

SENATE No. 1945

Text of amendment (937) (offered by Senator deMacedo) to the Ways and Means amendment (Senate, No. 3) to the House Bill making appropriations for the fiscal year 2016 for the maintenance of the departments, boards, commissions, institutions and certain activities of the Commonwealth, for interest, sinking fund and serial bond requirements and for certain permanent improvements

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

1 by inserting after section XX the following sections:-

2 “SECTION XX. Section 1 of chapter 94C of the General Laws, as appearing in the 2012
3 Official Edition, is hereby amended by inserting after the definition of “oral prescription” the
4 following definition:-

5 “Outsourcing facility,” an entity at 1 geographic location or address that (i) is engaged in
6 the compounding of sterile drug preparations, (ii) has registered with the federal Food and Drug
7 Administration as an outsourcing facility pursuant to 21 U.S.C. § 353b and (iii) has registered
8 with the board pursuant to M.G.L. c. 112, §36E.

9 SECTION XX. Section 6 of said chapter 94C, as so appearing, is hereby amended by
10 striking out, in line 2, the words “or wholesale druggist” and inserting in place thereof the
11 following words:- , wholesale druggist or outsourcing facility.

12 SECTION XX. Section 7 of said chapter 94C, as so appearing, is hereby amended by
13 striking out, in lines 1 and 2, the words “or wholesale druggist” and inserting in place thereof the
14 following words:- , wholesale druggist or outsourcing facility.

15 SECTION XX. Said section 7 of said chapter 94C, as so appearing, is hereby further
16 amended by inserting after the word druggist, in line 9, the following words:- and outsourcing
17 facility.

18 SECTION XX. Section 12 of said chapter 94C, as so appearing, is hereby amended by
19 striking out, in line 2 , the words “or wholesale druggist” and inserting in place thereof the
20 following words:- , wholesale druggist or outsourcing facility.

21 SECTION XX. Said section 12 of said chapter 94C, as so appearing, is hereby further
22 amended by striking out, in line 8, the words “or a wholesale druggist” and inserting in place
23 thereof the following words:- , wholesale druggist or outsourcing facility.

24 SECTION XX. Section 13 of said chapter 94C, as so appearing, is hereby amended by
25 striking out, in lines 2, 17, 28, 33 and 47, the words “or wholesale druggist” and inserting in
26 place thereof, in each instance, the following words:- , wholesale druggist or outsourcing facility.

27 SECTION XX. Section 14 of said chapter 94C, as so appearing, is hereby amended by
28 striking out, in lines 2 and 10, the words “or wholesale druggist” and inserting in place thereof,
29 in each instance, the following words:- , wholesale druggist or outsourcing facility.”; and

30 SECTION XX. Chapter 112 of the General Laws is hereby amended by inserting after
31 section 36D the following section:-

32 Section 36E. (a) As used in this section and in sections 24 to 42D, inclusive, the
33 following words shall, unless the context clearly requires otherwise, have the following
34 meanings:-

35 “Outsourcing facility”, an entity at 1 geographic location or address that (i) is engaged in
36 the compounding of sterile drug preparations and (ii) has registered with the federal Food and
37 Drug Administration (“FDA”) as an outsourcing facility pursuant to 21 U.S.C. § 353b.

38 “Operate as an outsourcing facility”, compound and distribute a sterile drug preparation
39 to pharmacies, wholesalers or prescribers within or outside of the commonwealth: (i) in volumes
40 inconsistent with routinely observed volume patterns associated with patient-specific
41 prescriptions or (ii) in the absence of accountability documentation.

42 (b) The board may, upon application made in such manner and form as it shall determine,
43 register an entity located within the commonwealth that intends to operate as an outsourcing
44 facility. An applicant for registration as an outsourcing facility shall provide proof of the
45 following: (i) valid, current registration with the federal Food and Drug Administration, pursuant
46 to 21 U.S.C. § 353b, federal Food Drug and Cosmetic Act § 503B; (ii) inspection by the FDA
47 within the 2 years immediately preceding the application that has not resulted in classification as
48 “Voluntary Action Indicated” (VAI) or “Official Action Indicated” (OAI) or, if it has resulted in
49 a VAI or OAI classification, corrective actions have been taken by the applicant and there are no
50 outstanding requests by the FDA to the applicant for response in connection with the inspection
51 or corrective actions; and (iii) application and eligibility for registration to manufacture or
52 distribute controlled substances pursuant to section 12 of chapter 94C. If the applicant has met
53 requirements (i) and (ii), but has not been inspected by the FDA within the 2 years immediately

54 preceding the application, the applicant may receive a provisional registration to compound, but
55 may not distribute a sterile drug preparation to pharmacies, wholesalers or prescribers within or
56 outside of the commonwealth until it has been inspected pursuant to the requirements of this
57 paragraph. The application for registration as an outsourcing facility shall be accompanied by a
58 fee for registration in an amount to be determined by the secretary of administration and finance
59 pursuant to section 3B of chapter 7. Said fee shall be deposited into the Quality in Health
60 Professions Trust Fund established by section 35X of chapter 10.

61 (c) The board may, upon application made in such manner and form as it shall determine,
62 register an entity located outside of the Commonwealth that intends to operate as a non-resident
63 outsourcing facility. An applicant for registration as a non-resident outsourcing facility shall
64 provide proof of the following: (i) valid, current registration with the FDA, pursuant to 21 U.S.C.
65 § 353b, federal Food Drug and Cosmetic Act § 503B; (ii) inspection by the FDA within the 2
66 years immediately preceding the application that has not resulted in classification as “Voluntary
67 Action Indicated” (VAI) or “Official Action Indicated” (OAI) or, if it has resulted in a VAI or
68 OAI classification, corrective actions have been taken by the applicant and there are no
69 outstanding requests by the FDA to the applicant for response in connection with the inspection
70 or corrective actions; and (iii) application and eligibility for registration to manufacture or
71 distribute controlled substances pursuant to section 12 of chapter 94C. The application for
72 registration as a non-resident outsourcing facility shall be accompanied by a fee for registration
73 in an amount to be determined by the secretary of administration and finance pursuant to section
74 3B of chapter 7. Said fee shall be deposited into the Quality in Health Professions Trust Fund
75 established by section 35X of chapter 10.

76 (d) Registrations issued pursuant to this section shall expire on December 31 of each odd
77 numbered year following the date of its issue and may be renewed upon application made in such
78 manner and form as the board shall determine. An applicant for renewal of a registration issued
79 pursuant to this section shall provide satisfactory proof of valid, current registration with the
80 FDA, pursuant to 21 U.S.C. § 353b, federal Food Drug and Cosmetic Act § 503B. The
81 application for renewal of a registration as an outsourcing facility shall be accompanied by a fee
82 for registration in an amount to be determined by the secretary of administration and finance
83 pursuant to section 3B of chapter 7. Said fee shall be deposited into the Quality in Health
84 Professions Trust Fund established by section 35X of chapter 10.

85 (e) Grounds for denial of a registration, revocation or suspension of a registration or non-
86 renewal of a registration issued pursuant to this section shall include, but shall not be limited to:
87 (i) failure to maintain current, valid registration with the FDA, pursuant to 21 U.S.C. § 353b; (ii)
88 an inspection by the FDA that results in classification as “Voluntary Action Indicated” (VAI) or
89 “Official Action Indicated” (OAI) and either (A) no corrective actions have been taken by the
90 applicant or (B) there are outstanding requests by the FDA to the applicant for response in
91 connection with the inspection or corrective actions or (C) the corrective actions taken by the
92 applicant or registrant are determined to be not adequate to remedy the conditions giving rise to
93 the FDA classifications; (iii) material misrepresentation, omission or falsification of any
94 information furnished to the board; (iv) failure to comply with reporting requirements established
95 by the board with respect to registration with, or inspections by, the FDA; (v) failure to adhere to
96 the most current standards established under cGMP; (vi) the applicant’s or registrant’s lack of
97 suitability; or (vii) failure to maintain a current, valid Massachusetts Controlled Substances

98 Registration. This provision shall not limit the board’s authority pursuant to M.G.L. ch. 112, §§
99 42A and 61.

100 SECTION XX. Subsection (a) of section 39D of said chapter 112, as appearing in section
101 18 of chapter 159 of the acts of 2014, is hereby amended by striking out the word “sections 39F”
102 and inserting in place thereof the following word:- sections 36E

103 SECTION XX. Section 39F of said chapter 112, as so appearing, is hereby amended by
104 striking out subsection (c) and inserting in place thereof the following subsection:-

105 (c) An entity that intends to compound and distribute a sterile drug preparation or a
106 complex non-sterile drug preparation to pharmacies, wholesalers or prescribers within or outside
107 of the commonwealth: (i) in volumes inconsistent with routinely observed volume patterns
108 associated with patient-specific prescriptions; or (ii) in the absence of accountability
109 documentation shall adhere to the most current standards established under cGMP when
110 engaging in any form of compounding. Such entities shall either: register as a producer of drugs
111 with the federal Food and Drug Administration pursuant to 21 U.S.C. § 360, federal Food Drug
112 and Cosmetic Act § 510; or register as an outsourcing facility with both the federal Food and
113 Drug Administration pursuant to 21 U.S.C. § 353b, federal Food Drug and Cosmetic Act § 503B,
114 and the board pursuant to section 36E before engaging in any sterile compounding or complex
115 non-sterile compounding.

116 SECTION XX. Section 39J of said chapter 112, as so appearing, is hereby amended by
117 striking out subsection (d), each time it appears, and inserting in place thereof the following 2
118 subsections:-

119 (d) No pharmacy, pharmacist or outsourcing facility operating outside of the
120 commonwealth shall be authorized to prescribe, ship, mail, sell, transfer or dispense sterile drug
121 preparations or complex non-sterile drug preparations in the commonwealth unless the sterile
122 drug preparations or complex non-sterile drug preparations are compounded in a pharmacy or
123 outsourcing facility that has been granted a non-resident sterile compounding license, non-
124 resident complex non-sterile compounding license or non-resident outsourcing facility
125 registration pursuant to this chapter.

126 (e) Non-resident pharmacies holding a non-resident pharmacy license under this section
127 shall be subject to the requirements of section 24A of chapter 94C; provided, however, that non-
128 resident pharmacies shall not be eligible for a waiver under said section 24A. An application for
129 licensure under this section shall not be approved unless the applicant has demonstrated the
130 ability to comply with said section 24A. The board may revoke a non-resident pharmacy license
131 for failure to comply with said section 24A.

132 SECTION XX. The first paragraph of section 42A of said chapter 112, as appearing in
133 the 2012 Official Edition, is hereby amended by striking out, in line 3, the words “ and
134 pharmacy” and inserting in place thereof the following words: - , pharmacies, outsourcing
135 facilities,.

136 SECTION XX. The second paragraph of section 42A of said chapter 112, as so
137 appearing, is hereby amended by striking out, in line 18, the words “or engage in the retail drug
138 business” and inserting in place thereof the following words:- , engage in the retail drug business
139 or operate an outsourcing facility.

140 SECTION XX. The fourth paragraph of said section 42A of said chapter 112, as
141 appearing in section 21 of chapter 159 of the acts of 2014, is hereby amended by inserting after
142 the words “renew a pharmacy license” the following words:- or outsourcing facility registration.

143 SECTION XX. The fifth paragraph of said section 42A of said chapter 112, as so
144 appearing, is hereby amended by striking out clause (i) and inserting in place thereof the
145 following clause:- (i)

146 issue a cease and desist notice or quarantine notice requiring the cessation or restriction
147 of any and all pharmacy operations or outsourcing facility operations and prohibiting the use of
148 medications prepared by or in possession of a pharmacy or outsourcing facility.”