Centers for Medicare and Medicaid Services (CMS) Docket CMS-2017-0165

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)

https://www.federalregister.gov/documents/2018/01/09/2017-27887/request-for-information-revisions-to-personnel-regulations-proficiency-testing-referral

CMS Request for Information Issue Brief

Background

On January 9, 2018 CMS published a Request for Information seeking comments, information, evidence, research, and trends related to CLIA personnel regulations. The Agency intends to use the information received through this process to update the existing CLIA personnel regulations in the future. This will be the first time since 1992 that there has been a comprehensive review of the regulations except for minor changes to doctoral high complexity laboratory director qualifications in 2003.

This is an opportunity for the laboratory community to guide the updating of quarter-century old regulations to reflect the current and future practices 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.

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.

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 professional 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. 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 sciences 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. *Detailed analyses comparing nursing, biological science, and medical laboratory science are contained in the Appendix.*

Equating a bachelor's degree in nursing with a degree in biological sciences would allow 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)

Of the roles above, the one most concerning is the qualification to perform high complexity testing without any additional, required training. Nurses seem to have no interest in taking on these roles understanding their competencies best prepare them to contribute to patient health in other ways. The fear is that nurses will be forced into roles for which they do not have adequate training by shorts-sighted administrators without a patient-centered focus.

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 that can form the basis for training standards. (§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. The CMS approach is the wrong solution for the problem at hand.

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. These are not roles nurses are pursuing.

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.

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 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, CLIAC 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.

Provide Comment at: https://www.regulations.gov/docket?D=CMS-2017-0165

Current CLIA Regulations: https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11403

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 [6]CHEM 130 (5) – Survey of Organic and Biochemistry, not a class for biology or chemistry majors
	Biology	10	19	7		5	6				8		4				
	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. [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.
	Biology	6	6	23		8	8				8						
	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**