

Take Action To Protect Standards

The laboratory community has a once-in-a-generation opportunity to guide the updating of Clinical Laboratory Improvement Amendments (CLIA) personnel regulations to reflect the current and future practices in clinical laboratories that support clinical decision-making in an ever-evolving healthcare system.

The Centers for Medicare and Medicaid Services (CMS) has requested comments that it intends to use to update the existing CLIA personnel regulations in the future. ASCLS has created a website with detailed analysis and easy-to-use tools for all laboratorians to respond. ASCLS urges all laboratory professionals to provide comments to CMS with a central focus on strengthening laboratory personnel standards and ensuring the ongoing, invaluable contributions of laboratory professionals in the healthcare system.

Visit our website and provide comments by the deadline on Monday March 12, 2018.

The key issues ASCLS is asking CMS to address:

- Rescind the April 16, 2016, ruling that nursing degrees are equivalent to biological sciences degrees. ASCLS raised deep concerns when the original ruling was made. The ASCLS position has not changed. Nursing and biological sciences degrees are not equivalent and creating a regulatory framework where they are, puts the lives of patients at risk.
- Non-laboratory personnel qualifications should be based on coursework, not degree label. If CMS considers allowing non-laboratory degree holders to qualify as moderate and high complexity testing personnel, the agency should follow well-established standards from institutions like the Board of Certification, which already has clear alternate pathways for those not trained as laboratorians. What a degree is called is far less important than the content of the courses completed while working towards a degree.
- Recognize that lowering personnel standards is risky, ineffective, and not patient-centric. Expanding a regulatory role for nursing and non-biological sciences degree holders is unlikely to overcome difficulty finding personnel to properly perform testing. If institutions are unable to fill necessary positions with qualified personnel, it should forgo providing laboratory services in ways that clearly put patients' lives at risk
- Address laboratory workforce shortages by embracing technology and using qualified professionals more efficiently. Updates to the CLIA regulations should anticipate changes in practice, management of clinical knowledge, advancing technology, and expansion of testing capabilities. Improved technology and its utilization in clinical laboratories should allow the Agency to allow a wider range of laboratory leadership to oversee multiple laboratories, effectively expanding the workforce

The deadline for comments to CMS is Monday, March 12, 2018. ASCLS will be submitting the Society's own detailed comments, but the Agency is more likely to react positively with large comment volume. Our goal is to secure 5,000 more comments by the deadline. An easy-to-use template for comments is provided at the link: <http://www.ascls.org/advocacy-issues/action-center>