

**Preliminary Assessment on Request for Licensure
Medical Laboratory Science Professionals
Summary of Testimony and Evidence**

Background

Medical Laboratory Science Professionals seek regulation via licensure by the State of Vermont. Pursuant to 3 V.S.A. § 3105(d) Medical Laboratory Science Professionals have requested that the Office of Professional Regulation prepare a Preliminary Assessment of their request for licensure. Their Application may be reviewed on the Office of Professional Regulation web site at <http://vtprofessionals.org/about/medlabscience.asp>. The supporting documentation they provided is also available on the same web page.

**Regulatory Considerations
State Policy on Regulation of Professions**

Chapter 57 of Title 26 of the Vermont Statutes states:

“26 V.S.A. § 3101 Policy and Purpose.

It is the policy of the state of Vermont that regulation be imposed upon a profession or occupation solely for the purpose of protecting the public. The legislature believes that all individuals should be permitted to enter into a profession or occupation unless there is a demonstrated need for the state to protect the interests of the public by restricting entry into the profession or occupation. If such a need is identified, the form of regulation adopted by the state shall be the least restrictive form of regulation necessary to protect the public interest....”

Vermont law 26 V.S.A. § 3105(a) provides a detailed set of criteria which must exist before regulation of a profession may occur:

“A profession or occupation shall be regulated by the state only when:

(1) it can be demonstrated that the unregulated practice of the profession or occupation can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is recognizable and not remote or

speculative;

(2) the public can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and

(3) the public cannot be effectively protected by other means.”

The legislature delegates responsibility for a preliminary assessment of requests for regulation to the Office of Professional Regulation. “Prior to review under this chapter and consideration by the legislature of any bill to regulate a profession or occupation, the office of professional regulation shall make, in writing, a preliminary assessment of whether any particular request for regulation meets the criteria set forth in subsection (a) of this section. The office shall report its preliminary assessment to the appropriate house or senate committee on government operations.” 26 V.S.A. § 3105(d). Pursuant to that mandate, the Office of Professional Regulation has reviewed the Sunrise Application of Medical Laboratory Science Professionals.

Process

The Office of Professional Regulation evaluated the Application and conducted its own investigation. As required by the Sunrise Review statutes 26 V.S.A. § 3101 et seq., the Director of the Office of Professional Regulation held a properly noticed hearing on November 10, 2009 at the Office of Professional Regulation Conference Room at the National Life Building in Montpelier. The hearing allowed evidence beyond what was contained in the Application for Sunrise Review to see if the Applicants, Medical Laboratory Science Professionals, satisfy the statutory prerequisites for regulation by the State of Vermont. Attending the hearing were several Medical Laboratory Science Professionals. No members of any other profession attended the meeting. The Application contained letters of support from several people. In 2004 the American Society of Clinical Pathologists surveyed its 68,000 members about licensure and obtained a 15% response, with approximately a 4:1 preference for licensure. Some Medical Laboratory Science Professionals in Vermont do not favor licensure feeling regulation is unnecessary. A Vermont survey conducted by the Applicants reached similar results.

Overview of the Profession

Medical Laboratory Science Professionals have achieved licensure in 12 states. In 10 or more other states their quest for governmental recognition is in various stages. Licensure has resulted from lobbying by the profession. Until this report, no state has conducted a Sunrise Review or similar evaluation to determine if leaving the profession unregulated would endanger the health, safety or welfare of the public. 3 V.S.A. § 3105(a)(1).

“Medical Laboratory Science Professionals” is the title which the Applicants use to cover several categories of trained health care laboratory workers. Medical Laboratory Science Professionals define their profession to include “Cytotechnologists,” “Histotechnologists,” “Histotechnicians,” “Pathologists’ Assistants,” and “Pathologist’s Technicians.” The Applicants do not include “phlebotomists” as Medical Laboratory Science Professionals. According to the

Application, 90% of Medical Laboratory Science Professionals employed in Vermont work in hospital laboratories. The remaining 10% work in private laboratories. The exact number of Medical Laboratory Science Professionals in Vermont is unknown, but is estimated to be approximately 400.

Medical Laboratory Science Professionals are responsible for ensuring accurate diagnoses of patient tissues and testing performed on patient samples. They claim that over 70% of all medical decisions are based on laboratory data. Whatever the number, their work is crucial. Some work in blood banks and prepare blood for transfusions. Mistakes can lead to serious injury or death.

The proposal for licensure does not include nurses or others who perform laboratory services in Vermont doctor's offices. Presumably, these workers are already licensed as nurses or are under the direct supervision of a licensed physician.

The Medical Laboratory Science Professionals are specially trained in their various fields. Generally, they are broken into two groups. Clinical laboratory technologists usually have a bachelor's degree with a major in medical technology or in one of the life sciences. Clinical laboratory technicians generally need either an associate degree or a certificate.¹ Medical Laboratory Science Professionals are not independent practitioners. They work as employees in laboratories.

At this time, all Medical Laboratory Science Professionals in Vermont are believed to have associate's or bachelor's degrees. Some have master's degrees. It is believed that all are certified by nationally recognized certification agencies. There is a national examination for each discipline. All are required to have supervised laboratory work experience before receiving certification. Certification requires continuing education. National certification of Medical Laboratory Science Professionals gives employers hiring Medical Laboratory Science Professionals a readily available means to assure Medical Laboratory Science Professionals applicants are appropriately trained and display initial professional ability. 3 V.S.A. § 3105(a)(2).

In Vermont's smaller hospitals there is little if any distinction between the pay, education or training required of different classes of laboratory professionals. Many laboratory workers fulfill multiple functions. Some who are hired with an associate's degree successfully take the examination for bachelor's trained technologists and practice at that higher level. All hospitals in Vermont hire people who have earned certification by one of the two major certifying organizations.² Some hospital laboratories in Vermont provide educational stipends for their

¹ Bureau of Labor Statistics, <http://www.bls.gov/oco/ocos096.htm>.

² The nationally recognized certifying organizations are: NCA (National Credentialing Agency for Laboratory Personnel), ASCP (American Society for Clinical Pathology)

laboratory personnel so that they may pursue continuing education. Those Vermont Medical Laboratory Science Professionals who are employed by the state's larger hospitals may be more specialized.

According to the Bureau of Labor statistics, in 2006 there were approximately 319,000 laboratory technician or technologist jobs held in the U.S.³

The Applicants submitted copies of four disciplinary decisions from other states where Medical Laboratory Science Professionals are licensed. (See, Attachment U in Application). None of the four disciplinary decisions submitted was for inadequate performance of professional duties. They were for issues regarding substance abuse (2), fraud in an application (3, all from New York State), and practicing before a license was issued. The Applicants posit, however, that there is a risk of harm should Vermont employers stray from currently accepted educational and certification standards, to allow less well-trained personnel to do laboratory work. Information submitted by the Applicants regarding malpractice comes from a website "Wrongdiagnosis.com" which claimed that in 2003 malpractice reports were made against 0.01% of technologists. This information could not be confirmed. The National Practitioner Data Bank showed that as of October 2009 it had received in total only sixty reports against laboratory personnel. Sixteen of those resulted in a judgment or "conviction report."⁴

Most Medical Laboratory Science Professionals work in hospital laboratories, already an environment subject to federal and industry set standards. Hospitals are subject to governmental, professional, and insurance requirements. Hospital laboratories must meet additional requirements. All health laboratories which receive Medicare or Medicaid funds are required to meet Clinical Laboratory Improvement Amendments (CLIA) standards. The CLIA standards, established in 1988 by the federal government, provide minimum standards for laboratories and hiring and training requirements for their employees.⁵ The Joint Commission on Accreditation of Healthcare Organizations has stated that CLIA permitted personnel standards are insufficient to adequately protect patients and the public health.

Medical laboratories in Vermont are not licensed by the State of Vermont. They do, however, receive accreditation from one or more of several nationally recognized accrediting organizations.⁶ The Joint Commission's accreditation, for example, uses the Comprehensive

³ See, <http://www.bls.gov/oco/ocos096.htm>

⁴ See, http://www.npdb-hipdb.hrsa.gov/pubs/stats/HIPDB_Organization_Subject_Summary_Report.pdf

⁵ See, <http://www.cms.hhs.gov/CLIA/downloads/060630.Backgrounder.rLEG.pdf>

⁶ Joint Commission on Accreditation of Healthcare Organizations (JCAHO) "The Joint Commission is a private, not-for-profit organization dedicated to continuously improving the safety and quality of care provided to the public. The Joint Commission is the nation's principal

Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB). “The standards emphasize the results a laboratory should achieve, instead of the specific methods of compliance, and were developed with input from professional laboratory organizations. In compliance with CLIA regulations, Joint Commission standards address processes that follow laboratory specimens through the laboratory from specimen collection to result reporting, focusing on the provision of high quality, safe laboratory services. These standards highlight the essential nature of laboratory services on the actual care and service delivery processes that contribute to and support the overall health care delivery system.”⁷ Accreditation includes requirements that laboratories document that their employees possess adequate training. Hospitals must therefore obtain certification documentation from new hires as well as the applicants’ diplomas. In addition, medical laboratories are CLIA approved in order to receive Medicaid and Medicare reimbursement. Most hospital insurance requires that the laboratories meet CLIA standards, and often more. Laboratory managers have their own national and regional professional associations.⁸

Laboratories are required by CLIA and JCAHO to be headed by qualified laboratory directors. The laboratory directors must ensure that laboratory personnel working under them use test methods that achieve accurate and reliable results. They ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.⁹

Most Vermont hospitals hire only certified Medical Laboratory Science Professionals. Some will hire those who are “certification eligible,” meaning people who have the required education for certification, but have not yet taken or passed the certification examination.

Laboratories in hospitals are required to have quality assurance and risk management departments. Hospital laboratories keep records of known errors for quality assurance and risk management purposes. They keep incident severity reports and perform “root cause” analyses. If a patient receives the wrong blood, the FDA is notified. If there has been some sort of catastrophic error or problem, it is reported to entities like the CDC or others outside the hospital. Sentinel events are reported to JCAHO.

standards setter and evaluator for a variety of health care organizations.” College of American Pathologists (CAP), CARF, NAACLS (National Accrediting Agency for Clinical Laboratory Sciences).

⁷ See, Joint Commission, Facts About Accreditation
http://www.jointcommission.org/AccreditationPrograms/LaboratoryServices/lab_facts.htm

⁸ <http://www.clma.org/index.php/chapters/chapter-finder>.

⁹ CLIA regulations, part M, Laboratory Personnel.

If Medical Laboratory Science Professionals were licensed, regulators would expect to take action on reports of intentional negligence or reports about a person whose conduct was so deficient that remedial action was necessary. Since Medical Laboratory Science Professionals would be subject to the mandatory reporting requirements of 3 V.S.A. § 128, any laboratory worker who was discharged or disciplined by an employer would be reported to the Office of Professional Regulation for investigation and possible prosecution. This could include reporting on activities or omissions that may or may not amount to unprofessional conduct.

The Applicants are proud of their profession's strong safety record. No reported harm has resulted from current Vermont hiring standards. No studies or statistics presented indicate that the members of this profession, left unregulated, pose a real threat to public health, safety and welfare.

Demographic Challenge?

The Medical Laboratory Science Professionals report that the average age of a Medical Laboratory Science Professional is around 48-50 years. According to the National Accrediting Agency for Clinical Laboratory Sciences, the current vacancy rate in the clinical laboratory sciences field is 13 percent. In the next five years, 13 percent of the workforce is expected to retire, with 25 percent of the workforce retiring over the next 10 years.¹⁰ In the recent past schools teaching medical laboratory technology have been closing. As Medical Laboratory Science Professionals retire, and as demand for laboratory tests continues to rise, the number of vacant positions for Medical Laboratory Science Professionals is expected to grow. It will be harder to fill the available spots with qualified people. The Medical Laboratory Science Professionals fear that pressure to fill the positions will lead to the hiring of less qualified people. We note that other health care professions face similar demographic challenges.

Why Licensure is Sought

The Applicants state that the existing federal CLIA standards for laboratory workers are insufficient to assure competence. For less than high complexity tests CLIA standards allow for some on the job training and do not require that laboratory personnel receive certification. It appears that the Medical Laboratory Science Professionals currently employed in Vermont do have appropriate education to perform their duties. No evidence presented suggested that Vermont that laboratories are employing unqualified personnel. At the public hearing the Applicants shared a Vermont hospital's advertisement for a laboratory technologist who may not be certified. This can mean that a hospital seeks a person with the educational background for certification, even though he or she has not yet taken or passed the certification examination.¹¹

¹⁰ See, <http://www.healthcarefinancenews.com/news/closure-clinical-lab-sciences-programs-threatens-healthcare-industry>

¹¹ This particular advertisement set hiring prerequisites as: "Baccalaureate degree in Medical Technology or an Baccalaureate degree in a related science with approved clinical laboratory scientist training. Non-traditional route to establish skill level may be accepted after

The Applicants feel that a “certification eligible” person can not be presumed to possess the competence to practice on the basis of education alone.

The Applicants feel that anything less than certification is insufficient training. They feel that a Medical Laboratory Science Professional who has received an associate’s or bachelor’s degree should not be employed until he or she has successfully completed the certification testing in their field of expertise. The examination must be passed within five years of completing the educational prerequisites or the person is no longer eligible to take it. They raise the possibility that a person who can’t pass the examination could work for up to five years. No evidence presented indicates that such a scenario exists. Nor was there any evidence showing that any “certification eligible” person had performed in a substandard manner.

The Applicants feel that if under-qualified people are allowed to perform laboratory testing, the quality of the results will be at a “much greater risk” of error. People without adequate training “grossing a specimen” could result in inadequate or improper sampling of specimens, inaccurate assessment of tumor size and distance to margins, misinformation and delay in diagnosis “from having to go back to the specimen if something is missed.”¹² This is speculative.

Laboratories are accountable for errors and conduct of their personnel. The Applicants feel that individual workers are now accountable only to their employers. They believe that Medical Laboratory Science Professionals should also be individually accountable to the State. The Applicants argue that licensure will assure retraining or discipline of those who commit serious errors. They say that other medical care professionals are surprised to learn that Medical Laboratory Science Professionals are not licensed.

Hiring concerns: Laboratory managers state that without licensure, they have no way to know whether an applicant has performed poorly in prior employment. Because of constraints imposed on them by their human resources departments, laboratory managers feel that they can not give accurate evaluations to prospective employers. When they hire someone, they say, they lack a means of assuring that the applicant has performed competently in the past. They state that a laboratory worker may be terminated for substandard performance, and that no one but the employee would know it. Licensure would allow laboratory directors to know whether an applicant has committed unprofessional conduct.

The Applicants argue that requiring certification and licensure will, in the near future, restrict the number of applicants nationally. This, they hope, will create a near term hardship and

review of education and experience. Associate Degree in Medical Technology or an Associate Degree in a related science with approved clinical laboratory scientist training, plus eight years working in a clinical laboratory. Nationally recognized certification credentials or equivalent preferred.”

¹² Application, § 8.

an eventual demand for more medical laboratory science schools. They hope that states and educational institutions will rush to create them. When the schools are created, their graduates will meet the demand for more Medical Laboratory Science Professionals. The University of Vermont has a training program for Medical Laboratory Science Professionals. So the pressure in Vermont is not as acute as in some other states. However, given the current economic climate, restricting the applicant pool to spur creation of new schools in other states is unrealistic.

Part of their rationale for licensure is the Applicants' desire to prevent current standards from eroding. Also, they wish to increase the visibility and the desirability of their profession for the future. Their hope is that by having their professionalism recognized by licensure, their profession will become better known and desirable for science students seeking a career. They suggest that licensing will increase their professional stature and overcome the demographic challenges the profession now faces.

Risk to the Public of Leaving Medical Laboratory Science Professionals Unregulated

In their Sunrise Review Application the Applicants merely state that CLIA standards are insufficient. JCAHO sets higher standards. Other than suggesting that CLIA standards are inadequate,¹³ the Applicants do not show that legal means other than regulation of individual Medical Laboratory Science Professionals have been insufficient to protect the public. 3 V.S.A. § 3105(a)(3) and 3105(b)(1).

Arguments Against Licensure

As discussed above, medical laboratories are already strictly controlled by hospitals and public and private accrediting agencies. The laboratories must meet high standards of performance to meet JCAHCO or CLIA performance standards or the standards of other laboratory accrediting agencies.

Vermont hospital laboratory directors are already responsible for assuring that the laboratories meet expected objective national standards. They currently hire certified or certification eligible Medical Laboratory Science Professionals, the very thing state regulation would require. Accredited hospital laboratories must continue to meet accreditation standards. Those standards are based on performance expectations which Vermont laboratories already meet. We cannot say that the advertisement referred to above shows a hiring standard that endangers public health.

Comparison to Statutory Criteria

26 V.S.A. § 3107 requires sunrise applicants to provide information about several criteria.

¹³ Answer to Sunrise Application Question #10. "Why isn't the public protected from unprofessional practitioners through means other than regulation? (For example, criminal penalties, consumer fraud laws, small claims court, civil litigation, etc.)?"

Based on the information presented we conclude that the nature of the potential harm or threat to the public if Medical Laboratory Science Professionals are not regulated is, at this time, speculative. At this time there are no specific examples of real or threatened harm. The *general public* will not directly benefit from a method of regulation which permits additional identification of competent practitioners. Certification allows laboratory directors to identify properly trained Medical Laboratory Science Professionals now.

Medical Laboratory Science Professionals are, for the most part, supervised, though they often work on their own during late or overnight shifts. They must use independent judgment, and have the skill or experience required in making such judgments. This comes with the education and training Medical Laboratory Science Professionals receive to become certified. Medical Laboratory Science Professionals have a code of ethics and conduct. They rarely, if ever, find themselves in disputes with consumers. As certified Medical Laboratory Science Professionals they already have continuing education requirements. We cannot conclude that existing law is inadequate to protect the public. Because hospital laboratories are already required to meet national standards and voluntarily meet certification standards, regulation of laboratories rather than their employee practitioners remains appropriate. Regulation will not reduce or eliminate the speculative harms or threats identified above.

We acknowledge that laboratory directors may have real difficulty gaining access to reliable prior employment information before hiring applicants. This does favor of some type of regulation, but alone does not justify state intervention.

Comment

The Applicants have made a compelling case for the need to preserve currently employed standards for hiring Medical Laboratory Science Professionals in Vermont. If their demographic projections are correct, there will be a pressing demand to find more Medical Laboratory Science Professionals. The temptation to lower hiring standards may become irresistible. The laboratory directors whose views are known indicate no current desire to lower the educational standards for Medical Laboratory Science Professionals. This may change. Vermont is fortunate to have a training program which may avoid that temptation here. If it does not, regulation of Medical Laboratory Science Professional may become necessary to assure initial and continued competence and protect the public.

Conclusion

Re: 26 V.S.A. § 3105:

- (1) It has not been demonstrated that the continued unregulated practice of Medical Laboratory Science Professionals in Vermont can clearly harm or endanger the health, safety, or welfare of the public. The potential for the harm from this group is not at this time recognizable. It remains remote and speculative.
- (2) We agree that the public can reasonably be expected to benefit from an assurance of

initial and continuing professional ability. This assurance is met by current hiring practices in Vermont.

(3) The public is at this time effectively protected by other non-governmental means.

Based on these conclusions, the Office of Professional Regulation does not recommend regulation of Medical Laboratory Science Professionals at this time.

Respectfully submitted:

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Office of Professional Regulation

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