ASCLS
The American Society for Clinical Laboratory Science

One Voice, One Vision

August 18, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-3326-P
P.O. Box 8016
Baltimore, MD 21244-8016.

DELIVERED ELECTRONICALLY

RE: Nursing Degree Qualification for High Complexity Laboratory Testing Personnel

Secretary Becerra,

The American Society for Clinical Laboratory Science (ASCLS) provides the following comments on behalf of the hundreds of thousands of laboratory professionals who are deeply concerned with the proposed regulation change to "§ 493.1489 Standard; Testing personnel qualifications" adding a bachelor's degree in nursing as a qualifying degree for high complexity testing personnel.

The proposal is incongruent with the narrative used to justify it.

After CMS indicates it agrees "that a nursing degree is not equivalent to a biological or chemical science degree," and "We also concur with some commenters' recommendation that nursing degrees be used as a separate qualifying degree for TP," it then proceeds to propose a change to the current rules that adds the degree as equivalent to, and not separate from, degrees in biology, chemistry and clinical laboratory science or medical technology.

Further, CMS says it has confidence that nurses can, "accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency" but fails to establish any training standards or requirements.

Our nursing colleagues can and do play a critical role in point of care testing, and nurses should not be prevented from engaging in clinical laboratory work if they are properly trained. The proposed rule, however, omits any requirement for training and demonstrated competency to perform high complexity testing relative to those who have four-year degrees in clinical laboratory science, chemistry, or biology.

11107 Sunset Hills Road, Suite 100 | Reston, VA 20190-5376
www.ascls.org · ascls@ascls.org · 571.748.3770

ASCLS is stunned that the agency has equated the experience with waived testing in point of care settings as somehow similar to high complexity testing. It suggests the authors have not stepped into a clinical laboratory, nor reviewed any of the agency's own reports, nor consulted any of the agency's own experts on the subject.

CMS paints a rosy picture of how waived testing is performed in point of care environments, but basic waived testing deficiencies (as CMS notes are mostly performed by nurses) are regularly among the most cited by CMS and other deemed status surveyors under CLIA.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) commissioned a CLIA Personnel Regulations Workgroup. In the discussion of their report at its April 2019 meeting, it is noted, "Individuals with nursing degrees should qualify based on having satisfied educational requirements for courses with a clinical laboratory science component."[1]

High complexity testing is performed on a variety of advanced instrumentation, which requires performing quality control (QC), calibration, maintenance, and sometimes repair, which must be performed by properly trained and certified laboratory professionals. These tasks require an understanding of pre-analytical, analytical, and post-analytical errors, an understanding of Levy-Jennings Chart data and compliance with Westgard Rules that determine if the testing system is working as intended.

High complexity tests, by FDA definition[2], require some or all of the following not required of waived tests:

- Specialized scientific and technical knowledge, training, and experience to perform pre-analytic, analytic, or post-analytic phases of the testing.
- Special handling and preparation of labile reagents and materials to assure reliability, including manual steps such as gravimetric or volumetric measurements.
- Close monitoring or control, and special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.
- Use of labile calibration, quality control and external proficiency testing materials.
- Decision-making and direct intervention to troubleshoot and resolve most problems, and special knowledge, skills, and abilities for maintenance.
- Extensive independent interpretation and judgment to perform the pre-analytic, analytic, or post-analytic processes and resolution of problems before reporting test results.

Failure to understand and perform these fundamental tasks leads to erroneous results from instrument failure or improper specimen types or preparation or incorrect result interpretation. This results in potential harm to patients via misdiagnosis, improper medication administration, or withheld or inappropriate treatment leading to increased morbidity and mortality.

The standard nursing curriculum does not cover this content. To address this, CMS could have proposed aligning this rule for nursing degrees with existing education standards in § 493.1489(3)(ii), but inexplicably chose not to do so.

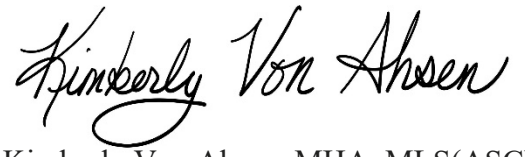
Our colleagues in nursing have no interest in assuming these additional roles. As proposed, this rule would be an open license for healthcare administrators to abusively push more complex and risky testing into point of care settings staffed by an already dangerously under-resourced nursing workforce.

This proposed rule, which opens a new vector for diagnostic error, is a reckless attempt to cover for a decades-old decision by CMS administrators to allow nurses to function in these roles as an "unwritten rule." After it was added to the CLIA interpretative guideline via Survey and Certification memo 16–18–CLIA in April 2016, industry experts provided ample and convincing evidence that this was inappropriate.

Still CMS has persisted in this misguided course, benefiting no one and harming patients.

We urge CMS to reverse this proposed rule and disallow individuals with nursing degrees without appropriate education/training to perform high complexity clinical laboratory testing.

Sincerely,



Kimberly Von Ahsen, MHA, MLS(ASCP)^{CM}, SLS(ASCP)^{CM}
President

1. Summary of April 2019 Meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC), Page 9
   https://www.cdc.gov/cliac/docs/summary/CLIAC_SUMMARY_APRIL2019.pdf
2. Food and Drug Administration CLIA Categorization of IVD
   https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations