

HOUSE BILL 241

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SB 305/22 – EHE

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CF SB 161

By: ~~Delegate Bagnall~~ Delegates Bagnall, Alston, Bhandari, Chisholm, Cullison, Guzzone, Hill, Hutchinson, S. Johnson, Kaiser, Kerr, Kipke, R. Lewis, Lopez, Martinez, M. Morgan, Pena-Melnyk, Reilly, Rosenberg, Szeliga, Taveras, White, and Woods

Introduced and read first time: January 23, 2023
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 1, 2023

CHAPTER _____

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

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.



(2021 Replacement Volume and 2022 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] WORDS 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.

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

(2) This title does not prohibit:

(i) A licensed veterinarian from:

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

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

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

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

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

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

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

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

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

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

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

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

18 A. Complies with the dispensing and labeling requirements
19 of this title;

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

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

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

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

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

1 G. Does not receive remuneration for referring patients to a
2 pharmacist or pharmacy;

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

5 I. Complies with drug recalls;

6 J. Maintains biennial inventories and complies with any
7 other federal and State record-keeping requirements relating to controlled dangerous
8 substances;

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

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

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

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

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

23 2. Has obtained a special written permit under § 14-509 of
24 this article;

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

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

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

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

1 12–102.1.

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

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

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

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

9 (1) An initial dispensing permit:

10 (i) Within 6 months after receiving the report required under §
11 12–102(l)(1) of this subtitle; and

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

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

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

18 12–102.2.

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

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

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

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

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

4 14-509.

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

7 (2) "ACCME" means the Accrediting Council for Continuing Medical
8 Education.

9 (3) "ADMINISTERING" MEANS THE DIRECT INTRODUCTION OF A
10 SINGLE DOSAGE OF A DRUG OR DEVICE AT A GIVEN TIME, WHETHER BY INJECTION
11 OR OTHER MEANS, AND WHETHER IN LIQUID, TABLET, CAPSULE, OR OTHER FORM.

12 (4) "DISPENSING PERMIT" MEANS A WRITTEN PERMIT ISSUED BY THE
13 BOARD TO A LICENSED PHYSICIAN TO PERSONALLY PREPARE AND DISPENSE DRUGS
14 OR DEVICES TO A PATIENT.

15 (5) "IN THE PUBLIC INTEREST" MEANS THE DISPENSING OF DRUGS
16 OR DEVICES BY A LICENSED PHYSICIAN TO A PATIENT WHEN A PHARMACY IS NOT
17 CONVENIENTLY AVAILABLE TO THE PATIENT.

18 (6) "PERSONALLY PREPARING AND DISPENSING" MEANS THAT THE
19 LICENSED PHYSICIAN:

20 (I) IS PHYSICALLY PRESENT ON THE PREMISES WHERE THE
21 PRESCRIPTION IS FILLED; AND

22 (II) PERFORMS A FINAL CHECK OF THE PRESCRIPTION BEFORE
23 IT IS PROVIDED TO THE PATIENT.

24 (7) "SAMPLE UNIT" HAS THE MEANING STATED IN 21 C.F.R. §
25 203.3(AA).

26 (8) "STARTER DOSAGE" MEANS AN AMOUNT OF A DRUG OR A DEVICE
27 SUFFICIENT TO BEGIN THERAPY:

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

29 (II) PRIOR TO OBTAINING A LARGER QUANTITY OF THE DRUG
30 OR DEVICE TO COMPLETE THE THERAPY.

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

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

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

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

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

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

16 **(1)] (II) DISPENSES ONLY A TOPICAL MEDICATION THAT IS**
17 **APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR THE**
18 **TREATMENT OF HYPOTRICHOSIS;**

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

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

23 **(2) PERSONALLY DISPENSES A DRUG OR DEVICE SAMPLE TO A**
24 **PATIENT IF:**

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

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

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

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

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

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

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

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

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

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

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

14 **(III) A PUBLIC HEALTH FACILITY, A MEDICAL FACILITY UNDER**
15 **CONTRACT WITH A STATE OR LOCAL HEALTH DEPARTMENT, OR A FACILITY FUNDED**
16 **WITH PUBLIC FUNDS.**

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

19 **(1) THE PHYSICIAN:**

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

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

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

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

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

29 **AND**

1 (VI) HAS A SIGN CONSPICUOUSLY POSITIONED AND READABLE
2 REGARDING THE PROCESS FOR RESOLVING INCORRECTLY FILLED PRESCRIPTIONS
3 OR INCLUDES WRITTEN INFORMATION REGARDING THE PROCESS WITH EACH
4 PRESCRIPTION DISPENSED;

5 (2) THE INDIVIDUAL FOR WHOM THE DRUG OR DEVICE IS
6 PRESCRIBED IS A PATIENT OF:

7 (I) THE PRESCRIBING PHYSICIAN;

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

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

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

16 (4) THE PHYSICIAN:

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

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

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

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

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

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

1 (VII) COMPLIES WITH DRUG RECALLS;

2 (VIII) MAINTAINS BIENNIAL INVENTORIES AND COMPLIES WITH
3 ANY OTHER FEDERAL AND STATE RECORD-KEEPING REQUIREMENTS RELATING TO
4 CONTROLLED DANGEROUS SUBSTANCES;

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

8 (X) COMPLIES WITH CONTINUING EDUCATION REQUIREMENTS
9 RELATING TO THE PREPARING AND DISPENSING OF PRESCRIPTION DRUGS AS
10 PROVIDED FOR IN REGULATIONS ADOPTED BY THE BOARD.

11 (D) A PHYSICIAN WHO FAILS TO COMPLY WITH THE PROVISIONS OF THIS
12 SECTION GOVERNING THE DISPENSING OF PRESCRIPTION DRUGS OR DEVICES
13 SHALL:

14 (1) HAVE THE DISPENSING PERMIT REVOKED; AND

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

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

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

22 (2) THE BOARD SHALL REPORT TO THE OFFICE OF CONTROLLED
23 SUBSTANCES ADMINISTRATION AND THE OFFICE OF THE ATTORNEY GENERAL ANY
24 VIOLATION RELATED TO CONTROLLED DANGEROUS SUBSTANCES FOUND DURING
25 AN INSPECTION REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION.

26 SECTION 2. AND BE IT FURTHER ENACTED, That, ~~on~~:

27 (a) On the effective date of this Act, the following shall be transferred to the State
28 Board of Physicians:

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

1 (2) subject to subsection (b) of this section, all books and records including
2 electronic records, real and personal property, equipment, fixtures, assets, liabilities,
3 obligations, credits, rights, and privileges held by the Office of Controlled Substances
4 Administration for the purposes of conducting inspections of offices of physicians who hold
5 dispensing permits under § 14–509 of the Health Occupations Article on the effective date
6 of this Act.

7 (b) If the record relates to a pending or ongoing investigation that was initiated
8 by the Office of Controlled Substances Administration before the effective date of this Act,
9 the Office may provide the State Board of Physicians with a copy of the record in lieu of the
10 original record.

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

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

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

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

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