A. Statement of Position
The 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 high complexity laboratory.

B. Implementation
1. Increase communication with CMS on the impact of agency decisions that affect quality laboratory testing
2. Encourage APHL members to sign the American Society for Clinical Pathology’s (ASCP) petition urging CMS to rescind its equivalency determination
3. Follow the development of potential rulemaking and work with APHL’s Public Policy Program to provide comments on the proposed changes
4. Provide guidance to CLIAC on personnel training requirements for moderate and high complexity laboratories
5. Work collaboratively with other APHL committees, ASCP and other professional clinical science organizations, to address the future workforce needs of high complexity laboratories

C. Background/Data Supporting Position
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 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 degree in nursing is not equal to a technical degree in biological science. While APHL has great respect for the work and contributions of nurses in patient care, an associate’s or bachelor’s degree in nursing does not sufficiently prepare an individual to perform and interpret moderate and high complexity laboratory services. ASCP has documented that nursing degrees only require a fraction of the scientific coursework required to earn a degree in biological sciences. For instance, a degree in biological sciences at the University of Maryland requires 63 hours of natural sciences, which includes courses in biology, chemistry, and physics. Almost half of these courses must be upper-level (300-400). However, a nursing degree at the same university only requires 16 hours of introductory 100-level natural sciences, mostly in biology and only 4 hours in chemistry. The nursing program itself focuses heavily on clinical practices and has no laboratory coursework in the curriculum.

There is a great discrepancy between the requirements to obtain a degree in nursing and biological sciences.

Moderate and high complexity laboratories require personnel who have been highly trained to perform and interpret diagnostic tests. Technical knowledge is required during the pre-analytical, analytical and post-analytical phases, as well as reagent and
material preparation, calibration of equipment, decision making to troubleshoot, direct intervention to solve problems and extensive independent interpretation and judgement on a test result. APHL believes laboratory professionals who have biological science degrees are more equipped by education, training and experience to make critical decisions that may impact the result of a test in a moderate or high complexity environment. With its equivalency position, APHL is concerned that CMS has lowered the threshold of education and training required to perform moderate and high complexity testing that may directly impact the quality of test results and jeopardize patient safety. Currently, it is already difficult for public health laboratories to recruit staff that are properly educated and trained because the depleting pool of Clinical Laboratory Scientist (CLS), Medical Lab Scientist (MLS), and Medical Technologist (MT) degrees. CLS/MLS/MT degrees ensure appropriate education and training specifically around regulatory issues, quality assurance and quality control. With this CMS ruling, public health laboratories are now faced with staff who not only do not have the training piece but also lack the basic education.

As CMS moves forward with decisions that impact laboratory quality, APHL urges CMS to foster discussion and gather input from the laboratory community.

D. References


3. Prerequisite Coursework List for University of Maryland School of Nursing. https://www.nursing.umaryland.edu/media/son/admissions/Prerequisite_Course_List-2.doc