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
(-)

by inserting after section XX the following sections:-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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