

POSITION STATEMENT

Modernization of CLIA: Moderate and High Complexity Testing

September 2020

Introduction

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988. The Centers for Medicare and Medicaid Services (CMS) developed and implemented the regulations between 1990 and 1995. Since then, the rules governing patient testing have largely remained unchanged. Over the past quarter century, however, medical care and the laboratory environment have evolved considerably, necessitating a review of the CLIA standards to ensure they remain current and assure high quality patient care.

The number of sites performing clinical laboratory testing in the United States has increased from 154,000 in 1993 to 266,000 in 2020. These facilities perform nearly 13 billion tests annually (1). Most of these tests are performed in hospitals and commercial laboratories. While technological improvements have simplified how certain tests are performed, some scientific advancements have resulted in more complex technologies (e.g., molecular pathology, mass spectrometry) that require very specialized knowledge, training, and experience to perform the testing. Each innovation has created new opportunities and challenges in the delivery of quality healthcare.

Background

Changing Laboratory Environment

Over the past few decades,

ADLM POSITION:

The Association for Diagnostics & Laboratory Medicine (ADLM) supports federal funding to increase the number of Medical Laboratory Scientists (MLS) who are vital to performing and ensuring quality patient testing. In addition, the association backs alternative pathways to qualify individuals to serve as testing personnel if they can demonstrate equivalency with the current requirements. ADLM urges policymakers to retain the existing standards for high complexity Medical Laboratory Directors (MLDs) who continue to play a critical and unique role in evaluating and developing new technologies and approaches to meet emerging healthcare needs.

technological advances and improved portability of devices have expanded the types of settings in which laboratory testing can be performed. Once limited to hospital and reference laboratories, testing is now routinely performed at the hospital bedside, in ambulances, mobile clinics, doctors' offices, and even the home. While many of these test systems are waived under CLIA and therefore largely exempt from direct regulatory oversight, many others are classified as moderate or high complexity, subjecting them to personnel, quality control, and proficiency testing standards.

Individuals performing moderate and high complexity testing are expected to have a certain level of scientific knowledge and experience, understand how to troubleshoot problems, and be able to perform applicable quality control checks, among other skills needed

to perform quality testing. Failure to accurately perform a test can cause incorrect results to be reported and acted upon by a physician, potentially placing patients at risk for harm. Unfortunately, there is a shortage of well-trained individuals to perform these tests.

Shortage of Laboratory Professionals

According to the Bureau of Labor Statistics (BLS), 72,100 additional clinical laboratory personnel are needed by 2028 just to meet the growing demand for testing services (2). This demand is likely to continue as the population grows older, point-of-care-testing (POCT) expands, and new tests are developed. Currently, MLS programs do not produce enough graduates to fill existing vacancies. Over the next ten years, clinical laboratories need approximately 7,000 laboratory professionals annually, but the MLS programs graduate only 6,000 students a year, leaving a sizeable deficit (3).

One contributing factor to this shortage is the decline in MLS programs. In 1990, there were 720 MLS training programs. Now there are 608—a reduction of 15 percent (3). Additionally, MLS students are required to participate in full-time clinical rotations during training, which are becoming more difficult to arrange. Most programs cite insufficient and shrinking numbers of hospital laboratories willing to accept students and provide them with supervised and guided clinical experiences. This training is essential to providing MLS students with a complete education necessary for ensuring accurate patient results that contribute to positive patient outcomes.

Increasing Importance of MLDs

Scientific advances have also led to the development of new, complex laboratory tests that can more precisely identify a medical condition, leading to earlier diagnosis and treatment, better patient outcomes, and more effective use of limited healthcare resources (e.g., SARS-CoV-2). Many of these tests are developed or adapted by highly educated, experienced, and trained individuals who serve as the MLD of a high complexity testing facility. The CLIA standards require that these individuals either: (a) have a doctoral degree in a chemical, physical, biological, or clinical laboratory science and be certified by a board approved by the Department

of Health and Human Services; (b) be a doctor of medicine or doctor of osteopathy and meet certain regulatory requirements; or (c) previously served as an MLD prior to February 24, 2003.

MLDs oversee all clinical, scientific, and business aspects of the laboratory. They consult with clinical colleagues on issues of test utilization and interpretation and determine the optimum instrumentation to efficiently meet clinical needs and effectively reduce the cost of care. In the age of personalized medicine, MLDs bring their deep scientific knowledge to developing, validating, and delivering new laboratory developed tests (LDTs) to assist clinicians in diagnosis and treatment decisions, providing a critical service and perspective to the healthcare team. The value of MLDs to the healthcare system is increasing as advances in testing contribute to more personalized, cost-effective care.

Considerations

Increasing Laboratory Personnel

CMS has proposed expanding the role of nurses within CLIA, in part due to the shortage of laboratory personnel. The agency recommended that a nursing degree be deemed equivalent to a medical laboratory professional degree, which would allow nurses to perform moderate and high complexity testing without obtaining prior laboratory training as well as serve in a supervisory capacity (4). Many in the laboratory community objected to this proposal, noting that nurses generally take only one-third of the coursework required for a biological sciences degree with little or no focus on clinical laboratory testing (5). Proposed alternatives to this approach include permitting nurses to demonstrate proficiency through the completion of a CLIA-approved competency exam, POCT certification program, and/or a curriculum of laboratory courses.

There are several actions that could address the shortage of qualified laboratory personnel. One is restoring federal funding for MLS training programs through Title VII of the Public Health Services Act. With more funding, these programs could train more students and reduce the growing shortage. Another option is reimbursing hospitals and commercial laboratories to provide MLS students with required clinical experiences. Finally, the creation of a loan

forgiveness program for laboratory personnel willing to work in underserved areas for a specified period could incentivize individuals to enter the field.

Ensuring Qualified Leadership

In recent years, there has been discussion regarding who should determine what is an acceptable non- MD doctoral degree under CLIA. One suggestion is to let each of the CMS-approved certifying bodies determine what is an acceptable degree. MLDs in high-complexity laboratories assume responsibility for all LDTs generated by their lab. It is therefore critical that they have documented skill in the independent and critical assessment of research data. Given this, CMS has generally accepted doctoral scientists that, in addition to the required coursework, have successfully completed a written dissertation that includes a strong independent original research component that advances scientific knowledge. There are concerns that transferring this responsibility to private sector accrediting bodies may create financial incentives to accept less-rigorous degrees, resulting in lesser-qualified individuals serving as a high complexity MLD, a decision that could jeopardize patient care and unnecessarily increase healthcare costs.

A person serving as an MLD should have a broad knowledge of laboratory operations, analytical theory and processes, and an understanding of the pathophysiology of disease. Board certification is essential to ensuring an MLD meets these criteria. Board certification along with the requisite continuing education requirements ensures a standardized knowledge base and reflects a broad, deep, and up-to-date understanding of laboratory medicine, which permits MLDs to educate and guide other healthcare providers, ensure the efficient use of resources, and maintain quality patient care. The appropriate education, training, and experience of MLD is essential to ensuring high-quality patient care at all levels of service

Positions

Technological improvements have expanded the scope and complexity of laboratory testing. ADLM is concerned that there are not sufficient laboratory professionals to perform quality testing. Further, the association is troubled by ongoing efforts to redefine

the educational requirements of high complexity MLDs, which could result in lesser qualified individuals serving in this capacity. ADLM urges the following actions to ensure the continued integrity of CLIA moderate and high-complexity testing.

Moderate and High Complexity Personnel

ADLM recommends that Congress and CMS work together to ensure sufficient numbers of qualified MLS professionals. Specifically, ADLM hold the following positions:

Congress

- ▶ Lawmakers should provide Title VII funding to allied health training programs to expand their MLS training programs.
- ▶ Elected officials should allocate funding to support the clinical rotation training of MLS students in hospitals and/or reference laboratories.
- ▶ Legislators should create a loan forgiveness program that reduces the student debt of laboratory professionals who work in underserved areas.

CMS

- ▶ CMS should not equate a bachelor's degree in nursing as equivalent to a bachelor's degree in the biological sciences under CLIA.
- ▶ Alternative pathways-aside from holding a bachelor's degree in biological sciences-should be created (e.g., defined laboratory curriculum, competency exams, certification) for individuals to qualify as testing personnel.

ADLM holds the following positions to maintain the highest standards for MLDs:

- ▶ CMS should retain authority for determining what is an acceptable doctoral degree. The agency should develop and circulate a consensus document to CMS regional offices to ensure uniformity.
- ▶ A doctoral scientist degree under CLIA should, in addition to its coursework, include independent original research intended to advance scientific knowledge, and a completed and approved written dissertation of the original work.
- ▶ Board certification should remain a requirement for demonstrating the competency of MLDs in high complexity laboratories.

References

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5. Association Society for Clinical Pathology June 16, 2016 letter to CMS regarding Memorandum (S&C-16-18-CLIA).