

SENATE BILL 603

J2

(2lr0704)

ENROLLED BILL

— *Education, Health, and Environmental Affairs/Health and Government Operations* —

Introduced by **Senators Montgomery and Conway**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

President.

CHAPTER _____

1 AN ACT concerning

2 **Health Care Practitioners – Licensed Dentists, Physicians, and Podiatrists –**
3 **Personally Preparing and Dispensing Prescription Drugs and Devices**

4 FOR the purpose of requiring certain dentists, physicians, and podiatrists to comply
5 with certain dispensing, labeling, inspection, packaging, recall procedure, and
6 record keeping, requirements as a condition of being allowed to personally
7 prepare and dispense prescription drugs or devices and to comply with certain
8 purchase, verification, reporting, and continuing education requirements as a
9 condition of being allowed to personally prepare and dispense prescription drugs
10 ~~or devices~~; requiring the State Board of Pharmacy, the State Board of Dental
11 Examiners, the State Board of Physicians, and the State Board of Podiatric
12 Medical Examiners to report certain information to the Division of Drug Control
13 on an annual basis; requiring the Division of Drug Control to enter and inspect
14 certain offices during certain time periods; requiring the Division of Drug

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.

Italics indicate opposite chamber/conference committee amendments.



Control to report the results of these inspections to certain licensing boards; requiring certain licensing boards to charge a certain fee to certain holders of dispensing permits in a certain amount; requiring the revenues collected by the boards to be paid into the General Fund of the State; providing that a certain fee shall apply to dispensing permits issued or renewed on or after a certain date; providing for a certain phase-in of a certain continuing education requirement; providing for a delayed effective date; and generally relating to the personal preparation and dispensing of prescription drugs or devices by dentists, physicians, and podiatrists.

BY repealing and reenacting, with amendments,
 Article – Health Occupations
 Section 12–102
 Annotated Code of Maryland
 (2009 Replacement Volume and 2011 Supplement)

BY adding to
 Article – Health Occupations
 Section 12–102.1 and 12–102.2
 Annotated Code of Maryland
 (2009 Replacement Volume and 2011 Supplement)

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

Article – Health Occupations

12–102.

(a) (1) In this section the following terms have the meanings indicated.

(2) “In the public interest” means the dispensing of drugs or devices by a licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently available to the patient.

(3) “Personally preparing and dispensing” means that the licensed dentist, physician, or podiatrist:

(i) Is physically present on the premises where the prescription is filled; and

(ii) Performs a final check of the prescription before it is provided to the patient.

(b) This title does not limit the right of an individual to practice a health occupation that the individual is authorized to practice under this article.

1 (c) This title does not prohibit:

2 (1) A licensed veterinarian from personally preparing and dispensing
3 the veterinarian's prescriptions;

4 (2) A licensed dentist, physician, or podiatrist from personally
5 preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

6 (i) The dentist, physician, or podiatrist:

7 1. Has applied to the board of licensure in this State
8 which licensed the dentist, physician, or podiatrist;

9 2. Has demonstrated to the satisfaction of that board
10 that the dispensing of prescription drugs or devices by the dentist, physician, or
11 podiatrist is in the public interest;

12 3. Has received a written permit from that board to
13 dispense prescription drugs or devices except that a written permit is not required in
14 order to dispense starter dosages or samples without charge; and

15 4. Posts a sign conspicuously positioned and readable
16 regarding the process for resolving incorrectly filled prescriptions or includes written
17 information regarding the process with each prescription dispensed;

18 (ii) The person for whom the drugs or devices are prescribed is a
19 patient of the prescribing dentist, physician, or podiatrist;

20 (iii) The dentist, physician, or podiatrist does not have a
21 substantial financial interest in a pharmacy; and

22 (iv) The dentist, physician, or podiatrist:

23 1. Complies with the **DISPENSING AND** labeling
24 requirements [of § 12-505] of this title;

25 2. Records the dispensing of the prescription drug or
26 device on the patient's chart;

27 3. Allows the Division of Drug Control to enter and
28 inspect the dentist's, physician's, or podiatrist's office at all reasonable hours **AND IN**
29 **ACCORDANCE WITH § 12-102.1 OF THIS SUBTITLE;**

30 4. **ON INSPECTION BY THE DIVISION OF DRUG**
31 **CONTROL, SIGNS AND DATES AN ACKNOWLEDGMENT FORM PROVIDED BY THE**

1 **DIVISION OF DRUG CONTROL RELATING TO THE REQUIREMENTS OF THIS**
2 **SECTION;**

3 [4.] 5. Except for starter dosages or samples without
4 charge, provides the patient with a written prescription, maintains prescription files
5 in accordance with § 12-403(b)(13) of this title, and maintains a separate file for
6 Schedule II prescriptions;

7 [5.] 6. Does not direct patients to a single pharmacist
8 or pharmacy in accordance with § 12-403(b)(8) of this title; [and]

9 [6.] 7. Does not receive remuneration for referring
10 patients to a pharmacist or pharmacy; [or]

11 8. COMPLIES WITH THE CHILD RESISTANT
12 PACKAGING REQUIREMENTS REGARDING PRESCRIPTION DRUGS UNDER TITLE
13 22, SUBTITLE 3 OF THE HEALTH – GENERAL ARTICLE;

14 9. COMPLIES WITH DRUG RECALLS;

15 10. MAINTAINS BIENNIAL INVENTORIES AND
16 COMPLIES WITH ANY OTHER FEDERAL AND STATE RECORD-KEEPING
17 REQUIREMENTS RELATING TO CONTROLLED DANGEROUS SUBSTANCES;

18 11. PURCHASES PRESCRIPTION DRUGS ~~OR DEVICES~~
19 FROM A PHARMACY OR WHOLESALE DISTRIBUTOR WHO HOLDS A PERMIT
20 ISSUED BY THE BOARD OF PHARMACY, AS VERIFIED BY THE BOARD OF
21 PHARMACY;

22 12. ANNUALLY REPORTS TO THE RESPECTIVE BOARD
23 OF LICENSURE WHETHER THE DENTIST, PHYSICIAN, OR PODIATRIST HAS
24 PERSONALLY PREPARED AND DISPENSED PRESCRIPTION DRUGS ~~OR DEVICES~~
25 WITHIN THE PREVIOUS YEAR; AND

26 13. COMPLETES TEN CONTINUING EDUCATION
27 CREDITS OVER A 5-YEAR PERIOD RELATING TO THE PREPARING AND
28 DISPENSING OF PRESCRIPTION DRUGS ~~AND DEVICES~~, OFFERED BY THE
29 ACCREDITATION COUNCIL FOR PHARMACY EDUCATION (ACPE) OR AS
30 APPROVED BY THE SECRETARY, IN CONSULTATION WITH EACH RESPECTIVE
31 BOARD OF LICENSURE, AS A CONDITION OF PERMIT RENEWAL; OR

32 (3) A hospital-based clinic from dispensing prescriptions to its
33 patients.

1 (d) This title does not prohibit:

2 (1) A licensed veterinarian from personally dispensing a drug or
3 device sample to a patient of the veterinarian; or

4 (2) A licensed dentist, licensed physician, or licensed podiatrist from
5 personally dispensing a drug or device sample to a patient of the licensed dentist,
6 licensed physician, or licensed podiatrist if:

7 (i) The sample complies with the labeling requirements of §
8 12–505 of this title;

9 (ii) No charge is made for the sample; and

10 (iii) The authorized prescriber enters an appropriate record in
11 the patient’s chart.

12 (e) (1) This title does not prohibit a dentist, physician, or podiatrist from
13 administering a prescription drug or device in the course of treating a patient.

14 (2) For the purposes of paragraph (1) of this subsection,
15 “administering” means the direct introduction of a single dosage of a drug or device at
16 a given time, whether by injection or other means, and whether in liquid, tablet,
17 capsule, or other form.

18 (f) (1) This title does not prohibit a dentist, physician, or podiatrist from
19 personally dispensing a starter dosage of a prescription drug or device to a patient of
20 the dentist, physician, or podiatrist, provided that:

21 (i) The starter dosage complies with the labeling requirements
22 of § 12–505 of this title;

23 (ii) No charge is made for the starter dosage; and

24 (iii) The dentist, physician, or podiatrist enters an appropriate
25 record on the patient’s chart.

26 (2) For the purposes of paragraph (1) of this subsection, “starter
27 dosage” means an amount of drug or device sufficient to begin therapy:

28 (i) Of short duration of 72 hours or less; or

29 (ii) Prior to obtaining a larger quantity of the drug or device to
30 complete the therapy.

31 (g) This title does not prohibit a dentist, physician, or podiatrist from
32 dispensing a prescription drug or device in the course of treating a patient:

1 (1) At a medical facility or clinic that specializes in the treatment of
2 medical cases reimbursable through workers' compensation insurance;

3 (2) At a medical facility or clinic that is operated on a nonprofit basis;

4 (3) At a health center that operates on a campus of an institution of
5 higher education; or

6 (4) At a public health facility, a medical facility under contract with a
7 State or local health department, or a facility funded with public funds.

8 (h) This title does not limit the right of a general merchant to sell:

9 (1) Any nonprescription drug or device;

10 (2) Any commonly used household or domestic remedy; or

11 (3) Any farm remedy or ingredient for a spraying solution, in bulk or
12 otherwise.

13 **(I) THE BOARD OF PHARMACY, THE BOARD OF DENTAL EXAMINERS,
14 THE BOARD OF PHYSICIANS, AND THE BOARD OF PODIATRIC MEDICAL
15 EXAMINERS ANNUALLY SHALL REPORT TO THE DIVISION OF DRUG CONTROL:**

16 **(1) THE NAMES AND ADDRESSES OF ITS LICENSEES WHO ARE
17 AUTHORIZED TO PERSONALLY PREPARE AND DISPENSE PRESCRIPTION DRUGS
18 ~~AND DEVICES~~; AND**

19 **(2) THE NAMES AND ADDRESSES OF ITS LICENSEES WHO HAVE
20 REPORTED, IN ACCORDANCE WITH SUBSECTION (C)(2)(IV)12 OF THIS SECTION,
21 THAT THEY HAVE PERSONALLY PREPARED AND DISPENSED PRESCRIPTION
22 DRUGS ~~OR DEVICES~~ WITHIN THE PREVIOUS YEAR.**

23 **[(i)] (J)** A dentist, physician, or podiatrist who fails to comply with the
24 provisions of this section governing the dispensing of prescription drugs or devices
25 shall:

26 (1) Have the dispensing permit revoked; and

27 (2) Be subject to disciplinary actions by the appropriate licensing
28 board.

29 **12-102.1.**

1 **(A) THE DIVISION OF DRUG CONTROL SHALL ENTER AND INSPECT THE**
 2 **OFFICE OF A DENTIST, PHYSICIAN, OR PODIATRIST WHO HOLDS:**

3 **(1) AN INITIAL DISPENSING PERMIT:**

4 **(I) WITHIN 6 MONTHS AFTER RECEIVING THE REPORT**
 5 **REQUIRED UNDER § 12-102(I)(1) OF THIS SUBTITLE; AND**

6 **(II) AT LEAST ONE MORE TIME DURING THE DURATION OF**
 7 **THE PERMIT; AND**

8 **(2) A RENEWED DISPENSING PERMIT AT LEAST TWO TIMES**
 9 **DURING THE DURATION OF THE PERMIT.**

10 **(B) THE DIVISION OF DRUG CONTROL PROMPTLY SHALL REPORT THE**
 11 **RESULTS OF THE INSPECTIONS REQUIRED UNDER SUBSECTION (A) OF THIS**
 12 **SECTION TO THE RESPECTIVE BOARD OF LICENSURE.**

13 **12-102.2.**

14 **(A) THE BOARD OF DENTAL EXAMINERS, THE BOARD OF PHYSICIANS,**
 15 **AND THE BOARD OF PODIATRIC MEDICAL EXAMINERS SHALL CHARGE A FEE TO**
 16 **A DENTIST, PHYSICIAN, OR PODIATRIST WHO HOLDS A DISPENSING PERMIT IN**
 17 **AN AMOUNT THAT WILL PRODUCE FUNDS TO APPROXIMATE BUT NOT EXCEED**
 18 **THE DOCUMENTED COSTS TO THE DIVISION OF DRUG CONTROL FOR**
 19 **INSPECTIONS OF DISPENSING PERMIT HOLDERS.**

20 **(B) REVENUES COLLECTED BY THE BOARD OF DENTAL EXAMINERS,**
 21 **THE BOARD OF PHYSICIANS, AND THE BOARD OF PODIATRIC MEDICAL**
 22 **EXAMINERS UNDER THIS SECTION SHALL BE PAID INTO THE GENERAL FUND OF**
 23 **THE STATE.**

24 SECTION 2. AND BE IT FURTHER ENACTED, That, notwithstanding §
 25 12-102(c)(2)(iv)13 of the Health Occupations Article, as enacted by Section 1 of this
 26 Act, a dentist, physician, or podiatrist who holds a dispensing permit issued by the
 27 respective board of licensure shall complete continuing education credits as a condition
 28 of permit renewal as follows:

29 (1) if the permit expires in ~~2013~~ 2014, the dentist, physician, or
 30 podiatrist shall complete two continuing education credits as a condition of permit
 31 renewal;

32 (2) if the permit expires in ~~2014~~ 2015, the dentist, physician, or
 33 podiatrist shall complete four continuing education credits as a condition of permit
 34 renewal;

1 (3) if the permit expires in ~~2015~~ 2016, the dentist, physician, or
2 podiatrist shall complete six continuing education credits as a condition of permit
3 renewal;

4 (4) if the permit expires in ~~2016~~ 2017, the dentist, physician, or
5 podiatrist shall complete eight continuing education credits as a condition of permit
6 renewal; and

7 (5) if the permit expires in or after ~~2017~~ 2018, the dentist, physician,
8 or podiatrist shall complete ten continuing education credits as a condition of permit
9 renewal.

10 SECTION 3. AND BE IT FURTHER ENACTED, That the fee charged under §
11 12-102.2 of the Health Occupations Article, as enacted by Section 1 of this Act, shall
12 apply to dispensing permits issued or renewed on or after July 1, 2013.

13 SECTION ~~3~~ 4. AND BE IT FURTHER ENACTED, That this Act shall take
14 effect July 1, ~~2012~~ 2013.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.