HOUSE BILL 986

J2 3lr0938
CF SB 896

By: **Delegate Hammen**
Introduced and read first time: February 8, 2013
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 27, 2013

CHAPTER _____

AN ACT concerning

State Board of Pharmacy – Sterile Compounding – Permits

FOR the purpose of requiring a sterile compounding facility to hold a sterile compounding permit issued by the State Board of Pharmacy before the sterile compounding facility may perform sterile compounding in the State; providing that a sterile compounding permit is required in addition to and does not replace certain other permits or licenses; requiring a sterile compounding facility that performs sterile compounding outside the State to hold a sterile compounding permit issued by the Board under certain circumstances; requiring a separate sterile compounding permit for each site at which sterile compounding is performed; prohibiting the transfer of a sterile compounding permit; providing that a person that prepares and distributes sterile drug products into or within the State is not required to hold a sterile compounding permit but must hold certain other permits; authorizing the Board to waive certain requirements in accordance with regulations adopted by the Board; establishing the requirements that must be met for a waiver to be issued; requiring the Board to post certain waivers on its Web site; requiring the Board to include certain information for each waiver posted on its Web site; providing for the duration, renewal, and rescission of a waiver; requiring an applicant for a sterile compounding permit to satisfy the Board that the applicant will perform sterile compounding in accordance with certain requirements; requiring the Board, by regulation, to establish permit requirements ~~in certain tiered permit categories and to require an applicant to obtain a permit in a certain category~~ based on risk; establishing certain application requirements for a sterile compounding permit; prohibiting the Board from issuing a sterile

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.

compounding permit unless the Board or its designee conducts an inspection and finds that the sterile compounding facility meets certain requirements; requiring the Board to issue a sterile compounding permit to any applicant that meets certain requirements; providing for the expiration and renewal of a sterile compounding permit; requiring the Board to adopt regulations to carry out certain provisions of this Act; requiring the regulations to require or include certain provisions; establishing inspection and reporting requirements for sterile compounding applicants and permit holders; authorizing the Board to take certain disciplinary actions and impose certain fines for certain violations; providing that each violation is grounds for a separate fine; requiring the Board to pay certain fines into the State Board of Pharmacy Fund; providing for a certain hearing and a certain appeal; requiring the Board to report on its Web site and make available to the public on request certain information relating to certain actions of the Board; prohibiting, with a certain exception, a sterile compounding facility from operating in the State or allowing the sterile compounded preparations of the sterile compounding facility to be dispensed in the State unless the sterile compounding facility holds a sterile compounding permit issued by the Board; prohibiting, with a certain exception, a person from distributing sterile drug products in the State unless the sterile drug products are produced in a facility that holds a certain permit; requiring the Board to maintain and submit to the Secretary with a certain frequency certain information relating to sterile compounding permit holders; requiring a wholesale distributor applicant or permit holder that prepares sterile drug products to submit to the Board, at certain times, a report of a certain inspection; establishing certain criminal penalties and a certain civil fine for certain violations; authorizing the Board to phase in the requirements of certain provisions of this Act, with full implementation on or before a certain date; requiring the Board to report to the Governor and the General Assembly on the implementation of certain provisions of this Act; defining certain terms; repealing a certain obsolete provision of law; and generally relating to sterile compounding permits and the State Board of Pharmacy.

BY adding to
Article – Health Occupations
Section 12–4A–01 through 12–4A–11 to be under the new subtitle "Subtitle 4A. Sterile Compounding Permits"; and 12–6C–03.2
Annotated Code of Maryland
(2009 Replacement Volume and 2012 Supplement)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–707
Annotated Code of Maryland
(2009 Replacement Volume and 2012 Supplement)

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

Article – Health Occupations

SUBTITLE 4A. STERILE COMPOUNDING PERMITS.

12–4A–01.

(A) IN THIS ~~SECTION~~ SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) ~~(1)~~ "COMPOUNDING" MEANS THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OF A DRUG ~~OR DEVICE~~ ONLY:

~~(I)~~ (1) AS THE RESULT OF A PRACTITIONER'S PRESCRIPTION DRUG ORDER OR INITIATIVE BASED ON THE PRACTITIONER/PATIENT~~/PHARMACIST~~ RELATIONSHIP IN THE COURSE OF PROFESSIONAL PRACTICE; ~~OR~~

~~(II)~~ (2) 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

~~(2)~~ (3) ~~"COMPOUNDING" INCLUDES THE PREPARATION OF DRUGS OR DEVICES IN~~ IN ANTICIPATION OF A PRESCRIPTION DRUG ORDER BASED ON ROUTINE, REGULARLY OBSERVED PRESCRIBING PATTERNS.

(C) "DESIGNEE" MEANS A PUBLIC AGENCY OR PRIVATE ENTITY APPROVED BY THE BOARD TO CONDUCT INSPECTIONS OF STERILE COMPOUNDING ~~APPLICANTS OR PERMIT HOLDERS LOCATED OUTSIDE THE STATE~~ 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 ~~STERILE WHEN ADMINISTERED TO PATIENTS~~ PREPARED USING ASEPTIC TECHNIQUES.

(E) "STERILE COMPOUNDING FACILITY" MEANS A PHARMACY, A HEALTH CARE PRACTITIONER'S OFFICE, OR ANY OTHER SETTING IN WHICH STERILE ~~PREPARATIONS ARE COMPOUNDED~~ 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.

~~(F)~~ (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 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) A STERILE COMPOUNDING PERMIT IS REQUIRED IN ADDITION TO AND DOES NOT REPLACE ANY OTHER PERMIT OR LICENSE A STERILE COMPOUNDING FACILITY HOLDS.

(C) 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) A SEPARATE STERILE COMPOUNDING PERMIT IS REQUIRED FOR EACH SITE AT WHICH STERILE COMPOUNDING IS PERFORMED.

(E) A STERILE COMPOUNDING PERMIT IS NOT TRANSFERABLE.

(F) 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) 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) (1) THE BOARD MAY WAIVE ANY REQUIREMENTS OF THIS SUBTITLE, INCLUDING THE REQUIREMENTS OF SUBSECTION (F) 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) 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) 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.

12–4A–03.

(A) TO QUALIFY FOR A STERILE COMPOUNDING PERMIT, AN APPLICANT SHALL SATISFY THE BOARD THAT THE APPLICANT WILL PERFORM STERILE COMPOUNDING IN ACCORDANCE WITH THE REQUIREMENTS OF THIS SUBTITLE.

(B) THE BOARD SHALL:

~~**(1) ESTABLISH PERMIT REQUIREMENTS FOR APPLICANTS IN THREE TIERED PERMIT CATEGORIES, BASED ON THE RISK CATEGORIES DESCRIBED IN USP 797:**~~

~~**(I) LOW RISK;**~~

~~**(II) MEDIUM RISK; AND**~~

~~**(III) HIGH RISK; AND**~~

~~**(2) REQUIRE AN APPLICANT TO OBTAIN A PERMIT IN THE CATEGORY APPROPRIATE TO THE HIGHEST RISK OF STERILE COMPOUNDING PERFORMED BY THE STERILE COMPOUNDING FACILITY**~~ **ESTABLISH, BY REGULATION, REQUIREMENTS FOR APPLICANTS BASED ON RISK.**

12–4A–04.

(A) TO APPLY FOR A STERILE COMPOUNDING PERMIT, AN APPLICANT SHALL:

(1) PAY TO THE BOARD AN APPLICATION FEE SET BY THE BOARD; AND

(2) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM THAT THE BOARD REQUIRES.

(B) THE BOARD MAY NOT ISSUE A STERILE COMPOUNDING PERMIT TO AN APPLICANT UNLESS THE BOARD OR ITS DESIGNEE:

(1) CONDUCTS AN INSPECTION OF THE STERILE COMPOUNDING FACILITY APPLYING FOR THE PERMIT; AND

(2) FINDS THAT THE STERILE COMPOUNDING FACILITY MEETS THE BOARD'S REQUIREMENTS.

(C) THE BOARD SHALL ISSUE A STERILE COMPOUNDING PERMIT TO ANY APPLICANT THAT MEETS THE REQUIREMENTS OF THIS SECTION.

12–4A–05.

(A) A STERILE COMPOUNDING PERMIT EXPIRES ON ~~THE SECOND ANNIVERSARY~~ MAY 31 OF THE NEXT EVEN–NUMBERED YEAR AFTER ITS EFFECTIVE DATE, UNLESS THE STERILE COMPOUNDING PERMIT IS RENEWED FOR ~~AN ADDITIONAL~~ A 2–YEAR TERM AS PROVIDED IN THIS SECTION.

(B) BEFORE A STERILE COMPOUNDING PERMIT EXPIRES, THE STERILE COMPOUNDING PERMIT MAY BE RENEWED FOR AN ADDITIONAL 2–YEAR TERM IF THE APPLICANT:

(1) OTHERWISE IS ENTITLED TO THE PERMIT;

(2) PAYS TO THE BOARD THE RENEWAL FEE SET BY THE BOARD IN REGULATION; AND

(3) SUBMITS TO THE BOARD:

~~(I)~~ ~~A~~ A RENEWAL APPLICATION ON THE FORM THE BOARD REQUIRES~~; AND~~

~~(II) SATISFACTORY EVIDENCE OF COMPLIANCE WITH ANY REQUIREMENT UNDER THIS SUBTITLE FOR RENEWAL OF THE PERMIT~~.

(C) THE BOARD SHALL RENEW A PERMIT IF THE APPLICANT MEETS THE REQUIREMENTS OF THIS SECTION.

12–4A–06.

(A) THE BOARD SHALL ADOPT REGULATIONS TO CARRY OUT THIS SUBTITLE.

(B) THE REGULATIONS SHALL:

(1) REQUIRE COMPLIANCE WITH USP 797;

(2) REQUIRE EACH STERILE COMPOUNDED PREPARATION TO BE DISPENSED OR ADMINISTERED IN ACCORDANCE WITH A PRESCRIPTION FROM AN AUTHORIZED PRESCRIBER;

(3) INCLUDE~~, FOR EACH STERILE COMPOUNDING PERMIT CATEGORY~~:

(I) IN ACCORDANCE WITH §§ 12–4A–07 AND 12–4A–08 OF THIS SUBTITLE, REQUIREMENTS FOR:

1. INSPECTIONS;

2. REPORTING OF ADVERSE EVENTS AND EVIDENCE OF ENVIRONMENTAL CONTAMINATION; AND

3. REPORTING OF DEFICIENCIES, DISCIPLINARY ACTION, OR CHANGES IN ACCREDITATION STATUS;

(II) QUALITY AND SAFETY STANDARDS; AND

(III) INITIAL PERMIT AND PERMIT RENEWAL FEES; AND

(4) REQUIRE A STERILE COMPOUNDING PERMIT HOLDER TO ENSURE THAT PERSONNEL ENGAGING IN STERILE COMPOUNDING ARE TRAINED AND DEMONSTRATE COMPETENCE IN THE SAFE HANDLING AND COMPOUNDING OF STERILE PREPARATIONS.

12–4A–07.

(A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD:

(1) SHALL INSPECT A STERILE COMPOUNDING PERMIT HOLDER~~:~~

~~(I) IN A HIGH–RISK OR MEDIUM–RISK CATEGORY, AT LEAST ANNUALLY; AND~~

~~(II) IN A LOW–RISK CATEGORY, AT INTERVALS REQUIRED~~ WITH A FREQUENCY BASED ON RISK AS SET FORTH IN REGULATIONS ADOPTED BY THE BOARD;

(2) SHALL INCLUDE, IN ALL INSPECTIONS UNDER ~~PARAGRAPH~~ ITEM (1) OF THIS SUBSECTION, ~~MICROBIAL~~ A REVIEW IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, OF:

(I) QUALITY ASSURANCE TESTING REPORTS; AND

(II) MICROBIAL TESTING OF A SAMPLING OF THE COMPOUNDED PREPARATIONS OF THE STERILE COMPOUNDING PERMIT HOLDER; AND

(3) MAY INSPECT A STERILE COMPOUNDING PERMIT HOLDER AT ANY TIME:

(I) TO VERIFY COMPLIANCE WITH PERMIT REQUIREMENTS; OR

(II) TO INVESTIGATE A COMPLAINT.

(B) (1) IF AN APPLICANT OR PERMIT HOLDER IS PERFORMING STERILE COMPOUNDING OUTSIDE THE STATE, THE BOARD MAY RELY ON AN INSPECTION CONDUCTED BY A DESIGNEE TO CONDUCT INSPECTIONS UNDER THIS SUBTITLE.

(2) THE BOARD MAY APPROVE A DESIGNEE TO CONDUCT INSPECTIONS OF APPLICANTS OR PERMIT HOLDERS OUTSIDE THE STATE ONLY IF THE INSPECTIONS ARE CONDUCTED IN ACCORDANCE WITH THIS SUBTITLE AND THE REGULATIONS ADOPTED BY THE BOARD.

(3) AN APPLICANT OR PERMIT HOLDER OUTSIDE THE STATE IS RESPONSIBLE FOR OBTAINING AN INSPECTION FROM A DESIGNEE TO MEET THE REQUIREMENTS OF THIS SUBTITLE.

12–4A–08.

(A) THE BOARD SHALL:

(1) DETERMINE THE ADVERSE EVENTS AND EVIDENCE OF ENVIRONMENTAL CONTAMINATION THAT MUST BE REPORTED BY A STERILE COMPOUNDING PERMIT HOLDER; AND

(2) REQUIRE A STERILE COMPOUNDING PERMIT HOLDER TO REPORT TO THE BOARD THE ADVERSE EVENTS OR EVIDENCE OF ENVIRONMENTAL CONTAMINATION WITHIN 5 CALENDAR DAYS AFTER BECOMING AWARE OF THE ADVERSE EVENTS OR EVIDENCE.

(B) (1) THE BOARD SHALL:

(I) DETERMINE THE DEFICIENCIES, DISCIPLINARY ACTIONS, AND CHANGES IN ACCREDITATION STATUS DESCRIBED IN PARAGRAPH

(2) OF THIS SUBSECTION THAT MUST BE REPORTED BY A STERILE COMPOUNDING PERMIT HOLDER; AND

(II) REQUIRE A STERILE COMPOUNDING PERMIT HOLDER TO REPORT TO THE BOARD THE DEFICIENCIES, DISCIPLINARY ACTIONS, AND CHANGES IN ACCREDITATION STATUS WITHIN 5 CALENDAR DAYS AFTER BECOMING AWARE OF THE DEFICIENCIES, DISCIPLINARY ACTIONS, OR CHANGES IN ACCREDITATION STATUS.

(2) THE BOARD MAY REQUIRE A STERILE COMPOUNDING PERMIT HOLDER TO REPORT UNDER PARAGRAPH (1) OF THIS SUBSECTION:

(I) A DEFICIENCY NOTED DURING AN INSPECTION, DURING AN ACCREDITATION SITE VISIT, OR IN OFFICIAL CORRESPONDENCE FROM A STATE OR FEDERAL AGENCY, A PROFESSIONAL ASSOCIATION, OR AN ACCREDITATION ORGANIZATION;

(II) DISCIPLINARY ACTION BY A STATE OR FEDERAL AGENCY, INCLUDING A REVOCATION, SUSPENSION, PROBATION, CENSURE, REPRIMAND, OR RESTRICTION PLACED ON A LICENSE, A PERMIT, OR ANY OTHER AUTHORIZATION OF THE STERILE COMPOUNDING PERMIT HOLDER OR A HEALTH CARE PRACTITIONER WHO IS AN OWNER, OPERATOR, OR EMPLOYEE OF A STERILE COMPOUNDING PERMIT HOLDER; OR

(III) A CHANGE IN ACCREDITATION STATUS ISSUED BY A PROFESSIONAL ASSOCIATION OR AN ACCREDITATION ORGANIZATION RELATING TO THE STERILE COMPOUNDING PERMIT HOLDER.

12–4A–09.

(A) (1) SUBJECT TO THE HEARING PROVISIONS OF SUBSECTION (C) OF THIS SECTION, FOR A VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE BOARD MAY:

(I) DENY A PERMIT TO AN APPLICANT;

(II) REPRIMAND A PERMIT HOLDER;

(III) PLACE A PERMIT HOLDER ON PROBATION; OR

(IV) SUSPEND OR REVOKE A PERMIT.

(2) INSTEAD OF OR IN ADDITION TO A REPRIMAND, PROBATION, SUSPENSION, OR REVOCATION, THE BOARD MAY IMPOSE A FINE NOT

EXCEEDING $10,000 FOR ANY VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE.

(3) EACH VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE IS GROUNDS FOR A SEPARATE FINE.

(B) THE BOARD SHALL PAY ANY FINE COLLECTED UNDER THIS SECTION INTO THE STATE BOARD OF PHARMACY FUND.

(C) (1) BEFORE THE BOARD TAKES ANY ACTION UNDER SUBSECTION (A) OF THIS SECTION, IT SHALL GIVE THE APPLICANT OR PERMIT HOLDER AN OPPORTUNITY FOR A HEARING BEFORE THE BOARD.

(2) THE BOARD SHALL GIVE NOTICE AND HOLD THE HEARING IN ACCORDANCE WITH THE ADMINISTRATIVE PROCEDURE ACT.

(3) ANY APPLICANT OR PERMIT HOLDER AGGRIEVED BY A FINAL DECISION OF THE BOARD MAY APPEAL AS PROVIDED UNDER THE ADMINISTRATIVE PROCEDURE ACT.

(D) THE BOARD SHALL REPORT ON ITS WEB SITE AND MAKE AVAILABLE TO THE PUBLIC ON REQUEST:

(1) WITHIN 5 CALENDAR DAYS AFTER TAKING THE ACTION, INFORMATION RELATING TO A SUSPENSION OR REVOCATION OF A PERMIT; AND

(2) WITHIN 30 CALENDAR DAYS AFTER TAKING THE ACTION, INFORMATION RELATING TO ANY OTHER FORMAL ACTION AGAINST AN APPLICANT OR PERMIT HOLDER.

12–4A–10.

(A) ~~A~~ EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A STERILE COMPOUNDING FACILITY MAY NOT OPERATE IN THE STATE OR ALLOW THE STERILE COMPOUNDED PREPARATIONS OF THE STERILE COMPOUNDING FACILITY TO BE DISPENSED IN THE STATE UNLESS THE STERILE COMPOUNDING FACILITY HOLDS A STERILE COMPOUNDING PERMIT ISSUED BY THE BOARD.

(B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A PERSON MAY NOT DISTRIBUTE STERILE DRUG PRODUCTS IN THE STATE UNLESS THE STERILE DRUG PRODUCTS ARE PRODUCED IN A FACILITY THAT HOLDS A MANUFACTURER'S PERMIT OR OTHER PERMIT DESIGNATED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO ENSURE THE SAFETY OF STERILE DRUG PRODUCTS.

(C) A PERSON MAY DISPENSE OR DISTRIBUTE STERILE COMPOUNDED PREPARATIONS OR STERILE DRUG PRODUCTS IN THE STATE WITHOUT MEETING THE REQUIREMENTS OF SUBSECTION (A) OR (B) OF THIS SECTION ONLY IN ACCORDANCE WITH A WAIVER ISSUED BY THE BOARD UNDER § 12–4A–02 OF THIS SUBTITLE.

12–4A–11.

THE BOARD SHALL MAINTAIN AND SUBMIT ANNUALLY TO THE SECRETARY INFORMATION RELATING TO EACH STERILE COMPOUNDING PERMIT HOLDER, INCLUDING:

(1) THE PERMIT HOLDER'S NAME AND ADDRESS;

(2) THE PERMIT HOLDER'S PERMIT CATEGORY; AND

(3) ANY DISCIPLINARY ACTIONS TAKEN AGAINST THE PERMIT HOLDER DURING THE REPORTING PERIOD.

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 BE:

(1) 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.

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

(1) § 12–311 ("Display of licenses");

(2) Subtitle 4 ("Pharmacy permits");

(3) § 12–502(b) ("Pharmaceutical information");

(4) § 12–505 ("Labeling requirements for prescription medicines"); and

(5) § 12–604 ("General power to inspect drugs, devices, and other products").

(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) § 12–602 ("Distribution permits");**]**

(1) § 12–4A–10 ("OPERATING A STERILE COMPOUNDING FACILITY WITHOUT PERMIT");

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

(3) § 12–702 ("License obtained by false representation");

(4) § 12–703 ("Operating a pharmacy without permit");

(5) § 12–704 ("Misrepresentations"); and

(6) § 12–6B–12 ("Working as an unregistered pharmacy technician").

(c) Each day that a violation of any section of Subtitle 4 of this title continues constitutes a separate offense.

(d) Within 10 days after a court renders the conviction, the court shall report to the Board each conviction of a pharmacist or registered pharmacy technician for:

(1) Any crime regarding the pharmacy or drug laws that involves professional misconduct; or

(2) Any crime that involves the State law regarding controlled dangerous substances or the federal narcotic laws.

(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"), or § 12–6B–12 ("Working as an unregistered pharmacy technician") 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 2. AND BE IT FURTHER ENACTED, That the State Board of Pharmacy may phase in the requirements of Title 12, Subtitle 4A of the Health Occupations Article, as enacted by Section 1 of this Act, with full implementation to be completed on or before April 1, 2014.

SECTION 3. AND BE IT FURTHER ENACTED, That on or before January 1, 2014, the State Board of Pharmacy shall report to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly on the implementation of Title 12, Subtitle 4A of the Health Occupations Article, as enacted by Section 1 of this Act.

SECTION ~~2.~~ 4. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ July 1, 2013.

Approved:

_____

Governor.

_____

Speaker of the House of Delegates.

_____

President of the Senate.