGERY

February 23, 2026

New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
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Attention: Katherine Ceroalo

Submitted electronically via regsqna@health.ny.gov

Dear Ms. Ceroalo,

On behalf of the American Academy of Dermatology Association (Academy) and the New York State Society of Dermatology and Dermatologic Surgery (NYSSDDS), we urge you not to finalize the proposed regulations that would limit clinical laboratory directors to board certified pathologists and exclude board certified dermatologists from serving in this role without additional training or experience.

The Academy is the leading society in dermatological care, representing more than 17,500 dermatologists nationwide. The Academy is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of skin disease.

We understand that the proposed state regulations are modeled after the federal regulations finalized in the rule titled "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" (CLIA Final Rule) that became

effective on December 28, 2024. **However, on June 23, 2025, the Centers for Medicare and Medicaid Services (CMS) published a memorandum regarding enforcement discretion of personnel regulations that effectively allows dermatologists certified by the American Board of Dermatology (ABD) and the American Osteopathic Board of Dermatology (AOBD) to serve as lab directors for testing in dermatopathology** (see [Clinical Laboratory Improvement Amendment \(CLIA\) Enforcement Discretion and Clarification on Personnel Regulations | CMS](#)). Specifically, the memorandum specifies that:

- Individuals who qualify as technical supervisors under §493.1449(f)(2)(i) are allowed to serve as high complexity laboratory directors for testing in dermatopathology. Licensed physicians certified by the ABD or AOBD qualify as technical supervisors under these regulations.
- A licensed physician may have either at least 1 year of experience directing or supervising nonwaived laboratory testing or 20 continuing education (CE) credit hours in laboratory director responsibilities to serve as a laboratory director of a moderate complexity lab. In order to be board-certified, dermatologists must demonstrate competence in pathology.

CMS issued this memorandum after discussions with the Academy, wherein CMS recognized that certification by the ABD and AOBD is comparable to certification by the American Board of Pathology (ABP) and American Osteopathic Board of Pathology (AOBP) for the purposes of laboratory director qualification for testing in dermatopathology. We understand that the memorandum reflected this recognition, and that it was intended to provide flexibility to achieve this outcome until formal rulemaking is promulgated. Therefore, we believe that all state departments of health should adhere to the standards specified in the June 23, 2025 memorandum, and **we strongly urge the New York Department of Health to amend the proposed regulation for clinical laboratory directors to include certification by the ABD and AOBD consistent with enforcement discretion CMS provided.**

By not including ABD and AOBD certification, the proposed regulations fail to account for the provision of laboratory oversight by dermatologists, dermatopathologists, Mohs surgeons, and immunodermatologists, all of whom have the training and expertise to safely and effectively serve in the laboratory director role. These dermatology subspecialties include training in laboratory procedures and management unique in their area of specialty and, as permitted by the CMS memo, meet requirements as laboratory directors.

We applaud your focus on quality improvement for clinical laboratories but are very concerned that the current regulations overlook the inherent value of ABD and AOBD certification, restricting the ability of dermatopathologists, Mohs surgeons, and all dermatologists to serve as clinical laboratory directors in New York. We request a meeting as soon as possible to address these concerns with your team. Please contact Lou Terranova, Associate Director, Health Policy and Payment at lterranova@aad.org or 202-340-2875.

Sincerely,



Karry La Violette
Senior Vice President, Advocacy and Policy
American Academy of Dermatology Association



Robert Shoss, MD, FAAD
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New York State Society of Dermatology and Dermatologic Surgery