

March 12, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Administrator Verma,

The American Society for Clinical Laboratory Science (ASCLS) welcomes the opportunity to provide comments for the recent Request for Information (RFI) on revisions to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, Docket CMS-2017-0165.

ASCLS is the nation's oldest and largest non-registry professional association representing clinical laboratory professionals. The Society's mission includes vigorously promoting high standards in all aspects of clinical laboratory science practice, education and management to ensure professional competence, and ultimately to ensure excellent, safe, accessible, efficient, and effective laboratory services for consumers of healthcare. Our 9,000 members include clinical laboratory directors, managers, administrators, supervisors, educators, and staff at all levels of practice and specialty.

ASCLS applauds CMS for beginning the process of updating these quarter-century-old regulations. We welcome this is once-in-a-generation opportunity for the laboratory community to support efforts to update these rules to reflect current and future practice in clinical laboratories that support clinical decision-making in an ever-evolving healthcare system.

Personnel Qualifications-Nursing Degree

In April 2016, CMS released a memo updating its interpretation of the personnel regulations allowing surveyors to consider a bachelor's degree in nursing as meeting the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. CMS also allowed an associate's degree in nursing to meet the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel.

As we have communicated previously with the agency, this interpretation is demonstrably inaccurate. A typical nursing degree requires just a small fraction of the science coursework as a degree in biology, chemistry, or medical laboratory science.

ASCLS provides a detailed comparative analysis of bachelors in nursing degrees to those of degrees earned in laboratory science and other natural sciences contained in attachment Attachment_2_BSN-MLS_Academic_FullComparision_20180306.pdf to our comments.

CMS claimed that this previous unwritten rule allowing nurses to perform and supervise high complexity testing was necessary for areas where there were not enough qualified laboratory personnel to perform the necessary work.

This ruling lowered standards for testing, putting the lives and wellbeing of patients at risk. It cuts corners on a critical element of the healthcare system, placing unqualified, unprepared, and potentially unwilling healthcare providers in unfamiliar roles.

While ASCLS and laboratory professionals have great respect for our nursing colleagues and believe that existing educational programs in nursing provide outstanding training for professionals in the nursing field, 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. Nurses are educated to deliver care and provide support directly to patients; not to run complex analytical devices, nor perform ongoing, robust quality assurance and control, nor evaluate the quality of the results they produce. Nursing training should be viewed for what it is, focused on nursing—not laboratory diagnostics.

In both scope and depth, the natural science coursework required for a biological science degree vastly outweighs the natural science coursework required as part of a nursing degree. Typical coursework requirements for a bachelor of sciences degree in biological sciences includes a total of at least 63 hours of natural sciences, including at least 39 hours of major requirements in the biological sciences and 32 hours of prerequisites—almost all of which are in chemistry and physics. In contrast, nursing degrees include only a quarter of the course hours in the natural sciences. Simply put, the nursing degree does not compare to the degree in biological sciences.

Laboratory professionals, who work closely with nursing colleagues daily, are unable to understand the misguided logic that now allows nurses to:

- Perform high complexity testing without any additional training. (§493.1489 (b)(1))
- Serve as a technical consultant for high complexity laboratories if the individual has at least 4 years of “laboratory experience” in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing with a specialty focus. (§493.1449)
- Serve as a moderate complexity laboratory director if the individual has at least 2 years of “laboratory experience” in non-waived testing and at least 2 years of supervisory laboratory experience in non-waived testing. (§493.1405)

- Serve as a technical consultant for moderate complexity labs if the individual has at least 2 years of “laboratory experience” in non-waived testing in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (§493.1411)

There seems to be no support from organized nursing organizations for this rule, leading us to believe that nurses have no interest in taking on these roles, understanding their competencies best prepare them to contribute to patient health in other ways.

Our fear is that nurses will be forced into roles for which they do not have adequate training by shorts-sighted administrators who have diverted their focus from patient-centered care to cutting corners and maximizing profits.

Personnel Qualifications-Nursing Degree Alternate Pathways

CMS seeks comment on 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 for moderate and high complexity testing personnel requirements.

Just as a nursing degree alone does not qualify an individual for roles performing high complexity laboratory testing, so should it not exclude them from these roles if they have the appropriate coursework and training. The Board of Certification has clear alternate pathways for those not trained as laboratorians. Nurses holding a BSN or an advanced degree should be able to undergo a standard evaluation to determine if they are prepared to perform these tests.

In the case of personnel performing high complexity tests, CMS already has training standards for those with associate degrees in laboratory science or medical laboratory technology, which sets precedent for detailing training standards within formal rules. (§493.1489 (b) (2))

Personnel Qualifications-Other Science Degrees

To more clearly define “physical science degree” for regulatory purposes, CMS is seeking comments on what is considered a “physical science degree” and whether any physical science degree(s) should meet the CLIA educational requirements.

If physical science is broadly defined as the study of non-living systems, such as astronomy, physics, and earth sciences, then those degrees alone should not qualify for CLIA in the same way as biology and chemistry degrees do.

However, it is possible, given the variability of coursework for graduates in those disciplines, that the underlying coursework does include substantial amounts of chemistry, biology and related disciplines to qualify an individual. Rather than focus on specific degrees, which may not be entirely descriptive of the coursework, CMS should define the educational requirements for

“other” bachelor degree holders instead of relying on the label of their degree. This is a consistent approach to what we suggest for those with nursing degrees.

Indiscriminately expanding the definition of qualifying degrees is not needed. Currently, there already appear to be significant numbers of chemistry and biology graduates who are underemployed in their fields and may be recruited and trained to properly perform clinical testing.

Addressing Workforce Shortages

While there are clearly shortages of qualified laboratory personnel, current regulations and their interpretation exacerbate that shortage by forcing laboratories to employ those personnel inefficiently. Current CLIA regulations fail to recognize improvements in technology that allow for the more efficient deployment of qualified laboratory professionals. Updates to the CLIA regulations should anticipate changes in practice, management of clinical knowledge, advancing technology, and expansion of testing capabilities.

In some cases, CLIA regulations already provide for a single person to serve in roles for multiple laboratories simultaneously. Improved technology and its utilization in clinical laboratories should allow the Agency to expand that allowance to a wider range of positions, effectively expanding the workforce and providing typically hard to reach institutions with access to qualified personnel.

For technical consultants, supervisors, and clinical consultants, CLIA has been interpreted to only allow individuals in those positions to work in one laboratory, since wording of the responsibilities suggest they need to be physically present.

Considering what is possible with current technology, that interpretation is no longer necessary. ASCLS encourages CMS to reconsider the interpretation of those position responsibilities and allow individuals to appropriately serve in those roles for multiple laboratories.

Not Patient-Centric, Risky, and Ineffective

The motivation for CMS to expand qualifying criteria is unclear. If this action is to address concerns about adequately staffing clinical laboratories, there are more effective approaches. Lowering standards is risky and is not supported by data.

The structure of the Request for Information is concerning. It suggests the agency is unable to granularly articulate the current deficiencies in the system, which has led to a mischaracterization of the best approaches to solving those deficiencies. The goal of the RFI seems to be finding justification to simplify the regulations for bureaucratic expedience.

Expanding a regulatory role for nursing and non-biological science degree holders is unlikely to overcome difficulty finding personnel to properly perform testing. The average salary for a nurse is substantially higher than a credentialed MLS or MLT professional, for instance, adding a financial disincentive to nurses who are generally unwilling to perform these roles.

If institutions are unable to fill necessary positions with qualified personnel, lowering standards is not an efficacious solution. These institutions should consider increasing compensation and benefits to attract appropriately trained and credentialed personnel or choose to forgo providing those services in ways that clearly put patients' lives at risk

In its 2015 report on diagnostic errors in health care, the Institute of Medicine focused on the causes of harm in our healthcare system, placing sufficient and accurate diagnostic testing at the center of a healthy diagnostic process. Forcing or allowing unqualified personnel to perform laboratory tests weakens the entire diagnostic process and harms patients.

“When errors occur, the “deficiencies” of health care providers (e.g., insufficient training and inadequate experience) and opportunities to circumvent “rules” are manifested as mistakes, violations, and incompetence. Violations are deviations from safe operating procedures, standards, and rules, which can be routine and necessary or involve risk of harm.”

- Patient Safety and Quality: An Evidence-Based Handbook for Nurses.” Agency for Healthcare Research and Quality 2008

As testing has moved closer to the patient and utilization of point of care testing (POCT) has increased, it is common for preanalytical errors to occur and inaccurate results reported. In most of those cases, these tests are performed by non-laboratory professionals, giving a glimpse into what lowering qualifications for performing high complexity testing may hold. Both the scientific literature and the experiences of most laboratorians are filled with examples of mistakes starting with specimen collection.

“There are many challenges associated with POCT, mainly related to quality assurance. POCT is performed by clinical staff rather than laboratory trained individuals which can lead to errors resulting from a lack of understanding of the importance of quality control and quality assurance practices. POCT is usually more expensive than testing performed in the central laboratory and requires a significant amount of support from the laboratory to ensure the quality testing and meet accreditation requirements.”

-Practical Laboratory Medicine, April 2016. “Practical challenges related to point of care testing” Julie L.V. Shaw. <https://doi.org/10.1016/j.plabm.2015.12.002>

Reviews by CMS and other laboratory accrediting authorities document the frequency of these kinds of errors in moderate complexity and physician office laboratories. If performance in those

environments can already be considered unsatisfactory, it is inappropriate to expand similar qualifications to high complexity laboratories.

Expanded Impact of Laboratory Professionals on Healthcare Quality

During 2018, the first person with a clinical Doctorate in Clinical Laboratory Science (DCLS) will graduate from Rutgers University. Soon after, DCLS graduates from University of Texas-Medical Branch (UTMB) will follow. These new degree-holders will be catalysts to fundamentally change how the healthcare system utilizes clinical laboratory testing. With significant interest from current laboratory professionals, ASCLS anticipates additional programs coming online and a growing cadre of uniquely skilled professionals entering the workforce.

By broadening the connection between the clinical laboratory and diagnosing/treating clinicians from data within an electronic medical record, to fully engaged consultation, these doctors of clinical laboratory science will help other clinicians ensure appropriate tests are ordered to meet clinical needs and expectations; results are properly reported to include pertinent information required for specific patient interpretation; and matters related to test quality and interpretation for specific patients are communicated.

Qualifications for Moderate Complexity Laboratory Director (§493.1405), Technical Consultant (§493.1411), High Complexity Laboratory Director (§493.1443), and High Complexity Technical Supervisor (§493.1449) include reference to “doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution.” ASCLS strongly encourages CMS to clarify that the Doctor of Clinical Laboratory Science qualifies as a doctoral degree under these provisions.

While DCLS graduates are likely to initially seek certification through one of the existing, approved bodies, clinical laboratory professional societies are working towards developing an independent certification for DCLS. We ask CMS to remain open to consideration of new certifications in the future.

With a focus on the future, ASCLS also encourages CMS to monitor developments in DCLS growth and certification as the Society believes that DCLS degree-holders will have the appropriate training to serve as Moderate Complexity Clinical Consultant (§493.1417) and High Complexity Clinical Consultant (§493.1455).

Conclusion

By addressing role CLIA regulations impact quality and value and the base level of the U.S. healthcare system, CMS can jump start efforts to generate improvements.

Results produced by clinical laboratories are the foundation of diagnoses and treatment decisions. Eroding standards threaten to produce first order declines in quality, but of greater concern are the second and third order hidden cascade of incorrect diagnoses and harmful care plans disconnected from reliable test results. Given the complexity of the healthcare system and its increasingly data-driven foundations, actions that lower standards and increase costs must be stopped.

The American Society for Clinical Laboratory Science stands ready to assist the Centers for Medicare and Medicaid Services (CMS) and other agencies involved in the federal regulation of clinical laboratories to improve the efficacy of our clinical laboratories as we work to transform healthcare in the United States into a highly-reliable and value-based system.

We are happy to discuss our concerns in greater detail if you will find it helpful

Sincerely,

A handwritten signature in black ink, appearing to read "Debra Rodahl". The signature is fluid and cursive, with a large initial "D" and "R".

Debra Rodahl, MBA, MLS(ASCP)^{CM}
ASCLS President

cc: James Flanigan, CAE, Executive Vice President

Appendix - COMPARISON OF CREDIT HOURS FOR BACHELOR DEGREE PROGRAMS

Academic Credit Hours																	
		Biology 100	Biology 200	Biology ≥ 300	Biology for non-majors*	Chemistry 100	Chemistry 200	Chemistry ≥ 300	Chemistry for Non-majors*	MLS Chemistry	MLS Hematology	MLS Microbiology	MLS Blood Bank	MLS Immunology/UA	MLS Other	MLS Clinical Rotation	Other
UNIVERSITY	DEGREE	BIOLOGY				CHEMISTRY				MEDICAL LABORATORY SCIENCE**							
Case Western Reserve University	BS Nursing	9			4 ¹	6											¹ NURS 342 – Medical Microbiology
	B.S. Biology		12	23		8	8	3									
University of Maryland	BS Nursing				12 ²				4 ²								² These are pre-requisites to enter into the nursing program. It is not specified whether these courses can be biology/chemistry for non-majors
	Biology	8 ³	7 ³	20		4 ³	12 ³	3									³ These are required specific benchmark courses which must be completed with a specific grade in the course, while maintaining a specific GPA and within a specific timeframe. Failure to meet these parameters will lead to dismissal from the major.
	Medical Laboratory Science	8	4	8 ⁴		8	8 ⁴			10	6	10	4	10	9	13	⁴ This is dependent on elective course selection, 8 credits can be in biology, chemistry or physics.
University of Illinois	BS Nursing	5		3	10 ⁵				5 ⁶								⁵ KN (10) - Human Physiological Anatomy is categorized as a Kinesiology course
	Biology	10	19	7		5	6			8		4					⁶ CHEM 130 (5) – Survey of Organic and Biochemistry, not a class for biology or chemistry majors
	Medical Laboratory Science	10		4		10	6			5	4	4	3			1	
Marquette University	BS Nursing				5 ⁷				6 ⁸								⁷ BISC1015 Principles of Human Anatomy & Physiology – a requirement for BSN. For MLS, either BISC1015 or BISC4145 (Human Physiology) is required.
	Biology	6	6	23		8	8			8							⁸ BISC 2070(3) is Biochemistry for Health Professionals and is a requirement for BSN. For MLS, either BISC2070 OR BISC 3213 (Biochemistry) is required.
	Medical Laboratory Science	6			5 ⁷	8	4		3 ⁸	7	8	11	3	2	10	15	

*non-majors – indicates a course taken to fulfill a science requirement for degree completion (usually not intended for science majors).

**Medical Laboratory Science courses are predominately at the 400 level.

Saint Louis University
Nursing vs MLS Curriculum Analysis

Nursing	MLS
CHEMISTRY	
CHEM 1083 Principles of Chemistry 1 with lab 4	CHEM 1110 General Chemistry I 3
	CHEM 1115 General Chemistry I Laboratory 1
	CHEM 1120 General Chemistry II 3
	CHEM 1125 General Chemistry II Laboratory 1
	CHEM 2410 Principles of Organic Chemistry I 3
	CHEM 2415 Principles of Organic Chemistry I Lab 1
	CHEM 2420 Principles of Organic Chemistry II 3
	CHEM 2425 Principles of Organic Chemistry II Lab 1
	BLS 4110 Medical Chemistry I 3
	BLS 4120 Medical Chemistry II 2
	MLS 4700 Clinical Chemistry Routine Testing Prac 2
	MLS 4710 Clinical Chemistry Routine Testing 1
	MLS 4720 Clinical Chemistry Special Testing Prac 1
	MLS 4730 Clinical Chemistry Special Testing 1
4 CH	26 CH
BIOLOGY	
NONE	BIOL 1040 Principles of Biology I 4
	BIOL 1060 Principles of Biology II 4
	BIOL 3020 Cell Biochemistry & Molecular Biology 3
0 CH	12 CH
MICROBIOLOGY	
BLS 2100 Microbiology 3	BLS 4510 Medical Microbiology 4
	MLS 4520 Medical Bacteriology 2
	MLS 4550 Medical Bacteriology Laboratory 2
	MLS 4530 Medical Mycology 1
	MLS 4560 Medical Mycology Laboratory 0.5
	MLS 4540 Medical Parasitology 1
	MLS 4570 Medical Parasitology Laboratory 0.5
	MLS 4800 Clinical Microbiology Practicum 3
	MLS 4810 Clinical Microbiology 2
3 CH	16 CH
MATH	
STAT 1100 Intro to Statistics 3	MATH 1400 Pre-Calculus 3
	MATH 1300 Elementary Stats w/Computers 3
3 CH	9 CH
OTHER SCIENCE	
PSY 1010 General Psychology 3	
Social Science 3	Social Science 3
ANAT 1000: Human Anatomy 3	
PPY 2545: Human Physiology 4	PPY 2540 Human Physiology 4
13 CH	7 CH
TOTAL SCIENCE = 23	TOTAL SCIENCE = 70

The following nursing and clinical laboratory science programs have the same science comparison:

Texas State University
Nursing vs MLS Curriculum Analysis

Nursing	MLS
CHEMISTRY	
CHEM 1341 General Chemistry 1 no lab 3	CHEM 1341 General Chemistry I 3
	CHEM 1141 General Chemistry I Laboratory 1
	CHEM 1342 General Chemistry II 3
	CHEM 1142 General Chemistry II Laboratory 1
	CHEM 2341 Organic Chemistry I 3
	CHEM 2141 Organic Chemistry I Lab 1
	CLS 3305 Intro to Clin Lab Techniques 3
	CLS 3410 Clinical Chemistry plus lab 4
	CLS 4370 Clinical Chemistry II 3
	CLS 3323 Clin Microscopy & Body Fluids 3
3 CH	25 CH
BIOLOGY	
BIO 1330 Functional Biology 3	BIO 1330 & 1130 Functional Biology plus lab 4
BIO 2451 Anatomy & Physiology I 4	BIO 1331 & 1131 Organismal Biology plus lab 4
BIO 2452 Anatomy & Physiology II 4	CLS 4341 Molecular Diagnostics plus lab 4
11 CH	12 CH
MICROBIOLOGY	
BIO 2440 Microbiology 4	CLS 4440 Clinical Microbiology I 4
	CLS 4340 Clinical Microbiology II 3
	CLS 3326 Medical Parasitology 3
	Clinical Microbiology Practicum
4 CH	10 CH
MATH	
MATH 1315 College Algebra 3	MATH 2321 Calculus for Life Science 3
	MATH 2328 Elementary Statistics 3
3 CH	6 CH
OTHER SCIENCE	
PSY 1300 General Psychology 3	CLS 3424 Clinical Immunology 4
	Social and Behavioral Science 3
	CLS 3412 Hematology/Coagulation I 4
	CLS 4318 Hematology II 3
	CLS 4460 Immunohematology 4
	CLS 4361 Research Methods 3
	CLS 4463 Clin Lab Practice I 4
	CLS 4364 Clin Lab Practice II 3
	CLS 3305 Intro to Clin Lab Techniques and Practice 3
3 CH	31 CH
TOTAL SCIENCE = 24	TOTAL SCIENCE = 84

Trident Technical College
Nursing vs MLT Curriculum Analysis

Nursing	MLS
CHEMISTRY	
NONE	CHM 110 College Chemistry I 3
	MLT 106 Urinalysis and Body Fluids 2
	MLT 131 Clinical Chemistry 3
0 CH	8 CH
BIOLOGY	
BIO 210 Anatomy & Physiology I 4	BIO 112 Anatomy & Physiology 4
BIO 211 Anatomy & Physiology II 4	
8 CH	4 CH
MICROBIOLOGY	
BIO 225 Microbiology 4	BLS 4510 Medical Microbiology 4
	MLS 4520 Medical Bacteriology 2
	MLS 4550 Medical Bacteriology Laboratory 2
	MLS 4530 Medical Mycology 1
	MLS 4560 Medical Mycology Laboratory 0.5
	MLS 4540 Medical Parasitology 1
	MLS 4570 Medical Parasitology Laboratory 0.5
	MLS 4800 Clinical Microbiology Practicum 3
	MLS 4810 Clinical Microbiology 2
4 CH	16 CH
MATH	
MAT 110 College Algebra 3	MAT 110 College Algebra 3
3 CH	3 CH
OTHER SCIENCE	
PSY 201 General Psychology 3	AHS 142 Phlebotomy 2
Social Science 3	Social Science 3
NUR 161 Basic Concepts of Pharmacology 2	MLT 102 Medical Lab Fundamentals
	MLT 109-111 Hematology I and II 4
NUR 05 Pharmacology for Nurses 1	MLT 219 Clinical Instrumentation 3
	MLT 105 Medical Microbiology 4
	MLT 112 Intro to Parasitology 2
	MLT 115 Immunology 3
	MLT 120 Immunohematology 4
	MLT 206-207 Advanced Microbiology I & II 4
	MLT 211-212 Advanced Hematology I & II 4
9 CH	33 CH
TOTAL SCIENCE = 24	TOTAL SCIENCE = 64