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February 26, 2025

Stephanie Carlton, RN, MBA  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Susan Monarez, PhD  
Acting Director  
Centers for Disease Control and Prevention  
Department of Health and Human Services  
1600 Clifton Road NE  
Atlanta, GA 30329

Re: CLIA Laboratory Director Requirements

Dear Acting Administrator Carlton and Acting Director Monarez:

Thank you for taking the time to read this important letter. On behalf of the over 21,000 members of the American Academy of Dermatology Association (Academy), I am writing to strongly urge that the recently enacted laboratory director (LD) qualifications, as specified under the Centers for Medicare & Medicaid (CMS) and Centers for Disease Control and Prevention (CDC) regulations implementing laboratory requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) are modified. Most recently, these requirements were finalized in a December 2023 regulation titled "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" (CLIA Final Rule) that only became effective as of December 28, 2024.

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

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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. Dermatologists diagnose and treat well over 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders.<sup>1</sup> One in four Americans suffers or will suffer from a skin disease.

Under current CLIA regulations at 42 CFR § 439.1405 for moderate complexity testing and § 493.1443 for high complexity testing, for individuals with a Doctor of Medicine (MD) or Doctor of Osteopathy (DO) degree, only those who are certified in anatomic pathology or clinical pathology, or both, by the American Board of Pathology (ABP) or the American Osteopathic Board of Pathology (AOBP) are qualified to serve as LDs without meeting additional experience or continuing education requirements. We highlight, however, that certification by the American Board of Dermatology (ABD) is comparable to certification by the ABP or AOBP for the purposes of LD qualification, as further detailed below. ***We therefore strongly urge CMS and CDC (the Agencies) to amend the CLIA LD regulations to add certification by the American Board of Dermatology (ABD) as an option for exempting physicians from having to meet additional experience or training requirements to qualify as an LD.*** Such a change would significantly reduce burden for dermatologists seeking appointment to LD positions, while still ensuring that LDs are qualified with the training and expertise necessary to ensure patient safety and quality of care.

### **Inclusion of American Board of Dermatology**

By not including ABD certification, the current regulations fail to account for the provision of laboratory services oversight by dermatologists, dermatopathologists Mohs surgeons, and immunodermatologists who have the training and expertise to safely and effectively serve in the LD role. These dermatology subspecialties include training in laboratory procedures and management unique in their area of specialty and prior to the current rule, met requirements as laboratory directors.

This expertise is widely recognized, as demonstrated by the fact that the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommended allowing ABD-certified physicians to serve as LDs without additional training or education requirements during its April 2019 meeting addressing CLIA personnel requirements. Specifically, CLIAC issued the following recommendation:

*Recommendation 7: As a prior education requirement, 20 CME or CE credit hours specifically addressing laboratory practice commensurate with laboratory director responsibilities (CFR493.1405 and 1443) should be required for both moderate and high complexity laboratory directors **except those certified by the American Board of Pathology, the American Board***

***of Osteopathic Pathology, the American Board of Dermatology, or other boards approved by HHS.<sup>2</sup>***

Unfortunately, the same recognition is not included in the current CLIA regulations for LD qualifications, thereby requiring dermatologists to meet burdensome and time-consuming additional training and experience requirements before they can newly serve as LDs. Ultimately, we firmly believe this can harm patients, as qualified dermatologists are not able to fill open LD positions and laboratory capacity is unnecessarily suppressed. This in turn will certainly affect access to care for patients, including those from underrepresented backgrounds in the need of dermatologic care. Furthermore, we highlight that the exclusion of ABD certification will also have a disproportionate impact on those dermatologists, dermatopathologists, and Mohs surgeons who might otherwise operate physician-owned laboratories as part of their clinical practice. This again will lead to delayed access to laboratory services and test results as these specialists will have to send specimens to outside laboratories and wait for processing of results that might otherwise be completed in their offices. Quality medical care is predicated on physicians having access to an acknowledged experts of their choice in the histopathologic diagnosis of skin diseases for the benefit of their patients.<sup>3</sup>

*Fellowship Training*

We strongly support the CLIAC recommendation and believe that all dermatologists board certified by ABD should be permitted to serve as LDs of moderate and high-complex labs. Further, dermatologists obtaining additional fellowship training and/or board certification in dermatopathology, immunodermatology and Mohs Micrographic surgery receive unique and specialized training in lab management.

Subspecialty certification in Dermatopathology is a joint function of the ABD and the ABP, with primary certification by either of these boards after the satisfactory completion of one year of training in dermatopathology in a program accredited for such training. Dermatologists pursuing fellowships in dermatopathology, must devote 50 percent of the remaining eight months of the program to education in anatomic pathology provided by the pathology teaching faculty as well learn laboratory management and molecular techniques.<sup>4</sup>

Further, Mohs micrographic surgery and dermatologic oncology is the subspecialty of dermatology concerned with the study, diagnosis, and surgical treatment of malignancies of the skin and adjacent mucous membranes, cutaneous appendages, hair, nails, and subcutaneous tissue, which incorporates medical, surgical, and dermatopathological knowledge of cutaneous malignancies. An essential technique is Mohs micrographic surgical excision, which is used for certain cancers of the skin and incorporates education in clinical dermatology and

dermatopathology as they apply to dermatologic surgery. A core requirement of Accreditation Council for Graduate Medical Education (ACGME) approved Mohs micrographic surgery programs includes training and experience in supervising and training laboratory personnel <sup>5</sup>

We applaud the Agencies' continued focus on quality improvement for CLIA laboratories but are very concerned that the current regulations overlook the inherent value of ABD certification, restricting the ability of dermatopathologists, Mohs surgeons, and alldermatologists to serve as CLIA LDs. We ask to meet with the agencies as soon as possible in either mid-March or early April 2025 to address these concerns. Please contact Lou Terranova, Associate Director, Practice and Payment Policy at [ltiranova@aad.org](mailto:ltiranova@aad.org).

Sincerely,

A handwritten signature in black ink that reads "Seemal R. Desai MD FAAD". The signature is fluid and cursive, with "Seemal" and "Desai" being the most prominent parts.

Seemal R. Desai, MD, FAAD

President, American Academy of Dermatology / Association

cc: Clinical Laboratory Improvement Advisory Committee (CLIAC)

#### References

<sup>1</sup> The Academy's Burden of Skin Disease briefs are a set of informational resources that capture the scope and importance of various skin conditions, and can be accessed at <https://www.aad.org/about/burden-of-skin-disease/burden-of-skin-disease-briefs>

<sup>2</sup> Clinical Laboratory Improvement Advisory Committee (CLIAC) Summary Report; April 2019, p. 11 [https://www.cdc.gov/cliac/docs/summary/cliac0419\\_summary.pdf](https://www.cdc.gov/cliac/docs/summary/cliac0419_summary.pdf).

<sup>3</sup> [PS-Physician Choice of Consultant for Interpretation of Skin Biopsy Specimens.pdf](https://www.acgme.org/globalassets/pfassets/programrequirements/100_dermatopathology_2023.pdf)

<sup>4</sup> page 19 of [https://www.acgme.org/globalassets/pfassets/programrequirements/100\\_dermatopathology\\_2023.pdf](https://www.acgme.org/globalassets/pfassets/programrequirements/100_dermatopathology_2023.pdf) accessed 2/15/25

<sup>5</sup> page 23

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