

HOUSE No. 2228

The Commonwealth of Massachusetts

PETITION OF:

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In the Year Two Thousand and Seven.

AN ACT PROVIDING FOR THE LICENSURE AND REGULATION OF CLINICAL
LABORATORY SCIENCE PRACTITIONERS AND FOR RELATED PURPOSES .

*Be it enacted by the Senate and House of Representatives in General Court
assembled, and by the authority of the same, as follows:*

SECTION 1. Short Title.
Chapter 13 of the General Laws, as appearing in the 2002 Official Edition, is hereby amended by inserting at the end thereof the following sections, which shall be known and may be cited as the *Clinical Laboratory Science Practice Act*.

SECTION 2. Declaration of Policy and Statement of Purpose.
It is hereby declared to be a policy of the Commonwealth that the practice of clinical laboratory science by health care professionals affects the public health, safety and welfare and is subject to control and regulation in the public interest. It is further declared that clinical laboratories and clinical laboratory science practitioners provide essential services to practitioners of the healing arts by furnishing vital information which may be used in the diagnosis, prevention and treatment of disease or impairment, and the assessment of the health of humans. The purpose of this Act is to provide for the better protection of public health by providing minimum qualifications for clinical laboratory science practitioners, and by ensuring that clinical laboratory tests are performed with the highest

degree of professional competency by those engaged in providing such services in the Commonwealth.

SECTION 3. Definitions.

The following words and terms when used in this Act shall have the following meanings unless otherwise indicated within the context:—

(1) “Accredited clinical laboratory program” means a program planned to provide a predetermined amount of instruction and experience in clinical laboratory science that has been accredited by one of the accrediting agencies recognized by the U.S. Department of Education.

(2) “Board” means the Board of Registration of Clinical Laboratory Science Practitioners within the Division of Professional Licensure.

(3) “Clinical laboratory test” or “laboratory test” means a microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunological or other pathological examination which is performed on material derived from the human body, or any other test or procedure conducted by a laboratory or facility which provides information for the diagnosis, prevention or treatment of a disease or assessment of a human medical condition.

(4) “Clinical laboratory” or “laboratory” means any facility or office in which clinical laboratory tests are performed.

(5) “Clinical laboratory science practitioner” or “one who engages in the practice of clinical laboratory science” means a health care professional who performs clinical laboratory tests or who is engaged in management, education, consulting or research in clinical laboratory science, and includes laboratory directors, supervisors, clinical laboratory scientists (technologists), specialists, and technicians working in a laboratory, but does not include persons employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests and does not include clinical laboratory trainees.

(6) “Clinical laboratory scientist” (technologist) means a person who performs tests pursuant to established and approved protocols requiring the exercise of independent judgment and responsibility, maintains equipment and records, performs quality assurance activities related to test performance, and may supervise and teach within a clinical laboratory setting.

(7) “Clinical laboratory technician” means a person who performs laboratory tests pursuant to established and approved protocols which require limited exercise of independent judgment and which are performed under the personal and direct supervision of a clinical laboratory scientist (technologist), laboratory supervisor, or laboratory director.

(8) “Division” means the Division of Professional Licensure.

(9) “Limited function test” means a test conducted using procedures which, as determined by the board, have an insignificant risk of an erroneous result, including those which:—

- (a) have been approved by the United States Food and Drug Administration for home use; or
- (b) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- (c) the board has determined pose no reasonable risk of harm to the patient if performed incorrectly.

SECTION 4. Exemptions.
This Act does not apply to:

- (1) Any person licensed in the Commonwealth under any other Act from engaging in the practice for which he is licensed.
- (2) Clinical laboratory science practitioners employed by the United States government or any bureau, division or agency thereof while in the discharge of the employee's official duties.
- (3) Clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis or treatment of disease.
- (4) Students or trainees enrolled in a clinical laboratory science education program provided that these activities constitute a part of a planned course in the program, that the persons are designated by title such as intern, trainee, or student, and the persons work directly under an individual licensed by this state to practice clinical laboratory science.
- (5) Individual performing only limited function tests.
- (6) Persons incidentally in this state to provide service as part of an emergency response team working in conjunction with disaster relief officials.

SECTION 5. License Required.

- (1) No person shall practice clinical laboratory science or hold himself out as a clinical laboratory science practitioner in this State unless he is licensed under this Act.
- (2) All persons engaged in the practice of clinical laboratory science on the date of enactment of this Act (existing practitioners), are certified by or eligible for certification by an Agency acceptable to the board, and who have applied to the board on or before the effective date and have complied with all necessary requirements for such application may continue to perform clinical laboratory tests until (1) the expiration of 12 months after the filing of such application, or (2) the denial of the application by the board, or (3) the withdrawal of the application, whichever occurs first.
- (3) Persons not meeting the education, training, and experience qualifications for any license described in this Act may, prior to twenty-four (24) months after the effective date of the board's regulation, be considered to have met qualifications providing they have three (3) years acceptable experience immediately prior to the effective date of the board's regulation and submit to the board the job

description of the position which the applicant has most recently performed, attested to by his/her employer and notarized.
 (4) Effective 24 months after the effective date of the board's regulation, no initial license shall be issued until an applicant meets all of the requirements under this Act and successfully completes a nationally recognized certification examination, or an appropriate categorical or specialty exam recognized by the board.

SECTION 6. Administration.
 There shall be a Board of Registration of Clinical Laboratory Science Practitioners, herein called the board, within the Division of Professional Licensure, which shall consist of seven (7) members, appointed by the governor, who have been residents of the Commonwealth for at least two years prior to their appointments and who are actively engaged in their areas of practice. Appointments to the board will be made after consulting lists submitted by organizations of clinical laboratory science practitioners and organizations of physician pathologists.
 The board shall be composed of:—
 (1) One physician certified by the American Board of Pathology or American Board of Osteopathic Pathology;
 (2) Four clinical laboratory science practitioners, at least one of whom is a non-physician laboratory director, one of whom is a clinical laboratory scientist (technologist), and one of whom is a clinical laboratory technician, and who, except for the initial appointments, hold active and valid licenses as clinical laboratory science practitioners in this state; and
 (3) Two public members who are not associated with or financially interested in the practice of clinical laboratory science.
 Board members shall serve for a term of three years and until their successors are appointed and qualified, except that the initial appointments, which shall be made within 90 days after the effective date of this Act, shall be as follows:—
 (1) A pathologist, a non-physician laboratory director, and a clinical laboratory scientist shall be appointed to serve for three years;
 (2) A public representative shall be appointed to serve for two years; and
 (3) The remaining members shall be appointed to serve for one year.
 Whenever a vacancy shall occur on the board by reason other than the expiration of a term of office, a successor of like qualifications shall be appointed for the remainder of the unexpired term. No person shall be appointed to serve more than two successive 3-year terms.
 The members of the board shall be public employees for the purposes of chapter 258 for all acts or omissions within the scope of their duties as board members.

SECTION 7. Duties and Powers of the board.
 In addition to powers conferred elsewhere in this Act, board shall:—

- (1) prescribe, publish, adopt and amend rules and regulations for the implementation of this Act including but not limited to regulations that delineate qualifications for licensure of clinical laboratory science practitioners; specify requirements for the renewal of licensure; establish standards of professional conduct; and have power to amend or repeal the same. Following their adoption, the rules and regulations shall govern and control the professional conduct of every person who holds a license to perform clinical laboratory tests or otherwise engages in the profession of clinical laboratory science;
- (2) authorize or administer standard written oral or practical examinations for purposes of licensure of clinical laboratory science practitioners as provided for in Section 5 of this Act;
- (3) promulgate rules and regulations governing qualifications for licensure of specialists in such clinical laboratory science specialties as the board may determine in accordance with Section 8(3) herein;
- (4) promulgate rules and regulations governing personnel performing tests in limited function laboratories;
- (5) establish criteria for the continuing education of clinical laboratory science practitioners as required for license renewal.

SECTION 8. Standards for Licensure.

- (1) Clinical Laboratory Scientist (Technologist). The board shall issue a clinical laboratory scientist's license to an individual who meets such qualifications as promulgated by the board, including at least one of the following qualifications:—
 - (a) A baccalaureate degree in clinical laboratory science (medical technology) from an accredited college or university whose curriculum included appropriate clinical education;
 - (b) A baccalaureate degree in biological, chemical or physical science from an accredited college or university, and subsequent to graduation has at least 12 months of appropriate clinical education in an accredited clinical laboratory science program;
 - (c) A baccalaureate degree which includes a minimum of thirty-six (36) semester (or equivalent) hours in the biological, chemical and physical sciences from an accredited college or university plus two years of full-time work experience including a minimum of four months in each of the four major disciplines of laboratory practice (clinical chemistry, clinical microbiology, hematology, immunology/immunoematology); or
 - (d) A baccalaureate degree consisting of 90 semester (or equivalent) hours, thirty-six of which must be in the biological, chemical or physical sciences, from an accredited university, and appropriate clinical education in an accredited clinical laboratory science program.
 - (e) A clinical laboratory scientist (technologist) who previously qualified under federal regulatory requirements such as 493.1433 of the March 14, 1990 Federal

Register or other regulations or criteria which may be established by the board.
 (f) A doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, the American Board of Medical Genetics, or other agencies deemed comparable by the board and has at least one year of pertinent full time laboratory training or experience.

(2) Clinical Laboratory Technician.

The board shall issue a clinical laboratory technician's license to an individual who meets such qualifications as promulgated by the board, including at least one of the following qualifications:—

(a) An associate degree or completion of sixty (60) semester (or equivalent) hours from a clinical laboratory technician program (CLT or equivalent) accredited by an agency recognized by the U.S. Department of Education that included a structured curriculum in clinical laboratory techniques;

(b) A high school diploma (or equivalent) and (a) completion of 12 months in a technician training program in an accredited school approved by the board; or
 (b) successful completion of an official military medical laboratory procedure course of at least 50 weeks duration and has held the military enlisted occupational specialty of medical laboratory specialist (laboratory technician);
 or

(c) A clinical laboratory technician who previously qualified under federal regulatory requirements such as 493.1441 of the March 14, 1990 Federal Register which meet or exceed the requirements for licensure set forth by the Board.

(3) Clinical Histotechnologist.

The board shall issue a Clinical Histotechnologist license to an individual who meets such qualifications as promulgated by the board, including at least one (1) of the following:—

(a) a baccalaureate degree which includes a combination of 30 semester hours of biological and chemical science coursework and successful completion of an accredited program in histotechnology.

(b) a baccalaureate degree which includes a combination of 30 semester hours of biological and chemical science coursework and completion of one full year post-baccalaureate experience in an histopathology laboratory under the supervision of a histotechnologist or certified histotechnology supervisor with at least three (3) years experience.

(4) Clinical Histologic Technician.

The board shall issue a Clinical Histologic Technician license to an individual who meets such qualifications as promulgated by the board, including at least one (1) of the following:—

(a) an associate degree or at least sixty (60) semester hours (or equivalent) from

an accredited college/university to include a combination of mathematics and at least twelve (12) semester hours of biology and chemistry, and successfully completes an accredited program in histologic technique or one full year of training in histologic technique under the supervision of a certified cytotechnologist or an appropriately certified histopathology supervisor with at least three (3) years experience.

(b) high school graduation (or equivalent) and completion of an accredited program or two years full time acceptable experience at a licensed clinical laboratory in histologic technique.

(5) Cytotechnologist.

The board shall issue a Cytotechnologist license to an individual who meets such qualifications as promulgated by the board including at least one (1) of the following:—

(a) a baccalaureate degree from an accredited college or university with twenty (20) semester hours (30 quarter hours) of biological science, eight (8) semester hours (12 quarter hours) or chemistry and three (3) semester hours (4 quarter hours) of mathematics and successful completion of a twelve (12) month cytotechnology program.

(b) a baccalaureate degree from an accredited college or university with twenty (20) semester hours (30 quarter hours) of biological science, eight (8) semester hours (12 quarter hours) of chemistry and three (3) semester hours (4 quarter hours) of mathematics and five (5) years full time acceptable clinical laboratory experience including cytopreparatory techniques, microscopic analysis and evaluation of the body systems within the last ten (10) years. At least two of these years must be subsequent to the completion of the academic component and at least two (2) years must be under the supervision of a licensed physician who is a pathologist, certified, or eligible for certification, by the American Board of Pathology in Anatomic Pathology or has other suitable qualification acceptable to the board.

(c) a cytotechnologist who previously qualified under federal regulatory requirements such as 493.1437 of the March 14, 1990 Federal Register.

(6) The board shall issue a Clinical Laboratory Science/Cytogenetic license to an individual who meets such qualifications as promulgated by the board including at least one (1) of the following:—

(a) a baccalaureate degree from an accredited college or university majoring in either biology, chemistry or clinical laboratory science and two years experience in clinical cytogenetics in the performance of diagnostic tests; or

(b) successful completion of a nationally recognized certification examination such as the National Certification Agency (NCA), Department of Health and Human Service (DHHS), American Board of Medical Genetics (ABMG), or others as may be recognized by the board.

(7) The board may establish standards for such other clinical laboratory science practitioners specializing in areas such as biophysics, chemistry, cytology,

hematology, histologic technique, immunohematology, microbiology, serology, nuclear medical technology, or similar recognized academic and scientific disciplines.

SECTION 9. Waiver of Requirements.
The board shall promulgate regulations providing procedures for waiver of the requirements under Section 8 for all applicants who hold a valid license or its equivalent issued by another jurisdiction; provided that the requirements under which that license or its equivalent was issued to or exceed the standards required by this Act.

SECTION 10. Licensure Application Procedures.
(1) Licensure applicants shall submit their application for licensure to the board in the manner prescribed by the board, and shall pay the designated application fee as determined by the secretary of administration and finance.
(2) Upon approval of an application and payment of a license fee, as determined by the secretary of administration and finance, the board shall issue a license for a Clinical Laboratory Scientist (technologist), a Clinical Laboratory Technician, Histologic Technologist, Histologic Technician, Cytotechnologist or an appropriate specialty license to any person who meets the qualifications specified in this Act and the regulations promulgated hereunder.
(3) The board may establish by regulation a procedure for issuance of provisional licenses to individuals who otherwise qualify under this Act but are awaiting the results of certification examinations. A provisional license so issued shall be converted to a license under the provision of Section 10 or expire not more than twelve (12) months after issuance. At the discretion of the board, the provisional license may be reissued at least one time.
(4) The board, subject to a vote of the majority of its members, is authorized to deny a license on the following grounds:
(a) conviction by a court of competent jurisdiction of a crime which the board determines to be of such a nature as to render such person unfit to practice as a laboratory scientist.
(b) violation of ethical standards of such a nature as to render such individual unfit to practice as laboratory scientist.
(c) fraud or misrepresentation in obtaining a license; or
(d) other just and sufficient cause which renders a person unfit to practice as a laboratory scientist.
(5) All fees collected pursuant to this section shall be deposited in the division of professional licensure trust fund established under chapter 10, section 35V.

SECTION 11. Licensure Renewal.
(1) Licenses issued under this Act shall expire every two years on the birthday of the licensee, with the exception that the term of initial licenses shall vary so

as to fall on a subsequent birthday.

(2) Every person licensed under this Act shall be issued a renewal license upon:

(a) Submission of an application for renewal in the manner prescribed by the board and payment of an appropriate fee determined by the secretary of administration and finance; and

(b) Proof of completion, in the period since the license was first issued or last renewed, of at least twenty hours of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to clinical laboratory practice which are approved or accepted by the board; or proof of recertification by a board-approved, national certification organization that mandates an annual minimum of twenty hours of continuing education.

(3) The board may require other such evidence of competency as it shall deem reasonably appropriate as a prerequisite to the renewal of any license provided for in this Act, so long as such requirements are uniform as to application, are reasonably related to the measurement of qualification, performance, or competence, and are desirable and necessary for the protection of the public health.

(4) All fees collected pursuant to this section shall be deposited in the division of professional licensure trust fund established under chapter 10, section 35V.

SECTION 12. Effective Date.
This Act shall take effect on January 1, 2005.

SECTION 13. Disciplinary Requirements.

Complaints alleging any violation of this chapter or board regulation may be initiated by any person or by the board. The board shall investigate all complaints relating to the proper practice of laboratory science and alleging any violation of this chapter or any rule or regulation of said board. The board may discipline the licensee if such a licensee has:

(1) engaged in conduct which places into question the holder's competence to practice the profession including, but not limited to, gross misconduct or misconduct in the practice of the profession;

(2) committed fraud or misrepresentation in obtaining a license;

(3) practiced the profession while the ability to practice impaired by alcohol, drugs, physical disability or mental instability;

(4) violated any law, rule or regulation of the board;

(5) been convicted of a criminal offense which reasonably calls into question the holder's ability to practice the profession;

(6) engaged in dishonesty, fraud or deceit which is reasonably related to the practice of the profession;

(7) knowingly permitted, aided, or abetted an unlicensed person to perform activities requiring a license, registration, or authority;

(8) had a license, certificate, registration, or authority issued by another state or

territory of the United States, the District of Columbia, or foreign state or nation with authority to issue such a license, certificate, registration, or authority revoked, canceled, or suspended, not renewed or otherwise acted against, or the license has been disciplined, if the basis for the action would constitute a basis for disciplinary action in the commonwealth;

(9) violated any ethical standard which the board determines to be of such a nature as to render such person unfit to practice as a laboratory scientist, such as:

- (i) inappropriate conduct or touching in the practice of laboratory science;
- (ii) negligence in the course of professional practice.

The board may, by a majority vote, after a hearing held subject to chapter 30A, impose sanctions on an individual practicing laboratory science. The board may undertake the following actions:

- (1) suspend, revoke, cancel or place on probation such license, certificate, registration or authority;
- (2) reprimand or censure a licensee;
- (3) assess upon such licensee an administrative penalty not to exceed \$1,000 for the first violation and an administrative penalty not to exceed \$2,500 for a second and any subsequent violation;
- (4) require such licensee to complete additional education and training as a condition of retention or future consideration or reinstatement of said license;
- (5) require such licensee to practice under appropriate supervision for a period of time as determined by the board as a condition of retention or future consideration of reinstatement of such license;
- (6) require such licensee to participate in medical treatment, mental health treatment, a substance abuse program, or a combination thereof, as a condition of retention or future consideration of reinstatement of said license, and
- (7) require restitution where appropriate.

The board may, by emergency action summarily suspend or refuse to renew the license of any licensee, whose continued practice poses an immediate threat to the public health, safety or welfare, pending a hearing on the merits of the allegation against the licensee, provided that the board shall hold a hearing pursuant to chapter 30A on the necessity for the emergency action within 10 days of the action. The board shall issue to the licensee a written summary suspension or refusal to renew which specifies the findings of the board and the reasons for its action and which includes notice of the date, time and place of the aforementioned 10-day hearing. At the request of the licensee, the board may reschedule this hearing to a date and time mutually agreeable to the board and licensee. Any such rescheduling of the hearing granted at the licensee's request shall not operate to lift or stay the summary suspension order. If such hearing is not held within 10 days of the board's emergency action or at such time as mutually agreed by the board and licensee, the license, against whom summary action was taken shall be deemed reinstated. At the hearing on the necessity for summary suspension or refusal to renew, the board shall receive evidence

limited to determining whether the summary suspension order shall continue in effect pending the final disposition of the complaint. Following such hearing, any continuing suspension imposed by a board shall remain in effect until the conclusion of any formal proceeding on the merits of the allegations against the holder, including judicial review thereof or withdrawn by such board. The board shall develop rules and regulations governing the emergency summary suspension procedure authorized by this section. Nothing in this section shall be deemed a limitation on the board's authority to impose such sanctions by consent agreement as are deemed reasonable and appropriate by the board. Any person aggrieved by any disciplinary action taken by the board may, pursuant to section 14 of chapter 30A, file a petition for judicial review of such disciplinary action with the superior court. The superior court shall have exclusive jurisdiction over all such petitions, and any such petition shall be limited to a review of the administrative record before the board. All administrative penalties assessed pursuant to this section shall be deposited in the General Fund.

SECTION 14. Unlicensed Practice.
The board may assess and collect an administrative penalty not to exceed \$1,000 for the first violation and an administrative penalty not to exceed \$2,500 for a second and any subsequent violation, per occurrence, upon any person who practices laboratory science at a time when his or her license to practice is not valid because it has been suspended, revoked or canceled under authority of this chapter, and upon any person who knowingly practices laboratory science at a time when his or her license authorizing him or her to do so has expired. The board may make application to the appropriate court for an order enjoining unlicensed practice and obtaining a restraining order or other order as may be appropriate. All administrative penalties assessed pursuant to this section shall be deposited in the General Fund. Except as otherwise permitted by law, the board, after a hearing held pursuant to chapter 30A, may assess and collect an administrative penalty not to exceed \$1,000 for the first violation and an administrative penalty not to exceed \$2,500 for a second and any subsequent violation, per occurrence, upon any person who, without holding the required license engages in the practice of laboratory science. The provisions of this section shall not affect, but shall be in addition to, any other penalty or remedy provided by law. The board may make application to the appropriate court for an order enjoining unlicensed practice, or ordering payment of any assessed administrative penalty, or both. All administrative penalties assessed pursuant to this section shall be deposited in the General Fund.

SECTION 15. Roster of Licenses. The board shall maintain a roster of the names and addresses of persons licensed and registered under the provision of this Act, and of all persons whose licenses have been suspended or revoked.

SECTION 16. Severability. The provisions of this Act are severable. If any part of this shall be declared invalid or unconstitutional, such declaration shall not affect the parts which remain.