

SENATE BILL 161

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HB 260/22 – HGO

3lr1325
CF 3lr1831

By: **Senator Lam (By Request – State Board of Physicians)**

Introduced and read first time: January 18, 2023

Assigned to: Finance

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; requiring that certain appropriations be transferred to the
7 Board on a certain date; providing for the transfer of certain functions, powers,
8 duties, property, records, fixtures, credits, assets, liability, obligations, rights, and
9 privileges; requiring that certain employees of the Office be transferred to the Board
10 without diminution of their rights, benefits, employment, or retirement status;
11 requiring that certain positions at the Office be transferred to the Board; providing
12 for the continuity of certain transactions affected by or flowing from this Act;
13 providing for the continuity of certain laws, regulations, standards and guidelines,
14 policies, orders and other directives, forms, plans, membership, contracts, property,
15 investigations, administrative and judicial responsibilities, rights, and other duties
16 and responsibilities; and generally relating to the dispensing of drugs or devices by
17 licensed physicians.

18 BY repealing and reenacting, with amendments,
19 Article – Health Occupations
20 Section 12–102(a) and (c), 12–102.1, 12–102.2, and 14–509
21 Annotated Code of Maryland
22 (2021 Replacement Volume and 2022 Supplement)

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

25 **Article – Health Occupations**

26 12–102.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

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

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

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

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

14 (2) This title does not prohibit:

15 (i) A licensed veterinarian from:

16 1. Personally preparing and dispensing the veterinarian’s
17 prescriptions; or

18 2. Dispensing, in accordance with § 2–313(c) of the
19 Agriculture Article, compounded nonsterile preparations or compounded sterile
20 preparations provided by a pharmacy;

21 **(II) A LICENSED PHYSICIAN FROM PERSONALLY PREPARING**
22 **AND DISPENSING PRESCRIPTIONS IF THE PHYSICIAN HAS OBTAINED A PERMIT**
23 **UNDER § 14–509 OF THIS ARTICLE;**

24 [(ii)] **(III)** A licensed dentist[, physician,] or podiatrist from
25 personally preparing and dispensing the dentist’s[, physician’s,] or podiatrist’s
26 prescriptions when:

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

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

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

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

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

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

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

12 A. Complies with the dispensing and labeling requirements
13 of this title;

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

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

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

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

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

27 G. Does not receive remuneration for referring patients to a
28 pharmacist or pharmacy;

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

31 I. Complies with drug recalls;

1 J. Maintains biennial inventories and complies with any
2 other federal and State record-keeping requirements relating to controlled dangerous
3 substances;

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

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

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

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

17 1. Otherwise complies with item (ii) of this paragraph; and
18 2. Has obtained a special written permit under § 14-509 of
19 this article;

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

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

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

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

29 12-102.1.

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

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

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

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

5 (1) An initial dispensing permit:

6 (i) Within 6 months after receiving the report required under §
7 12-102(l)(1) of this subtitle; and

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

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

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

14 12-102.2.

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

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

18 **(2) A LICENSED PHYSICIAN WHO OBTAINS A PERMIT FROM THE**
19 **STATE BOARD OF PHYSICIANS UNDER § 14-509 OF THIS ARTICLE.**

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

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

28 14-509.

29 (a) **(1) In this section[,] THE FOLLOWING WORDS HAVE THE MEANINGS**
30 **INDICATED.**

1 **(2)** “ACCME” means the Accrediting Council for Continuing Medical
2 Education.

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

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

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

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

14 **(I)** IS PHYSICALLY PRESENT ON THE PREMISES WHERE THE
15 PRESCRIPTION IS FILLED; AND

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

18 **(7)** “SAMPLE UNIT” HAS THE MEANING STATED IN 21 C.F.R. §
19 203.3(AA).

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

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

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

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

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

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

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

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

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

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

11 (III) Completes 1 hour of continuing medical education per year on
12 the dispensing of topical medications developed by an ACCME–accredited Maryland
13 nonprofit or governmental entity; and

14 [(2) (IV) Pays to the Board a \$100 permit fee;

15 (2) **PERSONALLY DISPENSES A DRUG OR DEVICE SAMPLE TO A**
16 **PATIENT IF:**

17 (I) **THE SAMPLE COMPLIES WITH THE LABELING**
18 **REQUIREMENTS OF § 12–505 OF THIS ARTICLE;**

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

20 (III) **THE AUTHORIZED PRESCRIBER ENTERS AN APPROPRIATE**
21 **RECORD IN THE PATIENT’S CHART;**

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

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

26 (I) **THE STARTER DOSAGE COMPLIES WITH THE LABELING**
27 **REQUIREMENTS OF § 12–505 OF THIS ARTICLE;**

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

29 (III) **THE LICENSED PHYSICIAN ENTERS AN APPROPRIATE**
30 **RECORD ON THE PATIENT’S CHART; OR**

1 (II) A PHYSICIAN ASSISTANT IN ACCORDANCE WITH A
2 DELEGATION AGREEMENT THAT COMPLIES WITH TITLE 15, SUBTITLE 3 OF THIS
3 ARTICLE; OR

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

7 (3) THE PHYSICIAN DOES NOT HAVE A SUBSTANTIAL FINANCIAL
8 INTEREST IN A PHARMACY; AND

9 (4) THE PHYSICIAN:

10 (I) COMPLIES WITH THE DISPENSING AND LABELING
11 REQUIREMENTS OF THIS TITLE, TITLE 12 OF THIS ARTICLE, AND THE BOARD'S
12 REGULATIONS;

13 (II) RECORDS THE DISPENSING OF THE PRESCRIPTION DRUG
14 OR DEVICE ON THE PATIENT'S CHART;

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

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

20 (V) DOES NOT RECEIVE REMUNERATION FOR REFERRING
21 PATIENTS TO A PHARMACIST OR PHARMACY;

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

25 (VII) COMPLIES WITH DRUG RECALLS;

26 (VIII) MAINTAINS BIENNIAL INVENTORIES AND COMPLIES WITH
27 ANY OTHER FEDERAL AND STATE RECORD-KEEPING REQUIREMENTS RELATING TO
28 CONTROLLED DANGEROUS SUBSTANCES;

29 (IX) PURCHASES PRESCRIPTION DRUGS FROM A PHARMACY OR
30 WHOLESALE DISTRIBUTOR THAT HOLDS A PERMIT ISSUED BY THE STATE BOARD OF
31 PHARMACY, AS VERIFIED BY THE STATE BOARD OF PHARMACY; AND

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

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

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

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

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

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

15 **(2) THE BOARD SHALL REPORT TO THE OFFICE OF CONTROLLED**
16 **SUBSTANCES ADMINISTRATION ANY VIOLATION RELATED TO CONTROLLED**
17 **DANGEROUS SUBSTANCES FOUND DURING AN INSPECTION REQUIRED UNDER**
18 **PARAGRAPH (1) OF THIS SUBSECTION.**

19 SECTION 2. AND BE IT FURTHER ENACTED, That, on the effective date of this
20 Act, the following shall be transferred to the State Board of Physicians:

21 (1) all appropriations, including State and federal funds, held by the Office
22 of Controlled Substances Administration for the purposes of conducting inspections of
23 offices of physicians who hold dispensing permits under § 14–509 of the Health Occupations
24 Article on the effective date of this Act; and

25 (2) all books and records including electronic records, real and personal
26 property, equipment, fixtures, assets, liabilities, obligations, credits, rights, and privileges
27 held by the Office of Controlled Substances Administration for the purposes of conducting
28 inspections of offices of physicians who hold dispensing permits under § 14–509 of the
29 Health Occupations Article on the effective date of this Act.

30 SECTION 3. AND BE IT FURTHER ENACTED, That all employees of the Office of
31 Controlled Substances Administration who are assigned more than 50% of the time to a
32 function related to conducting inspections of offices of physicians who hold dispensing
33 permits under § 14–509 of the Health Occupations Article on the effective date of this Act
34 shall be transferred to the State Board of Physicians without diminution of their rights,
35 benefits, employment, or retirement status.

1 SECTION 4. AND BE IT FURTHER ENACTED, That all positions of the Office of
2 Controlled Substances Administration who are assigned more than 50% of the time to a
3 function related to conducting inspections of offices of physicians who hold dispensing
4 permits under § 14–509 of the Health Occupations Article on the effective date of this Act
5 shall be transferred to the State Board of Physicians.

6 SECTION 5. AND BE IT FURTHER ENACTED, That any transaction affected by
7 the transfer of oversight of the conducting of inspections of offices of physicians who hold
8 dispensing permits under § 14–509 of the Health Occupations Article and validly entered
9 into before the effective date of this Act, and every right, duty, or interest flowing from it
10 remains valid after the effective date of this Act and may be terminated, completed,
11 consummated, or enforced under the law.

12 SECTION 6. AND BE IT FURTHER ENACTED, That all existing laws, regulations,
13 proposed regulations, standards and guidelines, policies, orders and other directives, forms,
14 plans, memberships, contracts, property, investigations, administrative and judicial
15 responsibilities, rights to sue and be sued, and all other duties and responsibilities
16 associated with the oversight of the conducting of inspections of offices of physicians who
17 hold dispensing permits under § 14–509 of the Health Occupations Article prior to the
18 effective date of this Act shall continue and, as appropriate, are legal and binding on the
19 State Board of Physicians until completed, withdrawn, canceled, modified, or otherwise
20 changed under the law.

21 SECTION 7. AND BE IT FURTHER ENACTED, That this Act shall take effect
22 October 1, 2023.