

Rescind CMS' Nursing Degree Equivalency Determination for Moderate and High-complexity Laboratory Testing

APHL POSITION STATEMENT



Statement of Position

The US Centers for Medicare and Medicaid Services (CMS) should immediately rescind its directive that an associate's or bachelor's degree in nursing is equivalent to an associate's or bachelor's degree in a biological science for a moderate and high-complexity laboratory.

Recommended by: **APHL Laboratory Systems and Standards Committee**
Approved by Board of Directors: **April 2023**
Approved by Membership: **June 2023**
Sunset Date: **June 2028**
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Background

On April 1, 2016, CMS released a memorandum (S&C-16-18-CLIA) to its state CLIA survey agency directors announcing that an associate's or bachelor's degree in nursing is equivalent to an associate's or bachelor's degree, respectively, in the biological sciences for the purpose of performing moderate and/or high complexity testing. Prior to this announcement, the rule was little known, and the release of this memorandum brought attention to the issue, causing concern in the laboratory community about CMS' decision. A petition was circulated to oppose the equivalency policy, which to date has garnered more than 35,000 signatures. The Association of Public Health Laboratories (APHL) encouraged its members to sign the petition.

APHL urges CMS to reevaluate its equivalency position because a bachelor's degree in nursing is not equivalent to a technical degree in a biological science. While APHL has great respect for the work and contributions of nurses in patient care, a bachelor's degree in nursing does not sufficiently prepare an individual to perform and interpret both moderate and high-complexity laboratory testing. The American Society for Clinical Pathology (ASCP) has documented that nursing degrees only require a fraction of the scientific coursework required to earn a degree in biological sciences,¹ whereas there are stringent educational requirements for testing personnel performing both moderate and high complexity testing (CLIA 42 CFR 493.1423 and CLIA 42 CFR 493.1489).^{2,3} For example, each individual performing high-complexity testing must have education and training which includes 60 semester hours from an accredited institution that at a minimum, includes either a) 24 semester hours of medical laboratory technology courses, or b) 24 semester hours of science courses (six hours of chemistry or biology and 12 semester hours of chemistry, biology or medical laboratory technology).⁴ Specifically, a degree in biological sciences at the University of Maryland requires 66 hours of natural sciences, which includes courses in biology, chemistry and physics.⁴ Almost half of these courses must be upper-level (300-400).⁴ However, a nursing degree at the same university only requires 16 hours of introductory, 100-level natural sciences, mostly in biology and only four hours in chemistry. The nursing program itself focuses heavily on clinical practice and has no laboratory coursework in the curriculum.⁵ Conversely, a laboratory degree does not qualify an individual to perform nursing activities. No reciprocity exists between the degrees.

Both moderate and high-complexity laboratories require skilled technical personnel who have been trained to perform and interpret diagnostic tests and successfully document annual competency, as per CLIA regulations (CLIA 42 CFR 493.1235).⁶ Technical knowledge is required during the pre-analytical, analytical and post-analytical phases, such as reagent and material preparation, equipment calibration, troubleshooting skills, direct intervention to solve problems, extensive independent interpretation and judgement on a testing process. APHL believes laboratory professionals who have biological, chemical and clinical laboratory science degrees are more equipped by education, training and experience to make critical decisions that may impact the result in a clinical laboratory environment. With its equivalency position, APHL is concerned that CMS has compromised the level of education and training required to perform moderate and high-complexity testing, which may directly impact the quality of test results and jeopardize patient safety.⁷ Currently, it is challenging for public health laboratories to recruit staff that are properly educated and trained due to the depleting pool of qualified candidates with Clinical Laboratory Scientist (CLS), Medical Lab Scientist (MLS), and Medical Technologist (MT) degrees. CLS, MLS and MT degrees ensure appropriate education and training in compliance with CLIA 42CFR493 for testing and reporting. With this CMS ruling, public health laboratories may be in a burdensome position to screen and interview unqualified personnel with minimal education and training requirements to perform high-complexity testing. As CMS moves forward with decisions that impact clinical laboratory testing, APHL urges CMS to foster discussion and gather input from the public health laboratory partners on the testing personnel qualifications and training requirements for moderate and high-complexity testing.

APHL's Recommendations

Clinical Laboratory Associations

1. Increase communication with CMS on the impact of agency decisions that affect quality laboratory testing.
2. Provide guidance to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on personnel education and training requirements for moderate and high-complexity laboratories.

Public Health Laboratories

1. Engage public health laboratory partners on discussions with CMS on the impact of agency decisions that affect quality laboratory testing.
2. Follow the development of potential rulemaking and work with APHL's Public Policy Program to provide comments on the proposed changes.
3. Provide guidance to CLIAC on personnel training requirements for moderate and high-complexity laboratories.
4. Work collaboratively with APHL committees, ASCP and other professional clinical science organizations to address the future workforce needs of moderate and high-complexity laboratories.

US Centers for Medicare and Medicaid Services

1. Rescind its directive that an associate's or bachelor's degree in nursing is equivalent to an associate's or bachelor's degree in a biological science for a moderate and high-complexity laboratory.
2. Re-evaluate the intention or needs behind this directive to assess and address the gaps and consider alternatives. For example, a rural assistance program for laboratory scientists, similar to the one that exists for doctors and nurses.

References

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2. National Archives, Code of Federal Regulations. "§493.1423 Standard; Testing personnel qualifications." Accessed January 12, 2023. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR10813e8157e2976/section-493.1423>.
3. National Archives, Code of Federal Regulations. "§493.1489 Standard; Testing personnel qualifications." Accessed January 5, 2023. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR2640b368593bdb0/section-493.1489>.
4. University of Maryland College of Computer, Mathematical and Natural Sciences Biological Sciences Undergraduate Program. "General Biology (GENB) Curriculum Sheet-Gen Ed." Accessed August 12, 2022. https://static1.squarespace.com/static/530b693ce4b01ddda83c8078/t/61409a76a53f035670a672b3/1631623799_168/GENB-Curriculum+Sheet-GENEd+2021.pdf.
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6. National Archives, Code of Federal Regulations. "§493.1235 Standard: Personnel competency assessment policies." Accessed January 12, 2023. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR6b8923402db3f2f/section-493.1235>.
7. Clinical Laboratory Improvement Advisory Committee. Comments from the American Society for Clinical Pathology. April 13-14, 2022. <https://aspcdn.s3.amazonaws.com/static/epolicy/2022/ASCP+Statement+to+CLIAC+041322+vF.pdf>

Association of Public Health Laboratories

APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.