

HOUSE BILL 1439

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By: **Delegate Kipke**

Introduced and read first time: February 7, 2020

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy – Specialty Practice Pharmacy – Permit**

3 FOR the purpose of authorizing the State Board of Pharmacy to issue a permit for a
4 pharmacy to operate as a specialty practice pharmacy; providing that a person that
5 holds a permit to practice as a specialty practice pharmacy and that does not hold a
6 pharmacy permit is only authorized to establish or operate a certain pharmacy;
7 requiring that a separate pharmacy permit to operate as a specialty practice
8 pharmacy is required for each pharmacy that a person establishes or operates;
9 providing that a pharmacy that holds a pharmacy permit is not required to obtain a
10 permit to practice as a specialty practice pharmacy before operating a certain
11 pharmacy; requiring the Board to adopt certain regulations; authorizing the Board
12 to require a certain applicant or pharmacy to meet certain requirements; authorizing
13 the Board to deny an application for a certain permit under certain circumstances;
14 providing for the term of a certain permit; authorizing the Board to suspend or
15 revoke a pharmacy permit if the pharmacy violates any of the standards specified
16 under certain provisions of this Act, as applicable; altering certain definitions;
17 defining certain terms; making conforming changes; providing for the application of
18 this Act; and generally relating to a permit to operate as a specialty practice
19 pharmacy.

20 BY repealing and reenacting, without amendments,
21 Article – Health Occupations
22 Section 12–101(a)
23 Annotated Code of Maryland
24 (2014 Replacement Volume and 2019 Supplement)

25 BY repealing and reenacting, with amendments,
26 Article – Health Occupations
27 Section 12–101(t) and (u), 12–401, 12–402, 12–403(c), 12–407, and 12–409(a)
28 Annotated Code of Maryland
29 (2014 Replacement Volume and 2019 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY adding to
2 Article – Health Occupations
3 Section 12–101(q–1) and (z–3) and 12–403.1
4 Annotated Code of Maryland
5 (2014 Replacement Volume and 2019 Supplement)

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

8 **Article – Health Occupations**

9 12–101.

10 (a) In this title the following words have the meanings indicated.

11 **(Q–1) “PERMIT TO PRACTICE AS A SPECIALTY PRACTICE PHARMACY” MEANS**
12 **A PERMIT ISSUED BY THE BOARD TO ESTABLISH AND OPERATE A SPECIALTY**
13 **PRACTICE PHARMACY.**

14 (t) **(1)** “Pharmacy” means an establishment in which prescription or
15 nonprescription drugs or devices are compounded, dispensed, or distributed.

16 **(2) “PHARMACY” INCLUDES, UNLESS THE CONTEXT REQUIRES**
17 **OTHERWISE, A SPECIALTY PRACTICE PHARMACY.**

18 (u) **(1)** “Pharmacy permit” means a permit issued by the Board to establish
19 and operate a pharmacy.

20 **(2) “PHARMACY PERMIT” INCLUDES, UNLESS THE CONTEXT**
21 **REQUIRES OTHERWISE, A PERMIT TO PRACTICE AS A SPECIALTY PRACTICE**
22 **PHARMACY.**

23 **(Z–3) “SPECIALTY PRACTICE PHARMACY” MEANS A PHARMACY THAT:**

24 **(1) IS OPERATED BY A FACILITY OR AN OFFICE WHERE SPECIALIZED**
25 **HEALTH OR MEDICAL CARE IS PROVIDED TO PATIENTS; AND**

26 **(2) DISPENSES DRUGS OR DEVICES PRESCRIBED AT THE FACILITY OR**
27 **OFFICE BY HEALTH CARE PRACTITIONERS AUTHORIZED TO PRESCRIBE DRUGS OR**
28 **DEVICES UNDER THIS ARTICLE.**

29 12–401.

30 (a) **(1)** A person shall hold a pharmacy permit **OR A PHARMACY PERMIT TO**

1 **OPERATE AS A SPECIALTY PRACTICE PHARMACY** issued by the Board before the person
2 may establish or operate a pharmacy in **[this] THE State**.

3 **(2) A PERSON THAT HOLDS A PERMIT TO PRACTICE AS A SPECIALTY**
4 **PRACTICE PHARMACY THAT DOES NOT HOLD A PHARMACY PERMIT MAY ONLY**
5 **ESTABLISH OR OPERATE A SPECIALTY PRACTICE PHARMACY IN THE STATE.**

6 (b) A separate pharmacy permit **OR PHARMACY PERMIT TO OPERATE AS A**
7 **SPECIALTY PRACTICE PHARMACY** is required for each pharmacy that a person
8 establishes or operates.

9 12-402.

10 To qualify for a pharmacy permit **OR A PERMIT TO OPERATE A SPECIALTY**
11 **PRACTICE PHARMACY**, an applicant shall satisfy the Board that the pharmacy for which
12 the application is made will be operated in accordance with the standards specified in **[§**
13 **12-403] §§ 12-403 AND 12-403.1** of this subtitle **OR ANY CORRESPONDING**
14 **REGULATIONS.**

15 12-403.

16 (c) Except as otherwise provided in this section **AND IN § 12-403.1 OF THIS**
17 **SUBTITLE**, a pharmacy for which a pharmacy permit has been issued under this title:

18 (1) Shall be operated in compliance with the law and with the rules and
19 regulations of the Board;

20 (2) Shall be located and equipped so that the pharmacy may be operated
21 without endangering the public health or safety;

22 (3) Shall ensure that a licensed pharmacist be immediately available on
23 the premises to provide pharmacy services at all times the pharmacy is in operation;

24 (4) Shall be supervised by a licensed pharmacist who is responsible for the
25 operations of the pharmacy at all times the pharmacy is in operation;

26 (5) Shall provide complete pharmaceutical service by preparing and
27 dispensing all prescriptions that reasonably may be expected of a pharmacist;

28 (6) Shall provide services to the general public and may not restrict or limit
29 its services to any group of individuals unless granted a waiver from this requirement by
30 the Board;

31 (7) May not offer pharmaceutical services under any term or condition that
32 tends to interfere with or impair the free and complete exercise of professional
33 pharmaceutical judgment or skill;

1 (8) May not make any agreement that denies a patient a free choice of
2 pharmacist or pharmacy services;

3 (9) May not participate in any activity that is a ground for Board action
4 against a licensed pharmacist under § 12–313 of this title, a registered pharmacy technician
5 under § 12–6B–09 of this title, or a registered pharmacy intern under § 12–6D–11 of this
6 title;

7 (10) (i) Shall maintain at all times a current reference library that is
8 appropriate to meet the needs of:

9 1. The practice specialty of that pharmacy; and

10 2. The consumers the pharmacy serves; and

11 (ii) Shall comply with any regulations adopted by the Board
12 establishing the types of texts required to be included in the reference libraries in each of
13 the various practice specialty pharmacies;

14 (11) (i) Shall maintain at all times the minimum professional and
15 technical equipment and sanitary appliances that are necessary in a pharmacy:

16 1. To prepare and dispense prescriptions properly; and

17 2. To otherwise operate a pharmacy; and

18 (ii) Shall:

19 1. Be equipped with the minimum equipment and appliances
20 specified by the Board under this section; and

21 2. Be kept in a clean and orderly manner;

22 (12) Shall store all prescription or nonprescription drugs or devices properly
23 and safely subject to the rules and regulations adopted by the Board;

24 (13) Shall:

25 (i) Make and keep on file for at least 5 years a record of each
26 prescription prepared or dispensed in the pharmacy;

27 (ii) Disclose the records and files maintained of prescriptions for
28 drugs or devices that identify or may be readily associated with the identity of a patient
29 only in accordance with the provisions of Title 4, Subtitle 3 of the Health – General Article;
30 and

1 (iii) Keep additional records as required by the rules and regulations
2 adopted by the Board;

3 (14) Except as otherwise provided under federal law, shall establish and
4 maintain mechanisms to ensure that all prescription drugs or devices used within
5 institutions that provide acute, subacute, or long-term care, or within their related
6 corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,
7 subject to rules and regulations adopted by the Board and policies established by the
8 institution;

9 (15) Shall provide such personnel, automation, and technology as are
10 necessary to allow the licensed pharmacist employee sufficient time to utilize the
11 pharmacist's knowledge and training and to perform competently the functions of a licensed
12 pharmacist as required by law;

13 (16) Shall provide such personnel, automation, and technology as are
14 necessary to comply with the labeling requirements specified in § 12-505 of this title;

15 (17) With regard to a prescription drug that is delivered in this State by the
16 United States mail, a common carrier, or a delivery service and is not personally hand
17 delivered directly to a patient or to the agent of the patient at the residence of the patient
18 or at another location designated by the patient, shall:

19 (i) Provide a general written notice in each shipment of a
20 prescription drug that alerts a consumer that, under certain circumstances, a medication's
21 effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

22 (ii) Provide a specific written notice in each shipment of a
23 prescription drug that provides a consumer with a toll-free or local consumer access
24 telephone number accessible during regular hours of operation, which is designed to
25 respond to consumer questions pertaining to medications;

26 (18) (i) May maintain a record log of any prescription that is requested
27 to be filled or refilled by a patient in accordance with the provisions of Title 4, Subtitle 3 of
28 the Health – General Article;

29 (ii) If the prescription record of a patient includes the patient's Social
30 Security number, shall keep the Social Security number confidential;

31 (iii) May not list in the record log the type of illness, disability, or
32 condition that is the basis of any dispensing or distribution of a drug by a pharmacist; and

33 (iv) May not list a patient's Social Security number, illness,
34 disability, or condition, or the name and type of drug received in the record log if the log is
35 available to other pharmacy customers;

36 (19) May not allow an unauthorized individual to represent that the

1 individual is a pharmacist, a registered pharmacy intern, or registered pharmacy
2 technician;

3 (20) Shall provide information regarding the process for resolving
4 incorrectly filled prescriptions in accordance with existing regulations by:

5 (i) Posting a sign that is conspicuously positioned and readable by
6 consumers at the point where prescription drugs are dispensed to consumers; or

7 (ii) Including written information regarding the process with each
8 prescription dispensed;

9 (21) Shall dispense or dispose of prescription drugs or medical supplies in
10 accordance with Title 15, Subtitle 6 of the Health – General Article;

11 (22) (i) May provide to an ophthalmologist for office use, without a
12 patient-specific prescription:

13 1. Compound antibiotics for the emergency treatment of
14 bacterial endophthalmitis or viral retinitis; and

15 2. Compound antivascular endothelial growth factor agents
16 for the emergency treatment of neovascular glaucoma, wet macular degeneration, or
17 macular edema; and

18 (ii) Shall require the ophthalmologist to inform the pharmacy of the
19 identity of any patient to whom the drugs are administered; and

20 (23) Subject to § 12–510 of this title, may provide compounded nonsterile
21 preparations or compounded sterile preparations without a patient-specific prescription to
22 a licensed veterinarian who intends to dispense the compounded nonsterile preparations
23 or compounded sterile preparations in accordance with § 2–313(c) of the Agriculture Article.

24 **12–403.1.**

25 **(A) (1) THE BOARD MAY ISSUE A PHARMACY PERMIT FOR A PHARMACY**
26 **TO OPERATE AS A SPECIALTY PRACTICE PHARMACY.**

27 **(2) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE A PHARMACY**
28 **THAT HOLDS A PHARMACY PERMIT AND OTHERWISE MEETS THE REQUIREMENTS OF**
29 **THIS SUBTITLE TO OBTAIN A PERMIT TO PRACTICE AS A SPECIALTY PRACTICE**
30 **PHARMACY BEFORE OPERATING A SPECIALTY PRACTICE PHARMACY.**

31 **(B) THE BOARD SHALL ADOPT REGULATIONS:**

32 **(1) ESTABLISHING A PROCESS BY WHICH A PHARMACY MAY APPLY**

1 FOR A PHARMACY PERMIT TO OPERATE AS A SPECIALTY PRACTICE PHARMACY, THAT
2 INCLUDES:

3 (I) REQUIRING THE BOARD TO MAKE A DECISION ON AN
4 APPLICATION WITHIN 150 DAYS AFTER THE APPLICATION IS FILED; AND

5 (II) IF THE BOARD FAILS TO MAKE A DECISION ON AN
6 APPLICATION IN THE TIME IMPOSED UNDER ITEM (I) OF THIS ITEM, REQUIRING THE
7 BOARD TO APPROVE THE APPLICATION AND ISSUE THE PERMIT, UNLESS THE DELAY
8 WAS CAUSED BY THE APPLICANT;

9 (2) ESTABLISHING REQUIREMENTS THAT AN APPLICANT MUST MEET
10 IN ORDER TO OBTAIN A PHARMACY PERMIT TO OPERATE AS A SPECIALTY PRACTICE
11 PHARMACY;

12 (3) PROHIBITING AN APPLICANT THAT IS A CORPORATION FROM
13 BEING ISSUED A PERMIT TO OPERATE AS A SPECIALTY PRACTICE PHARMACY
14 UNLESS THE BOARD DETERMINES THAT THE MANAGEMENT OF THE SPECIALTY
15 PRACTICE PHARMACY IS CONTROLLED SOLELY BY A LICENSED PHARMACIST;

16 (4) ESTABLISHING AN ANNUAL FEE FOR ISSUING A PERMIT UNDER
17 THIS SECTION AND ANY OTHER FEES NECESSARY FOR APPLYING FOR, RENEWING,
18 OR MAINTAINING A PERMIT UNDER THIS SECTION; AND

19 (5) ESTABLISHING REQUIREMENTS AND SAFETY PROCEDURES THAT
20 A SPECIALTY PRACTICE PHARMACY MUST MEET AND THAT INCLUDE:

21 (I) REQUIRING A SPECIALTY PRACTICE PHARMACY TO EMPLOY
22 AT LEAST ONE:

23 1. PHARMACY TECHNICIAN; AND

24 2. SUPERVISING PHARMACIST; AND

25 (II) REQUIRING THE SUPERVISING PHARMACIST TO OVERSEE
26 THE OPERATION OF THE PHARMACY AND REVIEW THE OPERATION ON-SITE AT
27 LEAST ONCE PER WEEK.

28 (C) THE BOARD MAY REQUIRE AN APPLICANT FOR OR A PHARMACY WITH A
29 PERMIT TO OPERATE AS A SPECIALTY PRACTICE PHARMACY TO MEET ANY OF THE
30 REQUIREMENTS FOR APPLYING FOR OR OPERATING WITH A PHARMACY PERMIT
31 ISSUED UNDER THIS SUBTITLE OR ANY CORRESPONDING REGULATIONS.

1 **(D) THE BOARD MAY DENY AN APPLICATION FOR A PERMIT UNDER THIS**
2 **SECTION IF THE BOARD FINDS THAT GRANTING THE PERMIT WOULD NOT BE IN THE**
3 **BEST INTEREST OF PUBLIC HEALTH, WELFARE, OR SAFETY.**

4 **(E) A PERMIT UNDER THIS SECTION:**

5 **(1) IS VALID FOR A TERM SET BY THE BOARD NOT TO EXCEED 2**
6 **YEARS; AND**

7 **(2) EXPIRES ON DECEMBER 31 OF THE FOLLOWING ODD-NUMBERED**
8 **YEAR AFTER THE DATE OF ISSUANCE.**

9 12-407.

10 **(A) THIS SECTION DOES NOT APPLY TO A PERMIT TO OPERATE AS A**
11 **SPECIALTY PRACTICE PHARMACY ISSUED UNDER § 12-403.1 OF THIS SUBTITLE.**

12 **[(a)] (B)** A pharmacy permit expires on the May 31 after its effective date, unless
13 the pharmacy permit is renewed for a 2-year term as provided in this section.

14 **[(b)] (C)** (1) Except as provided in paragraph (2) of this subsection, on or
15 before March 1 of the year the permit expires, the Board shall send to each pharmacy
16 permit holder a renewal notice for each pharmacy permit by first-class mail to the last
17 known address of the pharmacy permit holder.

18 (2) If requested by a pharmacy permit holder, the Board shall send to the
19 pharmacy permit holder, at least two times within the month before a pharmacy permit
20 expires, a renewal notice for each pharmacy permit by electronic means to the last known
21 electronic address of the pharmacy permit holder.

22 (3) If a renewal notice sent by electronic means under paragraph (2) of this
23 subsection is returned to the Board as undeliverable, the Board shall send to the pharmacy
24 permit holder a renewal notice for each pharmacy permit by first-class mail to the last
25 known address of the pharmacy permit holder.

26 (4) A renewal notice sent under this subsection shall state:

27 (i) The date on which the current pharmacy permit expires;

28 (ii) The date by which the renewal application must be received by
29 the Board for the renewal to be issued and mailed before the pharmacy permit expires; and

30 (iii) The amount of the renewal fee.

31 **[(c)] (D)** Before the pharmacy permit expires, the pharmacy permit holder
32 periodically may renew it for an additional 2-year term, if the pharmacy permit holder:

- 1 (1) Otherwise is entitled to the pharmacy permit;
- 2 (2) Pays to the Board a renewal fee set by the Board; and
- 3 (3) Submits a renewal application to the Board on the form that the Board
4 provides.

5 [(d)] (E) The Board shall renew the pharmacy permit of each pharmacy permit
6 holder who meets the requirements of this section.

7 [(e)] (F) If application for renewal is not made on or before May 1, the pharmacy
8 permit shall expire on the last day of its term and the Board may not reinstate the
9 pharmacy permit unless the applicant:

- 10 (1) Provides reason, sufficient to the Board, for the failure to file within the
11 time required; and
- 12 (2) Pays, in addition to the renewal fee, a late fee set by the Board.

13 12-409.

14 (a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may
15 suspend or revoke any pharmacy permit, if the pharmacy:

- 16 (1) Is conducted so as to endanger the public health or safety;
- 17 (2) Violates any of the standards specified in § 12-403 OR § 12-403.1 of
18 this subtitle, AS APPLICABLE, OR REGULATIONS ADOPTED UNDER THIS SUBTITLE
19 FOR A PHARMACY PERMIT ISSUED UNDER § 12-403.1 OF THIS SUBTITLE; or
- 20 (3) Otherwise is not conducted in accordance with the law.

21 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
22 October 1, 2020.