HOUSE DOCKET, NO. 2140 FILED ON: 1/19/2023

HOUSE . . . . . No. 3628

The Commonwealth of Massachusetts

PRESENTED BY:

Marjorie C. Decker

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 adoption of the accompanying bill:

An Act relative to clinical laboratories.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Marjorie C. Decker	*25th Middlesex*	*1/11/2023*

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HOUSE . . . . . No. 3628

By Representative Decker of Cambridge, a petition (accompanied by bill, House, No. 3628) of Marjorie C. Decker relative to clinical laboratories. Public Health.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

An Act relative to clinical laboratories.

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. Section 2 of chapter 111D of the General Laws, as appearing in the 2020 Official Edition, is hereby amended by striking out subsections (1) and (2) and inserting in place thereof the following subsections:-

(1) to establish and to enforce, requirements in addition to any prescribed in this chapter for the construction, maintenance, and utilization of clinical laboratories, including standards of performance in the examination of specimens;

(2) to require evidence of successful participation by clinical laboratories licensed by the department in proficiency testing programs, and by laboratory personnel in training programs, covering all or specific laboratory specialties and approved by the department;

SECTION 2. Said section 2 of said chapter 111D, as so appearing, is hereby further amended by striking out subsection (5) and inserting in place thereof the following subsection:-

(5) to inspect at any time any clinical laboratory and any records maintained in connection with such laboratory; provided, that a license has been issued or an application for a license has been filed pursuant to section 5;

SECTION 3. Said section 2 of said chapter 111D, as so appearing, is hereby further amended by striking out subsections (8), (9), and (10) and inserting in place thereof the following subsections:

(8) to make such rules, regulations, as may be necessary or appropriate for the administration or enforcement of this chapter;

(9) to classify, laboratory tests as exempt; and

(10) to establish minimum qualifications of laboratory personnel.

SECTION 4. Said chapter 111D is hereby further amended by striking out section 3, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 3. The department may from time to time convene an advisory committee on clinical laboratories, to advise the department on the administration of this chapter. The Advisory Committee shall serve solely in an advisory capacity and shall not have authority to make binding decisions. Such committee shall consist of 13 members, to be appointed by the commissioner, as follows: 5 persons, 3 physicians and 2 nonphysicians, who meet the requirements for a clinical laboratory director as defined in regulation by the department; 1 other physician not a clinical laboratory director; 1 medical laboratory technologist; 1 chief executive officer of a hospital licensed by the department; and 5 non-providers of health services, 1 of whom shall be a member of the Massachusetts Bar and 1 a representative of manufacturers of

clinical laboratory technology. Each member of the committee shall serve without compensation for a term of 3 years, or until a successor is appointed; provided, that no member shall serve more than 2 consecutive terms.

SECTION 5. Said chapter 111D is hereby further amended by striking out section 5, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 5. Any person seeking a license to maintain a clinical laboratory apart from a hospital or clinic licensed under section 51 of chapter 111 shall file with the department a license application containing such information as the department may reasonably require, including but not limited to: the identity of the applicant and any parent or associated company, including respective ownership interests, the identity and qualifications of the proposed laboratory director; and the procedures or categories of procedures for which the license is sought.

Upon receipt and review of an application for license and upon payment of the appropriate fee, the department shall issue a license if it finds that the applicant is responsible and suitable to maintain a clinical laboratory and meets such requirements as the department has established by regulation for a license. In the case of renewal application, the department may, subject to such regulations as it shall make, issue a provisional license to an applicant who does not meet every requirement for a license; provided, that the applicant has demonstrated to the department's satisfaction a good faith intention to correct deficiencies, and provided further, that the department finds that the licensee provides reliable reports of examinations of specimens and presents satisfactory evidence that the requirements for full licensure can and will be met within a period of time not to exceed 6 months. The department shall in no case issue a person more than 2 consecutive provisional licenses for the same clinical laboratory.

The department shall set forth in every license issued under this section the name and address of the licensee; the name by which the clinical laboratory shall be known; the address of the licensed premises; the period which such license is issued; the classification, if any, for which such license is issued; the conditions as to transfer and assignment prescribed by law; and such other terms of issuance as the department may reasonably prescribe. The period of a license shall be not more than 2 years and the period of a provisional license shall be for not more than 6 months.

No licensee shall transfer the license issued to the licensee, or assign any authority granted thereunder, in any manner voluntarily or involuntarily, directly or indirectly, or by transfer or control of any person, without first obtaining the department's written permission, upon application to the department. Every application therefor shall contain such information as the department may require, and shall be approved or denied within 60 days of filing with the department. The department shall grant written permission if the department finds that the transferee or assignee is responsible and suitable to maintain a clinical laboratory and meets such requirements as the department has established by regulation for a license. Every denial order shall include a statement of the reasons for denial and the provisions of law relied upon, and shall be subject to judicial review.

SECTION 6. Said chapter 111D is hereby further amended by striking out section 7, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 7. Every clinical laboratory licensed by the department shall have an individual appointed, who shall bear the title "clinical laboratory director", with responsibility for the direction of the technical and scientific operation of such laboratory, including the examination

of specimens and the making of reports thereon. The department shall, in regulations, set the qualifications and conditions as to the employment of individuals as clinical laboratory directors, which may include the following: educational and clinical experience needed to hold the position of clinical laboratory director and certifications needed.

SECTION 7. Said chapter 111D is hereby further amended by striking out section 8, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 8. A clinical laboratory shall not:

(1) misrepresent, by false statement, by omission of a material fact, or by scheme, trick, or device, the category or categories of procedures performed at, or the service or services available at, a clinical laboratory;

(2) obstruct, bar, or otherwise interfere with an inspection undertaken under the authority of section 2;

(3) make any false statement in or to omit a material fact from an application or other paper filed with the department;

(4) offer or give a commission, rebate, or other fee, directly or indirectly to any person as consideration for the referral of a specimen derived from a human body to a clinical laboratory for examination by such laboratory;

(5) solicit or accept a commission, rebate, or other fee, directly or indirectly, from any person as consideration for the referral of a specimen derived from a human body to a clinical laboratory for examination by such laboratory;

(6) lend the use of the name of a licensed clinical laboratory or of a licensed hospital or clinic, or of any employee of any such laboratory or institution, to an unlicensed clinical laboratory;

(7) to examine any specimen derived from a human body except upon the written request of a licensed physician, licensed dentist, licensed chiropractor, licensed surgeon, licensed podiatrist, licensed osteopath or other licensed health care practitioner acting within their scope of practice to make such a written request or, for the sole purpose of requesting urine drug screening, department of public health-licensed substance use disorder programs, state agencies or those vendors that contract with state agencies and are designated by the contracting agency to request such screenings, or other person authorized to use the report of such examination by provision of chapter 112, unless such examination is for the sole purpose of testing the accuracy or sufficiency of the procedures or equipment of a clinical laboratory and is by instruction of the director of such laboratory, or unless such examination is for the purpose of providing a health promotion screening program and is not used for diagnosis or treatment of patients;

(8) report an examination of any specimen derived from a human body except to or as directed by the licensed physician, licensed chiropractor, licensed surgeon, licensed podiatrist, licensed osteopath or other licensed health care practitioner acting within their scope of practice to make such a written request, or, for the sole purpose of requesting urine drug screening, department of public health-licensed substance use disorder programs, state agencies or those vendors that contract with state agencies and are designated by the contracting agency to request such screenings, or the patient who requested, in writing, the report of the patient's own examination, or other authorized person who requested such examination in writing, unless such examination was made for the sole purpose of testing the accuracy or sufficiency of the

procedures or equipment of a clinical laboratory and by instruction of the director of such laboratory, or unless such examination is for the purpose of providing a health promotion screening program and is not used for diagnosis or treatment of patients;

(9) make a report of an examination of any specimen derived from the human body without designating the name and address, of the clinical laboratory in which such examination was actually performed;

(10) represent, or to maintain a specimen collection station on behalf of, any clinical laboratory, unless such laboratory, if in the commonwealth, is licensed by the department, or unless such laboratory, if not in the commonwealth, has been accredited or is licensed in accordance with federal law;

(11) employ a person as a director of a clinical laboratory, or to serve as a director of a clinical laboratory, except as provided in section 7;

(12) fail to report evidence of infectious disease in violation of section 6 or of any rule, regulation, or order made to implement section 6;

(13) violate or fail to observe any requirement of this chapter or of a rule, regulation, or order made pursuant to this chapter, which the department has made subject to this section by regulation;

(14) knowingly and willfully make fraudulent representations regarding the results of any laboratory test or service. Any laboratory employee, clinical laboratory director, or owner of a clinical laboratory as defined in this chapter who knowingly and willfully makes fraudulent representation regarding the results of any laboratory test or service or who should have known

of the fraudulent representation of laboratory test results shall be subject to the penalties set forth in this chapter;

(15) engage in any misrepresentation or false advertising of the nature, quality or cost of such services or of the terms and conditions on which such services are provided;

(16) enter into any agreement or act in concert with any purchaser of or third party payor for laboratory services to commit any act which would be deemed to be a violation of section 3 of chapter 176D; provided further that for purposes of this subsection, all purchasers and third party payors entering into arrangements with clinical laboratories shall be deemed to be engaged in the business of insurance.

(17) knowingly solicit, accept or test any specimen derived from the human body that is received from, ordered, requested or referred by: (a) any person or company in which the clinical laboratory or its directors, owners, partners, employees or family members thereof have any direct or indirect ownership interest; or (b) any person or company or its directors, owners, partners, employees or family members thereof having any direct or indirect ownership interest in the clinical laboratory; provided, however, that this clause shall not apply to: (i) a clinical laboratory owned by a licensed physician or group of licensed physicians used exclusively in connection with the diagnosis and treatment of the physician's or group of physicians' own patients and where all testing is performed by or under the direct supervision of the physician or group of physicians; (ii) a hospital or clinic licensed under section 51 of chapter 111 used exclusively in connection with the diagnosis or treatment of the hospital's or clinic's own patients; (iii) a clinical laboratory operated by a college or university exclusively in connection with the diagnosis and treatment of the college or university’s own students, staff, and faculty

and that meets the requirements in section 7 and department regulations for clinical laboratory director and where all tests are performed under the direct supervision of the clinical laboratory director; or (iv) any case exempted under subsection (b) to (d), inclusive, of 42 U.S.C. section 1395nn, or specifically permitted by regulations or rules of the United States Secretary of Health and Human Services, the federal Centers for Medicare or Medicaid Services, the executive office of health and human services or the executive office for administration and finance.

SECTION 8. Said chapter 111D is hereby further amended by striking out section 8A, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 8A. No person or company shall knowingly refer, request, order or send any specimen derived from the human body for examination to a clinical laboratory in which the person or company, or any of its owners, directors, partners, employees or family members thereof have a direct or indirect ownership interest. This section shall not apply to: (i) a clinical laboratory owned by a licensed physician or group of licensed physicians and used exclusively in connection with the diagnosis and treatment of the physician's or group of physicians' own patients and where all testing is performed by or under the direct supervision of said physician or group of physicians; (ii) a hospital or clinic licensed under section 51 of chapter 111 used exclusively in connection with the diagnosis or treatment of the hospital's or clinic's own patients; (iii) a clinical laboratory operated by a college or university exclusively in connection with the diagnosis and treatment of the college or university’s own students, staff, and faculty and that meets the requirements in section 7 and department regulations for clinical laboratory director and where all tests are performed under the direct supervision of the clinical laboratory director; or (iv) any case exempted under subsections (b) to (d), inclusive, of 42 U.S.C. section 1395nn or specifically permitted by regulations or rules of the United States Secretary of Health

and Human Services, the federal Centers for Medicare or Medicaid Services, the executive office of health and human services or the executive office for administration and finance.

SECTION 9. Said chapter 111D is hereby further amended by striking out section 9, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 9. Whenever the department finds upon inspection, or through information in its possession, that a clinical laboratory licensed by the department is not in compliance with a requirement prescribed in or established under this chapter, it may by order require the licensee to correct such deficiency. Every correction order shall include a statement of the deficiencies found, the provisions of law relied upon, and the period prescribed for correction, which shall be reasonable and, except in an emergency declared by the commissioner, not less than 30 days after receipt of such order. Within 10 days of receipt, the affected licensee may file a written request with the department for administrative reconsideration of the order or any portion thereof. Failure by the department to grant, deny, or otherwise act upon a written request within 10 days after filing shall be deemed a denial.

SECTION 10. Said chapter 111D is hereby further amended by striking out section 10, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 10. Whenever the department finds upon inspection, or through information in its possession, that a clinical laboratory, licensed by the department is not able to provide or is not providing reliable reports of examinations pursuant to the terms of such license, it may by order modify any term of such license as it deems necessary to enable the laboratory to provide reliable reports of examinations. Every license modification order shall include a statement of the reasons for modification, the provisions of law relied upon, and the date fixed for compliance, which date

shall be reasonable and, except in an emergency declared by the commissioner, not less than 30 days after receipt of such order.

Except in the case of a license modification imposed as a sanction after hearing under section 11, a licensee in receipt of an order shall have the opportunity for a hearing under the provisions of chapter 30A. If after hearing the licensee establishes that the order, or any portion thereof, is not warranted, the department shall rescind or qualify such order, as appropriate. The filing of a request for a hearing shall not operate as a stay of the compliance date of a license modification order, but the department shall stay the compliance date upon written request, except to the extent that a stay would jeopardize the public health or public safety.

SECTION 11. Said chapter 111D is hereby further amended by striking out section 11, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 11. The department may revoke the license issued pursuant to section 5 or impose other appropriate administrative sanction upon a license, or both, for conduct by or chargeable to the licensee as follows:

(1) failure to observe any term of such license;

(2) failure to meet any requirement for such license established under section 5;

(3) failure to observe any order made under authority of this chapter or under other statutory authority vested in the department;

(4) engaging in, or aiding, abetting, causing, or permitting, any action prohibited under section 8; or

(5) other proper cause set forth in regulations made under this chapter.

Before sanctioning a licensee, the department shall give such licensee notice of the charges against such licensee, the provisions of law relied upon, and the proposed sanction, and shall afford the licensee the opportunity for a hearing under the provisions of chapter 30A. Where, after hearing, the department finds that cause exists for imposition of a sanction, it need not impose the sanction proposed but may instead impose a lesser sanction if, in its judgment, a lesser sanction is appropriate in the circumstances. In the event revocation is imposed, the licensee shall be permitted a reasonable period in which to cease operation, but in no case less than 30 days after notice of the decision of the department.

Notwithstanding any other provision of this section, the commissioner may, at any time upon notice to the licensee, whether a hearing has been first commenced or not, suspend such licensee's license or issue such other preliminary order as the commissioner considers appropriate for the protection of the health or safety of the public if the commissioner should find that either is in jeopardy; provided, that a hearing shall be commenced within 5 days after such notice in any case of suspension without a prior hearing unless the licensee shall request a postponement. The finding of the commissioner shall be included in such notice.

SECTION 12. Said chapter 111D is hereby further amended by striking out section 14, as appearing in the 2020 Official Edition, and inserting in place thereof the following section:-

Section 14. All clinical laboratories shall disclose ownership interests in writing to the Attorney General's office upon initial licensure and thereafter every 2 years. The disclosure shall contain the name and ownership interest of the disclosing person or company, as well as the names and ownership interests of all other parties with an ownership interest in the clinical laboratory.