

HOUSE No. 2142

The Commonwealth of Massachusetts

PRESENTED BY:

John F. Quinn

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act providing for the licensure and regulation of clinical laboratory science practitioners and for related purposes.

PETITION OF:

NAME:

John F. Quinn

DISTRICT/ADDRESS:

9th Bristol

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 2228 OF 2007-2008.]

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

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:

- 1 SECTION 1. Short Title.
2 Chapter 13 of the General Laws, as appearing in the 2002 Official Edition, is hereby amended by inserting at the end
3 thereof the following sections, which shall be known and may be cited as the *Clinical Laboratory Science Practice*
4 SECTION 2. Declaration of Policy and Statement of Purpose.
5 It is hereby declared to be a policy of the Commonwealth that the practice of clinical laboratory science by health
6 care professionals affects the public health, safety and welfare and is subject to control and regulation in the public
7 interest. It is further declared that clinical laboratories and clinical laboratory science practitioners provide essential
8 services to practitioners of the healing arts by furnishing vital information which may be used in the diagnosis,
9 prevention and treatment of disease or impairment, and the assessment of the health of humans. The purpose of this
10 Act is to provide for the better protection of public health by providing minimum qualifications for clinical
11 laboratory science practitioners, and by ensuring that clinical laboratory tests are performed with the highest degree
12 of professional competency by those engaged in providing such services in the Commonwealth.
13 SECTION 3. Definitions.
14 The following words and terms when used in this Act shall have the following meanings unless otherwise indicated
15 within the context:—
16 (1) “Accredited clinical laboratory program” means a program planned to provide a predetermined amount of
17 instruction and experience in clinical laboratory science that has been accredited by one of the accrediting agencies
18 recognized by the U.S. Department of Education.
19 (2) “Board” means the Board of Registration of Clinical Laboratory Science Practitioners within the Division of
20 Professional Licensure.
21 (3) “Clinical laboratory test” or “laboratory test” means a microbiological, serological, chemical, hematological,
22 radiobioassay, cytological, biophysical, immunological or other pathological examination which is performed on
23 material derived from the human body, or any other test or procedure conducted by a laboratory or facility which
24 provides information for the diagnosis, prevention or treatment of a disease or assessment of a human medical
25 condition.
26 (4) “Clinical laboratory” or “laboratory” means any facility or office in which clinical laboratory tests are
27 performed.
28 (5) “Clinical laboratory science practitioner” or “one who engages in the practice of clinical laboratory science”
29 means a health care professional who performs clinical laboratory tests or who is engaged in management,
30 education, consulting or research in clinical laboratory science, and includes laboratory directors, supervisors,

31 clinical laboratory scientists (technologists), specialists, and technicians working in a laboratory, but does not
32 include persons employed by a clinical laboratory to perform supportive functions not related to direct performance
33 of laboratory tests and does not include clinical laboratory trainees.

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

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

42 (8) "Division" means the Division of Professional Licensure.

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

45 (a) have been approved by the United States Food and Drug Administration for home use; or

46 (b) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible;
47 or

48 (c) the board has determined pose no reasonable risk of harm to the patient if performed incorrectly.

49 SECTION 4. Exemptions.

50 This Act does not apply to:

51 (1) Any person licensed in the Commonwealth under any other Act from engaging in the practice for which he is
52 licensed.

53 (2) Clinical laboratory science practitioners employed by the United States government or any bureau, division or
54 agency thereof while in the discharge of the employee's official duties.

55 (3) Clinical laboratory science practitioners engaged in teaching or research, provided that the results of any
56 examination performed are not used in health maintenance, diagnosis or treatment of disease.

57 (4) Students or trainees enrolled in a clinical laboratory science education program provided that these activities
58 constitute a part of a planned course in the program, that the persons are designated by title such as intern, trainee, or
59 student, and the persons work directly under an individual licensed by this state to practice clinical laboratory
60 science.

61 (5) Individual performing only limited function tests.

62 (6) Persons incidentally in this state to provide service as part of an emergency response team working in
63 conjunction with disaster relief officials.

64 SECTION 5. License Required.

65 (1) No person shall practice clinical laboratory science or hold himself out as a clinical laboratory science
66 practitioner in this State unless he is licensed under this Act.

67 (2) All persons engaged in the practice of clinical laboratory science on the date of enactment of this Act (existing
68 practitioners), are certified by or eligible for certification by an Agency acceptable to the board, and who have
69 applied to the board on or before the effective date and have complied with all necessary requirements for such
70 application may continue to perform clinical laboratory tests until (1) the expiration of 12 months after the filing of
71 such application, or (2) the denial of the application by the board, or (3) the withdrawal of the application,
72 whichever occurs first.

73 (3) Persons not meeting the education, training, and experience qualifications for any license described in this Act
74 may, prior to twenty-four (24) months after the effective date of the board's regulation, be considered to have met
75 qualifications providing they have three (3) years acceptable experience immediately prior to the effective date of
76 the board's regulation and submit to the board the job description of the position which the applicant has most
77 recently performed, attested to by his/her employer and notarized.

78 (4) Effective 24 months after the effective date of the board's regulation, no initial license shall be issued until an
79 applicant meets all of the requirements under this Act and successfully completes a nationally recognized
80 certification examination, or an appropriate categorical or specialty exam recognized by the board.

81 SECTION 6. Administration.

82 There shall be a Board of Registration of Clinical Laboratory Science Practitioners, herein called the board, within
83 the Division of Professional Licensure, which shall consist of seven (7) members, appointed by the governor, who
84 have been residents of the Commonwealth for at least two years prior to their appointments and who are actively
85 engaged in their areas of practice. Appointments to the board will be made after consulting lists submitted by
86 organizations of clinical laboratory science practitioners and organizations of physician pathologists.

87 The board shall be composed of:—

- 88 (1) One physician certified by the American Board of Pathology or American Board of Osteopathic Pathology;
89 (2) Four clinical laboratory science practitioners, at least one of whom is a non-physician laboratory director, one of
90 whom is a clinical laboratory scientist (technologist), and one of whom is a clinical laboratory technician, and who,
91 except for the initial appointments, hold active and valid licenses as clinical laboratory science practitioners in this
92 state; and
93 (3) Two public members who are not associated with or financially interested in the practice of clinical laboratory
94 science.

95 Board members shall serve for a term of three years and until their successors are appointed and qualified, except
96 that the initial appointments, which shall be made within 90 days after the effective date of this Act, shall be as
97 follows:—

- 98 (1) A pathologist, a non-physician laboratory director, and a clinical laboratory scientist shall be appointed to serve
99 for three years;
100 (2) A public representative shall be appointed to serve for two years; and
101 (3) The remaining members shall be appointed to serve for one year.

102 Whenever a vacancy shall occur on the board by reason other than the expiration of a term of office, a successor of
103 like qualifications shall be appointed for the remainder of the unexpired term. No person shall be appointed to serve
104 more than two successive 3-year terms.

105 The members of the board shall be public employees for the purposes of chapter 258 for all acts or omissions within
106 the scope of their duties as board members.

107 SECTION 7. Duties and Powers of the board.

108 In addition to powers conferred elsewhere in this Act, board shall:—

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

122 SECTION 8. Standards for Licensure.

123 (1) Clinical Laboratory Scientist (Technologist).

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

- 126 (a) A baccalaureate degree in clinical laboratory science (medical technology) from an accredited college or
127 university whose curriculum included appropriate clinical education;
128 (b) A baccalaureate degree in biological, chemical or physical science from an accredited college or university, and
129 subsequent to graduation has at least 12 months of appropriate clinical education in an accredited clinical laboratory
130 science program;
131 (c) A baccalaureate degree which includes a minimum of thirty-six (36) semester (or equivalent) hours in the
132 biological, chemical and physical sciences from an accredited college or university plus two years of full-time work
133 experience including a minimum of four months in each of the four major disciplines of laboratory practice (clinical
134 chemistry, clinical microbiology, hematology, immunology/immunohematology); or
135 (d) A baccalaureate degree consisting of 90 semester (or equivalent) hours, thirty-six of which must be in the
136 biological, chemical or physical sciences, from an accredited university, and appropriate clinical education in an
137 accredited clinical laboratory science program.
138 (e) A clinical laboratory scientist (technologist) who previously qualified under federal regulatory requirements such
139 as 493.1433 of the March 14, 1990 Federal Register or other regulations or criteria which may be established by the
140 board.
141 (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

143 Board of Bioanalysis, the American Board of Medical Laboratory Immunology, the American Board of Medical
144 Genetics, or other agencies deemed comparable by the board and has at least one year of pertinent full time
145 laboratory training or experience.

146 (2) Clinical Laboratory Technician.

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

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

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

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

158 (3) Clinical Histotechnologist.

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

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

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

166 (4) Clinical Histologic Technician.

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

169 (a) an associate degree or at least sixty (60) semester hours (or equivalent) from an accredited college/university to
170 include a combination of mathematics and at least twelve (12) semester hours of biology and chemistry, and
171 successfully completes an accredited program in histologic technique or one full year of training in histologic
172 technique under the supervision of a certified histotechnologist or an appropriately certified histopathology
173 supervisor with at least three (3) years experience.

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

176 (5) Cytotechnologist.

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

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

182 (b) a baccalaureate degree from an accredited college or university with twenty (20) semester hours (30 quarter
183 hours) of biological science, eight (8) semester hours (12 quarter hours) of chemistry and three (3) semester hours (4
184 quarter hours) of mathematics and five (5) years full time acceptable clinical laboratory experience including
185 cytopreparatory techniques, microscopic analysis and evaluation of the body systems within the last ten (10) years.

186 At least two of these years must be subsequent to the completion of the academic component and at least two (2)
187 years must be under the supervision of a licensed physician who is a pathologist, certified, or eligible for
188 certification, by the American Board of Pathology in Anatomic Pathology or has other suitable qualification
189 acceptable to the board.

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

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

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

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

199 (7) The board may establish standards for such other clinical laboratory science practitioners specializing in areas
200 such as biophysics, chemistry, cytology, hematology, histologic technique, immunohematology, microbiology,
201 serology, nuclear medical technology, or similar recognized academic and scientific disciplines.

202 SECTION 9. Waiver of Requirements.

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

206 SECTION 10. Licensure Application Procedures.

207 (1) Licensure applicants shall submit their application for licensure to the board in the manner prescribed by the
208 board, and shall pay the designated application fee as determined by the secretary of administration and finance.

209 (2) Upon approval of an application and payment of a license fee, as determined by the secretary of administration
210 and finance, the board shall issue a license for a Clinical Laboratory Scientist (technologist), a Clinical Laboratory
211 Technician, Histologic Technologist, Histologic Technician, Cytotechnologist or an appropriate specialty license to
212 any person who meets the qualifications specified in this Act and the regulations promulgated hereunder.

213 (3) The board may establish by regulation a procedure for issuance of provisional licenses to individuals who
214 otherwise qualify under this Act but are awaiting the results of certification examinations. A provisional license so
215 issued shall be converted to a license under the provision of Section 10 or expire not more than twelve (12) months
216 after issuance. At the discretion of the board, the provisional license may be reissued at least one time.

217 (4) The board, subject to a vote of the majority of its members, is authorized to deny a license on the following
218 grounds:

219 (a) conviction by a court of competent jurisdiction of a crime which the board determines to be of such a nature as to
220 render such person unfit to practice as a laboratory scientist.

221 (b) violation of ethical standards of such a nature as to render such individual unfit to practice as laboratory scientist.

222 (c) fraud or misrepresentation in obtaining a license; or

223 (d) other just and sufficient cause which renders a person unfit to practice as a laboratory scientist.

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

226 SECTION 11. Licensure Renewal.

227 (1) Licenses issued under this Act shall expire every two years on the birthday of the licensee, with the exception
228 that the term of initial licenses shall vary so as to fall on a subsequent birthday.

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

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

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

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

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

242 SECTION 12. Effective Date.

243 This Act shall take effect on January 1, 2005.

244 SECTION 13. Disciplinary Requirements.

245 Complaints alleging any violation of this chapter or board regulation may be initiated by any person or by the board.

246 The board shall investigate all complaints relating to the proper practice of laboratory science and alleging any
247 violation of this chapter or any rule or regulation of said board.

248 The board may discipline the licensee if such a licensee has:

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

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

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

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

- 255 (5) been convicted of a criminal offense which reasonably calls into question the holder's ability to practice the
256 profession;
- 257 (6) engaged in dishonesty, fraud or deceit which is reasonably related to the practice of the profession;
- 258 (7) knowingly permitted, aided, or abetted an unlicensed person to perform activities requiring a license,
259 registration, or authority;
- 260 (8) had a license, certificate, registration, or authority issued by another state or territory of the United States, the
261 District of Columbia, or foreign state or nation with authority to issue such a license, certificate, registration, or
262 authority revoked, canceled, or suspended, not renewed or otherwise acted against, or the license has been
263 disciplined, if the basis for the action would constitute a basis for disciplinary action in the commonwealth;
- 264 (9) violated any ethical standard which the board determines to be of such a nature as to render such person unfit to
265 practice as a laboratory scientist, such as:
- 266 (i) inappropriate conduct or touching in the practice of laboratory science;
- 267 (ii) negligence in the course of professional practice.

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

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

281 The board may, by emergency action summarily suspend or refuse to renew the license of any licensee, whose
282 continued practice poses an immediate threat to the public health, safety or welfare, pending a hearing on the merits
283 of the allegation against the licensee, provided that the board shall hold a hearing pursuant to chapter 30A on the
284 necessity for the emergency action within 10 days of the action. The board shall issue to the licensee a written
285 summary suspension or refusal to renew which specifies the findings of the board and the reasons for its action and
286 which includes notice of the date, time and place of the aforementioned 10-day hearing. At the request of the
287 licensee, the board may reschedule this hearing to a date and time mutually agreeable to the board and licensee. Any
288 such rescheduling of the hearing granted at the licensee's request shall not operate to lift or stay the summary
289 suspension order. If such hearing is not held within 10 days of the board's emergency action or at such time as
290 mutually agreed by the board and licensee, the license, against whom summary action was taken shall be deemed
291 reinstated. At the hearing on the necessity for summary suspension or refusal to renew, the board shall receive
292 evidence limited to determining whether the summary suspension order shall continue in effect pending the final
293 disposition of the complaint. Following such hearing, any continuing suspension imposed by a board shall remain in
294 effect until the conclusion of any formal proceeding on the merits of the allegations against the holder, including
295 judicial review thereof or withdrawn by such board. The board shall develop rules and regulations governing the
296 emergency summary suspension procedure authorized by this section.

297 Nothing in this section shall be deemed a limitation on the board's authority to impose such sanctions by consent
298 agreement as are deemed reasonable and appropriate by the board. Any person aggrieved by any disciplinary action
299 taken by the board may, pursuant to section 14 of chapter 30A, file a petition for judicial review of such disciplinary
300 action with the superior court. The superior court shall have exclusive jurisdiction over all such petitions, and any
301 such petition shall be limited to a review of the administrative record before the board. All administrative penalties
302 assessed pursuant to this section shall be deposited in the General Fund.

303 SECTION 14. Unlicensed Practice.

304 The board may assess and collect an administrative penalty not to exceed \$1,000 for the first violation and an
305 administrative penalty not to exceed \$2,500 for a second and any subsequent violation, per occurrence, upon any
306 person who practices laboratory science at a time when his or her license to practice is not valid because it has been
307 suspended, revoked or canceled under authority of this chapter, and upon any person who knowingly practices
308 laboratory science at a time when his or her license authorizing him or her to do so has expired. The board may
309 make application to the appropriate court for an order enjoining unlicensed practice and obtaining a restraining order
310 or other order as may be appropriate. All administrative penalties assessed pursuant to this section shall be deposited

311 in the General Fund.

312 Except as otherwise permitted by law, the board, after a hearing held pursuant to chapter 30A, may assess and
313 collect an administrative penalty not to exceed \$1,000 for the first violation and an administrative penalty not to
314 exceed \$2,500 for a second and any subsequent violation, per occurrence, upon any person who, without holding the
315 required license engages in the practice of laboratory science. The provisions of this section shall not affect, but
316 shall be in addition to, any other penalty or remedy provided by law. The board may make application to the
317 appropriate court for an order enjoining unlicensed practice, or ordering payment of any assessed administrative
318 penalty, or both. All administrative penalties assessed pursuant to this section shall be deposited in the General
319 Fund.

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

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