



CMS FACTS

History

On April 1, 2016, the Centers for Medicare and Medicaid services (CMS), in a policy memorandum (S&C - 16-18- CLIA) stated the following: A bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. The laboratory may show a Primary Source Verification (PSV) report verifying that a bachelor's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

An associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel. The laboratory may show a PSV report verifying that an associate's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

This memorandum has translated into nurses being able to perform non-waived laboratory testing under CLIA. Prior to this memo, this had not been the case.

Why

CMS officials have stated the memorandum reflected a long standing "internal policy" that had been developed to address concerns about a shortage of testing personnel at physician office laboratories in rural areas. These testing sites are not often staffed by qualified laboratory professionals, such as those individuals who may be certified by the American Society for Clinical Pathology, Board of Certification (ASCP BOC).

Laboratory Community Response

Representatives from the American Society for Clinical Pathology (ASCP), ASCP Board of Certification (BOC), and American Society for Clinical Laboratory Science (ASCLS) raised concerns about negative impacts on patient care that this memorandum would have and the need to ensure the accuracy and reliability of all laboratory test results. This group met with the Centers for Medicare and Medicaid Services (CMS) in opposition to the agency's April 1st Declaration that a nursing degree is equivalent to a degree in the biological sciences. These representatives presented CMS with a petition, signed by more than 35,000 individuals opposed to CMS's degree equivalency policy. The petition drive was a community-wide effort led by ASCP and ASCLS to raise concern about CMS's policy that the nursing degree is equivalent to a biological sciences degree for purposes of performing non-waived laboratory testing under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

Per the CLIA regulations, individuals with a bachelor's degree in a chemical, physical, or biological science are not required to complete training prior to performing high complexity laboratory testing. The April memorandum provided no reasoning behind the decision.

These groups pointed out the potential negative impacts on patient care and the importance of ensuring the accuracy and reliability of laboratory results.

Inequivalent Educational Degrees

Whenever there is an attempt to equalize two different professions, one must first compare the scope of practices of those professionals for similarities and contrasts. A side by side comparison of typical nursing degree programs and laboratory science programs were presented to CMS. This comparison demonstrated that nursing degrees fall far short of the scientific coursework required to earn a degree in the biological sciences. Furthermore, the ASCP BOC Board of Governors stated concerns that a nursing degree provides only a fraction of the scientific coursework required for a biological sciences degree and that what scientific coursework nursing programs do require does not approach the level of achievement involved in obtaining a biological sciences degree.

Comments were received from individuals from their respective memberships, including those from several individuals who hold degrees in both nursing and the biological sciences. People with both nursing and MLS degrees agreed that there is a glaring difference of path between the two degrees. These “dual-degreed” individuals confirmed that a nursing degree does not contain sufficient scientific background to allow someone to step in and reliably perform non-waived laboratory testing, just as a biological science degree does not prepare one to act as a nurse.

This does not downplay a nursing degree’s level of difficulty, but it points out that the science educational background that results in a deep understanding of the principles behind laboratory testing is not included in their coursework, as this is not the intent of a nursing degree.

Coursework

Nursing degrees and biologic science degrees are not alike. Biologic science degrees require much more academic and advanced level coursework in the sciences while nursing degrees do not. Therefore, nursing degrees are not equivalent to biologic science degrees. Given the significant lack of biologic and other science obtained through a nursing degree, it is not agreed that a nursing degree is equivalent to a biological sciences degree and most importantly, adequately prepares someone to perform non-waived laboratory services.

Training Concerns/Issues

A major concern with the CLIA regulations is that CLIA does not specify clinical training of those with a biological sciences degree.

The CMS regulations do not require specific training requirements from an accredited medical laboratory program for personnel performing and managing moderate and high complexity laboratory testing. Nor do they require certification as a benchmark for competency. The regulations do require a degree in the biological, chemical, physical, or clinical laboratory sciences to perform and manage complex laboratory testing procedures. Nursing degrees typically have only a few biology and chemistry courses in their degree requirements, and no clinical experience in performing complex laboratory test procedures. This would negatively affect the quality and reliability of complex clinical laboratory testing in our healthcare facilities.

Patient Safety is at risk

Moderate and high complexity testing should only be performed by those who understand the test methodology. Laboratory methodology is not part of the nursing curriculum. Without the knowledge of laboratory methods, patients will certainly be put at risk. If nurses are allowed the same rights to perform moderate and high complexity testing as certified laboratory professionals, it would certainly create issues of poor quality laboratory testing and put patients' health in danger.

You must have the right person for the right job. Laboratory professionals would never advocate to perform the work of a nurse. Laboratory and nursing careers require different background, knowledge, and skill sets to be performed optimally.

The VA Issue

In May of 2016, the U.S. Department of Veterans Affairs (VA) published a proposed rule expanding the authority of Advanced Practice Registered Nurses (APRNs). This rule gave the certified Nurse Practitioner (CNP) authority to "order, perform, supervise, and interpret laboratory and imaging studies." This was interpreted as a CNP being able to not only perform, but also to direct high-complexity lab testing.

The Clinical Laboratory Management Association's (CLMA) Legislative, Compliance, and Regulatory Committee (LCRC) met with other laboratory associations submitted comments the VA, and the VA took notice. In December, the VA announced an amended final rule. The revision removed the wording that allowed CNPs to perform and supervise laboratory testing. The VA also acknowledged the critical role that laboratorians play and the rigorous educational and training requirements necessary to understand and perform complex laboratory testing.

CMS Review

CMS agency representatives indicated that CMS will be working to address this issue and is currently examining how best to implement a change in policy. Resolving this issue may require the agency to produce new regulations and that if such a change is required, it will soon begin working on draft regulations.

While no final declaration has been issued, CMS has expressed its intent to review the policy and propose improved regulations that will alleviate concerns about the reliability of laboratory testing. ASCP, ASCLS, and the ASCP BOC intend to continue to work with CMS to come to a consensus.

No patient would want a nurse to perform their high complexity testing or examine their surgical specimen. Conversely, no patient would want a pathologists' assistant or medical technologist to be their nurse. The level of experience needed to be capable at either of these professions is too great to be able to perform both jobs well.

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