SENATE BILL 69

J2 EMERGENCY BILL 5lr0884
CF HB 181

By: **Senator Conway**
Introduced and read first time: January 23, 2015
Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable
Senate action: Adopted
Read second time: February 16, 2015

CHAPTER _____

AN ACT concerning

State Board of Pharmacy – Sterile Compounding – Compliance by Nonresident Pharmacies and Repeal of Permit Requirement

FOR the purpose of repealing the requirement that certain entities hold a sterile compounding permit issued by the State Board of Pharmacy before engaging in certain activities relating to sterile compounding; repealing the requirement that a person that prepares and distributes sterile drug products into or within the State hold a certain permit; repealing the qualifications, fees, and other requirements for applying for a sterile compounding permit; repealing the requirement for the Board to adopt regulations relating to sterile compounding permits; repealing requirements for inspections of and reporting by sterile compounding permit holders; repealing the authority of the Board to take certain disciplinary action or impose certain fines for violating sterile compounding permit requirements; repealing the requirement that the inspection report submitted by a wholesale distributor applicant or permit holder that prepares sterile drug products demonstrate compliance with certain standards; repealing certain criminal penalties and civil fines for operating a sterile compounding facility without a permit; requiring a nonresident pharmacy that will dispense compounded sterile preparations to patients in the State to obtain and submit to the Board a report of an inspection that meets certain standards and is conducted by a certain entity within a certain time period in order for the nonresident pharmacy to obtain a pharmacy permit from the Board; requiring a nonresident pharmacy, if dispensing compounded sterile preparations to patients in the State, to comply with certain standards and regulations; repealing certain definitions; defining certain terms; making this Act an emergency measure; and generally relating to sterile compounding and the State Board of Pharmacy.

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

BY renumbering
Article – Health Occupations
Section 12–101(d) through (t–1) and (u) through (w), respectively
to be Section 12–101(e) through (y), respectively
Annotated Code of Maryland
(2014 Replacement Volume)

BY repealing
Article – Health Occupations
Section 12–4A–01 through 12–4A–12 and the subtitle "Subtitle 4A. Sterile Compounding Permits"
Annotated Code of Maryland
(2014 Replacement Volume)

BY adding to
Article – Health Occupations
Section 12–101(d) and (z)
Annotated Code of Maryland
(2014 Replacement Volume)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–403(f)(1) and (g), 12–6C–03.2, and 12–707(b) and (e)
Annotated Code of Maryland
(2014 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 12–101(d) through (t–1) and (u) through (w), respectively, of Article – Health Occupations of the Annotated Code of Maryland be renumbered to be Section(s) 12–101(e) through (y), respectively.

SECTION 2. AND BE IT FURTHER ENACTED, That Section(s) 12–4A–01 through 12–4A–12 and the subtitle "Subtitle 4A. Sterile Compounding Permits" of Article – Health Occupations of the Annotated Code of Maryland be repealed.

SECTION 3. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health Occupations

12–101.

(D) "COMPOUNDED STERILE PREPARATIONS" MEANS BIOLOGICS, DIAGNOSTICS, DRUGS, NUTRIENTS, AND RADIOPHARMACEUTICALS THAT, UNDER USP 797, MUST BE COMPOUNDED USING ASEPTIC TECHNIQUES.

(Z) "USP 797" MEANS THE STANDARDS SET FORTH IN THE UNITED STATES PHARMACOPEIA, GENERAL CHAPTER 797, "PHARMACEUTICAL COMPOUNDING – STERILE PREPARATIONS".

12–403.

(f) (1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy shall:

(i) Submit an application to the Board on the form that the Board requires;

(ii) Pay to the Board an application fee set by the Board;

(iii) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located; **[**and**]**

(iv) On the required permit application, identify the name and current address of an agent located in this State officially designated to accept service of process**; AND**

(V) IF A NONRESIDENT PHARMACY WILL DISPENSE COMPOUNDED STERILE PREPARATIONS TO PATIENTS IN THE STATE, OBTAIN AND SUBMIT TO THE BOARD A REPORT OF AN INSPECTION THAT:

1. DEMONSTRATES COMPLIANCE WITH USP 797; AND

2. WITHIN 90 DAYS BEFORE THE DATE OF APPLICATION, IS CONDUCTED BY A BOARD DESIGNEE OR OTHER ENTITY APPROVED BY THE BOARD.

(g) Notwithstanding subsection (b) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (c)(2), (7) through (12), and (19) of this section when:

(i) Dispensing prescription drugs or prescription devices to a patient in this State; or

(ii) Otherwise engaging in the practice of pharmacy in this State;

(2) On an annual basis and within 30 days after a change of office, corporate officer, or pharmacist, disclose to the Board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescriptions for drugs or devices to persons in this State;

(3) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located and all requests for information made by the Board pursuant to this section;

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located;

(5) Maintain its records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;

(6) During its regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide toll–free telephone service to facilitate communication between patients in this State and a pharmacist or an individual who:

(i) Has access to the patient's prescription records; and

(ii) Is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate;

(7) Disclose its toll–free telephone number on a label affixed to each container of drugs or devices;

(8) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located; **[**and**]**

(9) Comply with the requirements of subsection (c)(17) and (20) of this section**; AND**

(10) IF DISPENSING COMPOUNDED STERILE PREPARATIONS TO PATIENTS IN THE STATE, COMPLY WITH:

(I) USP 797; AND

(II) REGULATIONS ADOPTED BY THE BOARD GOVERNING THE COMPOUNDING OF STERILE PREPARATIONS.

12–6C–03.2.

(a) Notwithstanding any other provision of this subtitle, a wholesale distributor applicant or permit holder that prepares sterile drug products shall submit to the Board a report of an inspection conducted by the U.S. Food and Drug Administration or a Board designee:

(1) At the time of application; and

(2) On renewal.

(b) The inspection report required under subsection (a) of this section shall:

(1) Be conducted within 1 year before the date of application or renewal; and

(2) Demonstrate compliance with applicable federal good manufacturing practice standards **[**or USP 797, as defined in § 12–4A–01 of this title**]**.

(c) An applicant or permit holder is responsible for obtaining an inspection to meet the requirements of this section.

12–707.

(b) A person who violates any provision of the following sections of this title is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1,000 or imprisonment not exceeding 1 year or both:

(1) **[**§ 12–4A–10 ("Operating a sterile compounding facility without permit");

(2)**]** § 12–701 ("Practicing pharmacy without license");

[(3)**] (2)** § 12–702 ("License obtained by false representation");

[(4)**] (3)** § 12–703 ("Operating a pharmacy without permit");

[(5)**] (4)** § 12–704 ("Misrepresentations");

[(6)**] (5)** § 12–6B–12 ("Working as an unregistered pharmacy technician"); and

[(7)**] (6)** § 12–6D–15 ("Practicing as an unregistered pharmacy intern").

(e) (1) Any person who violates **[**§ 12–4A–10 ("Operating a sterile compounding facility without permit"),**]** § 12–701 ("Practicing pharmacy without a license"), § 12–703 ("Operating a pharmacy without a permit"), § 12–6B–12 ("Working as an unregistered pharmacy technician"), or § 12–6D–15 ("Practicing as an unregistered pharmacy intern") of this title is subject to a civil fine of not more than $50,000 to be assessed by the Board.

(2) The Board shall pay any penalty collected under this subsection into the State Board of Pharmacy Fund.

SECTION 4. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.