April 8, 2025

Penny Keller
Clinical Laboratory Scientist
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Keller,

The American Academy of Dermatology Association (Academy) represents over 21,000 members and is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

On behalf of my colleagues who joined the call on Wednesday, March 19, 2025, thank you for taking the time to discuss the CLIA Lab Director (LD) requirements. We appreciate your willingness to be in dialogue about this issue of great importance to dermatologists.

We appreciate and support your work and that of the administration to simplify and clarify CLIA regulations. We also appreciate the offer by Director Gregg Brandush to report individual cases where dermatologists are deemed ineligible to serve as LDs directly to him so CMS can address them on a case-by-case basis.

As discussed on the call, dermatology has long been a laboratory-based specialty, with significant training in laboratory procedures and management beginning during residency. Dermatopathology fellowships are jointly administered by the American Board of Dermatology (ABD) and the American Board of Pathology (ABP). In some institutions, dermatology-trained fellows complete the exact same laboratory management coursework as pathology residents. Also, for Mohs surgery, laboratory work is embedded in both training and clinical practice as Mohs surgeons are responsible for the entire laboratory process: taking and marking the tissue,

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processing it in the lab, reading the slides, and returning to the patient to remove additional tissue if needed.

The Academy's request for amendments to the CLIA LD requirements are focused on dermatopathology testing, including related subspecialties such as immunodermatology and Mohs surgery, and are not requesting LD recognition for unrelated specialties apart from dermatology.

As pointed out during the call, 42 CFR § 493.1449 provides a carveout for dermatopathology to qualify in the Technical Supervisor role, whether through both the ABD and ABP, or through the ABD alone. **We advocate for CMS to provide a similar carveout under the LD requirements for lab directors of moderate and high complexity labs.** We propose that § eCFR :: 42 CFR 493.1405 -- Standard; Laboratory director qualifications be amended to read as (amended text in ***italics***)

(b) The laboratory director must—

(1)

(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(iii) Be certified by the American Board of Dermatology or the American Osteopathic Board of Dermatology

Such language will allow for clarity as well as increase access by removing restrictions for dermatologists as LDs. We are very concerned that the current rules limit access to dermatologic services and delay patient care such as direct point of care testing. For example, diagnosing scabies often depends on in-office testing. If dermatologists cannot direct a point-of-care laboratory, patients with scabies may go undiagnosed, as outside laboratories typically do not perform such tests. The unintended result of the rule could be delayed diagnoses and

reduced access to care.

Understanding that the rulemaking process takes time, we respectfully ask CMS to consider such amendments as expeditiously as possible, perhaps including any changes with rules currently in process or any other means you deem appropriate.

Again, we appreciate your willingness to engage in a dialogue about this issue and request an opportunity to meet with you again as soon as possible. You can reach Lou Terranova, Associate Director, Health Policy and Payment at lterranova@aad.org to set up a mutually agreeable date and time.

We thank you for your consideration of this important matter.

Sincerely,

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology / Association

cc: Gregg Brandush, RN, JD, Director, Clinical Laboratory Improvement and Quality
Angelique Daubert, Division of Clinical Laboratory Improvement and Quality
Debra Sydnor, CMS Division of Laboratory Services