November 25, 2026

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3478-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Clinical Laboratory Improvement Amendments of 1988 (CLIA); Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes — CMS-3478-P; Docket CMS-2026-3235

Dear Sir/Madam:

The Association for Diagnostics & Laboratory Medicine (ADLM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule published October 8, 2026 (*Federal Register* pages 64480-64529). The rule would make significant changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations, most notably the qualifications for a high complexity laboratory director (HCLD). ADLM believes several of the proposed changes rest on a misunderstanding of how clinical laboratories function and, if finalized, could jeopardize patient care.

Board certification for high complexity laboratory directors
Under current regulations, an HCLD must hold a doctoral degree in a recognized science, be certified by a CMS-approved board, have directed or supervised a high complexity laboratory for two years, and have completed 20 hours of continuing education (CE). CMS proposes to eliminate the board certification requirement and instead allow an individual to qualify with either one year of high complexity laboratory supervisory experience or 20 hours of one-time CE. ADLM strongly opposes these changes.

An objective measure of competency
Board certification is an essential, objective measure of a laboratory director's competency. HCLDs oversee the clinical and scientific aspects of laboratory testing. Their responsibilities include evaluating and validating test methods, monitoring test performance, overseeing quality management, interpreting complex results, consulting with healthcare providers, investigating laboratory errors, and when necessary, building new laboratory tools to meet the diagnostic and therapeutic needs of physicians and their patients. In short, HCLDs' contributions are primarily medical: applying clinical laboratory information to guide patient care decisions in real-time. Board certification provides assurance that directors have the knowledge, skills, and experience to meet these demands.

Key element of overall oversight responsibilities
CMS emphasizes the director's "administrative and supervisory duties" and cites the specialty expertise of technical supervisors and consultants. CLIA permits a qualified director to serve as the technical supervisor or clinical consultant, and when the director delegates those duties, the director remains responsible for their proper performance. The director must therefore have the expertise to evaluate a supervisor's findings or a consultant's advice and to determine what action the laboratory should take.

ADLM agrees that laboratories depend on that expertise, but CLIA also makes the director responsible for the overall operation of the laboratory and the quality of the results it reports. For example, when a test result is inconsistent with a patient's clinical presentation, the technical supervisor may investigate whether a substance in the specimen interfered with the assay. The director must be able to evaluate that finding, determine whether other patients' results may be affected, and ensure that the treating clinician receives the information needed to decide whether to act on the result. Board certification assesses the scientific and clinical knowledge on which those judgments depend.

Helps meet unmet diagnostic needs within the healthcare system
Laboratory Developed Tests (LDTs) are an essential tool for patient care. Laboratory directors work closely with clinicians to identify unmet diagnostic needs, develop and validate LDT assays, and monitor their clinical use and performance over time. The complexity of LDTs requires deep medical and technical expertise. Board certification is critical to ensuring high-complexity laboratory directors possess these skills and can meet this important patient care need.

Concerns with Alternative HCLD pathways
The proposed rule would allow one year of laboratory supervisory experience or 20 CE hours to qualify an individual as an HCLD. ADLM believes neither pathway is an equivalent substitute for board certification, and neither is sufficient to prepare someone to direct a high complexity laboratory.

Laboratory supervisors manage operational functions such as budgeting, staffing, personnel management, inventory control, and vendor relations. They are not responsible for advising clinicians on test selection, result interpretation, analytical limitations, clinical utility, or the appropriate use of laboratory results in patient care. A year of supervisory experience may build operational competence, but it cannot replace the years of structured postdoctoral clinical training that board certification represents.

Recent advances in clinical laboratory testing, including next-generation sequencing (NGS), mass spectrometry, capillary electrophoresis, flow cytometry, and multiplex bead assays, demand expert interpretation that 20 hours of CE cannot provide. HCLDs must understand these technologies and their underlying principles if they are to assess the validity of results, recognize

errors such as those caused by interfering substances and translate laboratory data into sound patient care decisions. Maintaining that knowledge requires continuous, career-long learning as technology evolves.

Board certification addresses this need by requiring certified directors to document CE at regular intervals. Requirements vary by board; the American Board of Clinical Chemistry (ABCC), for example, requires 50 credit hours every two years. This ongoing education keeps a diplomate's knowledge current well beyond the initial award of certification. Replacing board certification with one year of supervisory experience or a one-time 20 CE credits would eliminate this safeguard for sustained engagement in the field and continued exposure to the latest advances.

Provides consistency in oversight
Board certification provides independent verification that an individual seeking or holding a position as an HCLD has deep, validated content knowledge, strong critical thinking skills, and the ability to provide clinical consultation. Health systems, reference laboratories, and physician groups routinely expect board certification of their laboratory directors because it demonstrates clinical diagnostic authority. Virtually every medical specialty, including obstetrics and gynecology, endocrinology, and rheumatology, likewise requires board certification and robust continuation requirements to uphold high standards of patient care.

While under the proposed rule CMS would require MD/DO pathologists to be board certified or to have completed specific residency training, it would not impose a comparable requirement on doctoral-level (PhD) scientists who serve as HCLDs. Setting a lower threshold for non-pathologist doctoral directors creates an unequal standard of quality oversight, even though both groups carry the same regulatory responsibilities and accountability for patient results. Postdoctoral training programs in disciplines such as clinical chemistry, medical microbiology, and genomic medicine are designed to train individuals with skills comparable to those of physicians trained in laboratory medicine. Physicians should expect the same level of expertise without regard to the training of the director in charge of the laboratories they use.

Laboratory workforce
Laboratories face documented difficulty recruiting and retaining medical laboratory scientists and technicians, and the vacancy surveys cited in the proposed rule show staffing pressures across laboratory departments. These data, however, do not establish a national shortage of board-certified doctoral scientists available to direct high complexity laboratories. ADLM encourages CMS to focus its workforce efforts on the recruitment, training, and retention of testing personnel, and to examine vacancies in director positions before citing workforce needs as grounds for removing board certification.

Qualifications for directors of moderate complexity laboratories
ADLM also recommends retaining board certification for doctoral scientists who direct moderate complexity laboratories. CMS proposes to allow these candidates to qualify with either one year of experience directing or supervising nonwaived testing or 20 CE credits. These directors remain responsible for the quality of testing, staff competency, corrective action, and clinical consultation, and they should be held to a standard that reflects those responsibilities. For candidates with master's or bachelor's degrees, ADLM recommends retaining the existing requirements for laboratory training or experience and for supervisory experience. CMS would remove the separate laboratory training or experience requirement, allow 20 credits in place of supervisory experience, and reduce the required supervisory experience for candidates with bachelor's degrees from two years to one.

On-site visits by laboratory directors
ADLM recommends retaining the requirement that directors of moderate and high complexity laboratories visit each laboratory at least once every six months and document those visits. CMS proposes instead to require only that directors be accessible as needed. ADLM believes the director-related deficiencies cited in the preamble warrant continued oversight. In-person visits can provide information about personnel, equipment, specimen handling, and laboratory practices. Eliminating on-site visits would certainly decrease, rather than improve, the quality of testing and patient care.

Animal science and veterinary training
CMS proposes to recognize additional degrees in animal science and veterinary fields, remove references to human testing from certain thesis or research requirements, and rescind the definitions of "experience directing or supervising" and "laboratory training or experience." ADLM recommends that applicants who qualify on the basis of animal research or veterinary training be required to document supervised clinical experience relevant to the human testing they would oversee. Experience with an instrument or method is valuable, but directors must also understand its limitations in human specimens and the implications of its results for patient care.

Clinical Laboratory Improvement Advisory Committee
ADLM urges HHS to retain the requirement to establish the Clinical Laboratory Improvement Advisory Committee (CLIAC) and to restore an active standing committee. The CLIA statute directs the Secretary to consult with appropriate private organizations and public agencies. CLIAC provides a public forum in which laboratory professionals and other experts can examine technical issues and advise HHS on laboratory oversight.

Summary
ADLM urges CMS and CDC to retain HHS-approved board certification for doctoral scientists who direct high complexity or moderate complexity laboratories. The director remains accountable for the results clinicians use to make treatment decisions, including when other

qualified personnel perform the testing or advise on its interpretation. That responsibility warrants independent assessment of the director's own scientific and clinical judgment. ADLM further urges CMS to retain semiannual on-site director visits and to require documented clinical experience from applicants who qualify through animal science or veterinary training and urges HHS to retain an active CLIAC.

Thank you for considering ADLM's comments. If you have any questions, please email Vince Stine, PhD, ADLM's Chief Policy Officer, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs, at efortman@myadlm.org.

Sincerely,



Stanley F. Lo, PhD, DABCC, FADLM
ADLM President