SENATE BILL 1108

J2 4lr3403

By: **Senators Conway and Dyson**

Constitutional Requirements Complied with for Introduction in the last 35 Days of Session
Introduced and read first time: March 7, 2014
Assigned to: Rules
Re–referred to: Education, Health, and Environmental Affairs, March 10, 2014

Committee Report: Favorable with amendments
Senate action: Adopted with floor amendments
Read second time: March 11, 2014

CHAPTER _____

AN ACT concerning

Sterile Compounding Permits – ~~Exemptions –~~ Definition of "Compounding" ~~and Exemption for~~ ~~Sterile Compounding Facilities That Compound Only for Immediate Use~~

FOR the purpose of altering the definition of "compounding" for purposes of provisions of law governing sterile compounding to exclude certain acts performed by or under the supervision of certain individuals and in accordance with certain directions; ~~authorizing, under certain circumstances, the State Board of Pharmacy to exempt a certain sterile compounding facility from a certain permit requirement; providing that a sterile compounding facility that receives a certain exemption is subject to inspection by the Board; authorizing the Board to withdraw an exemption under certain circumstances; providing that, under certain circumstances, a licensed health care practitioner who performs sterile compounding in a sterile compounding facility that has received a certain exemption is subject to disciplinary action by the appropriate respective regulatory board; defining a certain term;~~ and generally relating to ~~exemptions from the~~ sterile compounding ~~permit requirement~~ ~~permits~~.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–4A–01 ~~and 12–4A–02~~
Annotated Code of Maryland

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.

(2009 Replacement Volume and 2013 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–4A–01.

(a) In this subtitle the following words have the meanings indicated.

(b) **(1)** "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug only:

[(1)**]** **(I)** As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient relationship in the course of professional practice;

[(2)**]** **(II)** For the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or

[(3)**]** **(III)** In anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(2) "COMPOUNDING" DOES NOT INCLUDE MIXING, RECONSTITUTING, OR OTHER ACTS PERFORMED:

(I) BY, OR UNDER THE SUPERVISION OF, AN ONCOLOGIST OR A HEMATOLOGIST WHO ADMINISTERS CHEMOTHERAPY, BIOLOGIC THERAPY, SUPPORTIVE CARE MEDICATION, OR ANY OTHER THERAPY IN THE TREATMENT OF CANCER OR A BLOOD CONDITION; AND

(II) IN ACCORDANCE WITH:

1. DIRECTIONS CONTAINED IN APPROVED LABELING PROVIDED BY THE PRODUCT'S MANUFACTURER; AND

2. OTHER MANUFACTURER DIRECTIONS CONSISTENT WITH THE LABELING.

(c) "Designee" means a public agency or private entity approved by the Board to conduct inspections of sterile compounding facilities or entities that prepare sterile drug products.

(d) "Sterile compounding" means compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be prepared using aseptic techniques.

(e) "Sterile compounding facility" means a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed.

(f) "Sterile drug product" means a drug product that:

(1) Must be prepared using aseptic techniques; and

(2) Is not required to be prepared in response to a patient specific prescription.

(g) "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations".

~~12–4A–02.~~

~~(a) [A] EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A sterile compounding facility shall hold a sterile compounding permit issued by the Board before the sterile compounding facility may perform sterile compounding in the State.~~

~~(B) (1) IN THIS SUBSECTION, "STERILE COMPOUNDING" DOES NOT INCLUDE MIXING, RECONSTITUTING, OR OTHER ACTS PERFORMED:~~

~~(I) BY, OR UNDER THE SUPERVISION OF, AN ONCOLOGIST OR A HEMATOLOGIST; AND~~

~~(II) IN ACCORDANCE WITH:~~

~~1. DIRECTIONS CONTAINED IN THE APPROVED PRODUCT LABELING PROVIDED BY THE MANUFACTURER; AND~~

~~2. OTHER MANUFACTURER DIRECTIONS THAT ARE CONSISTENT WITH THE APPROVED PRODUCT LABELING.~~

~~(2) (1) THE BOARD MAY EXEMPT A STERILE COMPOUNDING FACILITY THAT PERFORMS STERILE COMPOUNDING IN THE STATE ONLY FOR IMMEDIATE USE, AS DEFINED BY USP 797, FROM THE PERMIT REQUIREMENT IN SUBSECTION (A) OF THIS SECTION IF THE STERILE COMPOUNDING FACILITY:~~

~~(I) REQUESTS AN EXEMPTION ON A FORM THE BOARD REQUIRES;~~

~~(II) ATTESTS TO COMPLIANCE WITH USP 797 STANDARDS FOR IMMEDIATE USE, INCLUDING:~~

~~1. THE USE OF ASEPTIC TECHNIQUES;~~

~~2. THE USE OF QUALITY ASSURANCE MEASURES;~~

~~3. PERSONNEL TRAINING; AND~~

~~4. THE USE OF APPROPRIATE GARBING; AND~~

~~(III) PAYS A FEE SET BY THE BOARD FOR THE REVIEW OF THE REQUEST.~~

~~(3) (2)~~ ~~A STERILE COMPOUNDING FACILITY THAT RECEIVES AN EXEMPTION UNDER PARAGRAPH (2) (1) OF THIS SUBSECTION IS SUBJECT TO INSPECTION BY THE BOARD.~~

~~(4) (3)~~ ~~THE BOARD MAY WITHDRAW AN EXEMPTION IF A STERILE COMPOUNDING FACILITY:~~

~~(I) FAILS TO COMPLY WITH USP 797; OR~~

~~(II) FAILS TO COOPERATE WITH A BOARD INSPECTION.~~

~~(5) (4)~~ ~~IF A STERILE COMPOUNDING FACILITY THAT RECEIVED AN EXEMPTION UNDER PARAGRAPH (2) (1) OF THIS SUBSECTION FAILS TO COMPLY WITH USP 797, THE LICENSED HEALTH CARE PRACTITIONER WHO PERFORMS STERILE COMPOUNDING IN THE STERILE COMPOUNDING FACILITY IS SUBJECT TO DISCIPLINARY ACTION BY THE APPROPRIATE~~ RESPECTIVE ~~REGULATORY BOARD.~~

~~[(b)] (C)~~ ~~A sterile compounding permit is required in addition to and does not replace any other permit or license a sterile compounding facility holds.~~

~~[(c)] (D)~~ ~~A sterile compounding facility that performs sterile compounding outside the State shall hold a sterile compounding permit issued by the Board before the sterile compounded preparations of the sterile compounding facility are dispensed in the State.~~

~~[(d)] (E)~~ ~~A separate sterile compounding permit is required for each site at which sterile compounding is performed.~~

~~[(e)] (F)~~ ~~A sterile compounding permit is not transferable.~~

~~[(f)] (G) A person that prepares and distributes sterile drug products into or within the State:~~

~~(1) Is not required to hold a sterile compounding permit under subsection (a) or [(c)] (D) of this section; and~~

~~(2) Shall hold:~~

~~(i) A manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile drug products; and~~

~~(ii) A wholesale distributor's permit issued by the Board under Subtitle 6C of this title.~~

~~[(g)] (H) (1) The Board may waive any requirements of this subtitle, including the requirements of subsection [(f)] (G) of this section, in accordance with regulations adopted by the Board.~~

~~(2) A waiver may be issued to a sterile compounding facility or a person described in subsection [(f)] (G) of this section only:~~

~~(i) For specified sterile compounded preparations or sterile drug products for which there is a clinical need, as determined by the Board with input from health care providers in the State;~~

~~(ii) In exigent circumstances that, as determined by the Board, otherwise prevent health care providers from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products under item (i) of this paragraph; and~~

~~(iii) If the sterile compounding facility or person described in subsection [(f)] (G) of this section meets requirements established by the Board, including:~~

~~1. Provision of:~~

~~A. Reports of inspections conducted by a designee or the U.S. Food and Drug Administration;~~

~~B. A statement of compliance with USP 797; and~~

~~C. A review of adverse regulatory action; and~~

~~2. Any other requirement as determined by the Board.~~

~~(3) (i) The Board shall post on its Web site any waiver issued under this subsection.~~

~~(ii) For each waiver posted on its Web site, the Board shall include:~~

~~1. The name of the sterile compounding facility or other person receiving the waiver;~~

~~2. The sterile compounded preparation or sterile drug product for which the waiver is issued;~~

~~3. The basis for issuing the waiver;~~

~~4. The duration of the waiver; and~~

~~5. Any other information relating to the waiver or limitations on the waiver determined appropriate by the Board.~~

~~(4) Any waiver issued by the Board:~~

~~(i) May not exceed 2 years in duration;~~

~~(ii) May be renewed by the Board; and~~

~~(iii) May be rescinded by the Board if the Board finds that any requirements of this subtitle are not met.~~

~~(5) (i) The Board shall include in the regulations adopted under paragraph (1) of this subsection requirements for documenting, in a record acceptable to the Board, the administration to a patient of a sterile compounded preparation or sterile drug product obtained under a waiver issued under this subsection.~~

~~(ii) The requirements shall include:~~

~~1. Documentation of the lot number or other mechanism for identifying the sterile compounded preparation or sterile drug product for the purpose of tracing the sterile compounded preparation or sterile drug product back to the sterile compounding facility or other person that prepared it; or~~

~~2. If documentation of the lot number or other identification mechanism is not feasible, documentation of the source of the sterile compounded preparation or sterile drug product for the purpose of tracking the sterile compounded preparation or sterile drug product back to the sterile compounding facility or other person that prepared it.~~

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2014.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.