

HOUSE BILL 181

J2

EMERGENCY BILL

5lr0883
CF SB 69

By: **Delegates Hill, Bromwell, Cullison, Hammen, Kipke, Lam, Morhaim, Pendergrass, Ready, Reznik, ~~and K. Young~~ K. Young, Angel, Barron, Hayes, Kelly, Krebs, McDonough, McMillan, Miele, Morgan, Oaks, Pena-Melnyk, Sample-Hughes, and West**

Introduced and read first time: January 29, 2015

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: February 25, 2015

CHAPTER _____

1 AN ACT concerning

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

4 FOR the purpose of repealing the requirement that certain entities hold a sterile
5 compounding permit issued by the State Board of Pharmacy before engaging in
6 certain activities relating to sterile compounding; repealing the requirement that a
7 person that prepares and distributes sterile drug products into or within the State
8 hold a certain permit; repealing the qualifications, fees, and other requirements for
9 applying for a sterile compounding permit; repealing the requirement for the Board
10 to adopt regulations relating to sterile compounding permits; repealing requirements
11 for inspections of and reporting by sterile compounding permit holders; repealing the
12 authority of the Board to take certain disciplinary action or impose certain fines for
13 violating sterile compounding permit requirements; repealing the requirement that
14 the inspection report submitted by a wholesale distributor applicant or permit holder
15 that prepares sterile drug products demonstrate compliance with certain standards;
16 repealing certain criminal penalties and civil fines for operating a sterile
17 compounding facility without a permit; requiring a nonresident pharmacy that will
18 dispense compounded sterile preparations to patients in the State to obtain and
19 submit to the Board a report of an inspection that meets certain standards and is
20 conducted by a certain entity within a certain time period in order for the
21 nonresident pharmacy to obtain a pharmacy permit from the Board; requiring a
22 nonresident pharmacy, if dispensing compounded sterile preparations to patients in

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.



1 the State, to comply with certain standards and regulations; repealing certain
2 definitions; defining certain terms; making this Act an emergency measure; and
3 generally relating to sterile compounding and the State Board of Pharmacy.

4 BY renumbering

5 Article – Health Occupations
6 Section 12–101(d) through (t–1) and (u) through (w), respectively
7 to be Section 12–101(e) through (y), respectively
8 Annotated Code of Maryland
9 (2014 Replacement Volume)

10 BY repealing

11 Article – Health Occupations
12 Section 12–4A–01 through 12–4A–12 and the subtitle “Subtitle 4A. Sterile
13 Compounding Permits”
14 Annotated Code of Maryland
15 (2014 Replacement Volume)

16 BY adding to

17 Article – Health Occupations
18 Section 12–101(d) and (z)
19 Annotated Code of Maryland
20 (2014 Replacement Volume)

21 BY repealing and reenacting, with amendments,

22 Article – Health Occupations
23 Section 12–403(f)(1) and (g), 12–6C–03.2, and 12–707(b) and (e)
24 Annotated Code of Maryland
25 (2014 Replacement Volume)

26 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
27 That Section(s) 12–101(d) through (t–1) and (u) through (w), respectively, of Article –
28 Health Occupations of the Annotated Code of Maryland be renumbered to be Section(s)
29 12–101(e) through (y), respectively.

30 SECTION 2. AND BE IT FURTHER ENACTED, That Section(s) 12–4A–01 through
31 12–4A–12 and the subtitle “Subtitle 4A. Sterile Compounding Permits” of Article – Health
32 Occupations of the Annotated Code of Maryland be repealed.

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

35 **Article – Health Occupations**

36 12–101.

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

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

7 12-403.

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

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

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

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

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

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

22 1. DEMONSTRATES COMPLIANCE WITH USP 797; AND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 **(I) USP 797; AND**

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

30 12-6C-03.2.

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

5 (1) At the time of application; and

6 (2) On renewal.

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

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

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

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

14 12-707.

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

18 (1) [§ 12-4A-10 (“Operating a sterile compounding facility without
19 permit”);

20 (2)] § 12-701 (“Practicing pharmacy without license”);

21 [(3)] (2) § 12-702 (“License obtained by false representation”);

22 [(4)] (3) § 12-703 (“Operating a pharmacy without permit”);

23 [(5)] (4) § 12-704 (“Misrepresentations”);

24 [(6)] (5) § 12-6B-12 (“Working as an unregistered pharmacy
25 technician”); and

26 [(7)] (6) § 12-6D-15 (“Practicing as an unregistered pharmacy intern”).

27 (e) (1) Any person who violates [§ 12-4A-10 (“Operating a sterile
28 compounding facility without permit”),] § 12-701 (“Practicing pharmacy without a
29 license”), § 12-703 (“Operating a pharmacy without a permit”), § 12-6B-12 (“Working as
30 an unregistered pharmacy technician”), or § 12-6D-15 (“Practicing as an unregistered

1 pharmacy intern”) of this title is subject to a civil fine of not more than \$50,000 to be
2 assessed by the Board.

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.