

Del S. Simon, BS, CLS
PO Box 311
Big Sandy, MT 59520

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Pat Murdo
EAIC
P.O. Box 201706
Helena, Montana 59620

RE: Clinical Laboratory Science Licensure

Dear Ms. Murdo:

Having been in the profession of clinical laboratory science since 1975, I have direct knowledge of how valuable our licensure law in Montana is to the health and wellbeing of Montanans. During my tenure, our profession has gone from manual procedures to complex molecular procedures. Our education in the '70's has been augmented with continuing education and many of us have sought higher degrees to keep up with our ever-changing fields. Our profession is the "defensive end" of medicine. The clinicians posit a diagnosis, but we prove or disprove their diagnosis. We are the ones who initially tell if a teenager has infectious mononucleosis or lymphocytic leukemia. We are the ones that alert the pathologist to these anomalies so the proper diagnosis is made. Many of our procedures are automated and it is our role to ensure the quality control, maintenance, and reproducibility of these instruments. This is our education, our training, and expertise.

HB 525 criteria to determine if a board meets a public purpose ask seven questions.

1. Does the unregulated practice of the occupation or profession create a direct, immediate hazard to the public health, safety, or welfare?
 - a. We protect the public from substandard care and consequences of inaccurate results
 - b. We set standards that must be followed to assure quality and consistent laboratory testing
 - c. We define and protect the scope of practice of the profession
 - d. We facilitate an effective response in disaster preparedness by assisting in the identification, locating and mobilization of needed clinical laboratory professionals with the expertise to identify potential life-threatening human and animal pathogens
 - e. We improve access to accurate laboratory procedures and results.

2. Is the scope of practice readily identifiable and distinguishable from the scope of practice of other professions and occupations?
 - a. We are distinct from any other practice of medicine
 - b. We are characterized by our own, internally-defined Body of Knowledge and Scope of Practice and we certify our own practitioners
 - c. We require our practitioners to have competency in scientific, technical, managerial and scholarly principles; with high standards of performance and professional conduct.

3. Does the occupation or profession require a specialized skill or training for which nationally recognized standards of education and training exist?
 - a. The benchmark for the Clinical Laboratory Scientist is the baccalaureate degree as awarded by a regionally accredited college/university including or in addition to successful completion of a clinical laboratory scientist program accredited by an agency recognized by the U.S. Department of Education.
 - b. The benchmark for the Clinical Laboratory Technician is the associate degree as awarded by a regionally accredited college/university including successful completion of a clinical laboratory science technician program accredited by an agency recognized by the U.S. Department of Education.
 - c. The benchmark for personnel performing CLIA waived testing is successful completion of appropriate training for testing at this level. It is within the scope of practice of a certified clinical laboratory scientist to provide this training.

4. Are qualifications for licensure justified? By all means YES!
 - a. We assess, design, evaluate and implement new laboratory test methods.
 - b. We evaluate the appropriateness of existing and new laboratory methods for clinical utility, cost-effectiveness and cost-benefit analysis.
 - c. We develop, implement, and report results of clinical laboratory services research. (i.e. within the context of cost, quality, and access.
 - d. We design and implement cost-effective delivery models for clinical laboratories, including their services and personnel.
 - e. We develop and implement a comprehensive Quality Management System to include
 1. quality control and assurance of clinical laboratory testing services;
 2. competency assessment of personnel;
 3. integration with other aspects of the health care delivery system for ensuring appropriate utilization of clinical laboratory testing services.
 4. continuous process improvement activities to maximize human resources.
 - f. We help in the designing, implementing and evaluating process for the education of new clinical laboratory personnel, and the continued education, development and career growth of clinical laboratory professionals.
 - g. We promote awareness and understanding of the use of clinical laboratory.

5. Does licensure provide a public benefit? YES, because quality clinical laboratory testing is evidenced by: performing the correct test, on the right person, at the right time,

producing accurate test results, with the best outcome, in the most cost-effective manner. This is accomplished by:

- a. ensuring that appropriate laboratory tests are ordered.
- b. procuring laboratory test samples in an efficient, timely manner.
- c. producing accurate laboratory test results.
- d. correlating and interpreting laboratory test data.
- e. disseminating laboratory test information to clinicians and patients in a timely manner.
- f. evaluating the outcome of clinical laboratory testing for each individual patient and the entire health care system.

6. Does licensure significantly increase the cost of service to the public? NO.

Because of the economic and regulatory environment, expanded roles for non-physician healthcare professionals, including clinical laboratory scientists, will allow the important issues of cost containment, access, quality and appropriateness to be more effectively addressed. While the costs of healthcare continue to rise, there are significantly raised expectations from physicians and healthcare consumers to deliver information in a manner, which will facilitate rapid diagnosis and treatment. At a time when the cost of healthcare is over 14% of the country's gross national product, clinical laboratory services continue to provide a significant level of value, contributing up to 70% of the objective information used to make diagnostic decisions, while comprising only 5% of a typical hospital budget. (Clinical Chemistry, 1996, 42: (5): 813-816)

7. Is there public support for licensure? Yes.

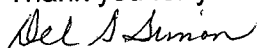
All patients want to be secure in the knowledge that their test results are accurately done in a cost effective manner with the results to the ordering clinician in the fastest possible time. We as a profession are dedicated to the cost containment and proper use of the laboratory for the benefit of all of Montana's residents.

*information supplied by American Society for Clinical Pathology and American Society for Clinical Laboratory Science

American Society for Clinical Laboratory Science (ASCLS) - "Employing individuals without the appropriate education and training creates the potential to place every patient and every caregiver in harm's way. Licensure, of clinical laboratory professionals, provides a means to assure that these requirements are maintained in all patient care environments"

I hope this information will cause you to think about the possibility of having someone very precious to you going to an ER and having a non-licensed lab employee running lab tests that could determine your loved ones outcome.

Thank you for your consideration,



Del S. Simon, BS, CLS