HOUSE DOCKET, NO. 1657 FILED ON: 1/17/2013

HOUSE . . . . . No. 1950

The Commonwealth of Massachusetts

PRESENTED BY:

John V. Fernandes and Garrett J. Bradley

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 prohibiting clinical laboratory self-referrals .

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John V. Fernandes	*10th Worcester*
Garrett J. Bradley	*3rd Plymouth*
Martha Coakley	*Attorney General*
Martin J. Walsh	*13th Suffolk*
Denise Provost	*27th Middlesex*
Ann-Margaret Ferrante	*5th Essex*
Karen E. Spilka	*Second Middlesex and Norfolk*
Jason M. Lewis	*Fifth Middlesex*
Daniel B. Winslow	*9th Norfolk*

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HOUSE . . . . . No. 1950

By Messrs. Fernandes of Milford and Bradley of Hingham, a petition (accompanied by bill, House, No. 1950) of John V. Fernandes and others relative to prohibiting clinical laboratory self-referrals. Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act prohibiting clinical laboratory self-referrals .

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. Chapter 111D of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by striking out section 1 and inserting in place thereof the following section:-

Section 1. As used in this chapter, the following words shall, unless the context requires otherwise, have the following meaning:—

(1) “Clinical Laboratory”, a facility or place, however named, the purpose of which is to make biological, serological, chemical, immuno-hematological, cytological, pathological, or other examinations of materials derived from a human body.

(2) “Commissioner”, the commissioner of public health.

(3) “Company”, a corporation, a partnership, a limited liability company, a limited liability partnership, an association, a trust, or an organized group of persons, whether incorporated or not.

(4) “Complex laboratory test” or “Highly complex laboratory test” tests which require sophisticated technique, interpretation of multiple signals or proven technical skill. Such tests shall require, but not be limited to, one or more of the following steps:--(a) highly skilled physical manipulation; (b) technique dependent steps in the testing, sampling or reading of results; (c) user programming of the device or devices; (d) detailed calculation of the results; (e) dilution of samples with chemically reactive substances; or (f) preparation of reagents.

20 (5) “Department”, the department of public health in the executive office of human
21 services.

22 (6) “Exempt test”, a test which is generally noninstrumental in nature, and the results of
23 which are determined by observation of a visual signal.

24 (7) “Ownership interest”, interests including, but not limited to, any membership,
25 proprietary interest, shares of stock in a corporation, units or other interest in a partnership,
26 bonds, debentures, notes or other equity interest or debt instrument , co-ownership in any form,
27 any profit sharing arrangement, or any compensation arrangement.

28 (8) “Person” and “whoever” shall include corporations, societies, associations,
29 partnerships, limited liability companies, limited liability partnerships, trusts, organized group of
30 persons, whether incorporated or not, an individual or his estate upon his death, any other entity
31 including but not limited to, medical practice, medical office, clinic, counseling center,
32 substance abuse treatment program or sober house, or a political subdivision of the
33 commonwealth, but not an agency of the commonwealth.

34 (9) “Simple laboratory test”, “waived laboratory test”, “moderately complex laboratory
35 test” tests which may require a series of steps, reagent additions or instrumentation, and the
36 results of which are generally determined by a visual signal, but which are not complex or
37 highly complex laboratory tests as defined in clause (4).

38 SECTION 2. Section 8 of said chapter 111D, as so appearing, is hereby amended by
39 inserting the following subsection:-

40 (17) Solicit, accept or test any specimen derived from the human body that is received
41 from, ordered, requested, or referred by: (a) any person or company in which the clinical
42 laboratory, or its directors, owners, partners, employees or family members thereof, have any
43 direct or indirect ownership interest; or (b) any person or company, or its directors, owners,
44 partners, employees or family members thereof, having any direct or indirect ownership interest
45 in the clinical laboratory; provided, however, this subsection shall not apply to a clinical
46 laboratory owned by a licensed physician, or group of licensed physicians, used exclusively in
47 connection with the diagnosis and treatment of said physician's or said group of physicians’ own
48 patients, and where all testing is performed by or under the direct supervision of said physician
49 or said physicians; provided, further this subsection shall not apply to a hospital or clinic licensed
50 under section 51 of chapter 111 used exclusively in connection with the diagnosis and treatment
51 of the hospital’s or clinic’s own patients.

52 SECTION 3. Said chapter 111D is hereby further amended by inserting after section 8
53 the following section:-

54 Section 8A. It shall be a violation of this section for any person or company to refer,
55 request, order or send any specimen derived from the human body for examination to a clinical
56 laboratory in which the person or company, or any of its owners, directors, partners, employees
57 or family members thereof have a direct or indirect ownership interest; provided, however, this
58 section shall not apply to a clinical laboratory owned by a licensed physician, or group of
59 licensed physicians, and used exclusively in connection with the diagnosis and treatment of said
60 physician's or said group of physicians' own patients, and where all testing is performed by or
61 under the direct supervision of said physician or said physicians; provided, further this
62 subsection shall not apply to a hospital or clinic licensed under section 51 of chapter 111 used
63 exclusively in connection with the diagnosis and treatment of the hospital's or clinic's own
64 patients.

65 SECTION 4. Said chapter 111D, as so appearing, is hereby further amended by striking
66 section 13 and inserting in place thereof the following section:-

67 Section 13. (a) Criminal Violations. Whoever maintains a clinical laboratory in the
68 commonwealth without a license in violation of section 4 or whoever, being licensed under
69 section 5 maintains a clinical laboratory in violation of the terms of such license, or whoever
70 engages in, aids, abets, causes or permits any act prohibited under section eight, or whoever
71 refers, requests, orders, or sends any specimen derived from the human body in violation of
72 section 8A shall be punished by imprisonment for not more than 5 years in state prison, or by
73 imprisonment in a jail or house of correction for not more than 2 and 1/2 years or by a fine of not
74 more than $10,000 dollars, or by both such fine and imprisonment. The commissioner shall
75 transmit to the attorney general such evidence of an offense as the department may have in its
76 possession.

77 (b) Civil Actions. If any person or company violates the provisions of subsection (17) of
78 section 8 or section 8A of this chapter, the attorney general may bring a civil action, either in lieu
79 of or in addition to a criminal prosecution, and may recover a civil penalty of not less than
80 $5,000 and not more than $10,000 per violation, plus three times the amount of damages
81 sustained, including consequential damages. A person violating subsection (17) of section 8 or
82 section 8A shall also be liable to the commonwealth for the expenses of the civil action brought
83 to recover any such penalty or damages, including without limitation reasonable attorney's fees,
84 reasonable expert's fees and the costs of investigation. No action shall be brought under this
85 section more than 6 years after it accrues. The commissioner shall transmit to the attorney
86 general such evidence of an offense as the department may have in its possession.

87 (c) Referral Arrangements or Schemes. Any person or company that solicits, offers or
88 enters into a referral arrangement or scheme with a clinical laboratory which the person or
89 company knows or should know has a principal purpose of assuring referrals by the person or
90 company to a particular clinical laboratory which, if the person or company directly made
91 referrals to such clinical laboratory, would be in violation of subsection (17) of section 8 or in

92 violation of section 8A, shall be liable to the commonwealth for a civil penalty of not more than
93 $100,000 for each referral arrangement or scheme plus three times the amount of damages
94 sustained, including consequential damages. No action shall be brought under this section more
95 than 6 years after it accrues. The commissioner shall transmit to the attorney general such
96 evidence of an offense as the department may have in its possession.

97 SECTION 5. Said chapter 111D is hereby further amended by inserting after section 13
98 the following section:-

99 Section 14. Pursuant to the authority of the department under subsection (8) of section 2,
100 the department shall require all clinical laboratories to disclose all ownership interests in writing
101 to the department every two years. Such disclosure shall contain the name and ownership
102 interest of the disclosing person or company, as well as the names and all ownership interests of
103 all other parties with an ownership interest in the clinical laboratory. A copy of said disclosure
104 shall be provided by the clinical laboratory to the attorney general. Failure to provide said
105 disclosure may result in a fine of up to $5,000.

106 SECTION 6. This act would become effective upon passage.