



Statement from the American Society for Clinical Pathology and the ASCP Board of Certification

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](#) 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*, the Centers for Medicare & Medicaid Services published a [Request for Information](#) 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 (See Appendix 4) 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.¹

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 attain an adequate supply of prepared laboratory professionals and thus, we offer the following recommendations:

- 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.

¹ Lunz, M.E.; Castleberry, B.M.; James, K.; and Stahl, J. The Impact of the Quality of Laboratory Staff on the Accuracy of Laboratory Results. JAMA. 1987; 258: 361-3