

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.

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 waived or 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 about vacancies, the data suggests that the nursing degree is not viewed as an appropriate way to

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.

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.

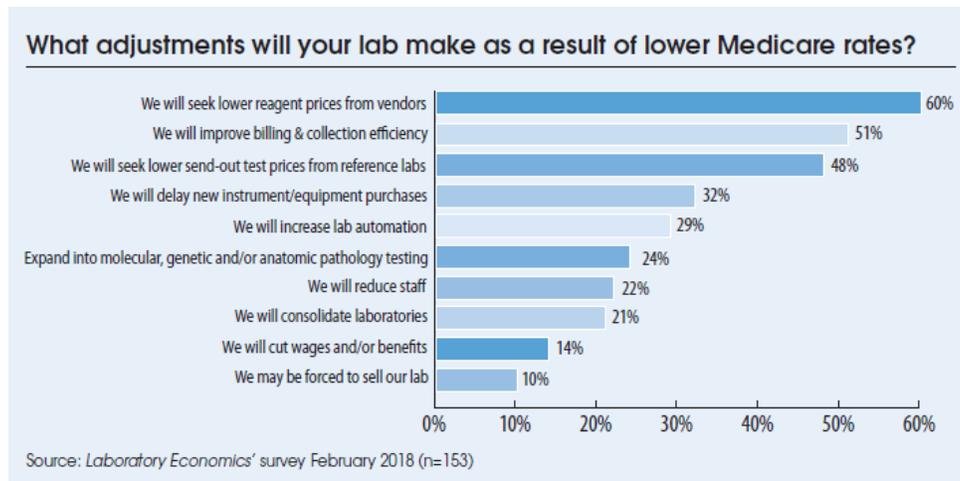
Another reason CMS's proposal will have a negligible impact on the labor market for laboratory professionals concerns wage differentials. According to the Bureau of Labor Statistics (BLS), the median salary for a [registered nurse](#) (*bachelor's level nurses*) was \$68,450 (2016). For [medical laboratory 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 rata data for the last 10 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).

Specific bench 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, grandparenting 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.

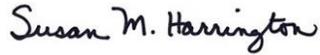
In conclusion, we are opposed to the Agency maintaining its equivalency position and are similarly opposed to allowing a nursing degree to be listed as a separately qualifying degree. Instead, CMS should allow individuals who have an earned bachelor's degree to be considered as having met the degree 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, 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.

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

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Sincerely,



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Attachments



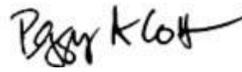
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