

SENATE BILL 896

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CF HB 986

By: **Senator Conway**

Introduced and read first time: February 11, 2013

Assigned to: Rules

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy – Sterile Compounding – Permits**

3 FOR the purpose of requiring a sterile compounding facility to hold a sterile
4 compounding permit issued by the State Board of Pharmacy before the sterile
5 compounding facility may perform sterile compounding in the State; providing
6 that a sterile compounding permit is required in addition to and does not
7 replace certain other permits or licenses; requiring a sterile compounding
8 facility that performs sterile compounding outside the State to hold a sterile
9 compounding permit issued by the Board under certain circumstances;
10 requiring a separate sterile compounding permit for each site at which sterile
11 compounding is performed; prohibiting the transfer of a sterile compounding
12 permit; requiring an applicant for a sterile compounding permit to satisfy the
13 Board that the applicant will perform sterile compounding in accordance with
14 certain requirements; requiring the Board to establish permit requirements in
15 certain tiered permit categories and to require an applicant to obtain a permit
16 in a certain category; establishing certain application requirements for a sterile
17 compounding permit; prohibiting the Board from issuing a sterile compounding
18 permit unless the Board or its designee conducts an inspection and finds that
19 the sterile compounding facility meets certain requirements; requiring the
20 Board to issue a sterile compounding permit to any applicant that meets certain
21 requirements; providing for the expiration and renewal of a sterile compounding
22 permit; requiring the Board to adopt regulations to carry out certain provisions
23 of this Act; requiring the regulations to require or include certain provisions;
24 establishing inspection and reporting requirements for sterile compounding
25 applicants and permit holders; authorizing the Board to take certain
26 disciplinary actions and impose certain fines for certain violations; providing
27 that each violation is grounds for a separate fine; requiring the Board to pay
28 certain fines into the State Board of Pharmacy Fund; providing for a certain
29 hearing and a certain appeal; requiring the Board to report on its Web site and
30 make available to the public on request certain information relating to certain
31 actions of the Board; prohibiting a sterile compounding facility from operating

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 in the State or allowing the sterile compounded preparations of the sterile
 2 compounding facility to be dispensed in the State unless the sterile
 3 compounding facility holds a sterile compounding permit issued by the Board;
 4 requiring the Board to maintain and submit to the Secretary with a certain
 5 frequency certain information relating to sterile compounding permit holders;
 6 establishing certain criminal penalties and a certain civil fine for certain
 7 violations; defining certain terms; repealing a certain obsolete provision of law;
 8 and generally relating to sterile compounding permits and the State Board of
 9 Pharmacy.

10 BY adding to

11 Article – Health Occupations
 12 Section 12–4A–01 through 12–4A–11 to be under the new subtitle “Subtitle 4A.
 13 Sterile Compounding Permits”
 14 Annotated Code of Maryland
 15 (2009 Replacement Volume and 2012 Supplement)

16 BY repealing and reenacting, with amendments,

17 Article – Health Occupations
 18 Section 12–707
 19 Annotated Code of Maryland
 20 (2009 Replacement Volume and 2012 Supplement)

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

23 **Article – Health Occupations**

24 **SUBTITLE 4A. STERILE COMPOUNDING PERMITS.**

25 **12–4A–01.**

26 **(A) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS**
 27 **INDICATED.**

28 **(B) (1) “COMPOUNDING” MEANS THE PREPARATION, MIXING,**
 29 **ASSEMBLING, PACKAGING, OR LABELING OF A DRUG OR DEVICE:**

30 **(I) AS THE RESULT OF A PRACTITIONER’S PRESCRIPTION**
 31 **DRUG ORDER OR INITIATIVE BASED ON THE**
 32 **PRACTITIONER/PATIENT/PHARMACIST RELATIONSHIP IN THE COURSE OF**
 33 **PROFESSIONAL PRACTICE; OR**

1 **(II) FOR THE PURPOSE OF, OR INCIDENTAL TO, RESEARCH,**
2 **TEACHING, OR CHEMICAL ANALYSIS AND NOT FOR THE SALE OR DISPENSING OF**
3 **THE DRUG OR DEVICE.**

4 **(2) “COMPOUNDING” INCLUDES THE PREPARATION OF DRUGS OR**
5 **DEVICES IN ANTICIPATION OF A PRESCRIPTION DRUG ORDER BASED ON**
6 **ROUTINE, REGULARLY OBSERVED PRESCRIBING PATTERNS.**

7 **(C) “DESIGNEE” MEANS A PUBLIC AGENCY OR PRIVATE ENTITY**
8 **APPROVED BY THE BOARD TO CONDUCT INSPECTIONS OF STERILE**
9 **COMPOUNDING APPLICANTS OR PERMIT HOLDERS LOCATED OUTSIDE THE**
10 **STATE.**

11 **(D) “STERILE COMPOUNDING” MEANS COMPOUNDING OF BIOLOGICS,**
12 **DIAGNOSTICS, DRUGS, NUTRIENTS, AND RADIOPHARMACEUTICALS THAT,**
13 **UNDER USP 797, MUST BE STERILE WHEN ADMINISTERED TO PATIENTS.**

14 **(E) “STERILE COMPOUNDING FACILITY” MEANS A PHARMACY, A**
15 **HEALTH CARE PRACTITIONER’S OFFICE, OR ANY OTHER SETTING IN WHICH**
16 **STERILE PREPARATIONS ARE COMPOUNDED.**

17 **(F) “USP 797” MEANS THE STANDARDS SET FORTH IN THE UNITED**
18 **STATES PHARMACOPEIA, GENERAL CHAPTER 797, “PHARMACEUTICAL**
19 **COMPOUNDING – STERILE PREPARATIONS”.**

20 **12-4A-02.**

21 **(A) A STERILE COMPOUNDING FACILITY SHALL HOLD A STERILE**
22 **COMPOUNDING PERMIT ISSUED BY THE BOARD BEFORE THE STERILE**
23 **COMPOUNDING FACILITY MAY PERFORM STERILE COMPOUNDING IN THE**
24 **STATE.**

25 **(B) A STERILE COMPOUNDING PERMIT IS REQUIRED IN ADDITION TO**
26 **AND DOES NOT REPLACE ANY OTHER PERMIT OR LICENSE A STERILE**
27 **COMPOUNDING FACILITY HOLDS.**

28 **(C) A STERILE COMPOUNDING FACILITY THAT PERFORMS STERILE**
29 **COMPOUNDING OUTSIDE THE STATE SHALL HOLD A STERILE COMPOUNDING**
30 **PERMIT ISSUED BY THE BOARD BEFORE THE STERILE COMPOUNDED**
31 **PREPARATIONS OF THE STERILE COMPOUNDING FACILITY ARE DISPENSED IN**
32 **THE STATE.**

1 **(D) A SEPARATE STERILE COMPOUNDING PERMIT IS REQUIRED FOR**
2 **EACH SITE AT WHICH STERILE COMPOUNDING IS PERFORMED.**

3 **(E) A STERILE COMPOUNDING PERMIT IS NOT TRANSFERABLE.**

4 **12-4A-03.**

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

8 **(B) THE BOARD SHALL:**

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

12 **(I) LOW RISK;**

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

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

15 **(2) REQUIRE AN APPLICANT TO OBTAIN A PERMIT IN THE**
16 **CATEGORY APPROPRIATE TO THE HIGHEST RISK OF STERILE COMPOUNDING**
17 **PERFORMED BY THE STERILE COMPOUNDING FACILITY.**

18 **12-4A-04.**

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

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

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

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

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

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

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

5 **12-4A-05.**

6 **(A) A STERILE COMPOUNDING PERMIT EXPIRES ON THE SECOND**
7 **ANNIVERSARY AFTER ITS EFFECTIVE DATE, UNLESS THE STERILE**
8 **COMPOUNDING PERMIT IS RENEWED FOR AN ADDITIONAL 2-YEAR TERM AS**
9 **PROVIDED IN THIS SECTION.**

10 **(B) BEFORE A STERILE COMPOUNDING PERMIT EXPIRES, THE STERILE**
11 **COMPOUNDING PERMIT MAY BE RENEWED FOR AN ADDITIONAL 2-YEAR TERM IF**
12 **THE APPLICANT:**

13 **(1) OTHERWISE IS ENTITLED TO THE PERMIT;**

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

16 **(3) SUBMITS TO THE BOARD:**

17 **(I) A RENEWAL APPLICATION ON THE FORM THE BOARD**
18 **REQUIRES; AND**

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

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

23 **12-4A-06.**

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

26 **(B) THE REGULATIONS SHALL:**

27 **(1) REQUIRE COMPLIANCE WITH USP 797;**

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

4 **(3) INCLUDE, FOR EACH STERILE COMPOUNDING PERMIT**
5 **CATEGORY:**

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

8 **1. INSPECTIONS;**

9 **2. REPORTING OF ADVERSE EVENTS AND EVIDENCE**
10 **OF ENVIRONMENTAL CONTAMINATION; AND**

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

13 **(II) QUALITY AND SAFETY STANDARDS; AND**

14 **(III) INITIAL PERMIT AND PERMIT RENEWAL FEES; AND**

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

19 **12-4A-07.**

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

21 **(1) SHALL INSPECT A STERILE COMPOUNDING PERMIT HOLDER:**

22 **(I) IN A HIGH-RISK OR MEDIUM-RISK CATEGORY, AT LEAST**
23 **ANNUALLY; AND**

24 **(II) IN A LOW-RISK CATEGORY, AT INTERVALS REQUIRED BY**
25 **THE BOARD;**

26 **(2) SHALL INCLUDE IN ALL INSPECTIONS UNDER PARAGRAPH (1)**
27 **OF THIS SUBSECTION, MICROBIAL TESTING OF A SAMPLING OF THE**
28 **COMPOUNDED PREPARATIONS OF THE STERILE COMPOUNDING PERMIT**
29 **HOLDER; AND**

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

3 **(I) TO VERIFY COMPLIANCE WITH PERMIT REQUIREMENTS;**
4 **OR**

5 **(II) TO INVESTIGATE A COMPLAINT.**

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

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

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

17 **12-4A-08.**

18 **(A) THE BOARD SHALL:**

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

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

26 **(B) (1) THE BOARD SHALL:**

27 **(I) DETERMINE THE DEFICIENCIES, DISCIPLINARY**
28 **ACTIONS, AND CHANGES IN ACCREDITATION STATUS DESCRIBED IN PARAGRAPH**
29 **(2) OF THIS SUBSECTION THAT MUST BE REPORTED BY A STERILE**
30 **COMPOUNDING PERMIT HOLDER; AND**

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

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

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

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

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

21 **12-4A-09.**

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

25 **(I) DENY A PERMIT TO AN APPLICANT;**

26 **(II) REPRIMAND A PERMIT HOLDER;**

27 **(III) PLACE A PERMIT HOLDER ON PROBATION; OR**

28 **(IV) SUSPEND OR REVOKE A PERMIT.**

29 **(2) INSTEAD OF OR IN ADDITION TO A REPRIMAND, PROBATION,**
30 **SUSPENSION, OR REVOCATION, THE BOARD MAY IMPOSE A FINE NOT**
31 **EXCEEDING \$10,000 FOR ANY VIOLATION OF THIS SUBTITLE.**

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

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

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

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

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

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

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

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

20 **12-4A-10.**

21 **A STERILE COMPOUNDING FACILITY MAY NOT OPERATE IN THE STATE OR**
22 **ALLOW THE STERILE COMPOUNDED PREPARATIONS OF THE STERILE**
23 **COMPOUNDING FACILITY TO BE DISPENSED IN THE STATE UNLESS THE STERILE**
24 **COMPOUNDING FACILITY HOLDS A STERILE COMPOUNDING PERMIT ISSUED BY**
25 **THE BOARD.**

26 **12-4A-11.**

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

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

1 **(2) THE PERMIT HOLDER’S PERMIT CATEGORY; AND**

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

4 12-707.

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

8 (1) § 12-311 (“Display of licenses”);

9 (2) Subtitle 4 (“Pharmacy permits”);

10 (3) § 12-502(b) (“Pharmaceutical information”);

11 (4) § 12-505 (“Labeling requirements for prescription medicines”); and

12 (5) § 12-604 (“General power to inspect drugs, devices, and other
13 products”).

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

17 [(1) § 12-602 (“Distribution permits”);]

18 **(1) § 12-4A-10 (“OPERATING A STERILE COMPOUNDING**
19 **FACILITY WITHOUT PERMIT”);**

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

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

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

23 (5) § 12-704 (“Misrepresentations”); and

24 (6) § 12-6B-12 (“Working as an unregistered pharmacy technician”).

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

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

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

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

7 (e) (1) Any person who violates **§ 12-4A-10 (“OPERATING A STERILE
8 COMPOUNDING FACILITY WITHOUT PERMIT”)**, § 12-701 (“Practicing pharmacy
9 without a license”), § 12-703 (“Operating a pharmacy without a permit”), or §
10 12-6B-12 (“Working as an unregistered pharmacy technician”) of this title is subject
11 to a civil fine of not more than \$50,000 to be assessed by the Board.

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

14 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
15 October 1, 2013.