

SENATE BILL 305

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CF HB 260

By: **Senator Lam**

Introduced and read first time: January 20, 2022

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Physicians – Dispensing Permits**

3 FOR the purpose of transferring oversight of the inspection of the offices of dispensing
4 physicians from the Office of Controlled Substances Administration to the State
5 Board of Physicians; altering the circumstances under which a physician may
6 dispense drugs or devices; and generally relating to the dispensing of drugs or
7 devices by licensed physicians.

8 BY repealing and reenacting, with amendments,
9 Article – Health Occupations
10 Section 12–102(a) and (c), 12–102.1, 12–102.2, and 14–509
11 Annotated Code of Maryland
12 (2021 Replacement Volume)

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

15 **Article – Health Occupations**

16 12–102.

17 (a) (1) In this section the following [terms] **WORDS** have the meanings
18 indicated.

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

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

5 (c) (1) This subsection does not apply to a licensed dentist who obtains a
6 permit from the State Board of Dental Examiners under subsection (h) of this section.

7 (2) This title does not prohibit:

8 (i) A licensed veterinarian from:

9 1. Personally preparing and dispensing the veterinarian's
10 prescriptions; or

11 2. Dispensing, in accordance with § 2-313(c) of the
12 Agriculture Article, compounded nonsterile preparations or compounded sterile
13 preparations provided by a pharmacy;

14 **(II) A LICENSED PHYSICIAN FROM PERSONALLY PREPARING**
15 **AND DISPENSING PRESCRIPTIONS IF THE PHYSICIAN HAS OBTAINED A PERMIT**
16 **UNDER § 14-509 OF THIS ARTICLE;**

17 ~~[(ii)]~~ **(III)** A licensed dentist[, physician,] or podiatrist from
18 personally preparing and dispensing the dentist's[, physician's,] or podiatrist's
19 prescriptions when:

20 1. The dentist[, physician,] or podiatrist:

21 A. Has applied to the board of licensure in this State which
22 licensed the dentist[, physician,] or podiatrist;

23 B. Has demonstrated to the satisfaction of that board that the
24 dispensing of prescription drugs or devices by the dentist[, physician,] or podiatrist is in
25 the public interest;

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

29 D. Posts a sign conspicuously positioned and readable
30 regarding the process for resolving incorrectly filled prescriptions or includes written
31 information regarding the process with each prescription dispensed;

1 2. The person for whom the drugs or devices are prescribed
2 is a patient of the prescribing dentist[, physician,] or podiatrist;

3 3. The dentist[, physician,] or podiatrist does not have a
4 substantial financial interest in a pharmacy; and

5 4. The dentist[, physician,] or podiatrist:

6 A. Complies with the dispensing and labeling requirements
7 of this title;

8 B. Records the dispensing of the prescription drug or device
9 on the patient's chart;

10 C. Allows the Office of Controlled Substances Administration
11 to enter and inspect the dentist's[, physician's,] or podiatrist's office at all reasonable hours
12 and in accordance with § 12–102.1 of this subtitle;

13 D. On inspection by the Office of Controlled Substances
14 Administration, signs and dates an acknowledgment form provided by the Office of
15 Controlled Substances Administration relating to the requirements of this section;

16 E. Except for starter dosages or samples without charge,
17 provides the patient with a written prescription, maintains prescription files in accordance
18 with § 12–403(c)(13) of this title, and maintains a separate file for Schedule II prescriptions;

19 F. Does not direct patients to a single pharmacist or
20 pharmacy in accordance with § 12–403(c)(8) of this title;

21 G. Does not receive remuneration for referring patients to a
22 pharmacist or pharmacy;

23 H. Complies with the child resistant packaging requirements
24 regarding prescription drugs under Title 22, Subtitle 3 of the Health – General Article;

25 I. Complies with drug recalls;

26 J. Maintains biennial inventories and complies with any
27 other federal and State record-keeping requirements relating to controlled dangerous
28 substances;

29 K. Purchases prescription drugs from a pharmacy or
30 wholesale distributor who holds a permit issued by the Board of Pharmacy, as verified by
31 the Board of Pharmacy;

1 L. Annually reports to the respective board of licensure
2 whether the dentist[, physician,] or podiatrist has personally prepared and dispensed
3 prescription drugs within the previous year; and

4 M. Completes ten continuing education credits over a 5-year
5 period relating to the preparing and dispensing of prescription drugs, offered by the
6 Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary, in
7 consultation with each respective board of licensure, as a condition of permit renewal; **OR**

8 [(iii) A licensed physician from dispensing a topical medication
9 without obtaining the permit required under item (ii)1C of this paragraph or completing
10 the continuing education required under item (ii)4M of this paragraph when the physician:

11 1. Otherwise complies with item (ii) of this paragraph; and

12 2. Has obtained a special written permit under § 14–509 of
13 this article;

14 (iv) A licensed physician who complies with the requirements of item
15 (ii) of this paragraph from personally preparing and dispensing a prescription written by:

16 1. A physician assistant in accordance with a delegation
17 agreement that complies with Title 15, Subtitle 3 of this article; or

18 2. A nurse practitioner who is authorized to practice under
19 Title 8, Subtitle 3 of this article and is working with the physician in the same office setting;
20 or]

21 [(v)] **(IV)** A hospital-based clinic from dispensing prescriptions to
22 its patients.

23 12–102.1.

24 (a) This section does not apply to [a]:

25 **(1)** A licensed dentist who obtains a permit from the State Board of Dental
26 Examiners under § 12–102(h) of this subtitle; **OR**

27 **(2)** A LICENSED PHYSICIAN WHO OBTAINS A PERMIT FROM THE
28 STATE BOARD OF PHYSICIANS UNDER § 14–509 OF THIS ARTICLE.

29 (b) The Office of Controlled Substances Administration shall enter and inspect
30 the office of a dentist[, physician,] or podiatrist who holds:

31 (1) An initial dispensing permit:

1 (i) Within 6 months after receiving the report required under §
2 12–102(l)(1) of this subtitle; and

3 (ii) At least one more time during the duration of the permit; and

4 (2) A renewed dispensing permit at least two times during the duration of
5 the permit.

6 (c) The Office of Controlled Substances Administration promptly shall report the
7 results of the inspections required under subsection (b) of this section to the respective
8 board of licensure.

9 12–102.2.

10 (a) This section does not apply to [a]:

11 (1) A licensed dentist who obtains a permit from the State Board of Dental
12 Examiners under § 12–102(h) of this subtitle; OR

13 (2) A LICENSED PHYSICIAN WHO OBTAINS A PERMIT FROM THE
14 STATE BOARD OF PHYSICIANS UNDER § 14–509 OF THIS ARTICLE.

15 (b) The Board of Dental Examiners[, the Board of Physicians,] and the Board of
16 Podiatric Medical Examiners shall charge a fee to a dentist[, physician,] or podiatrist who
17 holds a dispensing permit in an amount that will produce funds to approximate but not
18 exceed the documented costs to the Office of Controlled Substances Administration for
19 inspection of dispensing permit holders.

20 (c) Revenues collected by the Board of Dental Examiners[, the Board of
21 Physicians,] and the Board of Podiatric Medical Examiners under this section shall be paid
22 into the General Fund of the State.

23 14–509.

24 (a) (1) In this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS
25 INDICATED.

26 (2) “ACCME” means the Accrediting Council for Continuing Medical
27 Education.

28 (3) “ADMINISTERING” MEANS THE DIRECT INTRODUCTION OF A
29 SINGLE DOSAGE OF A DRUG OR DEVICE AT A GIVEN TIME, WHETHER BY INJECTION
30 OR OTHER MEANS, AND WHETHER IN LIQUID, TABLET, CAPSULE, OR OTHER FORM.

1 **(4) “DISPENSING PERMIT” MEANS A WRITTEN PERMIT ISSUED BY THE**
2 **BOARD TO A LICENSED PHYSICIAN TO PERSONALLY PREPARE AND DISPENSE DRUGS**
3 **OR DEVICES TO A PATIENT.**

4 **(5) “IN THE PUBLIC INTEREST” MEANS THE DISPENSING OF DRUGS**
5 **OR DEVICES BY A LICENSED PHYSICIAN TO A PATIENT WHEN A PHARMACY IS NOT**
6 **CONVENIENTLY AVAILABLE TO THE PATIENT.**

7 **(6) “PERSONALLY PREPARING AND DISPENSING” MEANS THAT THE**
8 **LICENSED PHYSICIAN:**

9 **(I) IS PHYSICALLY PRESENT ON THE PREMISES WHERE THE**
10 **PRESCRIPTION IS FILLED; AND**

11 **(II) PERFORMS A FINAL CHECK OF THE PRESCRIPTION BEFORE**
12 **IT IS PROVIDED TO THE PATIENT.**

13 **(7) “SAMPLE UNIT” HAS THE MEANING STATED IN 21 C.F.R. §**
14 **203.3(AA).**

15 **(8) “STARTER DOSAGE” MEANS AN AMOUNT OF DRUG OR DEVICE**
16 **SUFFICIENT TO BEGIN THERAPY:**

17 **(I) FOR A SHORT DURATION OF 72 HOURS OR LESS; OR**

18 **(II) PRIOR TO OBTAINING A LARGER QUANTITY OF THE DRUG**
19 **OR DEVICE TO COMPLETE THE THERAPY.**

20 **(9) “TOPICAL MEDICATION PERMIT” MEANS A WRITTEN PERMIT**
21 **ISSUED BY THE BOARD TO A LICENSED PHYSICIAN TO DISPENSE TOPICAL**
22 **MEDICATIONS THAT ARE APPROVED BY THE FEDERAL FOOD AND DRUG**
23 **ADMINISTRATION FOR THE TREATMENT OF HYPOTRICHOSIS.**

24 (b) [A physician may dispense a topical medication that is approved by the federal
25 Food and Drug Administration for the treatment of hypotrichosis without obtaining a
26 dispensing permit or completing the continuing education required under § 12–102(c)(2)(ii)
27 of this article if the physician:

28 (1) Otherwise complies with the requirements of § 12–102(c)(2)(ii) of this
29 article; and

30 (2)] **THIS SECTION DOES NOT APPLY TO A PHYSICIAN WHO:**

31 (1) (I) Has received a [special class of written] **TOPICAL MEDICATION**
32 **permit from the Board[.];**

1 [(c) The Board may issue a special class of written permit to a physician under
2 subsection (b) of this section if the physician:

3 (1) **(II) DISPENSES ONLY A TOPICAL MEDICATION THAT IS**
4 **APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR THE**
5 **TREATMENT OF HYPOTRICHOSIS;**

6 (III) Completes 1 hour of continuing medical education per year on
7 the dispensing of topical medications developed by an ACCME-accredited Maryland
8 nonprofit or governmental entity; and

9 [(2) **(IV) Pays to the Board a \$100 permit fee[.];**

10 **(2) PERSONALLY DISPENSES A DRUG OR DEVICE SAMPLE TO A**
11 **PATIENT IF:**

12 **(I) THE SAMPLE COMPLIES WITH THE LABELING**
13 **REQUIREMENTS OF § 12-505 OF THIS ARTICLE;**

14 **(II) NO CHARGE IS MADE FOR THE SAMPLE; AND**

15 **(III) THE AUTHORIZED PRESCRIBER ENTERS AN APPROPRIATE**
16 **RECORD IN THE PATIENT'S CHART;**

17 **(3) ADMINISTERS A PRESCRIPTION DRUG OR DEVICE IN THE COURSE**
18 **OF TREATING A PATIENT;**

19 **(4) PERSONALLY DISPENSES A STARTER DOSAGE OF A PRESCRIPTION**
20 **DRUG OR DEVICE TO A PATIENT IF:**

21 **(I) THE STARTER DOSAGE COMPLIES WITH THE LABELING**
22 **REQUIREMENTS OF § 12-505 OF THIS ARTICLE;**

23 **(II) NO CHARGE IS MADE FOR THE STARTER DOSAGE; AND**

24 **(III) THE LICENSED PHYSICIAN ENTERS AN APPROPRIATE**
25 **RECORD ON THE PATIENT'S CHART; OR**

26 **(5) DISPENSES A PRESCRIPTION DRUG OR DEVICE IN THE COURSE OF**
27 **TREATING A PATIENT AT:**

28 **(I) A MEDICAL FACILITY OR CLINIC THAT IS OPERATED ON A**
29 **NONPROFIT BASIS;**

1 **(II) A HEALTH CENTER THAT OPERATES ON A CAMPUS OF AN**
2 **INSTITUTION OF HIGHER EDUCATION; OR**

3 **(III) A PUBLIC HEALTH FACILITY, A MEDICAL FACILITY UNDER**
4 **CONTRACT WITH A STATE OR LOCAL HEALTH DEPARTMENT, OR A FACILITY FUNDED**
5 **WITH PUBLIC FUNDS.**

6 **(C) A LICENSED PHYSICIAN MAY PERSONALLY PREPARE AND DISPENSE**
7 **PRESCRIPTIONS ONLY IF:**

8 **(1) THE PHYSICIAN:**

9 **(I) HAS AN ACTIVE LICENSE IN GOOD STANDING;**

10 **(II) HAS APPLIED TO THE BOARD FOR A DISPENSING PERMIT;**

11 **(III) HAS PAID A FEE DETERMINED BY THE BOARD TO PRODUCE**
12 **FUNDS TO APPROXIMATE BUT NOT EXCEED THE DOCUMENTED COSTS TO THE**
13 **BOARD FOR CONDUCTING INSPECTIONS OF DISPENSING PERMIT HOLDERS;**

14 **(IV) HAS DEMONSTRATED TO THE SATISFACTION OF THE BOARD**
15 **THAT THE DISPENSING OF PRESCRIPTION DRUGS OR DEVICES BY THE PHYSICIAN IS**
16 **IN THE PUBLIC INTEREST;**

17 **(V) HAS RECEIVED A DISPENSING PERMIT FROM THE BOARD;**

18 **AND**

19 **(VI) HAS A SIGN CONSPICUOUSLY POSITIONED AND READABLE**
20 **REGARDING THE PROCESS FOR RESOLVING INCORRECTLY FILLED PRESCRIPTIONS**
21 **OR INCLUDES WRITTEN INFORMATION REGARDING THE PROCESS WITH EACH**
22 **PRESCRIPTION DISPENSED;**

23 **(2) THE INDIVIDUAL FOR WHOM THE DRUG OR DEVICE IS**
24 **PRESCRIBED IS A PATIENT OF:**

25 **(I) THE PRESCRIBING PHYSICIAN;**

26 **(II) A PHYSICIAN ASSISTANT IN ACCORDANCE WITH A**
27 **DELEGATION AGREEMENT THAT COMPLIES WITH TITLE 15, SUBTITLE 3 OF THIS**
28 **ARTICLE; OR**

29 **(III) A NURSE PRACTITIONER WHO IS AUTHORIZED TO PRACTICE**
30 **UNDER TITLE 8, SUBTITLE 3 OF THIS ARTICLE AND IS WORKING WITH THE**
31 **PHYSICIAN IN THE SAME OFFICE SETTING;**

1 **(3) THE PHYSICIAN DOES NOT HAVE A SUBSTANTIAL FINANCIAL**
2 **INTEREST IN A PHARMACY; AND**

3 **(4) THE PHYSICIAN:**

4 **(I) COMPLIES WITH THE DISPENSING AND LABELING**
5 **REQUIREMENTS OF THIS TITLE, TITLE 12 OF THIS ARTICLE, AND THE BOARD'S**
6 **REGULATIONS;**

7 **(II) RECORDS THE DISPENSING OF THE PRESCRIPTION DRUG**
8 **OR DEVICE ON THE PATIENT'S CHART;**

9 **(III) PROVIDES THE PATIENT WITH A WRITTEN PRESCRIPTION,**
10 **MAINTAINS PRESCRIPTION FILES IN ACCORDANCE WITH § 12-403(C)(13) OF THIS**
11 **ARTICLE, AND MAINTAINS A SEPARATE FILE FOR SCHEDULE II PRESCRIPTIONS;**

12 **(IV) DOES NOT DIRECT PATIENTS TO A SINGLE PHARMACIST OR**
13 **PHARMACY IN ACCORDANCE WITH § 12-403(C)(8) OF THIS ARTICLE;**

14 **(V) DOES NOT RECEIVE REMUNERATION FOR REFERRING**
15 **PATIENTS TO A PHARMACIST OR PHARMACY;**

16 **(VI) COMPLIES WITH THE CHILD RESISTANT PACKAGING**
17 **REQUIREMENTS REGARDING PRESCRIPTION DRUGS UNDER TITLE 22, SUBTITLE 3**
18 **OF THE HEALTH – GENERAL ARTICLE;**

19 **(VII) COMPLIES WITH DRUG RECALLS;**

20 **(VIII) MAINTAINS BIENNIAL INVENTORIES AND COMPLIES WITH**
21 **ANY OTHER FEDERAL AND STATE RECORD-KEEPING REQUIREMENTS RELATING TO**
22 **CONTROLLED DANGEROUS SUBSTANCES;**

23 **(IX) PURCHASES PRESCRIPTION DRUGS FROM A PHARMACY OR**
24 **WHOLESALE DISTRIBUTOR THAT HOLDS A PERMIT ISSUED BY THE STATE BOARD OF**
25 **PHARMACY, AS VERIFIED BY THE STATE BOARD OF PHARMACY; AND**

26 **(X) COMPLIES WITH CONTINUING EDUCATION REQUIREMENTS**
27 **RELATING TO THE PREPARING AND DISPENSING OF PRESCRIPTION DRUGS AS**
28 **PROVIDED FOR IN REGULATIONS ADOPTED BY THE BOARD.**

29 **(D) A PHYSICIAN WHO FAILS TO COMPLY WITH THE PROVISIONS OF THIS**
30 **SECTION GOVERNING THE DISPENSING OF PRESCRIPTION DRUGS OR DEVICES**
31 **SHALL:**

1 **(1) HAVE THE DISPENSING PERMIT REVOKED; AND**

2 **(2) BE SUBJECT TO DISCIPLINARY ACTION BY THE BOARD.**

3 **(E) (1) (I) WITHIN 6 MONTHS AFTER THE BOARD ISSUES AN INITIAL**
4 **DISPENSING PERMIT TO A LICENSED PHYSICIAN, THE BOARD SHALL ENTER AND**
5 **INSPECT THE OFFICE OF THE PHYSICIAN.**

6 **(II) IF THE BOARD RENEWS A DISPENSING PERMIT TO A**
7 **LICENSED PHYSICIAN, THE BOARD SHALL ENTER AND INSPECT THE OFFICE OF THE**
8 **PHYSICIAN AT LEAST ONE TIME DURING THE DURATION OF THE RENEWED PERMIT.**

9 **(2) THE BOARD SHALL REPORT TO THE OFFICE OF CONTROLLED**
10 **SUBSTANCES ADMINISTRATION ANY VIOLATION RELATED TO CONTROLLED**
11 **DANGEROUS SUBSTANCES FOUND DURING AN INSPECTION REQUIRED UNDER**
12 **PARAGRAPH (1) OF THIS SUBSECTION.**

13 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
14 October 1, 2022.