

SENATE No. 1932

The Commonwealth of Massachusetts

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In the Year Two Thousand Thirteen
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SENATE, Thursday, November 21, 2013

The committee on Public Health to whom was referred the petition (accompanied by bill, Senate, No. 1013) of Barry R. Finegold, Attorney General Martha Coakley, Gale D. Candaras, Karen E. Spilka and other members of the General Court for legislation to prohibit clinical laboratory self-referrals and (accompanied by bill, House, No. 1950) of John V. Fernandes and others relative to prohibiting clinical laboratory self-referrals reports the accompanying bill of the same title (Senate, No. 1932).

For the committee,
John F. Keenan

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An Act prohibiting clinical laboratory self-referrals.

Whereas, The deferred operation of this act would tend to defeat its purpose, which is to prevent clinical laboratory self-referrals, therefore, it is hereby declared to be an emergency law, necessary for the immediate preservation of the public health.

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

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

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

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

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

13 (4) “Complex laboratory test” or “Highly complex laboratory test” tests which
14 require sophisticated technique, interpretation of multiple signals or proven technical skill. Such
15 tests shall require, but not be limited to, one or more of the following steps:--(a) highly skilled
16 physical manipulation; (b) technique dependent steps in the testing, sampling or reading of

17 results; (c) user programming of the device or devices; (d) detailed calculation of the results; (e)
18 dilution of samples with chemically reactive substances; or (f) preparation of reagents.

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

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

23 (7) "Ownership interest", interests including, but not limited to, any membership,
24 proprietary interest, shares of stock in a corporation, units or other interest in a partnership,
25 bonds, debentures, notes or other equity interest or debt instrument, co-ownership in any form or
26 any profit sharing arrangement; provided, however, profit sharing arrangements shall not include
27 arrangements that share profits or savings by or between provider organizations under an
28 alternative payment methodology such as a shared savings arrangement, bundled payment, or a
29 global payment contract.

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

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

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

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

53 the hospital's or clinic's own patients; provided further, this subsection shall not to apply to any
54 case exempted under 42 U.S.C. section 1395nn(b)–(d), or specifically permitted by regulations
55 or rules of the United States Secretary of Health and Human Services, the federal Centers for
56 Medicare or Medicaid Services, the Massachusetts Executive Office of Health and Human
57 Services or the Massachusetts Executive Office of Administration and Finance.

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

60 Section 8A. It shall be a violation of this section for any person or company to knowingly
61 refer, request, order or send any specimen derived from the human body for examination to a
62 clinical laboratory in which the person or company, or any of its owners, directors, partners,
63 employees or family members thereof have a direct or indirect ownership interest; provided,
64 however, this section shall not apply to a clinical laboratory owned by a licensed physician, or
65 group of licensed physicians, and used exclusively in connection with the diagnosis and
66 treatment of said physician's or said group of physicians' own patients, and where all testing is
67 performed by or under the direct supervision of said physician or said physicians; provided,
68 further this subsection shall not apply to a hospital or clinic licensed under section 51 of chapter
69 111 used exclusively in connection with the diagnosis or treatment of the hospital's or clinic's
70 own patients; provided further, this section shall not to apply to any case exempted under 42
71 U.S.C. section 1395nn(b)–(d), or specifically permitted by regulations or rules of the United
72 States Secretary of Health and Human Services, the federal Centers for Medicare or Medicaid
73 Services, the Massachusetts Executive Office of Health and Human Services or the
74 Massachusetts Executive Office of Administration and Finance.

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

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

87 (b) Civil Actions. If any person or company violates the provisions of subsection (17) of
88 section 8 or section 8A of this chapter, the attorney general may bring a civil action, either in lieu
89 of or in addition to a criminal prosecution, and may recover a civil penalty of not less than

90 \$5,000 and not more than \$10,000 per violation, plus three times the amount of damages
91 sustained, including consequential damages. A person violating subsection (17) of section 8 or
92 section 8A shall also be liable to the commonwealth for the expenses of the civil action brought
93 to recover any such penalty or damages, including without limitation reasonable attorney's fees,
94 reasonable expert's fees and the costs of investigation. No action shall be brought under this
95 section more than 6 years after it accrues. The commissioner shall transmit to the attorney
96 general such evidence of an offense as the department may have in its possession.

97 (c) Referral Arrangements or Schemes. Any person or company that solicits, offers or
98 enters into a referral arrangement or scheme with a clinical laboratory which the person or
99 company knows or should know has a principal purpose of assuring referrals by the person or
100 company to a particular clinical laboratory which, if the person or company directly made
101 referrals to such clinical laboratory, would be in violation of subsection (17) of section 8 or in
102 violation of section 8A, shall be liable to the commonwealth for a civil penalty of not more than
103 \$100,000 for each referral arrangement or scheme plus three times the amount of damages
104 sustained, including consequential damages. No action shall be brought under this section more
105 than 6 years after it accrues. The commissioner shall transmit to the attorney general such
106 evidence of an offense as the department may have in its possession.

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

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

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