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**Statement of
the American Society for Clinical Pathology and
the ASCP Board of Certification
before the
Clinical Laboratory Improvement Advisory Committee**

November 7-8, 2018 Atlanta, Georgia

Thank you for the opportunity to provide public comments on today's discussion of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel standards, particularly as it relates to this year's [Request for Information](#) (RFI) from the Centers for Medicare & Medicaid Services (CMS). My name is Susan Harrington, PhD, D(ABMM), MLS(ASCP)^{CM} and I'm here today representing the American Society for Clinical Pathology (ASCP) and the ASCP Board of Certification (BOC) where I serve as the Chair of the ASCP BOC Board of Governors.

In the January 9 *Federal Register*, CMS published a RFI seeking comment on a proposal to formalize its controversial policy of considering a baccalaureate degree in nursing to be equivalent to a baccalaureate degree in the biological sciences. This policy would allow nursing degree holders to perform high complexity testing and serve as technical consultants for moderate complexity testing, and it is similar to the Agency's current policy, announced in an [April 1, 2016 Memorandum](#) (S&C-16-18-CLIA), which allows individuals with a baccalaureate degree in nursing to perform and supervise high complexity testing.

As I'm sure the Committee is aware, there is significant opposition within the laboratory community to the idea that a nursing degree is sufficient to perform high complexity testing and supervise non-waived testing. In response to CMS's April 1 memorandum, the ASCP BOC and its partner organizations provided CMS with a petition signed by 35,000 laboratory professionals and other stakeholders urging it to reverse its policy. With regard to this year's RFI, the ASCP BOC and 10 of its partner laboratory professional associations launched a grassroots campaign to encourage laboratory professionals and other concerned stakeholders to urge CMS not to move forward with its policy proposal. The ASCP and ASCP BOC is proud to say that all but a handful of the more than 8,700 comments received by the Agency opposed its proposal to allow a baccalaureate degree in nursing to be considered sufficient to perform high complexity testing and supervise moderate complexity testing.

While we have no doubt that nursing degrees can provide outstanding instruction in the knowledge areas relevant to the practice of nursing, it should be clear that these two degrees are not similar and that biological science degrees vastly outweigh nursing degrees both in terms of their scientific coursework and rigor. In our [June 2016 letter](#) to CMS, we cited as an example the significant differences in coursework requirements for the biological sciences and nursing bachelor's degrees at the University of Maryland College Park. There, the bachelor of

sciences degree in biological sciences requires at least 63 hours of natural sciences, including 39 or more hours of major requirements in the biological sciences and 32 or more hours of prerequisites—almost all of which are in chemistry and physics. In contrast, the nursing degree appears to include only 16 hours of natural sciences, including only 12 hours of biological sciences (Human Anatomy and Physiology I and II and Microbiology) and 4 hours of chemistry (General Chemistry). All told, the nursing degree involves less than a third of the biological sciences as a biological sciences degree and appears to have no advanced/upper-level biological coursework requirement. The ASCP BOC provided other examples to support our contention that nursing degrees do not provide a foundation in the academic sciences similar to that provided by the biological sciences.

CMS's proposals concerning nursing degrees should also raise a concern about clinical training. Currently, CLIA's high complexity testing personnel regulations do not have a specific laboratory training requirement for individuals with a bachelor's or higher degree. Without adequate academic and clinical training, it is unclear how nursing degree holders that are tasked with supervisory responsibilities would be able to ensure quality testing, even if supervising medical laboratory scientists and medical laboratory technicians.

As a laboratory professional dedicated to quality practice, I believe it is imperative to point out that lowering personnel standards could adversely affect the quality of laboratory testing and patient care. Numerous studies have supported the premise that more education and training positively affects quality. Consequently, the Committee should expect that lowering standards, both for test performance and supervision, has the potential to negatively affect patient care. Moreover, as it considers CMS's proposal to accept nursing as equivalent to a biological sciences degree or as a separately qualifiable degree, the Committee should recognize the potential for "degree-creep." What other allied health degrees might be considered as equivalent and what impact could this have on the laboratory profession? The ASCP and ASCP BOC is seriously concerned that the potential for "degree-creep" and additional lowering of personnel standards could adversely affect patient care and diminish the traditional pathways to training the next generation of laboratory professionals. CMS's proposal could ultimately complicate efforts to ensure clinical laboratories are adequately staffed.

Another CLIA personnel issue ASCP and the ASCP BOC would like to address concerns histology. When CMS last revised the CLIA regulations, it excluded from oversight many pre-analytic processes because they were considered relatively simple, low risk procedures. Since then, the processing of tissue specimens—histotechnology—has become highly complex. The CAP, through its Laboratory Accreditation Program (LAP) check list notes that *slides must have adequate technical quality to be diagnostically useful* (ANP 11734). Unfortunately, this is not always the case. The ASCP and ASCP BOC believes that CMS should treat histotechnology pre-examination and examination processes as highly complex. This would require that these services be performed in a CLIA-certified facility under the direction of a board-certified anatomic pathologist, subject to applicable proficiency testing requirements and performed only by properly trained histotechnicians and histotechnologists.

In addition, the ASCP and ASCP BOC urge that the CLIA personnel regulations integrate a certification requirement for the performance and supervision of high complexity testing. We wish to highlight one study in particular that found that in laboratories employing both certified and non-certified technologists, the accuracy of PT results increased as the proportions of certified laboratory personnel increased.

The ASCP and ASCP BOC is very concerned about staffing shortages and ensuring that clinical laboratories have a sufficient labor supply from which to hire qualified laboratory professionals. Although we recognize that specific coursework in medical laboratory science programs provides the best education and training to prepare individuals to perform high complexity testing, given the lack of sufficient numbers of educational programs we do not support a “degree-specific” approach to expanding the laboratory personnel labor market. That said, we do believe that the CLIA personnel regulations could do a better job to help clinical laboratories find an adequate supply of prepared laboratory professionals and thus, we offer the following recommendations from our [comments](#) on the CMS RFI:

- Allow an earned baccalaureate degree with at least 30 semester hours (or equivalent) of coursework in biological and chemical sciences pertinent to laboratory medicine to satisfy the academic degree requirements for high complexity testing;
- Clarify that all high complexity testing personnel must complete clinical training, either from an accredited clinical training program or documented laboratory training prior to testing patient samples;
- Create personnel standards for histotechnology professionals, requiring that they complete an associate degree (or equivalent) in the chemical or biological sciences and complete an accredited training program or a structured training program under the auspices of a board certified pathologist or his or her designee; and
- Require all high complexity laboratory personnel to pass a national certification examination, such as that provided by the ASCP BOC.

The ASCP and ASCP BOC believe that these policy changes will help increase patient safety and expand the labor market of qualified laboratory professionals. As the Committee considers CLIA personnel requirements, we suggest that it establish a subcommittee to help the Committee develop its recommendations. We look forward to working with the CLIAC as it further considers this important issue.

Thank you.

March 12, 2018

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1678-FC Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); CMS-3326-NC

Dear Administrator Verma:

On behalf of the undersigned member associations of the American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Board of Governors (BOG), we are writing to provide comment on the Centers for Medicare & Medicaid Services (CMS) recent Request for Information (RFI) on revisions to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel regulations. These comments are generally focused on the RFI's policy proposals specific to laboratory testing personnel regulations.

The ASCP BOC BOG is composed of representatives from our partner laboratory professional organizations and serves as the governing body to the ASCP Board of Certification (BOC). The ASCP BOC's mission is to provide excellence in certification of laboratory professionals on behalf of patients worldwide. We are considered the gold standard certification for medical laboratory professionals around the world. The ASCP Board of Registry (BOR) began in 1928. In 2009, the BOC was formed by the merger of the ASCP BOR and the National Credentialing Agency. We are an independent, non-profit certification agency that develops appropriate standards and procedures to assure the competence of medical laboratory personnel and have certified over 500,000 laboratory professionals in the United States and internationally. We are the only ANSI accredited certifying body of laboratory professionals in the United States and have one of the largest accredited certification programs (21 certifications) in the country. Our credentials are recognized for licensure in all US licensure states and we are the sole provider of licensure exams in the state of New York.

We are opposed to the Agency's flawed and erroneous policies and proposals recognizing nursing degrees as equivalent to biological science degrees, as well as, allowing holders of nursing degrees to perform and supervise non-waived laboratory testing. The Agency's equivalency position and proposal to allow nursing degrees to be separately qualifiable for purposes of performing high complexity testing or serving as a technical consultant significantly lower the qualifications necessary to perform non-waived testing and could have serious repercussions for test quality and patient safety. We firmly believe that only those individuals who have completed bachelor's *degrees and sufficient coursework in the biological, chemical and clinical laboratory sciences* should be considered to have satisfied the bachelor's degree requirement necessary to perform high complexity testing or serve in supervisory roles within non-waived laboratories. Given that we presented to CMS in September 2016 a petition signed by 35,000 individuals concerned about CMS'

April 1, 2016 equivalency position, we believe our comments on the inappropriateness of the nursing degree to non-waived testing are reflective of the views of laboratory professionals across the United States.

I. Personnel Requirements

The following section outlines our views and positions on the CLIA regulation's personnel requirements, including those outlined in the CMS RFI. This discussion covers the issue of the nursing degree as sufficient to meet the CLIA high complexity degree requirements for purposes of performing high complexity testing and serving as technical consultants of a moderate complexity laboratory, as well as the physical science degree and non-traditional degrees.

A. Nursing Degrees

In the RFI, CMS notes that it currently considers a bachelor's degree in nursing to be equivalent to a bachelor's degree in biological science for purposes of the educational requirements for moderate and high complexity testing personnel under CLIA. Further the Agency states that it is:

"considering drafting proposals to amend 42 CFR 493.1411 (moderate complexity technical consultant), 493.1423 (moderate complexity testing personnel), and 493.1489 (high complexity testing personnel) to expressly reflect that policy. [CMS is] also considering whether a nursing degree should be considered as a separate qualifying degree, as opposed to the equivalent of a biological science degree, for purposes of meeting the educational requirements for moderate and high complexity testing personnel and technical consultants. As such, we are also considering proposing to amend §§ 493.1411, 493.1423, and 493.1489 to add a nursing degree as a separate qualifying degree to the current list of qualifying degrees for the moderate and high complexity testing personnel and technical consultants."

CMS states in the RFI that it is seeking public comments as to whether a nursing degree is equivalent to a biological science degree; or (2) whether it should add nursing degrees as a separate qualifying degree (as opposed to the equivalent of a biological science degree) to the current list of qualifying degrees. **Our response is that (1) nursing is NOT equivalent to a biological sciences degree; and (2) CMS should NOT add nursing as a separately qualifying degree allowing its holders to perform high complexity testing or supervise non-waived testing.**

1. Evidence that a Nursing Degree is not Equivalent to a Biological Sciences Degree

We have great respect for the nursing profession and fully believe that nursing degrees, both at the associate and baccalaureate degree level, offer individuals outstanding training pertinent to the practice of nursing. Nurses fulfill essential functions in point-of-care testing, the vast majority of which is CLIA waived. But the fundamental reality is that the nursing degree is not intended to be, nor should it be viewed as, equivalent to a biological science degree or any other science degree earned by laboratory testing professionals who perform, supervise, or direct moderate and high complexity diagnostic testing services. Similarly, nursing degrees should not be recognized separately as they do not provide adequate instruction to enable its holder to perform high

complexity testing or to supervise non-waived laboratory procedures. It should be viewed for what it is, a health services degree focused on the practice of nursing—not laboratory medicine or histology. The proposition that a nursing degree is equivalent to a degree in the biological sciences is erroneous and inconsistent with the CLIA regulations.

Biological sciences degrees vastly outweigh nursing degrees both in terms of their course load and rigor. In Appendix 1, we provide an overview of the academic science course requirements for nursing and biological sciences bachelor's degree programs. The comparison of biology and nursing degree requirements in the table in Appendix 1 shows that at least 32 hours of 200 level or higher coursework in chemistry or biology combined is required for biology, but not for nursing. For nursing programs science course are limited and introductory (100 level). They are not equivalent of those required for a science degree, and thus are not intended to be equivalent. As a specific example, the course catalog for the Nursing program at Case Western Reserve University gives the following description of Biology 114. Principles of Biology: "A one-semester course in biology designed for the non-major. A primary objective of this course is to demonstrate how biological principles impact an individual's daily life. BIOL 114 introduces students to the molecules of life, cell structure and function, respiration and photosynthesis, molecular genetics, heredity and human genetics, evolution, diversity of life, and ecology. Minimal background is required; however, some exposure to biology and chemistry at the high school level is helpful. This course is not open to students with credit for BIOL 214 or BIOL 250. *This course does not count toward any Biology degree* (emphasis added)."

One of the other misconceptions inherent in CMS' erroneous policy that nursing is equivalent to the biological sciences is the presumption that nursing degrees provide similar "lab" time as biological sciences degrees. Considering the differences in course credits and rigor, clearly this is not the case. Furthermore, nursing programs do not address the laboratory competencies in 42 CFR 493.17,¹ particularly at the level of high complexity testing. This is an issue because CLIA appears to assume that individuals with a bachelor's degree in a "chemical, physical, biological, or clinical laboratory science, or medical technology" have sufficient hands-on laboratory experience to perform high complexity testing, and with sufficient experience, to supervise non-waived testing. This may help explain why the CLIA regulations have no specific training requirement for individuals qualifying on the basis of these bachelor's degrees [See 42 CFR 493.1489(b)(1)]. While this presumption of appropriate training is clearly true for clinical laboratory science, medical laboratory science and medical technology degrees, it is not always the case for chemical, physical, and biological sciences degrees and it is certainly not true for nursing degrees. Training, however, is essential to ensure a thorough understanding of the quality assurance and quality control practices necessary to produce accurate laboratory test results and ensure quality patient care. Equating nursing to the biological science would seem to suggest that all of these degree holders have received sufficient laboratory expertise to perform and/or supervise high complexity testing, which is not the case.

¹ The Code of Federal Registry (493.17; Test Categorization) defines the skills needed to conduct moderate and high complexity tests. The following (abbreviated) criteria abstracted from CFR 493.17, applied to pre-analytic, analytic and post-analytic phases of testing are evaluated and graded by the FDA to place a test within moderate and high complexity categories: specialized scientific and technical knowledge; training and experience; operational skills such as monitoring, measurement, pipetting and calculation; assessment of specimens and calibration and quality control materials; troubleshooting and decision-making skills related to test performance and equipment maintenance; independent interpretation and judgment. These competencies are taught in Medical Laboratory Technician (MLT) and Medical Laboratory Science (MLS) a.k.a. Medical Technology (MT) or Clinical Laboratory Science (CLS) programs, as well as, in basic science curricula.

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Further, we believe the idea that nursing is NOT EQUIVALENT to a biological science is well-accepted within academic and professional circles. As part of our research on nursing degrees, the ASCP BOC consulted with the National Association of Credentials Evaluation Services (NACES)²—the experts on degree equivalency—as to whether it is appropriate to consider a nursing degree as equivalent to a biological sciences degree. NACES responded that these are NOT equivalent degrees. Moreover, the ASCP BOC has conducted extensive research into how the biological sciences and nursing degrees are organized within academe, and we have been unable to find a single biological sciences department that includes or recognizes nursing as a biological science or the equivalent. This further supports our belief that the idea that the biological sciences and nursing are equivalent or similar is inherently erroneous and inconsistent with the regulations.

This brings up an important point regarding the authority of the Agency to interpret the CLIA regulations such that nursing and the biological sciences are equivalent for the purposes of performing high complexity testing or supervising non-waived testing. First, we note we are unable to find any documents published in the Federal Register that specifically delineates such an Agency rule or policy. Per the *Auer Deference (Seminole Rock)*,³ the federal courts have provided agencies wide discretion to interpret their regulations. That said, *Auer supports this deference only where the regulation is ambiguous and the regulatory interpretation is not “plainly erroneous or inconsistent with the regulation.”*

As we explained in our June 16, 2016 letter to you (See attached), the term “biological science” is an *unambiguous term* with a broadly understood meaning. Moreover, as discussed above the Agency’s position that nursing is a biological science fails to pass the Supreme Court’s test that the interpretation must not be erroneous and that it must be consistent with its regulations. Consequently, the Agency’s interpretation that a degree in nursing is equivalent to a degree in biological science exceeds its authority and is invalid. We urge the Agency to fully and immediately rescind this interpretation.

2. Concerns Regarding Possible Supervisory Roles of Nursing Degree Holders

While the RFI indicates that CMS would allow individuals with a bachelor’s degree in nursing to serve as a technical consultant of a moderate complexity laboratory, it is unclear whether the Agency’s equivalence policy could not be used to allow individuals with a bachelor’s degree in nursing to serve in other supervisory roles. If the nursing degree is currently equivalent to a degree in the biological sciences, then without a specific restriction in the regulations, such a degree holder might be able to work as either a laboratory director of a moderate complexity laboratory (See 42 CFR 493.1405(b)(5)) or as a general supervisor of a high complexity laboratory (See 42 CFR 493.1461(c)(2) if they have 2 years of experience. The rules would also seem to allow an individual with a bachelor’s degree in nursing to serve as a high complexity technical supervisor for numerous laboratory specialties, e.g. 42 CFR 493.1449(h)[hematology], with just 4 years of experience. The CLIA rules need to be very clear that only those individuals who have completed acceptable degrees and completed appropriate training or necessary full-time experience should be able to serve in these roles.

² NACES® is an independent professional organization that promotes excellence in the field of credential evaluation and supports knowledgeable evaluation staff and member organizations engaged in providing professional service in the field of applied comparative educational evaluation.

³ Auer v. Robbins (95-897), 519 U.S. 452 (1997)

3. Impact on Test Quality and Patient Care

CMS' current and proposed policy regarding nursing degrees significantly lowers the qualifications necessary to perform high complexity testing and could have significant repercussions for test quality and patient safety (See Appendix 2). Such a development would likely lead to lower quality testing. We note that a study by Lunz et al. noted that as the proportion of certified laboratory personnel increased so too did accuracy on proficiency testing. Since certification reflects more demanding education and training, it stands to reason that lower personnel standards will likely lower test quality.⁴ Moreover, if CMS is willing to consider a degree that may have only 15 semester hours of biological and/or chemical sciences as equivalent to a biological sciences degree, which often requires upwards of 60 hours of biological, chemical and other sciences, then it would stand to reason that numerous other degrees that are similarly lacking in the relevant sciences could be deemed equivalent to the bachelor's degrees required in 42 CFR 493.1489(b)(1). At that point, the CLIA personnel standards cease to be relevant as a means to ensure that testing personnel have the knowledge and training necessary to ensure test quality and patient safety.

We recognize the vital role that nurses play in the point-of-care (POC) setting and are aware of the trend towards increased access to waived and moderate complexity tests developed specifically for this setting. Rapid, POC testing can be critical to immediate care of the patient. The definition of POC settings has expanded to include radiology suites, ambulances, mobile stroke units, ambulatory surgery centers, and others. In some cases the classification of a POC test as moderate complexity limits it to be performed in the hospital setting only. Furthermore, changes in patient population, setting, or other user modifications of the FDA-approved package insert changes the complexity to high complexity/laboratory developed test classification. We suggest that rather than allow nurses to perform any and all high complexity testing, a revision in the definition of POC should be considered such that these tests might remain moderately complex and allow performance by nurses and other appropriate health care providers such as radiology personnel. Alternatively, new classification of tests specific to POC might be developed.

4. Labor Market Factors Relevant to the Nursing Degree Proposal

During our September 2016 meeting with CMS, Agency officials indicated that one of the primary motivations for its decision to declare that the biological sciences include nursing was because of concern about a shortage of laboratory testing personnel. While we share the Agency's concern about the labor supply, the Agency's proposed policy is inherently flawed and will have little if any positive impact on the labor market for laboratory personnel. Given the lack of adequate instruction in the sciences—both in the number of credit hours and the basic “survey” nature of these courses—nursing degrees do not provide adequate scientific instruction to perform quality high complexity testing or to properly supervise non-waived laboratory testing. Thus, these degree holders are unlikely to be viewed by employers as viable candidates for laboratory testing positions.

While data from the ASCP's recently released 2016-2017 Vacancy Survey does confirm concerns

⁴ Lunz M, Castleberry B, James K, Stahl J. The Impact of the Quality of Laboratory Staff on the Accuracy of Laboratory Results. *JAMA*. 1987; 258:361-363.

about vacancies, the data suggests that the nursing degree is not viewed as an appropriate way to address these concerns (See Section B on Physician Science and Non-Traditional Degrees for our thoughts on more appropriate ways to help laboratories recruit more laboratory professionals). First, the data reveals that clinical laboratories are very concerned about the qualifications of individuals applying for testing positions. Indeed, the new data finds that the issue of greatest importance (24 percent) to laboratory hiring managers is access to *qualified* (emphasis added) laboratory staff. This apprehension is similarly reflected in the fact that that 10 percent of hiring managers reported concerns about nurses doing high complexity testing as their most pressing concern.

ASCP Survey respondents did indicate that the number of job applicants is extremely low in comparison to the number of retiring personnel. As a number of laboratories appear to be experiencing an increased workload (compared with the last survey, this year more respondents indicated their laboratories having an average test volume of over a million tests per year), supervisors feel increasingly compelled to consider less qualified applicants, i.e., bachelor's degree holders who either have not completed an accredited or approved training program and/or who have little or no laboratory experience or training. As the number of individuals graduating from accredited or approved training programs is relatively fixed, hiring managers are increasing reliant on individuals who have not attended such programs and may have limited training. The Survey results suggest that vacancies are being filled at a faster rate. If vacancies are being filled at a faster rate, then the question arises concerning the qualifications of the new hires. Without more appropriate personnel standards for testing personnel, we envision the quality of testing personnel would decrease and in turn so would the quality of laboratory testing.

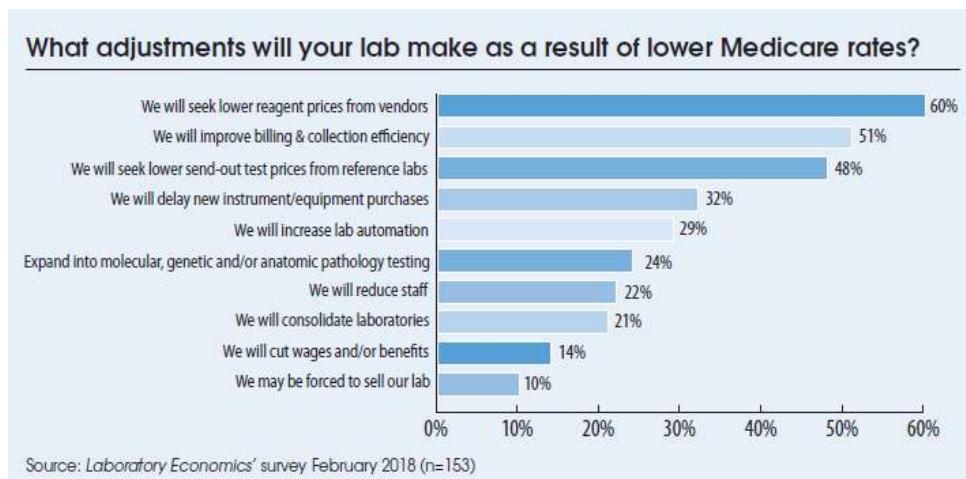
Another reason CMS's proposal will have a negligible impact on the labor market for laboratory professionals concerns wage differentials. According to the Bureau of Labor Statistics (BLS), the median salary for a registered nurse (*bachelor's level* nurses) was \$68,450 (2016). For medical laboratory professionals,⁵ the Bureau indicates the median salary is \$50,930 (2016). Given tight staffing budgets, *it is highly improbable that clinical laboratories would pay almost \$20,000, or 34 percent, more for personnel who would require extensive academic instruction and clinical training before they could perform quality high complexity patient testing.* Employers who are willing to increase salaries that much would have greater success recruiting qualified laboratory professionals (with presumably less need to pay for necessary training).

We should also point out that CMS recently implemented a new Medicare Clinical Laboratory Fee Schedule, per the Protecting Access to Medicare Act (PAMA). The significant reductions in payment rates PAMA imposes, coupled with the likelihood that private payers will adopt similar payment cuts will significantly reduce laboratory revenues. This has already resulted in the restructuring of the market for laboratory services, and it is likely to continue over the foreseeable future. Unfortunately, one of the likely results of this restructuring is layoffs of laboratory professionals. These layoffs will have the effect of increasing the laboratory professional's workforce, which will help lessen any personnel shortages.

We believe that Laboratory Economics' PAMA Survey February 2018 provides ample evidence of PAMA's impact on the labor market, which reported on the findings of its recent survey of

⁵ BLS's salary data is based on data for medical laboratory scientists (bachelor's degree level laboratory professionals) and medical laboratory technicians (associate degree level personnel), both of whom may perform high complexity laboratory testing.

laboratory executives.⁶ Their findings indicate that private payers are following CMS' lead and reducing laboratory test payment rates. In expectation of reduced reimbursement, *Laboratory Economics* reports that 22 percent of surveyed laboratory executives indicated that they plan to reduce staff; 21 percent indicated they would consolidate laboratories; and 29 percent indicated they would increase laboratory automation (see below). Such responses to reduced revenues should result in less demand for (and reduced regional shortages of) laboratory personnel. As a result, we believe that decreasing the personnel requirements to enable high complexity testing by individuals with a degree in nursing is unnecessary.



We would also urge CMS to consider the impact of this policy proposal on the nursing profession. The field of nursing is currently suffering from severe staffing shortage and implementing a policy designed to encourage these individuals to consider alternative careers undermines federal and state policies intended expand the nursing work force.

The notion that a nursing degree includes sufficient academic instruction and clinical training to enable its holder to perform high complexity testing is widely rejected by laboratory professionals. In 2016, we launched a campaign urging laboratory professionals and other concerned individuals to sign a petition arguing that the nursing degree is not equivalent to the biological sciences in terms of the instruction necessary to perform high complexity testing. We presented that petition to CMS in September 2016 when we met with the Agency to discuss our concerns about its April 1, 2016 Memorandum. A copy of that petition is attached to this submission.

In addition, we should note that on December 14, 2016 the U.S. Department of Veterans (VA) released a [Final Rule](#) on the scope of practice (SOP) of Advanced Practice Registered Nurses (APRNs). The Final Rule was a significant departure from the Proposed Rule, which would have allowed APRNs to "order, interpret, perform and supervise" all complexity levels of clinical laboratory testing. In commenting on the Proposed Rule, we noted that the academic credentials of APRNs, while impressive and exceeding those of registered or bachelor's degree nurses, still do not satisfy the CLIA high complexity requirements (though the VA is technically exempt from CLIA, the Department's policy is to follow it). *The VA agreed with our concerns; in the Final Rule, the VA*

⁶ Labs Bracing For Private-Payer Rate Cuts. *Laboratory Economics*, Volume 18, Number 2. February 2018. p. 1.

adopted a policy that APRNs' may not perform or supervise laboratory testing regardless of its complexity level.

To summarize our position on the nursing degree, we are opposed to the Agency maintaining any policy, i.e., CMS' existing and proposed interpretative positions as well as its proposal to make nursing a separately qualifiable degree, that allows the holder of a bachelor's degree in nursing to perform high complexity testing or supervise non-waived testing. We recognize that the CLIA regulations' bachelor's degree requirements would benefit from being updated, but we do not believe that lowering high complexity standards in the manner suggested by CMS is wise or appropriate for patient care. We discuss our proposals for how this can be accomplished below.

B. Physical Science and Non-Traditional Degrees

CMS indicates in the RFI that it is seeking input on whether bachelor's degrees in physical science or other non-traditional degrees provide appropriate instruction in the sciences relevant to performing laboratory testing. We believe that physical science and non-traditional degrees should be accepted, but only if the degree holder has completed 30 hours of biological and chemical sciences, including courses at an advanced level. Coursework only in physics, astronomy, geology, and other earth sciences does not qualify as medical laboratory science. We believe it depends on the coursework behind the degree. If the degree includes enough of the coursework relevant to laboratory medicine, then it should be acceptable.

1. Principles for High Complexity Testing and Supervision

This section of our comments outlines the guiding principles that we believe CMS should embrace as it works to modernize the CLIA personnel regulations in the best interests of test quality and optimum patient care. We believe that to ensure quality testing, all individuals who either supervise or perform high complexity testing need sufficient academic instruction and clinical training, as well as an appropriate assessment of their understanding of laboratory medicine. The literature on the notion that education, training, and certification have a positive impact on quality is well-established. As a supplement, we provide an overview of several studies specifically examining this dynamic within laboratory medicine (See Appendix 2). To expand on this, we are suggesting criteria we believe CMS should adopt for *all testing personnel* (not just those with physical science or non-traditional degrees) who perform high complexity testing or supervise non-waived testing.

a. Appropriate Academic Education

We value accredited programs in the medical laboratory sciences as providing the best training possible for quality patient testing in the high complexity clinical laboratory.⁷ These programs require foundational biology and chemistry as prerequisite courses and provide rigorous classroom, student laboratory and clinical practicum experience in all aspects of laboratory

⁷ We note, and believe, that the current CLIA personnel requirements (See 42 CFR 1483) for cytology are appropriate and thus our comments do not apply to these regulations.

medicine. We note that historical data⁸ on ASCP certification examinations document that individuals with degrees in the laboratory sciences tend to have higher pass rates than individuals with degrees in the biological and chemical sciences (See Appendix 3). However, recognizing that the number of MLS/MLT training programs is insufficient to provide adequate numbers of graduates to meet the needs of CLIA-certified laboratories, we acknowledge that an earned bachelor's degree in a chemical or biological science from an accredited academic institution can also provide the foundational scientific knowledge necessary to perform quality patient testing.

What makes these degrees relevant to laboratory medicine, however, is not the degree itself but the coursework completed as part of the degree. Currently if an individual has earned a bachelor's degree in Education—a degree not recognized by the CLIA high complexity regulations—they would not be eligible to perform or supervise high complexity testing, even if they have completed significant coursework applicable to a degree in a biological, chemical, or clinical laboratory science. We do not believe that it makes sense to automatically preclude such individuals from performing high complexity testing or supervising testing as a technical consultant (See 42 CFR 493.1411) or technical supervisor (See 42 CFR 493.1449).

As a result, we urge CMS modify 42 CFR 493.1489(b)(1) to allow individuals who have an earned baccalaureate degree, or the equivalent, from an accredited academic institution and at least 30 semester hours, or the equivalent, in the chemical, biological, and/or clinical laboratory sciences to perform high complexity testing. We also believe it should also be acceptable for such degree holders to serve as general supervisors of a high complexity laboratory or as technical consultants of a moderate complexity laboratory. Corresponding changes would also need to be made to 42 CFR 493.1411 and 42 CFR 493.1449 to operationalize these changes.

For individuals with an associate degree, we believe that the current provisions outlined in 42 CFR 493.493.1489(b)(2) provide appropriate guidance: all associate degree holders (or the equivalent), must have either an associate degree in medical laboratory technology (or the equivalent) or an associate degree (or the equivalent) and 24 semester hours (or the equivalent) of scientific coursework clinical laboratory science/medical technology, or chemistry and biological science AND laboratory training.

Under our proposal, we envision the laboratory director (or appropriate designee) should have the responsibility for reviewing and verifying academic transcripts to recognize these non-traditional routes to performing high complexity testing and (with appropriate experience) supervising non-waived testing. To facilitate this task, we believe the laboratory director (or designee) should be able to rely on primary source verification to ensure the individual has completed sufficient coursework in the relevant sciences. To help support this proposal, we believe that it would be appropriate to create a new definition of the help clarify the chemical or biological science that are relevant to laboratory science. We provide possible wording for such a definition later in this letter. Also in the RFI, CMS requests comment on whether the CLIA regulations should be amended to allow general supervisors, with associate's degrees, to perform competency assessment for moderate complexity testing personnel in laboratories that perform both moderate and high complexity testing. Moderate complexity testing is inherently less complicated than high complexity testing. Thus, we believe that it would be acceptable for a general supervisor to assess personnel competency at all levels of laboratory testing.

⁸ The data outlined in Appendix 3 covers examination pass rate data for the last 5 years.

b. Appropriate Clinical Laboratory Training

As noted earlier, the CLIA personnel regulations do not *explicitly* require clinical training of most testing personnel. Under the high complexity testing personnel regulations (See 42 CFR 493.1489), only those qualified with an associate degree are required to complete training—either an accredited or approved laboratory training program or documented laboratory training. Similarly, at the moderate complexity level, only those individuals qualifying on the basis of a high school diploma are specifically required to complete training under CFR 493.1423 for moderate complexity testing. We believe that lack of an explicit training requirement, particularly at the bachelor's level, is an oversight.

We believe that the studies detailed in Appendices 2 and 3 are particularly relevant to this issue. Here, we wish to highlight the ASCP BOC's historical pass rate data for the medical laboratory scientist examination (bachelor's degree level laboratory professionals). This data illustrates that individuals who have completed an accredited or approved laboratory training programs consistently have higher pass rates than individuals who satisfy ASCP BOC training/experience requirement via five years of on-the-job (OJT) experience. Given this fact, the data suggest that training, particularly formal training, has advantages over experience when it comes to pass rates. This suggests that a lack of appropriate training may result in lower quality testing and that quality would be better supported by specifying in the regulations that bachelor's level personnel should satisfy a training requirement.

Considering that some high complexity testing personnel have not completed accredited training programs in Medical Laboratory Science and because training is imperative to ensure a full understanding of the quality assurance and quality control practices necessary to produce accurate laboratory test results and ensure quality patient care, *the CLIA regulations should be clarified to ensure that individuals performing high and moderate complexity testing must complete documented laboratory training prior to testing patient samples*. The College of American Pathologists (CAP) currently requires of the laboratories it certifies that personnel receive training prior to performing laboratory testing (See Attachment 4 – GEN.55450: CAP Laboratory Accreditation Program checklist).

Because clinical training is imperative to ensure a full understanding of the quality assurance and quality control practices necessary to produce accurate laboratory test results and ensure quality patient care, *the CLIA regulations should be clarified to ensure that individuals performing high and moderate complexity testing must complete documented laboratory training prior to testing patient samples*. Training should comprise pre-analytic, analytic and post-analytic elements of a test system and include direct observation of all steps in the testing process. Competency with major procedural steps within each element should be documented by both the trainee and trainer. A qualified general supervisor, technical supervisor or technical consultant, as applicable, should review training documents and acknowledge in writing readiness of the trainee prior to testing of patient samples and reporting of results in the medical record.

Moreover, to ensure quality testing, we believe CMS should also clarify that any experience required to serve in supervisory roles must be *full-time* experience performing laboratory testing—the vast majority of which must be non-waived. In other words, if a health care professional spends only a portion of their work day performing non-waived testing, only that portion of the day should count towards the applicable experience requirements.

c. Passage of an Accredited Certification Examination

Laboratory testing forms the basis for many, if not most, medical diagnosis and ensures optimum therapeutic choices. As a result, patient outcomes require accurate and reliable test results; the potential exists for potentially serious patient harm when laboratory testing errors occur. Fortunately, test quality and optimum patient outcomes are heavily influenced by some of the very requirements inherent in CLIA, such as education, training, and experience. But missing from CLIA is certification, which provides the most reliable, unbiased, and cost-effective tool to assess the knowledge and potential ability of testing personnel to perform quality testing.

Several studies have considered the relationship between laboratory test quality and laboratory personnel. These studies detailed in Appendix 2, lend support to the premise that test quality is influenced by academic education, clinical training and/or work experience, and an accredited certification. We wish to highlight one study in particular that found that laboratories employing only certified medical laboratory scientists (referred to as “medical technologists” in the study) produce significantly more accurate results on proficiency tests than laboratories that employ only non-certified technologists.⁴ Moreover, the authors found that in laboratories employing both certified and non-certified technologists, the accuracy of PT results increased with higher proportions of certified laboratory personnel.

We urge that the CLIA regulations be amended to require individuals supervising non-waived testing or performing high complexity testing to pass a qualifying examination developed by an accredited, nationally recognized certification organization, such as the ASCP BOC.

To prevent such a requirement from adversely affecting the ability of accredited clinical laboratories to hire and retain testing and supervisory personnel, we believe an exemption should be made for laboratory personnel during their first 3 years performing in high complexity testing services, provided these individuals are supervised by a qualified laboratory director or a certified laboratory professional that satisfies the CLIA general supervisor requirements. Moreover, testing personnel and supervisors in some laboratories may be specialized, making categorical certification necessary. We recognize, and support, grandfathering provisions to smooth the transition of this requirement.

2. Other Aspects of the CLIA Regulations:

A. Histology

When CMS last revised the CLIA regulations, it excluded from oversight many pre-analytic processes because they were generally relatively simple, low risk procedures. That said, much has changed, particularly with respect to the specialty of anatomic pathology. The processing of tissue specimens—histotechnology—has become highly complex, with numerous new methodologies in traditional areas (tissue processing, Histochemistry) as well as in the fields of immunohistochemistry, molecular diagnostics, and computerized assisted digital analysis. In addition, personalized medicine, which is highly dependent on laboratory diagnostics, has evolved and is now the standard of care, and as a result the technical quality of the tissue specimen is imperative to ensuring optimum patient outcomes.

This reality is well-recognized by the industry. The CAP, through its Laboratory Accreditation Program (LAP) check list (See Appendix 4) notes that *slides must have adequate technical quality to be diagnostically useful* (ANP 11734). Unfortunately, this is not always the case. Data from proficiency testing, such as Nordic Immunohistochemistry Quality Control (NordIQC), indicate that approximately 20 percent of breast cancer slides and 30 percent of general slides were found to be of insufficient quality for diagnostic use.⁹ The study found that the vast majority of these insufficient slides (90 percent) were characterized by poor staining (either too weak or false negative staining). The CAP/National Society for Histotechnology (NSH) Quality Improvement Program, (HQIP) has associated poor tissue processing to poor routine hematoxylin & eosin staining (Appendix 5). This stain is performed on each tissue sample that is received in the pathology laboratory for diagnosis. To ensure that pathologists are able to provide patients with the most diagnostically useful information, we believe that CMS must increase its oversight of histology. To begin, we believe that CMS should treat histotechnology pre-examination and examination processes as highly complex, thus requiring these services to fall under CLIA's oversight. This would require that these services be performed in a CLIA-certified facility under the direction of a board-certified anatomic pathologist, subject to applicable proficiency testing requirements and performed only by properly trained laboratory professionals, i.e., histotechnicians and histotechnologists.

Such a requirement should specify that histology professionals complete an associate degree in a chemical or biological science (or the substantial equivalent), and complete either (1) an accredited training or approved training program, or (2) a structured training program provided under the auspices of a board-certified anatomic pathologist or his or her designee. Such staff should be certified in the same manner as discussed elsewhere in this letter.

In conclusion, we are opposed to the Agency maintaining its equivalency position and are similarly opposed to allowing a nursing degree to be listed as a separately qualifying degree. Instead, CMS should allow individuals who have an earned bachelor's degree to be considered as having met the degree requirement, provided they have completed at least 30 semester hours (or equivalent) of coursework in the biological and chemical sciences pertinent to laboratory medicine. CMS should also clarify the need for testing personnel that perform high complexity testing to complete appropriate clinical laboratory training and pass an accredited certification examination. Further,

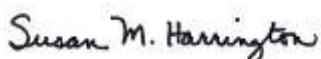
⁹ Mogens V. Proficiency testing in immunohistochemistry-experiences from Nordic Immunohistochemical Quality Control (NordiQC). Virchows Archiv. 2016;468:19-29.

The Honorable Seema Verma
March 12, 2018
Page 13

we urge CMS to increase oversight of histology operations by requiring those facilities or entities that perform histologic processing of anatomic tissues to be classified as CLIA-certified high complexity laboratories, requiring that these procedures be performed in an appropriately accredited CLIA laboratory, under the oversight of a board-certified anatomic pathologist, and performed by an appropriately qualified laboratory professional as outlined in the previous section of this letter.

We appreciate the opportunity to comment on this Request for Information and look forward to working with the Agency to ensure quality testing. If we can be of any assistance, please contact Matthew Schulze, Director of the ASCP Center for Public Policy, at 202-408-1110 (x 2905) or Matthew.Schulze@ASCP.org.

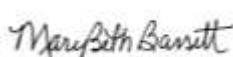
Sincerely,



Susan M. Harrington, PhD, D(ABMM), MLS(ASCP)^{CM}
Chair, ASCP Board of Certification



James Wisecarver, MD, PhD, FASCP
President, American Society for Clinical Pathology



Mary Beth Bassett, BS, MT(ASCP)
President, AABB



John Eckman, MHS, PA(ASCP)^{CM}
Board of Trustees Chair, American Association of
Pathologists' Assistants

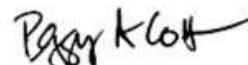


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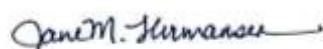
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The Honorable Seema Verma

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Jeff Pleines, CCSQ/BOG

Attachments



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February 15, 2017

Karen W. Dyer, MT(ASCP)DLM
Director, Division of Laboratory Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, S3-02-01
Baltimore, Maryland 21244

RE: Memorandum (S&C -16-18-CLIA)

Dear Ms. Dyer:

On behalf of the American Society for Clinical Pathology (ASCP), the ASCP Board of Certification (BOC), and the American Society for Clinical Laboratory Science (ASCLS), we are writing to inquire about CMS's efforts to reverse its illogical regulatory interpretation allowing bachelor's or associate's degrees in nursing to meet the requirement for earning the same level degrees in a biological science. The interpretation would allow individuals with a bachelor's degree in nursing to perform and supervise all levels of laboratory testing under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. When we met on September 27 to discuss this issue on behalf of the more than 30,000 ASCP and ASCLS members who signed the petition opposed to the Agency's position, CMS indicated that it would need several months to determine by what method it would rescind it.

Recently, the U.S. Department of Veterans Affairs (VA) released a [Final Rule](#) on the scope of practice (SOP) of Advanced Practice Registered Nurses (APRNs). The Final Rule was a significant departure from the Proposed Rule, which would have allowed APRNs to "order, interpret, perform and supervise" all complexity levels of clinical laboratory testing. In commenting on the [Proposed Rule](#), we noted that the academic credentials of APRNs, while impressive and exceeding those of registered or bachelor's degree nurses, still do not satisfy the CLIA high complexity requirements (though the VA is technically exempt from CLIA, the Department's policy is to follow it). When the VA released its Final Rule, it concurred with our points and significantly scaled back the APRNs' SOP, such that *they will not be allowed to perform high complexity testing or supervise laboratory testing of any complexity level.*

This recent development creates an incongruity in federal policy (i.e., VA versus CMS policy). This juxtaposition reinforces our belief that action is needed as soon as possible. Therefore, we urge CMS to rescind its interpretation that nursing is a biological science.

Another key concern pertains to whether the Agency has sufficient legal authority to enforce this interpretation of the CLIA regulations. To be sure, under *Auer*¹, federal agencies have wide discretion to interpret their regulations. That said, the *Auer* deference is not legally warranted where the regulation is unambiguous or the offered interpretation is "plainly erroneous or inconsistent with the regulation." We believe that to be the case here. As we explained in our June 16 letter to you, the term "biological science" is an unambiguous term with a broadly understood meaning. A degree in biological science entails an in-depth study of biology, with courses ranging from ecology to evolutionary biology to genetics to biochemistry to molecular biology. This is decidedly different from a degree in nursing. Consistently, we are unable to find any evidence of any other entities recognizing nursing as a biological science. Consequently, the Agency's position that a degree in nursing is equivalent to a degree in biological science exceeds its interpretative authority and should be rescinded. As CMS developed this position without rulemaking, it should be able to reverse its position in the same manner—without rulemaking.

¹ *Auer v. Robbins* (95-897), 519 U.S. 452 (1997)

Karen W. Dyer, MT(ASCP)DLM

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February 15, 2017

Further, our review of ASCP's most recent Wage Survey, which compiled responses from approximately 16,000 individuals working in clinical laboratories, did not find any responses from individuals reporting to have a nursing degree. Currently, available data suggests the impact of correcting the Agency's flawed interpretation would be minimal; however, as dissemination of the Agency's April 1 Memorandum becomes more wide-spread, further delay puts more patients at risk.

We strongly concur with the VA that it is inappropriate for an individual with a bachelor's degree in nursing to perform or supervise high complexity testing (though per CLIA such individuals working in non-VA facilities are legally permitted to perform waived and moderate complexity testing (see 42 CFR 493.1423(b)(4))). Thus, we urge CMS to promptly rescind, without rulemaking, its erroneous position that nursing and biological science degrees are equivalent. **Therefore, we are asking for written clarification whether CMS continues to believe that bachelor's and associate's degrees in nursing meet the requirement for earning the same level degree in a biological science for purposes of performing or supervising high complexity clinical laboratory testing.**

We appreciate the opportunity to provide comments about this urgent issue and look forward to continuing to collaborate with you on this and other issues of concern to the laboratory field and patient care. If we can be of further assistance on this issue, please contact us or Matthew Schulze, Director of ASCP's Center for Public Policy at 202.347.4450 x 2905.

Sincerely

Kathleen Hansen, MLS(ASCP)^{CM}
Chair, Board of Certification Board of Governors

Jim Flanigan, CAE
Executive Vice President, ASCLS

William E. Schreiber, MD, FASCP
President, ASCP

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Attachment



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www.ascp.org

June 16, 2016

Thomas Hamilton
Director, Survey and Certification Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard, C2-21-16
Baltimore, MD 21244-1850

Re: Memorandum (S&C -16-18-CLIA)

Dear Mr. Hamilton:

The undersigned societies represented on the ASCP Board of Certification (BOC) Board of Governors are writing to address several issues pertaining to a recent Memorandum (S&C -16-18-CLIA) from the Centers for Medicare and Medicaid Services (CMS) to State CLIA Survey Agency Directors. In it, CMS announces that an associate's or bachelor's degree in nursing is the equivalent to an associate or bachelor's degree, respectively, in biological sciences for purposes of performing moderate and/or high complexity testing. CMS also instructs CMS surveyors to accept Primary Source Verification (PSV) documents as evidence of laboratory compliance with the personnel requirements specified in 42 CFR 493, Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 regulations. The ASCP BOC would like to meet with CMS staff to discuss these issues.

I. Recognition of the Nursing Degree as Equivalent to a Degree in Biological Sciences

We would like to begin by noting that we have great respect for the nursing profession and fully believe that the associate's and bachelor's degrees in nursing provides outstanding training for professionals in the nursing field. That said, the nursing degree is not intended to be, nor should it be viewed as, the equivalent of a degree in biological sciences or any other natural science degree required of laboratory testing professionals to perform moderate and high complexity diagnostic testing services. It should be viewed for what it is, a health services degree focused on nursing—not laboratory diagnostics.

In both scope and depth, the natural science coursework required for a biological sciences degree vastly outweighs the natural science coursework required as part of a nursing degree. For sake of discussion, we are attaching the coursework requirements for a baccalaureate degree in biological sciences and nursing from the University of Maryland, which reflects the coursework requirements typical for these degrees. We are also attaching the coursework requirements for several other programs to further illustrate this point.

At the University of Maryland, the coursework requirements for a bachelor of sciences degree in biological sciences includes a total of at least 63 hours of natural sciences (mathematics course hours subtracted from degree requirements), including at least 39 hours of major requirements in the biological sciences and 32 hours of prerequisites—almost all of which is in chemistry and physics. In contrast, the University of Maryland nursing degree appears to include only 16 hours of natural sciences, including only 12 hours of biological sciences (Human Anatomy and Physiology I and II and Microbiology) and 4 hours of chemistry (General Chemistry). Moreover, we note that the degree requirements for biological science degrees involve more advanced science instruction than does

Thomas Hamilton

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nursing. For biological sciences, approximately 40 percent of the coursework must be 300/400 level classes. In contrast, the nursing degree does not appear to specify that the science coursework be beyond an introductory level (100-level coursework may be sufficient). University of Maryland nursing degree would still appear to contain less than a third of the biological sciences contained in a biological science degree (12 vs. 39 hours) and approximately a quarter of the natural sciences of a general biological sciences degree (16 hours v. 63 hours). Simply put, the nursing degree does not compare to the degree in biological sciences.

A similar contrast exists at the associate degree level.

Besides the comparative lack of academic coursework in the relevant natural sciences, we are also troubled with CMS's action to excuse individuals with a degree in nursing from the requirement to complete clinical training prior to engaging in patient testing. Per the CLIA regulatory requirements for high complexity testing, individuals who possess a bachelor's degree or higher in a "chemical, physical, biological science" are exempt from the requirement to complete specific clinical training in laboratory sciences before performing diagnostic testing [See 42 CFR 493.1489(b)(1)]. Ironically, only those individuals with an earned "associate degree in a laboratory science or medical laboratory technology" are required to complete an accredited training program or other documented laboratory training prior to performing patient testing [See 42 CFR 493.1489(b)(ii)(B)]. We have serious concerns about individuals performing laboratory testing without adequate/appropriate clinical training. This training is essential to ensure a thorough understanding of quality assurance and quality control requirements necessary to produce quality laboratory test results and ensure quality patient care.

Another point that bears mentioning is that CMS appears to have opened a pathway for the nursing degree to qualify individuals to serve in senior technical leadership positions within moderate and high complexity clinical laboratories. Under CLIA, an individual with a bachelor's degree in a chemical, physical or biological science (nursing) may serve as a laboratory director or technical supervisor in a moderate complexity laboratory [See 42 CFR 493.1405(b)(5) and 42 CFR 493.1411(b)(4), respectively]. Additionally, such a degree holder would also be able to serve as a general supervisor or technical supervisor (over certain non-anatomic specialties) in a high complexity laboratory [See 42 CFR 493.1461(c)(2) and 42 CFR 493.1449], respectively]. Of course, these positions require work experience but no requirement to complete specific clinical training prior to engaging in patient testing.

We are concerned that the equivalency determination significantly lowers the qualifications necessary to perform high and moderate complexity testing and could have significant repercussions for test quality and patient safety. We request an opportunity to meet with CMS to discuss this issue to better understand the Agency's purpose behind its declaration and to determine if there may be alternative approaches that may better address our shared goals of ensuring access to quality laboratory testing.

II. Changes in CMS Acceptance of PSV Documentation for CLIA Compliance

In the April 1 Memorandum, CMS states that it "had many requests from laboratories, accreditation organizations, and other health care facilities to accept Primary Source Verification (PSV) of education, training, experience, and licensure in laboratory services in order to demonstrate compliance with regulatory requirements." In the memorandum, CMS states that "PSV companies merely confirm that the asserted training, degrees and credentialing have been achieved or conferred" so that "the surveyor and laboratory [can] determine if the applicant meets the [CLIA] personnel requirements."

CMS notes that its “*Central Office (CO) continues to receive inquiries from CLIA surveyors as to whether the laboratory can present an individual’s professional certification, such as medical technology certification or nursing licenses, as the only type of documentation to meet the CLIA personnel requirements*” (emphasis added). Unfortunately, the memorandum then states, “this type of documentation **IS NOT** considered sufficient evidence of meeting the personnel qualifications.” CMS also notes that it is the Agency’s “current understanding [that] PSV companies do not verify transcripts.”

It is this point we wish to discuss with CMS. We believe that CMS should allow ASCP BOC to serve as a PSV entity. CMS should be aware that as part of the process of certifying laboratory professionals ASCP *DOES* verify earned degrees, academic transcripts, clinical training and/or work experience. The ASCP BOC certification program is a formal process that requires education; clinical training and/or experience; and successful completion of the certification examination. Below are eligibility requirements for routes 1 & 4 for Medical Laboratory Scientist.

MEDICAL LABORATORY SCIENTIST ELIGIBILITY ROUTES 1 & 4

ROUTE 1: A baccalaureate degree from a regionally accredited college/university including courses in biological science, chemistry and mathematics, AND successful completion of a NAACLS accredited Medical Laboratory Scientist program within the last five years.

ROUTE 4: A baccalaureate degree from a regionally accredited college/university, including 16 semester hours (24 quarter hours) of biological science (with one semester in microbiology), 16 semester hours (24 quarter hours) of chemistry (with one semester in organic or biochemistry), one semester (one quarter) of mathematics, AND five years of full time acceptable clinical laboratory experience in blood banking, chemistry, hematology, microbiology, immunology, and urinalysis/body fluids in the U.S., Canada or an accredited laboratory* within the last ten years.

In the above example, the ASCP BOC verifies the following: transcripts for the appropriate number of hours and category (biological science, chemistry, mathematics, etc.) of coursework; transcript conferring baccalaureate degree; training program completion; and/or documentation of required amount of clinical experience. These eligibility requirements must be met utilizing PSV documentation before an individual is found eligible to sit for the ASCP BOC certification examination. ASCP BOC provides primary source verification (PSV) of all BOC certifications through an online order process.

Because of its ability to reduce the documentary burden of verifying compliance with the CLIA personnel requirements, we warmly welcomed the news that CMS would accept PSV documentation as evidence of compliance. We further believe that allowing clinical laboratories to utilize ASCP BOC certification verification as a PSV document would significantly reduce the burden on laboratories and surveyors of documenting compliance with these requirements. Therefore, we are requesting that CMS recognize the ASCP Board of Certification as a PSV entity on which clinical laboratories could rely for purposes of determining whether the degrees, certificates, diplomas, training programs and/or work experience of their testing personnel satisfies CLIA personnel requirements.

Thomas Hamilton

June 16, 2016

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The ASCP Board of Certification's mission is to provide excellence in certification of laboratory professionals on behalf of patients worldwide. We are considered the gold standard certification for medical laboratory professionals around the world. The ASCP Board of Registry (BOR) began in 1928. In 2009, the BOC was formed by the merger of the ASCP-Board of Registry (BOR) and the National Credentialing Agency (NCA). We are an independent certification agency that develops relevant standards and procedures to assure the competence of medical laboratory personnel and have certified over 514,000 laboratory professionals in the United States and internationally. We are the only ANSI accredited certifying body of laboratory professionals and have one of the largest accredited certification programs (21 certifications). Our credentials are recognized for licensure in all US licensure states and we are the sole provider of licensure exams in New York and provide many of the California licensure exams. The BOC's governing body is the Board of Governors (BOG). The Board of Governors (BOG) of the BOC is composed of representatives from many laboratory professional organizations including the three sponsoring organizations (AGT, ASCLS, and ASCP), six participating organizations (AABB, AAPA, ASC, ASM, CLMA and NSH), two collaborating partners (AACC and ASH) and one public member. The BOG oversees the BOC credential program ensuring its impartiality and continually monitoring the performance of existing credentials while considering the potential of new credential products and services.

We appreciate the opportunity to raise these concerns. Matthew Schulze, Director of ASCP's Center for Public Policy, will be in contact with your office soon to set up a meeting. Should you need to contact him, he can be reached at (202) 347-4450.

Sincerely,

Kathleen Hansen, MLS(ASCP)^{CM}
Chair
Board of Certification Board of Governors

Jim Flanigan, CAE
Executive Vice President
American Society for Clinical Laboratory Science

Jon Wagner
Chair, Board of Trustees
American Association of Pathologists' Assistants

Patty J. Eschliman, MHA, MLS(ASCP)^{CM} DLM^{CM}
President
Clinical Laboratory Management Association

Miriam A. Markowitz
CEO
AABB

Patricia Dowling, PhD, FACMG
President
Association of Genetic Technologists

David N.B. Lewin, MD, FASCP
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American Society for Clinical Pathology

Eva M. Wojcik, MD, MIAC, FASCP
President
American Society of Cytopathology

Elizabeth Sheppard, MBA, HT(ASCP)
President
National Society for Histotechnology

cc: Karen Dyer, MT(ASCP)DLM, CMS, DLS
Burton W. Wilcke, Jr., Ph.D., CLIAC Chair

Attachments



BSN

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As a BSN student, you will learn from faculty who are leaders in their fields, scientists who are on the cutting edge of nursing research, and expert clinicians with decades of experience. While they're a diverse group, they have one main goal: Help you become an exceptional registered nurse.

During your coursework, you will build your nursing competencies in state-of-the-art facilities and develop relationships with bright, driven students like you. You will also take part in engaging clinical experiences that challenge you to succeed in real-life situations and teach you clinical decision making. Simulation is

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Program Details

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- Locations

Sample Plan of Study For Students Enrolled Fall 2014 and Later

A typical plan of study for full-time, upper-division BSN students enrolled **fall 2014 and later**:

First Semester

Course Number/Title	Credits
NURS 310: Professional Role of the Registered Nurse	3
NURS 314: Physiologic and Pharmacologic Considerations for Health Promotion	4
NURS 316: Research and Evidence-based Practice	3
NURS 317: Fundamentals of Nursing Care in the Context of Older Adults	3
NURS 319: Health Assessment	3
Total	16

Second Semester

Course Number/Title	Credits
NURS 324: Pathopharmacology in Adults	3
NURS 327: Medical-Surgical Nursing in the Adult Population	7
NURS 329: Psychiatric Mental Health Nursing	5
Total	15

Third Semester

Course Number/Title	Credits
NURS 410: Health Care Delivery System and Informatics	2
NURS 411: Infant, Child, and Adolescent Nursing	5

NURS 414: Complex Nursing Care of Patients with Co-Morbid Conditions	3
NURS 417: Maternity, Newborn and Women's Health Nursing	5
Total	15

Fourth Semester

Course Number/Title	Credits
NURS 421: Public Health: Population-Focused Nursing Care	5
NURS 429: Leadership and Clinical Practicum	7
NURS 418: Nursing Elective	3
Total	15
Total Credits	61
General Education & Prerequisite Courses	59
Total Credits for BSN Option	120

Sample Plan of Study For Students Enrolled Prior to Fall 2014

A typical plan of study for full-time, upper-division BSN students enrolled **prior to fall 2014**:

First Semester

Course	Title	Credits
NURS 304	Introduction to Professional Nursing Practice	4
NURS 315	Pathopharmacology	5
NURS 320	Science and Research for Nursing Practice	3
NURS 333	Health Assessment	3
	Total	15

Second Semester

Course	Title	Credits
NURS 325	Context of Health Care Delivery I	2
NURS 330	Adult Health Nursing	7
NURS 331	Gerontological Nursing	3
NURS 405	Informatics and Technology	3
	Total	15

Third Semester

Course	Title	Credits
NURS 407	Nursing Care of the Childbearing Family	5
NURS 308	Nursing Care of Infants/Children: A Family Perspective	4

NURS 402 Psychiatric/Mental Health Nursing	5
NURS 418 Directive Elective (if not previously completed)	3
Total	17

Fourth Semester

Course	Title	Credits
NURS 403 Community Health Nursing		5
NURS 425 Organizational Leadership and Management		3
NURS 487 Clinical Emphasis Practicum and Seminar		6
Total		14
Total Credits		61
General Education & Prerequisite Courses		59
Total Credits for BSN Option		120

For registered nurses, UMSON also offers an RN-BSN option. Take classes in person, online, or both.

Admissions Requirements

Before applying to the BSN program, you must have:

- Official transcripts from all schools attended
- Applicable Advanced Placement (AP) or CLEP score reports
- Entrance Exam Requirement
- Personal résumé
- Prerequisite Course List (Word)
- Personal essay
- Two academic letters of recommendation from recent instructors (PDF)
- English Proficiency & Foreign Coursework Evaluation (only for applicants without a degree from a U.S. high school, college, or university must submit TOEFL scores)
- Payment of the \$75 application fee
- An overall GPA of 3.0
- A science GPA of 3.0 (chemistry, Anatomy and Physiology I and II, Microbiology)

What You'll Do

Program Outcomes for Students Enrolled Fall 2014 and Later

- Combine theoretical knowledge from the sciences, humanities, and nursing as a foundation to professional nursing practice that focuses on health promotion and prevention of disease for individuals, families, communities, and populations.
- Use the nursing process to manage care for individuals, families, communities, and populations integrating physical, psychological, social, cultural, spiritual, and environmental considerations. Integrate competencies in leadership, quality improvement, and patient safety to improve health and promote interdisciplinary care.
- Use the research process through translation of evidence-based findings to advance professional nursing and the delivery of health care.
- Incorporate information management and patient care technology in the delivery of quality patient-centered care.
- Integrate knowledge of health care policy from social, economic, political, legislative, and professional perspectives to influence the delivery of care to individuals, families, communities, and populations.
- Employ interprofessional communication and collaboration to ensure safe, quality care across the lifespan.
- Use principles of ethics, legal responsibility, and accountability to guide professional nursing practices across the lifespan and across the health care continuum.
- Accept personal accountability for lifelong learning, professional growth, and commitment to the advancement of the profession.

Program Outcomes for Students Enrolled Prior to Fall 2014

- Articulate a personal philosophy of nursing that serves as a framework for professional practice.
- Adhere to ethical, legal, and regulatory mandates and professional standards for nursing practice.
- Use insight, intuition, empathy, empirical knowledge, reasoning and creative analysis for critical thinking in all aspects of professional practice.
- Use evidence-based knowledge from nursing and related disciplines to shape practice.
- Use communication skills to establish therapeutic, caring, and collaborative relationships.
- Conduct assessments of individuals, families, groups, communities, and populations as the basis for planning and delivering care.
- Demonstrate clinical competencies needed for the delivery of safe and effective nursing care in a variety of health care settings and additional competencies in an individually selected emphasis area.
- Provide nursing care that reflects sensitivity to physical, social, cultural, spiritual, and environmental diversity of persons.

- Use current and emerging information handling and other technologies as integral components of professional nursing practice.
 - Use resource management, delegation, and supervision strategies in planning, implementing, and evaluating nursing care.
 - Critique research findings for their applicability to theory-based practice.
 - Collaborate with experienced investigators in identification of clinical problems, access to sites, protection of human subjects, data collection, and dissemination of findings.
 - Use political, economical, organizational, educational, and advocacy strategies to improve health care delivery to individuals, groups, families, communities, and national and global populations.
 - Function as a leader in health care systems, in professional organizations, and within interdisciplinary teams for the promotion of health, prevention of disease, and management of care delivery.
 - Accept personal accountability for lifelong learning, professional growth, and commitment to the advancement of the profession.
-
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Undergraduate

You are here:



A nursing education designed to be among the best in America.

The U.S. Bureau of Labor Statistics projects that more than 581,500 new RN jobs will be created through 2018. The need for proven, dedicated nursing professionals has never been greater. Whether you're new to nursing or looking to expand and enhance your expertise, the University of Maryland School of Nursing offers you an exciting opportunity to make a difference.

UMSON offers a Bachelor of Science in Nursing (BSN) degree with two options:

- The traditional BSN option is for those who do not have a previous nursing degree, as well as those who have a bachelor's degree in a field other than nursing.
- The RN-to-BSN option is for licensed RNs who have either a diploma in nursing or an associate degree in nursing. Classes are available in a classroom setting, online, or in a blended format.

Locations

Students may complete the traditional BSN option at either the University of Maryland School of Nursing in Baltimore, Md. or at The Universities at Shady Grove in Rockville, Md. Both the Baltimore and Shady Grove locations admit students in the fall and spring semesters. Both locations have identical curricula, course progression, and graduate requirements. Students may attend full-time or part-time. RN-to-BSN students may take classes at either location or at the Laurel College Center.

Choosing Your Location

Baltimore

The University of Maryland, Baltimore (UMB) is an urban university accessible by MARC trains, light rail, and bus lines. The main building for the School of Nursing was opened in 1998 and has integrated technology in the classrooms. Master's and doctoral nursing students attend classes at UMB, creating options for collaboration. Limited student housing is available. Reduced fees for student parking are available. Clinical assignments are typically in Baltimore, Annapolis, Washington, D.C. triangle. Students must furnish their own transportation to clinical sites.

Universities at Shady Grove

The Universities at Shady Grove is a small interprofessional campus run by the University System of Maryland, located in the I-270 corridor, just off of Shady Grove Road. Many state-supported universities have programs at this location. The location has the advantages of a suburban setting, free parking, a smaller student body with a more intimate feel, and state-of-the-art technology in the classrooms. No student housing is available. Clinical assignments for nursing students at The Universities at Shady Grove are typically located at nearby institutions. Students are expected to furnish their own transportation to clinical sites.

Laurel College Center

The Laurel College Center (LCC) is located in downtown Laurel, convenient to major highways, mass transit, parking, and shopping. The LCC allows students living and working in Howard, Prince Georges, and Anne Arundel counties a convenient alternative to driving to Baltimore or Shady Grove. Beginning fall 2015, RN-to-BSN core courses will be taught in this new instructional site. Elective courses are offered online and at the Baltimore and Shady Grove locations. Clinical assignments are typically in the Baltimore-Washington, D.C.-

Annapolis triangle. Students must furnish their own transportation to clinical sites.

BSN & RN-to-BSN Prerequisites

Students must successfully complete required coursework in the social and behavioral sciences, the natural and physical sciences and the arts and humanities. These lower-division pre-professional courses may be completed at any accredited college or university. Students who have completed coursework in Maryland may review transfer courses at ARTSYS – Articulation System for Maryland Colleges and Universities. This is an online evaluation system that enables students to determine how courses taken at any two year college in Maryland transfer to any four year college or university in Maryland. Visit the ARTSYS website at <http://artweb.usmd.edu>.

Only the courses in bold (below) are required for applicants who will have an undergraduate degree from an accredited four-year institution prior to the start term:

Prerequisite Courses	Credits
English Composition	6
General Chemistry with Lab	4
Human Anatomy & Physiology with Lab I	4
Human Anatomy & Physiology with Lab II	4
Microbiology with Lab	4
Introduction to Psychology	3
Introduction to Sociology	3
Social Science Elective (sociology, psychology, anthropology, political science, economics, geography, history, social work)	3
Human Growth and Development	3
Statistics	3
Mathematics (college algebra or higher)	3
Humanities* (literature, language, art, mathematics, philosophy, speech, music)	9
Nutrition	3
General Electives	7
Minimum Total	59

Please Note:

- *Each course may only be used to fulfill one prerequisite.*

- A minimum of seven general electives are needed.
- Social science electives include psychology, sociology, anthropology, social work, political science, geography, history, criminal justice, economics, and women's studies.
- Humanities include three courses from at least two of the following disciplines: literature, language, art, music, history, philosophy, speech, mathematics, communications, women's studies, theatre, and dance.

Get Started

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Biological Sciences: General Biology GENB (0404C)

effective August 2016

A minimum of 120 credits earned and a 2.0 cumulative GPA is needed to meet University graduation requirements.

Major courses (Basic, Supporting, and Advanced) require a C– or better in each and a 2.0 average GPA.

1. Basic Program 15-16 credits

Sem	Gr	Cr	
		3	BSCI160 Ecology and Evolution *
		1	BSCI161 Ecology and Evolution Lab *
		3	BSCI170 Molecular and Cellular Biology *
		1	BSCI171 Molecular and Cellular Biology Lab *
		3	BSCI207 Principles of Biology III *
		4	BSCI222 Principles of Genetics *
		1	Freshmen seminar UNIV100 ¹ , HONR100, GEMS100, HLSC100, HACS100 ² , HDCC105 ² , HEIP143, HHUM105 ³ , BSCV181

¹All Biological Sciences majors must take UNIV100 or another approved freshman seminar from the list above in their first semester.

² Two credit course. ³ Three credit course.

NOTE: Students who are enrolled in the Integrated Life Sciences Honors program will complete the following courses in lieu of the parenthetical course: HLSC207 (BSCI207), HLSC322 (BSCI222) and HLSC374 (BSCI374).

2. Supporting Courses 32 credits

Sem	Gr	Cr	
		4	MATH130 OR MATH140 Calculus I *
		4	MATH131 OR MATH141 Calculus II *
		3	CHEM131 General Chemistry I *
		1	CHEM132 General Chemistry I Lab *
		3	CHEM231 Organic Chemistry I *
		1	CHEM232 Organic Chemistry I Lab *
		3	CHEM241 Organic Chemistry II *
		1	CHEM242 Organic Chemistry II Lab *
		2	CHEM271 Gen Chem & Energetics *
		2	CHEM272 Bioanalytical Chem Lab *
		4	PHYS131 OR PHYS141 Physics I
		4	PHYS132 OR PHYS142 Physics II

* These are required benchmark courses, see:

<http://bsci.umd.edu/benchmarks>

3. General Education Requirements (at least 27 credits)

(For more information on General Education visit: www.gened.umd.edu)
Fundamental Studies Math (MA), Analytic Reasoning (AR), Natural Sciences (NS) & Natural Sci. Lab (NL) are satisfied by major requirements.
Courses may double or triple count between Distributive Studies, I-Series, and Diversity.

Sem	Gr	Course	
Fundamental Studies			
Academic Writing (AW) (ENGL101)			
Professional Writing (PW)			
Oral Communication (OC)			
Distributive Studies			
History and Social Sciences (HS)			
History and Social Sciences (HS)			
Humanities (HU)			
Humanities (HU)			
Scholarship in Practice (SP)			
Scholarship in Practice (SP) outside of major			
I-Series			
I-Series (IS)			
I-Series (IS)			
Diversity			
Understanding Plural Societies (UP)			
Understanding Plural Societies (UP) or Cultural Competence (CC) (1–3 credits)			

4. Advanced Program courses: Please see reverse page.

NOTES:

Student name _____ UID _____

Advisor's signature _____ Date of audit _____

NOTE: The curriculum in Biological Sciences changes as faculty review and improve the program. The curriculum descriptions provided here are the latest versions. Your curriculum may look slightly different depending on when you declared the Biological Sciences major. Your academic advisor can provide you with the most accurate information on which curriculum you are under. Any questions can be referred to the Undergraduate Academic Programs Office, 301-405-6892.

Updated 4/2016

General Biology GENB (0404C) Advanced Program

27 credits minimum ◆ At least two courses designated as **Lab must be taken**

1. Required courses: 6–7 credits

Sem	Gr	Cr	Biochemistry
		3	BCHM461 Biochemistry OR BCHM463 Biochemistry of Physiology

Sem	Gr	Cr	Quantitative Course: one from below
		3	BIOM301 Introduction to Biometrics
		4	BSCI374 Mathematical Modeling in Biology w/ Lab ¹
		3	STAT400 Applied Probability & Statistics
		3	STAT464 Introduction to Biostatistics
		3–4	MATH240 or higher w/ advisor approval

2. GENB Area Courses: 20–21 credits

- At least one course from each of the categories 1, 2, and 3

Sem	Gr	Cr	1. Genetics & Evolution
		3	BCHM465 Biochemistry III
		3	BSCI370 Principles of Evolution
		3	BSCI410 Molecular Genetics
		4	BSCI411 Bioinformatics and Integrated Genomics w/ Lab
		4	BSCI412 Microbial Genetics w/ Lab
		3	BSCI414 Recombinant DNA Lab
		3	BSCI415 Molecular Genetics Lab
		3	BSCI416 Human Genetics
		4	BSCI470 Evolutionary Mechanisms
		3	BSCI471 Molecular Evolution
		3	BSCI339J Population and Evolutionary Genetics w/ Lab
2. Cell Biology, Development, Physiology			
		3	BCHM462 Biochemistry II
		3	BCHM464 Biochemistry Lab
		4	BSCI330 Cell Biology & Physiology w/ Lab
		1	BSCI339C Cell Biology Lab ^{2, 3}
		3	BSCI342 Biology of Reproduction
		3	BSCI353 Principles of Neuroscience
		3	BSCI404 Cell Biology from a Biophysical Perspective
		3	BSCI417 Microbial Pathogenesis
		3	BSCI420 Cell Biology Lectures
		4	BSCI421 Cell Biology w/ Lab
		3	BSCI422 Principles of Immunology
		2	BSCI423 Immunology Lab ³
		4	BSCI424 Pathogenic Microbiology w/ Lab
		3	BSCI426 Membrane Biophysics
		3	BSCI430 Developmental Biology
		3	BSCI433 Biology of Cancer
		4	BSCI434 Mammalian Histology w/ Lab
		3	BSCI437 General Virology
		4	BSCI440 Mammalian Physiology
		2	BSCI441 Mammalian Physiology Lab ³
		4	BSCI442 Plant Physiology w/ Lab
		3	BSCI443 Microbial Physiology
		3	BSCI446 Neural Systems
		3	BSCI447 General Endocrinology
		3	BSCI451 Physical Chemistry for Biologists
		1	BSCI454 Neurobiology Lab ³

Sem	Gr	Cr	3. Ecology, Behavior & Organismal
		3	BSCI334 Mammalogy
		1	BSCI335 Mammalogy Lab ³
		4	BSCI337 Insect Biology w/ Lab
		3	BSCI338B Marine Biology
		1	BSCI338Q Conservation Biology Lab ³
		3	BSCI348M Epidemiology of Microbial Pathogens
		3	BSCI360 Animal Behavior
		4	BSCI361 Principles of Ecology
		3	BSCI363 Biology of Conservation & Extinction
		3	BSCI373 Natural History Chesapeake Bay
		3	BSCI392 Biology of Extinct Animals
		1	BSCI393 Biology of Extinct Animals Lab ³
		3	BSCI401 Animal Communication
		3	BSCI403 Biology of Vision
		3	BSCI460 Plant Ecology
		2	BSCI461 Plant Ecology Lab ³
		3	BSCI462 Population Ecology
		3	BSCI464 Microbial Ecology
		3	BSCI465 Behavioral Ecology
		4	BSCI467 Freshwater Biology w/ Lab
		3	BSCI473 Marine Ecology
		4	BSCI480 Arthropod Form and Function w/ Lab
		4	BSCI481 Insect Diversity & Classification w/ Lab
		4	BSCI483 Medical & Veterinary Entomology w/ Lab
		3	BSCI493 Medicinal and Poisonous Plants
Additional courses (Optional)			
		4	BSCI223 General Microbiology ⁴ OR BSCI283 Principles of Microbiology ⁴
		1	Departmental Honors Seminars ⁵ BSCI378H and BSCI398H
			Special Topics Courses ⁶ see Testudo BSCI328, 338, 339, 348
			Dept. Research Credit ⁷ : BSCI379, 389, 399

¹ Formerly BSCI474, cross-listed as HLSC374. Credit will be given for either BSCI374, HLSC374 or BSCI474.

² BSCI339C is the lab-only portion of BSCI421. BSCI339C together with BSCI420 counts as a GENB Area lab course. It is not a stand-alone lab. Credit only granted for BSCI339C or BSCI421.

³ Requires a "C–" or better in the pre-/co-requisite lecture to count as a **Lab**. Requires a "C–" or better in the pre/co-requisite lecture to satisfy the Area category.

⁴ Credit will be given for either BSCI223 OR BSCI283. BSCI223/283 is a pre-requisite for some upper level BSCI courses. BSCI223/283 may count in the GENB Area credits but NOT as an upper-level lab.

⁵ One credit of Departmental Honors seminar may be applied to major requirements. Additional Departmental Honors seminar credits count as electives.

⁶ Special Topics courses allowed if specifically approved for upper level courses in GENB. See your advisor for applicability in a specific category above.

⁷ Up to 3 credits of Departmental Research, including H and L versions, may be applied to major requirements. Additional research credits count as electives. Courses from other departments can be used with permission of advisor. Multiple semesters in research courses can possibly count for one of the two required lab lab courses. See your advisor for more details.

BS in Nursing < University of Illinois at Chicago

BS in Nursing

Degree Requirements

Summary of Requirements	
Pre-Nursing Studies	57
Course Requirements in the College of Nursing	63
Total Hours	120

Course Requirements—Pre-Nursing Studies

Required Courses	
ENGL 160	Academic Writing I: Writing in Academic and Public Contexts 3
ENGL 161	Academic Writing II: Writing for Inquiry and Research 3
BIOS 350	General Microbiology ^a 3
CHEM 122	General Chemistry I Lecture ^{b,f} 4
CHEM 123	General Chemistry Laboratory I ^{b,f} 1
CHEM 130	Survey of Organic and Biochemistry ^{b,f} 5
KN 251	Human Physiological Anatomy I 5
KN 252	Human Physiological Anatomy II 5
NUEL 250	Human Development Across the Life Span 3
HN 196	Nutrition 3
STAT 101	Introduction to Statistics ^g 4
or STAT 130	Introduction to Statistics for the Life Sciences
Exploring World Cultures course ^c	3

Understanding the Creative Arts course ^c	3
Understanding the Individual and Society course ^{c,d}	3
Understanding the Past course ^c	3
Understanding U.S. Society course ^{c,d}	3
One 3-semester-hour, 200-level, upper-division course in the arts and sciences ^e	3
LAS electives (hours vary)	
Total Hours	57

- a *[BIOS 100](#) is a prerequisite for this course.*
- b *This course is approved for the Analyzing the Natural World General Education category.*
- c *Students should consult the [General Education](#) section of the catalog for a list of approved courses in this category.*
- d *For the Understanding the Individual and Society requirement, [PSCH 100](#) is recommended; for the Understanding U.S. Society requirement, [SOC 100](#) is recommended.*
- e *Upper Division Elective: Students may choose a course from one of these categories: physical sciences, life sciences, mathematical sciences, social sciences, fine arts, performing arts, or humanities. Must be 200-level or above at a four-year college or university. Though the requirement may be completed after entry to the program, it is very highly recommended that students complete an upper division elective with other prerequisite courses prior to enrollment.*
- f *Students applying for the RN/BSN Program are required to take a total of 4-5 hours of chemistry. This requirement can be fulfilled by taking any of the following UIC courses which are approved for the Analyzing the Natural World General Education category: [CHEM 100](#), [CHEM 105](#), [CHEM 122/CHEM 123](#), [CHEM 124/CHEM 125](#), [CHEM 116](#), [CHEM 118](#), or [CHEM 130](#). These students may need to take additional course/s approved for General Education to meet the university requirement of 24 hours distributed across the six categories.*
- g *Students applying for the RN/BSN Program are not required to take introductory statistics. As a result, these students will need to take hours of LAS electives to meet the 57 hours of pre-nursing requirements.*

Course Requirements in the College of Nursing: BSN

Required Courses		
<u>NURS 204</u>	Professional Nursing 1	4
<u>NURS 212</u>	Health Assessment and Communication	3
<u>NURS 221</u>	Foundations of Nursing Practice	6
<u>NURS 223</u>	Concepts in Pathophysiology and Pharmacology 1	4
NURS 233	(Concepts in Pathophysiology & Pharmacology II)	3
NURS 254	(Professional Nursing II)	3
NURS 304	(Professional Nursing III)	4
NURS 321	(Nursing Care of Adults Across the Lifespan)	7
NURS 331	(Nursing Care of Childbearing Women and Families)	4
NURS 341	(Nursing Care of Children and Families)	4
NURS 351	(Nursing Care in Mental & Behavioral Health)	4
NURS 354	(Professional Nursing Care IV)	4
NURS 361	(Nursing Care of Populations (BSN))	4
NURS 371	(Acute Care Nursing and Care Management)	4
NURS 377	(Integrative Practice Experience)	2
NURS 387	(Senior Nursing Seminar)	3
Total Hours		63

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BS with a Major in Biological Sciences

Degree Requirements

To earn a Bachelor of Science in Liberal Arts and Sciences degree from UIC, students must complete University, college, and departmental degree requirements. The Department of Biological Sciences degree requirements are outlined below. Students should consult the [College of Liberal Arts and Sciences](#) section for additional degree requirements and college academic policies.

Summary of Requirements	
Required Prerequisite and Collateral Courses	28-30
Major Requirements	36
General Education and Electives to reach minimum Total Hours	54-56
Total Hours	120

General Education

See *General Education and Writing-in-the-Discipline* in the [College of Liberal Arts and Sciences](#) section for information on meeting these requirements. Students should consult the course lists below and their advisors to determine which courses are counted toward the General Education and Writing-in-the-Discipline requirements.

Required Prerequisite and Collateral Courses

Required Courses	
Select one of the following math courses:	4
MATH 170 Calculus for the Life Sciences ^{a,b}	
MATH 180 Calculus I ^{a,b,c}	
STAT 130 Introduction to Statistics for the Life Sciences	
Select one of the following sequences in physics:	8-10
PHYS 141 General Physics I (Mechanics) ^{b,c}	
PHYS 142 General Physics II (Electricity and Magnetism) ^{b,c}	
OR	
PHYS 105 Introductory Physics I - Lecture ^{b,d}	
PHYS 106 Introductory Physics I - Laboratory ^{b,d}	
PHYS 107 Introductory Physics II - Lecture ^{b,d}	
PHYS 108 Introductory Physics II - Laboratory ^{b,d}	
Select one of the following sequences in general chemistry:	10
CHEM 116 Honors and Majors General and Analytical Chemistry I ^b	

<u>CHEM 118</u>	Honors and Majors General and Analytical Chemistry II ^b	
OR		
<u>CHEM 122</u>	General Chemistry I Lecture ^c	
<u>CHEM 123</u>	General Chemistry Laboratory I ^{c,e}	
<u>CHEM 124</u>	General Chemistry II Lecture ^c	
<u>CHEM 125</u>	General Chemistry Laboratory II ^{c,e}	
<u>CHEM 232</u>	Organic Chemistry I	4
<u>CHEM 233</u>	Organic Chemistry Laboratory I	2
Total Hours		28-30

a MATH 170 and MATH 180 fulfill the LAS Quantitative Reasoning requirement.
 b This course is approved for the Analyzing the Natural World General Education category.
 c MATH 180 and MATH 181 are recommended for students planning advance work in population biology and required for enrollment in PHYS 141 and PHYS 142.
 d Each of the following pairs will be considered one course in meeting the LAS General Education requirements: PHYS 105/PHYS 106 and PHYS 107/PHYS 108.
 e General Education credit is given for successful completion of both CHEM 122 and CHEM 123 or CHEM 124 and CHEM 125.

Major Requirements

Of the 36 semester hours for the major, no more than 10 hours may be at the 100-level and at least 5 hours must be at the 300-level or above, excluding BIOS 391 and BIOS 399.

Required Courses		
<u>BIOS 100</u>	Biology of Cells and Organisms ^a	5
<u>BIOS 101</u>	Biology of Populations and Communities ^a	5
<u>BIOS 220</u>	Mendelian and Molecular Genetics	3
<u>BIOS 221</u>	Genetics Laboratory ^b	3
<u>BIOS 222</u>	Cell Biology	3
<u>BIOS 230</u>	Ecology and Evolution	3
<u>BIOS 240</u>	Principles of Animal Physiology	3
Select at least two laboratory courses from the following list, assuming all prerequisites have been met: ^c		4-10
<u>BIOS 223</u>	Cell Biology Laboratory	
<u>BIOS 272</u>	Comparative Vertebrate Anatomy and Physiology	
<u>BIOS 321</u>	Developmental Biology Laboratory	
<u>BIOS 323</u>	Molecular Biology Laboratory	
<u>BIOS 325</u>	Vertebrate Embryology	

<u>BIOS 331</u>	General Ecology Laboratory
<u>BIOS 336</u>	Animal Behavior Laboratory
<u>BIOS 351</u>	Microbiology Laboratory
<u>BIOS 443</u>	Advanced Mammalian Physiology
Additional courses at the 200-level or above, chosen with the consent of an advisor, to bring the total to 36 semester hours in biological sciences. No more than 5 hours of independent study and research courses may be applied to the minimum hours required for the major.	1-7
Total Hours	36

- a *This course is approved for the Analyzing the Natural World General Education category.*
- b BIOS 221 fulfills the Writing-in-the-Discipline requirement.
- c Students who complete KN 251 and KN 252, or an advanced-level course equivalent to KN 252, may request that KN 252 be substituted for one required biological sciences laboratory course.

Recommended Plan of Study

First Year	
Fall Semester	Hours
<u>ENGL 160</u>	Academic Writing I: Writing in Academic and Public Contexts
<u>MATH 180</u>	Calculus I ^a
or <u>MATH 170</u>	or Calculus for the Life Sciences
or <u>STAT 130</u>	or Introduction to Statistics for the Life Sciences
Select one of the following:	5
<u>CHEM 116</u>	Honors and Majors General and Analytical Chemistry I
<u>CHEM 122</u> & <u>CHEM 123</u>	General Chemistry I Lecture and General Chemistry Laboratory I
General Education Requirement course	3
Term Hours:	15
Spring Semester	
<u>ENGL 161</u>	Academic Writing II: Writing for Inquiry and Research
Select one of the following:	5
<u>CHEM 118</u>	Honors and Majors General and Analytical Chemistry II
<u>CHEM 124</u> & <u>CHEM 125</u>	General Chemistry II Lecture and General Chemistry Laboratory II
General Education Requirement course	3
Elective	3

	Term Hours:	14
Second Year		
Fall Semester		
<u>CHEM 232</u>	Organic Chemistry I	4
<u>BIOS 100</u>	Biology of Cells and Organisms ^b	5
or <u>BIOS 101</u>	or Biology of Populations and Communities	
Foreign Language		4
Elective		3
	Term Hours:	16
Spring Semester		
<u>BIOS 100</u>	Biology of Cells and Organisms ^b	5
or <u>BIOS 101</u>	or Biology of Populations and Communities	
<u>CHEM 233</u>	Organic Chemistry Laboratory I	2
Foreign Language		4
General Education Requirement course		3
	Term Hours:	14
Third Year		
Fall Semester		
<u>BIOS 222</u>	Cell Biology	3
BIOS lab course or Electives ^c		2-5
<u>PHYS 105</u> & <u>PHYS 106</u>	Introductory Physics I - Lecture and Introductory Physics I - Laboratory	4-5
or <u>PHYS 141</u>	or General Physics I (Mechanics)	
Foreign Language		4
General Education Requirement course		3
	Term Hours:	16-20
Spring Semester		
<u>BIOS 220</u>	Mendelian and Molecular Genetics	3
<u>BIOS 230</u>	Ecology and Evolution	3
<u>PHYS 107</u> & <u>PHYS 108</u>	Introductory Physics II - Lecture and Introductory Physics II - Laboratory	4-5
or <u>PHYS 142</u>	or General Physics II (Electricity and Magnetism)	
BIOS lab course or Electives ^c		2-5

Foreign Language		4
	Term Hours:	16-20
Fourth Year		
Fall Semester		
<u>BIOS 221</u>	Genetics Laboratory	3
<u>BIOS 240</u>	Principles of Animal Physiology	3
General Education Requirement course		3
Electives		6
	Term Hours:	15
Spring Semester		
BIOS lab courses or Electives ^c		1-7
Electives		13
	Term Hours:	14-20
	Total Hours:	120

- a *MATH 170, MATH 180, or STAT 130, individually, will satisfy the Quantitative Reasoning requirement with a grade of C or better.*
- b *The Analyzing the Natural World and the two additional general education course requirements can be satisfied with four courses chosen from PHYS 105/PHYS 106, PHYS 107/PHYS 108, PHYS 141, PHYS 142, BIOS 100, BIOS 101 and/or CHEM 122/CHEM 123 and CHEM 124/CHEM 125.*
- c *Students must take 11 additional hours, including two laboratory courses and Biological Science electives, chosen in consultation with a Biological Sciences advisor. Five of these 11 credit hours must be taken at the 300-400 level (excluding BIOS 391 and BIOS 399).*

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NURSING (AS)

OVERVIEW

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COURSES

Nursing Program Accreditation

Normandale's nursing program is approved by the Minnesota Board of Nursing and accredited by the Accrediting Commission for Education in Nursing (ACEN), 3343 Peachtree Rd NE, Suite 850, Atlanta, Georgia 30326. Contact at 404-975-5000 or online at ACENursing.org.

The Normandale Community College Nursing program is located within the Health Sciences Division. The Normandale Nursing Department educates students to become entry-level professional nurses who are prepared to begin their careers as competent, caring members of today's health care team. The Normandale Nursing program has adopted the Minnesota Alliance for Nursing Education (MANE) curriculum which is a collaboratively-developed curriculum designed to remove barriers for students wishing to obtain their baccalaureate degree in nursing (BSN). Normandale offers five semesters of an eight semester BSN program. Students admitted to Normandale's Nursing program will be dually admitted to Metropolitan State University's Nursing program.

Normandale students will receive their associate of science degree following successful completion of the fifth semester of the program and may elect to take the National Council Licensure Examination (NCLEX) for Registered Nurse Licensure. Students will have the opportunity to complete the remaining three semesters of the MANE BSN curriculum as Metropolitan State University students on the Normandale campus. Each nursing course is offered every semester. This program is committed to quality, integrity, active life-long learning, student success, alliances and community service.

Students entering the nursing program are expected to meet the MnSCU Performance Standards for Entry-Level Nursing Programs, which are available on the Non-academics Requirements page on the Nursing website. These performance standards are required abilities for effective performance in MnSCU nursing education programs. The standards are compatible with the scope of practice as defined by the Minnesota Board of Nursing. The examples show how a standard may be applied in entry-level nursing education programs. The examples listed are for illustrative purposes only and are not intended to be a complete list of all tasks in an entry-level nursing program.

Reasonable accommodations for meeting standards may be available for otherwise program-qualified individuals with disabilities. Information is available in the Office for Students with Disabilities at 952-358-8625.

Admission Requirements and Application Process

- Submit the Normandale Community College general application form and the \$20 application fee to the Admissions Office (applicants new to Normandale only).
- The nursing curriculum MANE application deadlines are February 1 for fall and June 1 for spring the following year.
- Please see the Nursing program website for application information for detailed application instructions.
- Students wishing to petition an exemption of admission requirements must do so prior to the application deadline.
- New students are encouraged to attend a college information session; current students should call 952-358-8261 to schedule a meeting with an advisor.
- MANE information sessions are offered each semester. Visit our nursing website for session dates and locations.

Applicants must meet the following requirements before the application is processed:

- Complete semester one of the MANE curriculum plan. (ENG 1101, CHEM 1050 or CHEM 1061, BIOL 2041, and an elective in MnTC Goal 4, 6, 7, 8, 9, or 10.)
- Have a GPA of 2.75 or higher in the semester one coursework shown above.
- Complete the ATI TEAS V pre-entrance exam. Visit Normandale's Nursing website or visit the ATI-TEAS testing page.

Submission of Nursing Program Application

When the program admission requirements are met, the nursing application form may be completed and mailed to the Health Sciences Enrollment Manager at:

Betty Blazer
Health Science Enrollment Manager
Normandale Community College
9700 France Avenue S
Bloomington, MN 55431

Applications to Normandale's nursing program are available on campus in the Activities building, online on the Nursing Department website and by downloading the Nursing Application PDF.

Admissions policies are subject to change. Applications will be accepted under the terms in place at the time an application is received by the Health Science Division. It is the responsibility of the student to keep up-to-date on any changes which may affect their qualifications for acceptance.

Application Deadlines

The application to the nursing program is February 1 for fall semester and June 1 for spring semester. The application and all required documents must be postmarked on or before the due date.

Application Notification

Applicants will be notified in writing on or before March 15 for fall semester and July 15 for spring semester. Candidates will be instructed in their acceptance letter of the due date to accept or decline the admission offer. If a response is not received by the due date, the seat will be considered declined.

Students who are not admitted must reapply to the nursing program the following year.

Required Courses - 35 credits, For LPN - 30 credits total.

LPN students will substitute NURS 2720 for NURS 2700.

Code	Title	Credits
NURS 2700	Foundations of Nursing-Health Promotion	9
NURS 2720	Transition to the Role of the Professional Nurse	4
NURS 2750	Nutrition and the Role of the Professional Nurse	2
NURS 2800	Chronic and Palliative Care	7
NURS 2820	Pharmacology and the Role of the Professional Nurse	3
NURS 2850	Applied Pathophysiology for Nursing I	2
NURS 2910	Acute and Complex Care	7
NURS 2920	Applied Pathophysiology for Nursing 2	2
NURS 2950	Nursing Leadership I	3

General Education Requirements - 40 credits

Code	Title	Credits
ENGC 1101	Freshman Composition	4
CHEM 1050	Foundations of Organic and Biochemistry	3
BIOL 2041	Human Anatomy	4
BIOL 2042	Human Physiology	4
BIOL 2204	Microbiology	4
PSYC 1110	Introduction to Psychology	4

COMM 1111	Interpersonal Communication	3
PSYC 2210	Developmental Psychology: Life Span	4
SOC 1104	Introduction to Sociology	3
or ANTH 1127	Cultural Anthropology - The Global Human Experience	3
PHIL 1103	Ethics	3
or PHIL 1180	Biomedical Ethics	3

Elective Credits

Complete 4 credits from MnTC Goal Areas: 4, 6, 7, 8, 9, or 10.

Sequence of Courses:

The sequence suggested is for full-time students who wish to complete the program in two years following admission to the nursing program.

Semester 1

Code	Title	Credits
ENGC 1101	Freshman Composition	4
CHEM 1050	Foundations of Organic and Biochemistry	3
BIOL 2041	Human Anatomy	4

Elective Credits: 2 courses in 2 different areas selected from MnTC Goals:

4, 6, 7, 8, 9 or 10.

Semester 2

Code	Title	Credits
PSYC 1110	Introduction to Psychology	4
BIOL 2042	Human Physiology	4
BIOL 2204	Microbiology	4
COMM 1111	Interpersonal Communication	3

Semester 3

Code	Title	Credits
NURS 2700	Foundations of Nursing-Health Promotion	9
or NURS 2720	Transition to the Role of the Professional Nurse	4
NURS 2750	Nutrition and the Role of the Professional Nurse	2
PSYC 2210	Developmental Psychology: Life Span	4

Semester 4

Code	Title	Credits
NURS 2820	Pharmacology and the Role of the Professional Nurse	3
NURS 2850	Applied Pathophysiology for Nursing I	2
NURS 2800	Chronic and Palliative Care	7
SOC 1104	Introduction to Sociology	3
or ANTH 1127	Cultural Anthropology - The Global Human Experience	3

Semester 5

Code	Title	Credits
NURS 2910	Acute and Complex Care	7
NURS 2920	Applied Pathophysiology for Nursing 2	2
NURS 2950	Nursing Leadership I	3
PHIL 1103	Ethics	3
or PHIL 1180	Biomedical Ethics	3

Upon completion of Semester 5, students are eligible for the AS in Nursing and NCLEX-RN/licensure.

Semester 6 - Upper division coursework begins 15 credits

Title

Credits

Nursing Care of the Family	4
Epidemiology for Nursing	3
General Education – Statistics (Completing both Normandale's MATH 0990 & MATH 1090 will fulfill this requirement –Statway Statistics 1 & 2)	4
General Education – Writing in your Major	4

Semester 7 - Upper division coursework 16 credits

Title	Credits
Population Based Care	7
Nursing Leadership II	4
Nursing Informatics	2
General Education - elective	3

Semester 8 - Upper division coursework 14 credits

Title	Credits
Integrative Seminar & Practicum	7
Global Health Perspectives for Nursing	3
General Education - elective	4

Home > Departments > STEM and Education > Biology

BIOLOGY

Normandale has an open biology lab called the Biology Learning Center which has been remodeled for Fall 2013.

For more information about Normandale's open biology lab, [click here](#).

PRE-BIOLOGICAL SCIENCES

Normandale offers coursework typically required for majors in -

- Biology
- Biochemistry
- Ecology
- Evolution and behavior
- Genetics and cell biology
- Microbiology
- Neuroscience
- Plant biology.

^ All of these majors typically require the following core courses:

All of these majors typically require the following core courses:

Course	Course Name	Credits
BIOL 1105	General Biology: Cells to Organisms	4
BIOL 1106	General Biology: Ecology and Evolution	4
CHEM 1061	Principles of Chemistry 1	5
CHEM 1062	Principles of Chemistry 2	5
CHEM 2061	Organic Chemistry 1	5
CHEM 2062	Organic Chemistry 2	5

MATH 1510	Calculus 1	5
MATH 1520	Calculus 2	5
PHYS 1121	Physics with Calculus 1	5
PHYS 1122	Physics with Calculus 2	5
	<ul style="list-style-type: none">• <i>Begin specific liberal arts classes for the intended transfer institution or complete the Minnesota Transfer Curriculum and/or complete the Associate of Arts degree.</i>• <i>Consult the current transfer guide in the Mehandra Nath Career Academic and Planning Center</i>	3

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MISSION STATEMENT

The mission of the Biology department is to provide a high-quality educational experience in the biological sciences to students in a traditional community college setting. The department serves the College and students by offering courses that satisfy requirements for general education, allied health and pre-professional transfer programs. Biology instructors are committed to excellence in teaching and scholarship.

A variety of laboratory/field experiences are provided for students in the Biology Learning Center (BLC). Hours listed for individual courses reflect the recommended minimum time students spend per week on individual work in the BLC or on field trips.



Center for Clinical Standards and Quality/Survey & Certification Group

**Ref: S&C: 16-18- CLIA
REVISED 05.03.16**

DATE: April 1, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Personnel Policies for Individuals Directing or Performing Non-waived Tests
*****Revised due to typographical error under citation of §493.1443(b)(3)*****

Memorandum Summary

This policy memorandum supersedes S&C-10-07-CLIA “Consolidation of Personnel Policies for Individuals Directing or Performing Non-waived Tests under the Clinical Laboratory Improvement Amendments (CLIA).”

- CLIA surveyors will now accept Primary Source Verification (PSV) as evidence of compliance with the personnel qualifications mandated in Subpart M of the Clinical CLIA Regulations.
- If there are required elements in the personnel regulations that the PSV company does not verify, it is the laboratory director's (LD) responsibility to ensure that these personnel qualifications are met by other means.
- CLIA personnel regulations and the policy on mandatory citations are not changing.
- Laboratories may choose to submit primary source verification for LD qualifications.
- Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.

Background

The Centers for Medicare & Medicaid Services (CMS) CLIA surveyors are required to make compliance determinations regarding whether individuals in prescribed positions meet the CLIA personnel qualification and responsibility requirements stated in 42 CFR, Part 493, Subpart M. This includes the positions of LD, clinical consultant (CC), technical supervisor and consultant (TS, TC), general supervisor (GS), testing personnel (TP), cytology general supervisor (CGS), and cytotechnologist (CT). The process for verification of personnel qualifications requires surveyors to observe direct evidence of academic achievement.

A laboratory is considered to be non-compliant if: a required position is not filled, if an individual does not meet the required qualifications based on education, training and experience for that position, or if an individual does not fulfill the responsibilities of the position.

PSV is the process of confirming an applicant's credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; and, by confirming reported work history, such as company names and locations, dates, and positions held. Verifications are obtained either directly from an institution, former employers, or their authorized agents.

In the past, CMS has required surveyors to verify educational qualifications by reviewing direct evidence of academic achievement, e.g. a diploma or transcript. This required the laboratory to collect and maintain paper documentation on its personnel in addition to maintaining paper records on large numbers of point-of-care testing personnel that perform testing throughout a medical facility.

CMS has had many requests from laboratories, accreditation organizations, and other health care facilities to accept PSV of education, training, experience, and licensure in laboratory services in order to demonstrate compliance with regulatory requirements. Meetings were held with representatives of several PSV companies to review their processes and the documentation that results from a primary source verification. Effective immediately, CMS surveyors will accept PSV documentation as evidence of laboratory compliance with the personnel requirements stated in 42 CFR, Part 493, Subpart M. It should be noted that the PSV company is **NOT** responsible for determining whether a given individual meets the personnel requirements under CLIA; PSV companies merely confirm that the asserted training, degrees and credentialing have been achieved or conferred. It is always the responsibility of the laboratory to ensure that its personnel meet the CLIA requirements, and CMS, its agents and accreditation organizations retain full authority to determine compliance with those requirements. The PSV report is one tool that can be used by the surveyor and laboratory to determine if the applicant meets the personnel requirements. The laboratory is responsible for ensuring that individuals' qualifications meet the personnel requirements.

General Guidance

- **CLIA personnel regulations and the policy on mandatory citations are not changing.** By allowing the use of PSV companies, CMS is giving laboratories another means of verifying and documenting the qualifications of its laboratory personnel.
- CMS is not issuing standards to be applied to PSV companies – laboratories will need to judge the services offered by PSV companies for themselves. CMS is merely permitting surveyors to use PSV reports when they compare employees' qualifications against the regulatory personnel requirements. As needed, surveyors will continue to ask LDs to provide additional documentation on their employees' qualifications when they find the PSV reports inadequate to confirm compliance.
- The use of a PSV report as evidence of meeting CLIA personnel qualifications is **optional** for the laboratory. Surveyors will continue to accept direct observation of documents, and the laboratory may also achieve compliance through a combination of the two.

- Laboratories electing to use the PSV option must maintain either paper or electronic reports from the PSV company.
- If there are required elements in the personnel regulations that the PSV company does not verify, it is the LD's responsibility to ensure that these personnel qualifications are met by other means. Each LD should collect and maintain documentation and records as may be necessary to provide any information that is not included in the PSV report.
- If the surveyor identifies potentially serious isolated or pervasive test quality problems that may be attributed to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may request such documentation as may be necessary for the surveyor to confirm compliance with the personnel requirements.
- When there is a change in the LD for an accredited laboratory, the accreditation organization is responsible for checking credentials of the new LD. The State Agency is not responsible for verifying the LD credentials under this circumstance. See State Operations Manual (SOM), Chapter 6, Section 6006.7.
- Certain laboratory positions are **NOT** evaluated by the surveyor; examples include phlebotomists who do not perform testing, or individuals who do reagent preparation, specimen preparation, microbiology plating, etc., but no actual testing.
- Surveyors may not require an individual to test for and obtain a General Education Degree (G.E.D.). If records for a high school diploma or G.E.D are not available and a high school diploma or G.E.D. is required, **this individual is unqualified.**
- If a high school is closed, it is possible for the individual to solicit documentation from the local school board or State Board of Education to verify graduation.

Qualification Guidance

The LD qualifications are reviewed for all new laboratory applications (form CMS-116) prior to acceptance for enrollment in CLIA for provider-performed microscopy (PPM), accreditation, and compliance certificates, and when there is a change in laboratory director for a registration, compliance, or PPM certificate. Laboratories may choose to submit primary source verification for this requirement. When initially surveying the laboratory, surveyors evaluate the qualifications of the LD, TS or TC, CC, GS, CT, CGS, and a sample of TP. Surveyors are NOT required to evaluate qualifications for every TP. For subsequent surveys, surveyors evaluate all changes to personnel (for the positions of LD, TS or TC, CC, GS, CT, CGS) that have occurred since the previous survey, in addition to another sample of TP. The surveyor does not have to look for records on each TP.

It is important to note that not all personnel qualifications will be verifiable by a PSV company. Based on our current understanding, PSV companies do not verify transcripts. Laboratories need to be aware that, even if they choose to use PSV, personnel may still need to produce documentation that cannot be verified by PSV companies for those positions in which a transcript is necessary to qualify the individual. Ultimately, the LD is responsible for making sure that personnel qualifications are met for each position and that there is available evidence of the qualifications.

Provider Performed Microscopy (PPM) Personnel Qualifications

To obtain a certificate of PPM, the laboratory director must be an (Doctor of Medicine: MD, Doctor of Osteopathy: DO, Doctor of Podiatric Medicine: DPM, Doctor of Dental Surgery: DDS), or midlevel practitioner, as defined at §42 CFR 493.2 (nurse midwife, nurse practitioner, physician assistant) and must be licensed by the State in which the laboratory is located, if required by that State. Only these individuals can perform PPM tests; otherwise, routine moderate complexity personnel and other applicable requirements apply and the laboratory must obtain a certificate of accreditation or compliance.

Professional Certification and State Licensure Requirements

CMS Central Office (CO) continues to receive inquiries from CLIA surveyors as to whether the laboratory can present an individual's professional certification, such as medical technology certification or nursing licenses, as the only type of documentation to meet the CLIA personnel requirements. This type of documentation **IS NOT** considered sufficient evidence of meeting the personnel qualifications. More detailed information, such as degrees, transcripts, or PSV documents verifying degrees and transcripts, are required.

One exception to this exists where professional certification is required by the CLIA regulations: CT and cytology CGS positions require American Society of Clinical Pathology (ASCP) certification, **in addition** to documentation of their highest level of academic achievement in education, training, and experiential requirements.

When the CLIA regulations specify that the individual must possess a license for any personnel in Subpart M (e.g., laboratory director, testing personnel), **if required by the State**, such as a physician (M.D., D.O., DDS) Midlevel practitioner (as defined at 42 CFR §493.2), testing personnel or otherwise, the laboratory need only produce a copy of the individual's State license or a report from a PSV company verifying the State license. No further academic documentation, such as diploma or transcripts, is required.

For individuals not required to be licensed under CLIA's express cross reference to state law in Subpart M, academic credentials, such as degrees, transcripts, or PSV documents, are required. Qualifications need only be provided at the highest level of academic achievement **applicable to CLIA** for the position held by the individual. It is not necessary to review a high school diploma, for example, of an individual whose position requires an advanced degree.

Bachelor Degree in Nursing

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 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.

Foreign Trained Personnel

Surveyors are not to review foreign academic credentials, but, instead, should point individuals with foreign credentials to SOM, Chapter 6, Section 6122 and CLIA Interpretive Guidelines at §42 CFR 493.2 (generally instructing such individuals to seek the services of a foreign credential evaluation agency). Allowing laboratories to make use of PSV when confirming personnel qualifications does not change this policy regarding how one should document a foreign degree's equivalency.

Foreign trained personnel that have a PhD equivalent must hold current HHS approved board certification or meet the regulation at 42 CFR §493.1405(b)(3) or 42 CFR **§493.1443(b)(3)**

Foreign trained physicians (M.D., D.O., DDS) who are licensed to practice in the State in which the laboratory is located do not need to produce educational equivalencies. A valid State license is sufficient proof of academic achievement.

Moderate and high complexity testing personnel who attended a foreign school would still need to have foreign equivalencies done. Per the SOM, Chapter 6, Section 6122 states “personnel employed in laboratories subject to CLIA that perform tests of moderate and/or high complexity must meet the specific education, training, and experience requirements. Individuals who attended foreign schools **MUST** have an evaluation of their credentials determining equivalency of foreign to United States education.”

Each person examining cytology slide preparations must (1) meet the qualifications of §493.1449(b) or (k), or (2) possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required, and meet one of several sets of requirements. One set of requirements states that on or before September 1, 1994 cytotechnologists examining cytology slide preparations must have full-time experience of at least two years or equivalent examining cytology slide preparations within the preceding five years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1), and on or before September 1, 1995, have met the requirements in §493.1483(b)(1) or (2).

Federal Laboratories

The regulation at §493.3(c) states that “laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.” Therefore, with respect to the employment of physicians and similar medical and scientific professionals in federal laboratories, the Secretary’s noted discretion in applying CLIA regulations to federal laboratories would offer other federal agencies a means for adopting hiring criteria that only require possession of a valid license in one state in order to work in any federally operated laboratory.

Home Schooling

There is no standardized approach to home schooling across the country. Should a surveyor be presented with a home school diploma, in general, they would accept the home school diploma at face value and focus on the employee's training and competency. At this time, CMS is not aware of any primary source verification company that verifies home school programs.

Military Training

Primary source verification companies are able to verify most military schooling and training. If the PSV company is unable to provide verification of the successful completion of “an official U.S. Military medical laboratory procedures training course of at least 50 weeks duration and that the applicant has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician),” (§493.1423(b)(3) for moderate complexity testing and §493.1489(b)(4)(ii) for high complexity testing), the laboratory must present documentation that the testing personnel has the qualifications to meet the CLIA personnel requirements.

Regents Bachelor's Degree (RBD)

An RBD is a baccalaureate degree program designed for adult students. The basic principle is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents of an accredited institution. CLIA regulations require that a bachelor's degree be from an accredited institution. The RBD may meet this requirement. However, CLIA also requires that the bachelor's degree be in a “chemical, physical, biological, or clinical laboratory science, or medical technology...” The RBD without the designation of one of the above majors does not meet this requirement, as it is a general education degree.

Mandatory Citations

Noncompliance with personnel regulations must be cited at the condition level if not met; i.e., the individual does not meet the required education, training, or experience, the position is not filled, or the corresponding responsibilities of that position are not met at the time of survey. See attached list of mandatory citations. As indicated in the list, **both the condition level AND standard level deficiencies must be cited.**

Competency Assessment

The current CLIA guidelines for competency assessment is attached. Personnel competency is addressed in the CLIA regulations for the laboratory director responsibilities at §493.1407, for moderate complexity, and §493.1445 for high complexity as well as for the TC and TS, §493.1413 and §493.1451, respectively.

Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: CC, TC, TS, GS and TP. Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities. If the CC, TC, TS, or GS are **not** performing any testing on patient specimens, their competency should be based only on their federal regulatory responsibilities.

If the LD is the only individual testing and reporting test results, the LD must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting.

Contact: Questions related to this memorandum may be submitted to:
LabExcellence@cms.hhs.gov

Effective Date: Immediately. The information contained in this memorandum is current policy and is in effect for all laboratory facilities. The State Agency should disseminate this information within 30 days of the date of this memorandum.

/s/
Thomas E. Hamilton

Attachment(s): 1. Practical Application of the Personnel Qualification Determinations
2. Mandatory Citations Personnel
3. Competency Assessment Guidelines

cc: Survey and Certification Regional Office Management

Attachment 1

Practical Application of the Personnel Qualification Determinations

Surveyors are instructed to cite the most appropriate mandatory deficiency(s) if the laboratory does not meet the personnel requirements for the CLIA position categories which are included on Forms CMS-1557 and CMS-209. Some examples are included here, though this is not an exhaustive list.

Example 1: A CLIA surveyor is evaluating a sample of TP qualifications in a moderate complexity laboratory and is presented with a home school diploma as evidence of compliance. What would the surveyor do?

Answer: Surveyor would accept the diploma at face value and focus on the testing personnel's training and competency.

Example 2: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with proof of a medical technology degree from an accredited institution. Does this degree satisfy the personnel requirement or are transcripts needed?

Answer: Yes, a medical technology degree from an accredited institution is sufficient. A PSV report verifying a medical technology degree from an accredited institution would also meet the requirement.

Example 3: If a laboratory is applying for a CLIA certificate and the LD is not board certified, but is board eligible, what evidence is needed for CMS to issue a Certificate of Registration?

Answer: If an LD is only eligible to be board certified, the PSV Company may not be able to verify eligibility status. The LD would need to provide the documentation of training and experience required by the board to be eligible to take such examinations.

Example 4: A laboratory is hiring a military trained medical laboratory technician. What evidence is needed for the laboratory to maintain compliance with CLIA personnel qualifications?

Answer: Primary source verification companies are able to verify most military schooling and training. If the PSV company cannot verify the successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and that the applicant has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician), the laboratory must present documentation that the testing personnel has the qualifications to meet the requirement.

Example 5: A CLIA surveyor evaluating qualifications of a nurse performing moderate complexity laboratory is presented with a nursing license as evidence of compliance. What would the surveyor do?

Answer: CLIA surveyors **do not** accept nursing licenses as evidence of compliance. An associate's or bachelor's degree in nursing meets the requirement of having earned a degree in a biological science for moderate complexity testing personnel. The laboratory must provide the surveyor with a PSV report verifying the type of degree earned, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 6: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with a report from a primary source verification company. The report verifies that the TP has a degree in Medical Technology from an accredited university and that the TP has worked for 3 years as a medical technologist at a hospital. Does this report satisfy the personnel requirement or are transcripts needed?

Answer: Yes, the PSV company report is sufficient; no further evidence is needed.

Example 7: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory located in a state that requires licensure for medical technologists. The surveyor is presented with a PSV company report that verifies the TP's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?

Answer: No. It is acceptable for the laboratory to present the surveyor with a PSV report verifying State licensure. The State license would also be acceptable. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8a: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The surveyor is presented with a PSV report verifying the LD's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?

Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. The State license would also meet the requirement. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8b: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The LD is a foreign trained physician. The surveyor is presented with a PSV company report verifying the LD's State license as evidence of meeting the personnel requirement. Does the LD also need to produce foreign educational equivalencies?

Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. The State license would also meet the requirement. Foreign trained physicians (MD, DO, DPM or DDS) who are licensed to practice medicine in the State in which the laboratory is located do not need to produce educational equivalencies. The state license is also sufficient proof of academic achievement.

Example 9: A CLIA surveyor is evaluating TP qualifications in a high complexity laboratory. The surveyor is presented with a bachelor's of science in nursing diploma as evidence of compliance. Does this satisfy the personnel requirement?

Answer: Yes. 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 must show a PSV report verifying the degree, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 10: A CLIA surveyor is evaluating TP qualifications in a high complexity laboratory. The surveyor is presented with a PSV report verifying that the TP received a bachelor's degree from an accredited university in 2008. Is this sufficient evidence of meeting the personnel requirement?

Answer: No. Regulation §493.1489(b)(1) states that high complexity testing personnel will have earned a "...bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology..." The documentation in the PSV report did not state the type of BS degree earned. The surveyor would need to look for additional evidence of the type of bachelor's degree earned, a diploma showing the type of degree earned, or transcripts. Just having evidence of a BS degree does not meet the personnel requirement.

Attachment 2**Personnel Mandatory Citations**

Requirement	Cite the Standard at least:	Cite the Condition at least:
Laboratory Director (LD) High complexity	D6078	D6076
Technical Supervisor (TS) High complexity	D6111	D6108
Clinical Consultant (CC) High complexity	D6135	D6134
General Supervisor (GS) High complexity	D6143	D6141
Cytology General Supervisor (CGS) High Complexity	D6155	D6153
Cytotechnologist (CT) High Complexity	D6164	D6162
Testing Personnel (TP) High complexity	D6171	D6168
Laboratory Director (LD) Moderate complexity	D6003	D6000
PPM Laboratory Director	D5981	D5980
PPM Testing Personnel Moderate complexity	D5991	D5990
Technical Consultant (TC) Moderate complexity	D6035	D6033
Clinical Consultant (CC) Moderate complexity	D6057	D6056
Testing Personnel (TP) Moderate complexity	D6065	D6063

Attachment 3

Competency Assessment Guidelines

Technical consultant, clinical consultant, technical supervisor, general supervisor

Documented competency assessment is required for individuals fulfilling the following positions listed on Laboratory Personnel Report (Form CMS-209): clinical consultant (CC), technical consultant (TC), technical supervisor (TS), and general supervisor (GS). The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. Cite D5209 (§493.1235). It is mandatory for clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens to have the six required procedures of competency assessed at intervals specified in the regulations in addition to a competency assessment based on their federal regulatory responsibilities. Note: The individual named on the CMS-209 must be the individual who is actually responsible for the functions of the position for CLIA purposes, whether that individual is an employee or a contracted consultant, and must meet the regulatory qualifications for the position.

Testing personnel

All testing personnel must be listed on the CMS-209 and must undergo documented competency assessment using the 6 procedures denoted under the technical consultant/supervisor's responsibilities for all testing performed. Depending on the situation, non-compliance can be cited at general lab systems (D5209), lab director (D6030/§493.1407 or D6103/§493.1445) or technical consultant/supervisor (D6046-6055, D6121-D6129).

Testing personnel in laboratories with a PPM certificate

Testing personnel, including mid-level practitioners, in PPM laboratories are required to undergo competency assessment. The requirements for performing the assessment and its frequency are determined by the regulations. If it is necessary to cite non-compliance, use D5209 or the appropriate D-tag under the technical consultant responsibilities (D6046-6055).

Other staff

Personnel performing pre-analytic and post-analytic activities are not required to be listed on the CMS-209. Surveyors do not normally check for documented competency evaluation on these individuals. However, if you discover problems in the laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (lab director).

Quality assessment

Problems in competency assessment that are not picked up and/or corrected by QA should be cited at D5291.

Discussion: Regular competency assessment is an important element of assuring that all personnel are capable of performing their duties correctly. In situations in which more than one citation may be used, choose the one that is most applicable to the situation. For example, if the assessments of testing personnel do not include all six required procedures, cite the Technical Consultant (D6046-D6052) or Technical Supervisor (D6120-D6126). **KEY POINT: Use the most appropriate citation for non-compliance with competency assessment requirements, depending on the situation. Use the citation that will best allow the laboratory to understand the problem and correct it.**