

SENATE No. 1394

The Commonwealth of Massachusetts

PRESENTED BY:

Brendan P. Crighton

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 modernizing the regulation of clinical laboratories.

PETITION OF:

NAME:

Brendan P. Crighton

DISTRICT/ADDRESS:

Third Essex

SENATE No. 1394

By Mr. Crighton, a petition (accompanied by bill, Senate, No. 1394) of Brendan P. Crighton for legislation to modernize the regulation of clinical laboratories. Public Health.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Second General Court
(2021-2022)**

An Act relative to modernizing the regulation of 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:

1 SECTION 1. Section 1. Chapter 111D of the General Laws is hereby amended by
2 striking out section 1 and inserting in place thereof the following section:- As used in this
3 chapter, the following words shall, unless the context requires otherwise, have the following
4 meaning:-

5 (1) "CLIA-waived test", a test that the federal Centers for Medicare and Medicaid
6 Services has
7 determined qualifies for a Certificate of Waiver under the federal Clinical Laboratory
8 Improvement Amendments of 1988 (CLIA).

9 (2) "Clinical Laboratory", a facility or place, however named, the purpose of which is
10 to make

11 biological, serological, chemical, immuno-hematological, cytological, pathological, or
12 other examinations of materials derived from a human body.

13 (3) "Commissioner", the commissioner of public health.

14 (4) "Company", a corporation, partnership, limited liability company, limited liability
15 partnership, an association, a trust or and organized group of persons, whether
16 incorporated or not.

17 (5) "Department", the department of public health in the executive office of human
18 services.

19 (6) "Exempt test", a test designated by the department as a simple laboratory
20 examination or a

21 procedure that has an insignificant risk of error, including but not limited to, CLIA-
22 waived tests. Exempt test also may include tests designated by the department that the federal
23 Centers for Medicare and Medicaid Services has determined qualify for a Certificate of Provider
24 Performed Microscopy under the federal Clinical Laboratory Improvement Amendments of 1988
25 (CLIA).

26 (7) "Ownership interest", interests including, but not limited to, any membership,
27 proprietary

28 interest, shares of stock in a corporation, units or other interest in a partnership, bonds,
29 debentures, notes or other equity interest or debt instrument or co-ownership in any form.

30 (8) "Person", corporations, societies, associations, partnerships, limited liability
31 companies,

32 limited liability partnerships, trusts, organized group of persons, whether incorporated or
33 not, an individual or the individual's estate upon death, any other entity including, but not limited
34 to, medical practice, medical office, clinic, counseling center, substance use disorder treatment
35 program or sober house or a political subdivision of the commonwealth.

36 SECTION 2. Section 2 of said chapter 111D of the General Laws, as appearing in the
37 2018 Official Edition, is hereby amended by striking out clause (9) and inserting in place thereof
38 the following 2 clauses:-

39 “(9) to classify, with the advice of the advisory committee on clinical laboratories,
40 laboratory

41 tests as exempt for purposes of licensing physician clinical laboratories;” and

42 “(10) to establish minimum qualifications of laboratory personnel.”

43 SECTION 3. Section 7 of said chapter 111D is hereby repealed.

44 SECTION 4. Section 8 of said chapter 111D of the General Laws, as appearing in the
45 2018 Official Edition, is hereby amended by striking out clause (7) and inserting in place thereof
46 the following clause:-

47 “(7) examine any specimen derived from a human body except upon the written request
48 of a licensed physician or other licensed health care practitioner authorized under chapter 112 to
49 make such a written request or, for the sole purpose of requesting urine drug screening,
50 department-licensed substance abuse programs, state agencies or those vendors that contract with
51 state agencies and are designated by the contracting agency to request such screenings, or other
52 person authorized to use the report of such examination by provision of chapter 112, unless such

53 examination is for the sole purpose of testing the accuracy or sufficiency of the procedures or
54 equipment of a clinical laboratory and is by instruction of the director of such laboratory, or
55 unless such examination is for the purpose of providing a health promotion screening program
56 and is not used for diagnosis or treatment of patients;”

57 SECTION 5. Said section 8 of said chapter 111D, as so appearing, is hereby further
58 amended by striking out clause (11) and inserting in place thereof the following clause:-

59 “(11) employ a person as a director of a clinical laboratory, or to serve as a director of a
60 clinical laboratory, except as authorized by department regulation, rule or order pursuant to
61 section 2 of this chapter;”