

SENATE BILL 603

J2

2lr0704

By: **Senators Montgomery and Conway**

Introduced and read first time: February 3, 2012

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 8, 2012

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, record
6 keeping, purchase, verification, reporting, and continuing education
7 requirements as a condition of being allowed to personally prepare and dispense
8 prescription drugs or devices; requiring the State Board of Pharmacy, the State
9 Board of Dental Examiners, the State Board of Physicians, and the State Board
10 of Podiatric Medical Examiners to report certain information to the Division of
11 Drug Control on an annual basis; requiring the Division of Drug Control to
12 enter and inspect certain offices during certain time periods; requiring the
13 Division of Drug Control to report the results of these inspections to certain
14 licensing boards; providing for a certain phase-in of a certain continuing
15 education requirement; and generally relating to the personal preparation and
16 dispensing of prescription drugs or devices by dentists, physicians, and
17 podiatrists.

18 BY repealing and reenacting, with amendments,
19 Article – Health Occupations
20 Section 12–102
21 Annotated Code of Maryland
22 (2009 Replacement Volume and 2011 Supplement)

23 BY adding to

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 Article – Health Occupations
2 Section 12–102.1
3 Annotated Code of Maryland
4 (2009 Replacement Volume and 2011 Supplement)

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

7 **Article – Health Occupations**

8 12–102.

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

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

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

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

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

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

21 (c) This title does not prohibit:

22 (1) A licensed veterinarian from personally preparing and dispensing
23 the veterinarian’s prescriptions;

24 (2) A licensed dentist, physician, or podiatrist from personally
25 preparing and dispensing the dentist’s, physician’s, or podiatrist’s prescriptions when:

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

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

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

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

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

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

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

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

12 1. Complies with the **DISPENSING AND** labeling
13 requirements [of § 12–505] of this title;

14 2. Records the dispensing of the prescription drug or
15 device on the patient’s chart;

16 3. Allows the Division of Drug Control to enter and
17 inspect the dentist’s, physician’s, or podiatrist’s office at all reasonable hours **AND IN**
18 **ACCORDANCE WITH § 12–102.1 OF THIS SUBTITLE;**

19 4. **ON INSPECTION BY THE DIVISION OF DRUG**
20 **CONTROL, SIGNS AND DATES AN ACKNOWLEDGMENT FORM PROVIDED BY THE**
21 **DIVISION OF DRUG CONTROL RELATING TO THE REQUIREMENTS OF THIS**
22 **SECTION;**

23 [4.] 5. Except for starter dosages or samples without
24 charge, provides the patient with a written prescription, maintains prescription files
25 in accordance with § 12–403(b)(13) of this title, and maintains a separate file for
26 Schedule II prescriptions;

27 [5.] 6. Does not direct patients to a single pharmacist
28 or pharmacy in accordance with § 12–403(b)(8) of this title; [and]

29 [6.] 7. Does not receive remuneration for referring
30 patients to a pharmacist or pharmacy; [or]

31 8. **COMPLIES WITH THE CHILD RESISTANT**
32 **PACKAGING REQUIREMENTS REGARDING PRESCRIPTION DRUGS UNDER TITLE**
33 **22, SUBTITLE 3 OF THE HEALTH – GENERAL ARTICLE;**

1 **9. COMPLIES WITH DRUG RECALLS;**

2 **10. MAINTAINS BIENNIAL INVENTORIES AND**
3 **COMPLIES WITH ANY OTHER FEDERAL AND STATE RECORD-KEEPING**
4 **REQUIREMENTS RELATING TO CONTROLLED DANGEROUS SUBSTANCES;**

5 **11. PURCHASES PRESCRIPTION DRUGS OR DEVICES**
6 **FROM A PHARMACY OR WHOLESALE DISTRIBUTOR WHO HOLDS A PERMIT**
7 **ISSUED BY THE BOARD OF PHARMACY, AS VERIFIED BY THE BOARD OF**
8 **PHARMACY;**

9 **12. ANNUALLY REPORTS TO THE RESPECTIVE BOARD**
10 **OF LICENSURE WHETHER THE DENTIST, PHYSICIAN, OR PODIATRIST HAS**
11 **PERSONALLY PREPARED AND DISPENSED PRESCRIPTION DRUGS OR DEVICES**
12 **WITHIN THE PREVIOUS YEAR; AND**

13 **13. COMPLETES TEN CONTINUING EDUCATION**
14 **CREDITS OVER A 5-YEAR PERIOD RELATING TO THE PREPARING AND**
15 **DISPENSING OF PRESCRIPTION DRUGS AND DEVICES, OFFERED BY THE**
16 **ACCREDITATION COUNCIL FOR PHARMACY EDUCATION (ACPE) OR AS**
17 **APPROVED BY THE SECRETARY, IN CONSULTATION WITH EACH RESPECTIVE**
18 **BOARD OF LICENSURE, AS A CONDITION OF PERMIT RENEWAL; OR**

19 (3) A hospital-based clinic from dispensing prescriptions to its
20 patients.

21 (d) This title does not prohibit:

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

24 (2) A licensed dentist, licensed physician, or licensed podiatrist from
25 personally dispensing a drug or device sample to a patient of the licensed dentist,
26 licensed physician, or licensed podiatrist if:

27 (i) The sample complies with the labeling requirements of §
28 12-505 of this title;

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

30 (iii) The authorized prescriber enters an appropriate record in
31 the patient's chart.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

28 (1) Any nonprescription drug or device;

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

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

3 (I) THE BOARD OF PHARMACY, THE BOARD OF DENTAL EXAMINERS,
4 THE BOARD OF PHYSICIANS, AND THE BOARD OF PODIATRIC MEDICAL
5 EXAMINERS ANNUALLY SHALL REPORT TO THE DIVISION OF DRUG CONTROL:

6 (1) THE NAMES AND ADDRESSES OF ITS LICENSEES WHO ARE
7 AUTHORIZED TO PERSONALLY PREPARE AND DISPENSE PRESCRIPTION DRUGS
8 AND DEVICES; AND

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

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

16 (1) Have the dispensing permit revoked; and

17 (2) Be subject to disciplinary actions by the appropriate licensing
18 board.

19 **12-102.1.**

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

22 (1) AN INITIAL DISPENSING PERMIT:

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

25 (II) AT LEAST ONE MORE TIME DURING THE DURATION OF
26 THE PERMIT; AND

27 (2) A RENEWED DISPENSING PERMIT AT LEAST TWO TIMES
28 DURING THE DURATION OF THE PERMIT.

29 (B) THE DIVISION OF DRUG CONTROL PROMPTLY SHALL REPORT THE
30 RESULTS OF THE INSPECTIONS REQUIRED UNDER SUBSECTION (A) OF THIS
31 SECTION TO THE RESPECTIVE BOARD OF LICENSURE.

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

6 (1) if the permit expires in 2013, the dentist, physician, or podiatrist
7 shall complete two continuing education credits as a condition of permit renewal;

8 (2) if the permit expires in 2014, the dentist, physician, or podiatrist
9 shall complete four continuing education credits as a condition of permit renewal;

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

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

14 (5) if the permit expires in or after 2017, the dentist, physician, or
15 podiatrist shall complete ten continuing education credits as a condition of permit
16 renewal.

17 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
18 July 1, 2012.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.