THE CLINICAL LABORATORY TECHNOLOGY PRACTICE ACT OF NEW YORK

The information on the website has been compiled by the New York State Society of Pathologists to assist pathologists, clinical laboratory workers, and interested parties to understand the background and implications of NY's clinical laboratory technology practice act, commonly referred to as the lab tech licensure law.

1. THE CLINICAL LABORATORY TECHNOLOGY PRACTICE ACT: A CALL TO ARMS

The clinical laboratories of New York are facing a looming crisis in their ability to recruit and hire appropriately skilled workers due to the 2004 passage of the Clinical Laboratory Technology Practice Act. The law itself was unnecessary in these post-CLIA '88 days, but even worse are the very unfortunate current regulations written to interpret and implement the law. Because this is a licensing law, the NY State Education Department (SED), and not the NYS Department of Health (DOH), is responsible for implementing the regulations. Beyond merely registering laboratory employees and confirming their educational and training backgrounds, the law and the regulations have dramatically altered educational requirements and definitions of laboratory workers. Quite bluntly, the current regulations, issued as emergency regulations, reflect a profound misunderstanding on the part of the SED of the practice of clinical laboratory science. To add insult to injury, the SED has chosen to exempt out-of-state New York-licensed laboratories. At the very least, the mandates of the law, purportedly meant to protect the health of New York's citizens, should apply to all labs supplying medical testing to New Yorkers.

The information on this website is intended to offer background information on laboratory personnel licensure and how implementation of this state law is interfering with the ability of New York's clinical laboratories to provide high quality medical care to the citizens of New York. The New York State Society of Pathologists strongly encourages all affected and interested parties to communicate their concerns (via email, letters, phone calls, personal visits) to the State Education Department, Senator Balboni (the prime sponsor of the legislation) and your local state senator.

2. USEFUL ADDRESSES

Kathleen M. Doyle, PhD, Executive Secretary
NYS Board for Clinical Laboratory Technology
NYS Education Dept, 2nd floor, East Wing
89 Washington Ave.
Albany, NY 12234
clinlabd@mail.nysed.gov

Deputy Commissioner Johanna Duncan-Poiter
Office of the Professions
NY State Education Department
State Education Building- 2nd floor
89 Washington Ave.
Albany, NY 12234

Senator Michael Balboni (the law's major sponsor)
Legislative Office Bldg, Rm 803
Albany, NY 12247
518 455-2471 or 516 873-0736

balboni@senate.state.ny.us

Assemblyman Ronald Canastrari (the assembly sponsor)
Legislative Office Bldg, Rm 722
Albany, NY 12248
518-371-0568
canastr@assembly.state.ny.us

web addresses of interest:
Need more information from NYSSPath? Ask us at info@nysspath.org
NY SED website on this bill and the regulations: www.op.nysed.gov/clp.htm
College of American Pathologists: www.cap.org
American Society for Clinical Pathology: www.ascp.org
American Society for Clinical Laboratory Science: www.ascls.org
Find your district's assemblyman: www.assembly.state.ny.us
Find your district's senator: www.senate.state.ny.us

3. THE LABORATORY PERSONNEL SHORTAGE

Approximately 80% of medical decisions depend on laboratory data.

In response to a 2004 CAP House of Delegates resolution, the Council on Government and Professional Affairs (CGPA) released a memorandum on the laboratory personnel shortage at the 2006 HOD meeting. The CGPA memo shows that demand for laboratory workers remains strong- Bureau of Labor Statistics reported that employment in this sector has grown 17% over the past 5 years as compared to a 14% growth in overall employment. Sixty percent of laboratory workers are employed in hospitals, 15% in physician offices, 14% in independent laboratories, and 11% evenly distributed in education, research and manufacturing, and government.

The CAP report quotes an ASCP survey revealing that 46% of medical labs report problems in recruiting qualified staff, especially those in small hospitals and rural areas. The hardest positions to fill were for Medical Technologists and Medical Laboratory Technicians. The survey shows an average of 3 to 12 months to fill a position. Although a trend for decreased vacancies are noted, there is no true understanding of the definition of a vacancy- some of the fluctuations could be due to budget constraints and subsequent FTE reductions and the use of part-time or temporary staff.

The CAP report noted a number of factors involved in the current shortage of lab staff, including the shrinking pool of available students (the traditional pool of workers in their 20s and 30s is shrinking while the population, on the whole, ages), reductions in the number of training programs, and low wages. In the 1970s, the number of clinical laboratory science/medical technology programs was approximately 800. Today there are 234. Training programs for clinical laboratory technicians/medical laboratory technicians has remained somewhat more steady- currently there are 205 programs. As expected, this translates into fewer graduates of these training programs. Over a 10 year period, the number of graduates from accredited programs declined 50%, down to 4, 265 in 2003.

The CAP report quotes data that suggests that wages of clinical laboratory workers are increasing and outpacing inflation; however, the overall level of wages is still below other positions with similar levels of education in the health care area- an average of $21/hour for lab workers versus $23/hr for a diagnostic medical sonographer and $24/hours for RNs.

The CAP report summarized some key findings. Labs are finding it necessary to substitute lower-paid lesser qualified personnel as well as high-paid, shorter-term personnel to fill staffing needs. The role of automation and its efficiencies is counterbalanced by the growing requirements for more sophisticated and complex testing protocols. There is likely a need for more training programs and educational opportunities to increase the labor force, and cures for the lab personnel shortage will likely have to address salary trends and working conditions. The CAP report states that "many of the strategies are 'macro' in nature and are difficult to control with public policies with the exception of reimbursement and training issues."

The ASCP policy on state licensure of laboratory personnel notes no difference in average wages or labor force supply between states with and without licensure.
Those of you on the ASCP's listserve recently received a summary of their 2006 laboratory wage and vacancy survey. The ASCP reports that almost 44% of laboratories claim current difficulties recruiting or hiring medical personnel, that certified medical technologist staff vacancies were most severe in the Far Western and North Eastern states, that the average hourly wage is rising more slowly (at 3.5% annually versus about 7% between 2003 and 2005), and that about 30% of labs indicate non-traditional working shifts for their staffs to accommodate needs.

4. CLIA '88 PERSONNEL STANDARDS

Personnel standards under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) were published in the Federal Register in 1992. CLIA '88 was passed in response to problems reported in cytology laboratories and resulted in educational requirements across the clinical laboratory that were greater than those in CLIA '67. These standards defined personnel standards according to the test complexity level of the laboratory (waived, provider performed microscopy, moderate complexity, and high complexity) and required explicit assessments of personnel competency.

The standards under CLIA '88 are, in general, as follows:
Waived testing: no standards
Moderate Complexity: minimum requirement of a high school diploma or equivalent and documentation of training for testing performed.
High complexity: minimum requirement of an associate degree with an accredited or approved clinical laboratory training program or appropriate laboratory training in the specialty in which the individual performs testing.
General supervisor: Bachelor's degree in suitable field with at least 1 year experience with high complexity testing OR associate degree in suitable field with at least 2 years experience with high complexity testing.

5. POLICY STATEMENTS FOR LICENSURE OF LABORATORY PERSONNEL

Eleven states plus Puerto Rico have state laboratory licensure laws. All but New York's were passed prior to CLIA '88- meaning states were trying to deal with some of the issues that CLIA '88 eventually addressed with regard to personnel standards. And today, many of the staffing issues facing laboratories are not related to inadequate personnel standards- they are problems due to the shortage of qualified individuals.

- College of American Pathologists

The CAP Council on Government and Professional Affairs approved a policy on licensure in October of 2003 that states it is the policy of the College of American Pathologists that clinical laboratory scientists and other laboratory personnel are sufficiently regulated by the federal requirements and standards of CLIA '88. State laws requiring the licensure and regulation of laboratory personnel are unnecessary and increase administrative burdens without improving patient care. The College believes that it is the appropriate responsibility of the laboratory director, consistent with CLIA requirements, to select, assign and qualify persons for laboratory positions.

- American Society for Clinical Pathology (licensure policy approved June 2005)

The ASCP policy on state licensure of laboratory personnel states that "because the important work performed by the laboratory professional affects the health, safety and welfare of the public, the American Society for Clinical Pathology believes that states should license laboratory personnel." This policy (available on their website) notes that their "review of the literature has not revealed any studies that have directly examined the question of whether licensure of laboratory practitioners improves test quality; however, there are studies that provide support for the idea that education, training and/or experience, and certification of laboratory personnel are linked to higher quality testing and performance." The supportive articles quoted in the policy rely on studies comparing the results of proficiency testing performed in physician office laboratories and waived testing facilities versus such testing in hospital or independent laboratory settings. The ASCP policy advocates equivalent personnel standards and licensure for all testing sites; however, state licensure bills, including New York's, exempt physician office laboratories (POLs) from licensure.

The ASCP also has a policy on personnel standards for laboratory professional in which they state that such standards should include academic and clinical training, competency examinations by an approved national certification organization, and continuing competency standards. These standards assert that technologists should have a bachelor's degree from an accredited or approved training program or specified work experience, and that technicians should have an associate degree from an accredited or approved medical laboratory training program.

- American Society for Clinical Laboratory Science (licensure policy approved July 2006)

A position paper of the ASCLS for laboratory personnel licensure states that "laboratory personnel licensure is essential to protect the public from substandard laboratory services and possibly misleading information by assuring that only adequately educated and qualified individuals perform testing." Their paper notes that the society, as well its predecessor, the American Society for Medical Technology, has supported licensure as far back as 1977. They further note that when CLIA '88 "developed into a facility regulation with personnel standards inadequate to protect the public, ASMT renewed its efforts to press for state licensure to accomplish this goal. The ASCLS paper quotes no objective studies from the literature to support their position relating licensure to testing quality.

Ironically, the ASCLS also has a position paper on independent practice in which they state that clinical laboratory testing "is the defined practice of qualified clinical laboratory personnel and includes the performance, supervision, direction and interpretation of laboratory testing." In other words, the ASCLS advocates that "(t)he current economic and regulatory healthcare environment benefits from expanded roles for non-physician allied health professionals in order to provide quality, cost-effective assessment, diagnosis, treatment and information for healthcare consumers." No supportive references are quoted in this policy and one is left to wonder if such expansion of the scope of practice by non-physicians would (to paraphrase their licensure policy) protect the public from substandard and misleading assessment, diagnosis, and treatment.

6. THE NY CLINICAL LABORATORY TECHNOLOGY PRACTICE ACT: THE LAW AND THE REGULATIONS

The New York legislature had been presented with several precursor licensure bills over the years preceding passage of the clinical laboratory technology practice act in 2004. At the 2002 Assembly hearings on a licensure bill, Harriet B. Rolen-Mark, MA, MT(ASCP) presented the views of the ASCP. During her testimony, Ms. Rolen-Mark stated that "licensure can be an effective tool to strengthen the quality of laboratory testing" and the ASCP appreciated "efforts to license medical laboratory personnel in New York." However, the ASCP had several criticisms of the 2002 bill: it did not require medical technologists to have a bachelor's degree, it did not require medical lab technicians to have an associate degree, there was no continuing education requirement, and although the bill required an examination it did not specify a "competency-based national certification examination."

The successful 2004 bill addressed the issues raised by the ASCP; however, given that the current New York regulations would deny future employment to MT(ASCP) and MLT(ASCP) candidates, the ASCP has distanced itself from the New York licensure bill. In a recent communication to their members, the ASCP noted that New York's approach to licensure appears markedly different than that of almost every other licensure state. Furthermore, they noted that "those considering possible employment in New York, even if it is years from now, should consider applying for licensure now." In other words, the ASCP certification standards don't meet the qualifications demanded of New York's licensure bill.

It is generally acknowledged that beyond the support of such organizations as the ASCP and ASCLS for state licensure, the New York bill was passed due to the enthusiastic support of 1199 SEIU United Healthcare Workers East. Senator Michael Balboni of Nassau County was the important Senate sponsor. Because this is a licensure bill, its implementation is under the jurisdiction of the State Education Department (SED) and not the Department of Health (DOH). Many pathologists in New York, who are licensed by the SED, have a certificate of qualification (C of Q) from the DOH and work in laboratories accredited and licensed by the DOH.

The following 6 sections discuss major problem areas with the bill and the regulations. Four of them are within the power of the SED to fix (regulatory relief). Two of them (limited permits and point-of-care testing) will need legislative relief. You may have additional issues that should be addressed in your communications to the SED.

I. Categories of Clinical Laboratory Practitioners

- LANGUAGE OF THE LAW: The actual language of the bill defines 3 categories of clinical laboratory practitioners: clinical laboratory technologist, clinical laboratory technician, and clinical laboratory cytotechnologist. The bill's language often mimics ASCP's language, including defining clinical laboratory technology to mean "the performance of microbiology, virological, serological, chemical…..cytological or histological procedures." This "or" is very important as it acknowledges that there is subspecialization within the clinical laboratory and effectively allows the SED to define subcategories under the 3 main laboratory personnel categories
- THE REGULATION: The regulations do not recognize subcategorization, despite long-standing practice in the clinical laboratory. The SED, in its implementation of the law, changed the "or" in the law's definitions to an "and" in the regulations. This little change essentially removed the subspecialties, including that of histotechnology and led to the board's decision to mandate that medical technology and technician programs include histological techniques. However, there has been less discussion about other categories of workers in the lab- the grossing assistants, the prep techs, and pathologists' assistants (who now have an ASCP certifying examination). Those who have attempted to ask the SED for clarification on these employees have been told "to read the regulations

and applications forms." In other words, the SED has no clue about who works in the laboratory and how best to define them, leaving laboratories and their employees to try to decide which of the 3 categories (each with its own application form) is a "best fit."

- IMPACT: As currently written, the regulations erase the subspecialty of histotechnology, and possibly pathologists' assistants, and require that medical technology and medical technician programs incorporate histological techniques into their programs.
- REMEDY: The SED has the authority to establish subcategories of laboratory clinical practitioners based upon the language of the law and a proper understanding of the practice of clinical laboratory science.

II. Educational Requirements

- LANGUAGE OF THE LAW: The actual language of the bill allows for the education of clinical laboratory technologists to include "a bachelor's degree in clinical laboratory technology from a program registered by the department or determined by the department to be the substantial equivalent, or have received a bachelor's degree that includes a minimum number of credit hours in the sciences and received appropriated clinical education in an accredited clinical laboratory technology program or a program to be determined by the department to be the substantial equivalent."
- REGULATION: The curriculum requirements of the regulations require generalized laboratory training (e.g. inorganic chemistry, microbiology, hematology) plus histological techniques for all those who are classified as technologists or technicians. With respect to histotechnology, the level of complexity of the coursework greatly exceeds that necessary for successful performance as a histotechnologist. Similar concerns are being raised about other subspecialties, such as pathologist's assistant, where such coursework is unrelated to the educational and training needs of these employees.
- IMPACT: The current interpretation of the curriculum requirements is at once too broad and too narrow and the overall effect is devastating to the laboratories of New York. The current SED regulations would prohibit laboratories from hiring specialized employees with suitable associate degrees, bachelor's degrees, or post-doctoral degrees in critical areas such as microbiology, molecular methods, blood banking, histotechnology, and gross room assisting (pathologists' assistant), because they do not meet the criteria for a generalized laboratory education. Not only will this inevitably lead to an exacerbation of the shortage of clinical laboratory personnel in NY, it will also make it virtually impossible for New York doctoral-level staff to gain the experience they need to obtain a certification of qualification (C of Q) from the NYSDOH.
- REMEDY: The law allows for education that has been "determined by the department to be the substantial equivalent." Given that that the law allows for subcategorization, the SED has the authority to interpret the curriculum requirements as to bring them into alignment with reasonable and necessary personnel standards.

III. Certifying Examinations

- LANGUAGE OF THE LAW: The law mandates that laboratory practitioners "pass an examination satisfactory to the board" except for those who qualify under the grandfathering exemptions.
- REGULATION: As currently written, the regulations force all clinical laboratory practitioners to take 1 of 3 certifying examinations, regardless of the needs of the employee's subspecialty (e.g. histotechnology, pathologists' assistant).
- IMPACT: Because the SED does not recognize subcategorization of clinical laboratory practitioners, the current regulations do not allow for subspecialty certification. As with the educational requirements, these generalized examinations will sometimes be unrelated to the educational and

training background of certain crucial employees and the needs of specialized testing areas in the clinical laboratory. In addition, the advisory board is currently looking at vendors of certifying examinations- suggesting that the SED will develop, with a sole vendor, a single NY examination that will exclude examinations offered for other national certifying organizations.

- REMEDY: The SED has the authority to make the necessary changes in the regulations with regard to employee categorizations and educational requirements, and to accept results of all national certifying examinations in the relevant categories and subcategories. In addition, it is paramount that the SED embrace the concept of permanent limited permits.

IV. Limited Permits

- LANGUAGE OF THE LAW: The law included allowances for limited permits for those individuals who could not meet the grandfather clauses. The law allows for a 2 year period during which otherwise qualified individuals may register under a limited permit prior to taking a certifying examination.
- REGULATION: Unfortunately, the SED is bound by the language of the law.
- IMPACT: There are many vital laboratory practitioners with the appropriate and necessary education, training, or experience to work in specialized areas of the clinical laboratory (e.g. microbiology, molecular methods,) who not meet educational and certification requirements of the regulations. Many of these individuals have associate degrees, bachelor's degrees, master's degrees, and even PhDs with education and training in vital areas of medical testing. If this law is allowed to stand as written, New York laboratories will be prohibited from hiring the most suitable candidates, to the greater harm of the citizens of New York.
- REMEDY: There must be legislative relief to allow for permanent limited permits.

V. Point-of-Care Testing

- LANGUAGE OF THE LAW: Although the law exempts testing activities performed by physicians, physician assistants, dentists, podiatrists, nurse practitioners, respiratory therapists, and respiratory therapy technicians, the law makes no exemption for testing performed by nurses or other employees trained in point of-care hospital, clinic, or limited testing sites with NYSDOH licenses.
- REGULATION: Unfortunately, the SED is bound by the language of the law.
- IMPACT: Many essential health care and public health programs are dependant on the point-of-care waived tests performed by personnel without formal laboratory training who, nonetheless, are trained to perform specific waived tests.
- REMEDY: There must be legislative relief to allow for waived testing procedures to be performed by individuals qualified to perform such testing by virtue of specific education and training.

VI. Out-of-State Licensed Laboratory Exemptions

- LANGUAGE OF THE LAW: There is no specific wording in the statue allowing for the exemption of out-of-state clinical laboratories.
- REGULATION: The SED has chosen to exempt out-of-state clinical laboratories with a New York Department of Health (NYSDOH) license from compliance with the statute.
- IMPACT: From a logical point of view, any law regulating medical testing and purportedly meant to protect the health of New York's citizens, should apply to all labs supplying medical testing to New Yorkers. A significant portion of testing performed on New York State citizens is performed in out-or-state laboratories, often by very large national commercial laboratories. This outrageous exemption

results in a significant competitive disadvantage to New York State laboratories with regard to their ability to recruit and hire adequately trained and suitable staff.

- REMEDY: The SED can immediately rescind the out-of-state exemption. There is no specific wording in the statue allowing for the exemption of out-of-state clinical laboratories. Title V of the NYS Public Health Law mandates that out-of-state clinical laboratories performing testing on NY patients must obtain a permit from NYSDOH. The language of the Chapter 755 states that "clinical laboratory technology" means the "performance of….procedures and examinations and any other test or procedure conducted by a laboratory as defined by title five of article five of the public health law…" Furthermore, the law states that a "clinical laboratory practitioner" means those "who work in licensed clinical laboratories."