

SENATE BILL 884

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By: Senator Montgomery

Introduced and read first time: February 18, 2011

Assigned to: Rules

A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drugs – Dispensing Permits**

3 FOR 4 the purpose of authorizing certain individuals who are licensed to practice
5 certain health occupations in the State to dispense prescription drugs to
6 patients under certain circumstances; requiring certain applicants to comply
7 with certain standards; establishing certain standards for the operation of
8 certain offices; establishing certain requirements to apply for a dispensing
9 permit; requiring the State Board of Pharmacy to issue a dispensing permit
10 under certain circumstances; authorizing a permit holder to dispense
11 prescription drugs under certain circumstances; providing for the expiration
12 and renewal of certain permits; authorizing certain inspections under certain
13 circumstances; authorizing certain individuals to dispense starter dosages of
14 prescription drugs under certain circumstances; prohibiting certain individuals
15 from having a certain financial interest; authorizing the Board to deny a permit
16 to an applicant, reprimand a permit holder, place a permit holder on probation,
17 or suspend or revoke a permit; establishing certain hearing and appeal
18 procedures for permit holders; defining certain terms; and generally relating to
19 the authority of licensed dentists, physicians, and podiatrists to dispense
prescription drugs.

20 BY repealing and reenacting, with amendments,
21 Article – Health Occupations
22 Section 12–315 and 12–316
23 Annotated Code of Maryland
24 (2009 Replacement Volume and 2010 Supplement)

25 BY adding to
26 Article – Health Occupations
27 Section 12–6D–01 through 12–6D–12 to be under the new subtitle “Subtitle 6D.
28 Dispensing Permits”
29 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

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1 (i) The proceedings, records, or files of the Board or any of its
2 investigatory bodies are not discoverable and are not admissible in evidence; and

3 (ii) Any order passed by the Board is not admissible in evidence.

4 (3) If any medical or hospital record or any other exhibit is
5 subpoenaed and otherwise is admissible in evidence, the use of that record or exhibit 6
in a proceeding before the Board or any of its investigatory bodies does not prevent its 7
production in any other proceeding.

8 12-316.

9 (a) Except as provided in this section for an action under § 12-313 of this
10 subtitle or § 12-6B-09 **OR § 12-6D-12** of this title, any person aggrieved by a final
11 decision of the Board in a contested case, as defined in the Administrative Procedure
12 Act, may:

13 (1) Appeal that decision to the Board of Review; and

14 (2) Then take any further appeal allowed by the Administrative
15 Procedure Act.

16 (b) (1) Any person aggrieved by a final decision of the Board under §
17 12-313 of this subtitle or § 12-6B-09 **OR § 12-6D-12** of this title may not appeal to
18 the Secretary or Board of Review but may take a direct judicial appeal.

19 (2) The appeal shall be made as provided for judicial review of final
20 decisions in the Administrative Procedure Act.

21 **SUBTITLE 6D. DISPENSING PERMITS.**

22 **12-6D-01.**

23 **(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS**
24 **INDICATED.**

25 **(B) "CONVENIENTLY AVAILABLE" MEANS THE AVAILABILITY OF**
26 **PHARMACY SERVICES TO A PATIENT WITHIN A 10-MILE RADIUS OF THE HOME**
27 **OF THE PATIENT.**

28 **(C) "PERMIT" MEANS A PERMIT ISSUED BY THE BOARD TO DISPENSE**
29 **PRESCRIPTION DRUGS.**

30 **(D) "PERMIT HOLDER" MEANS A DENTIST, PHYSICIAN, OR PODIATRIST:**

1 **(1) WHO IS LICENSED BY THE APPROPRIATE BOARD TO PRACTICE**
2 **DENTISTRY, MEDICINE, OR PODIATRY IN THE STATE UNDER THIS ARTICLE; AND**

3 **(2) WHO HAS BEEN ISSUED A PERMIT BY THE BOARD TO**
4 **DISPENSE PRESCRIPTION DRUGS UNDER THIS SUBTITLE.**

5 **12-6D-02.**

6 **A DENTIST, PHYSICIAN, OR PODIATRIST SHALL HOLD A DISPENSING**
7 **PERMIT ISSUED BY THE BOARD BEFORE THE DENTIST, PHYSICIAN, OR**
8 **PODIATRIST MAY DISPENSE A PRESCRIPTION DRUG TO A PATIENT.**

9 **12-6D-03.**

10 **TO QUALIFY FOR A DISPENSING PERMIT, AN APPLICANT SHALL SATISFY**
11 **THE BOARD THAT THE OFFICE FOR WHICH THE APPLICATION IS MADE WILL BE**
12 **OPERATED IN ACCORDANCE WITH THE STANDARDS SPECIFIED IN § 12-6D-04**
13 **OF THIS SUBTITLE.**

14 **12-6D-04.**

15 **AN OFFICE FOR WHICH A DISPENSING PERMIT HAS BEEN ISSUED UNDER**
16 **THIS SUBTITLE SHALL:**

17 **(1) BE OPERATED IN COMPLIANCE WITH FEDERAL AND STATE**
18 **LAW AND WITH THE REGULATIONS OF THE BOARD;**

19 **(2) STORE ALL PRESCRIPTION DRUGS PROPERLY AND SAFELY**
20 **SUBJECT TO THE REGULATIONS ADOPTED BY THE BOARD;**

21 **(3) MAKE AND KEEP ON FILE FOR AT LEAST 5 YEARS A RECORD**
22 **OF EACH PRESCRIPTION PREPARED OR DISPENSED IN THE OFFICE;**

23 **(4) PROVIDE FOR THE SECURITY OF PRESCRIPTION DRUGS**
24 **INVENTORY AND THE REMOVAL OF EXPIRED DRUGS FROM THE INVENTORY;**

25 **(5) ESTABLISH SAFEGUARDS AGAINST THE DIVERSION OF**
26 **PRESCRIPTION DRUGS;**

27 **(6) COMPLY WITH RESTRICTIONS FOR REPACKAGING OF**
28 **PRESCRIPTION DRUGS;**

29 **(7) COMPLY WITH REQUIREMENTS FOR CHILD RESISTANT**
30 **PACKAGING;**

1 (8) MAINTAIN INVENTORIES OVER A 2-YEAR PERIOD FOR
2 CONTROLLED DANGEROUS SUBSTANCES;

3 (9) PROVIDE INFORMATION REGARDING THE PROCESS FOR
4 RESOLVING INCORRECTLY FILLED PRESCRIPTIONS IN ACCORDANCE WITH 5
EXISTING REGULATIONS BY:

6 (I) POSTING A SIGN THAT IS CONSPICUOUSLY POSITIONED
7 AND READABLE BY PATIENTS; AND

8 (II) INCLUDING WRITTEN INFORMATION REGARDING THE
9 PROCESS WITH EACH PRESCRIPTION DISPENSED;

10 (10) POST A SIGN THAT IS CONSPICUOUSLY POSITIONED AND
11 READABLE BY PATIENTS THAT PRESCRIPTION DRUGS MAY BE PURCHASED
12 FROM THE PERMIT HOLDER IF A PHARMACY IS NOT CONVENIENTLY AVAILABLE
13 TO THE PATIENT; AND

14 (11) COMPLY WITH AN ONGOING QUALITY ASSURANCE PROGRAM.

15 **12-6D-05.**

16 (A) TO APPLY FOR A DISPENSING PERMIT, AN APPLICANT SHALL:

17 (1) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM THAT
18 THE BOARD PROVIDES; AND

19 (2) PAY TO THE BOARD AN APPLICATION FEE SET BY THE BOARD.

20 (B) THE APPLICATION SHALL INCLUDE THE LICENSE NUMBER TO
21 PRACTICE DENTISTRY, MEDICINE, OR PODIATRY IN THE STATE OF THE
22 APPLICANT.

23 **12-6D-06.**

24 (A) THE BOARD SHALL ISSUE A PERMIT UNDER THIS SUBTITLE TO ANY
25 APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SUBTITLE.

26 (B) IF THE BOARD DENIES A PERMIT TO AN APPLICANT, THE BOARD
27 SHALL GIVE THE APPLICANT WRITTEN NOTICE OF ITS DECISION AND THE
28 REASONS FOR THE DENIAL.

29 **12-6D-07.**

1 **(2) PAYS TO THE BOARD A RENEWAL FEE SET BY THE BOARD;**
2 **AND**

3 **(3) SUBMITS A RENEWAL APPLICATION TO THE BOARD ON THE**
4 **FORM THAT THE BOARD PROVIDES.**

5 **(D) THE BOARD SHALL RENEW THE PERMIT OF EACH PERMIT HOLDER**
6 **WHO MEETS THE REQUIREMENTS OF THIS SECTION.**

7 **(E) IF APPLICATION FOR RENEWAL IS NOT MADE ON OR BEFORE**
8 **DECEMBER 1, THE PERMIT SHALL EXPIRE ON THE LAST DAY OF ITS TERM AND**
9 **THE BOARD MAY NOT REINSTATE THE PERMIT UNLESS THE APPLICANT:**

10 **(1) PROVIDES REASON, SUFFICIENT TO THE BOARD, FOR THE**
11 **FAILURE TO FILE WITHIN THE TIME REQUIRED; AND**

12 **(2) PAYS, IN ADDITION TO THE RENEWAL FEE, A LATE FEE SET BY**
13 **THE BOARD.**

14 **12-6D-09.**

15 **(A) THE BOARD SHALL ISSUE A PERMIT TO AN APPLICANT FOR A**
16 **SPECIFIC LOCATION.**

17 **(B) A PERMIT IS NOT TRANSFERABLE.**

18 **(C) EACH PERMIT SHALL BE DISPLAYED CONSPICUOUSLY IN THE**
19 **OFFICE OF THE PERMIT HOLDER FOR WHICH THE PERMIT IS ISSUED.**

20 **12-6D-10.**

21 **(A) PRIOR TO THE ISSUANCE OF A PERMIT BY THE BOARD, THE BOARD**
22 **OR AN AGENT OF THE BOARD MAY INSPECT THE OFFICE OF THE APPLICANT**
23 **DURING BUSINESS HOURS.**

24 **(B) THE BOARD SHALL NOTIFY THE DIVISION OF DRUG CONTROL OF**
25 **THE NAME AND ADDRESS OF A PERMIT HOLDER AUTHORIZED TO DISPENSE**
26 **PRESCRIPTION DRUGS UNDER THIS SUBTITLE.**

27 **(C) DURING BUSINESS HOURS, THE BOARD OR AN AGENT OF THE**
28 **BOARD OR THE DIVISION OF DRUG CONTROL MAY ENTER AND INSPECT A**
29 **PERMIT HOLDER'S OFFICE FOR COMPLIANCE WITH FEDERAL AND STATE LAWS**
30 **AND REGULATIONS.**

1 (D) AT THE DIRECTION OF THE SECRETARY, THE BOARD, THE CHIEF
2 OF THE DIVISION OF DRUG CONTROL, OR THEIR AGENTS MAY ENTER A PERMIT
3 HOLDER'S OFFICE AT ANY TIME AND INVESTIGATE WITH LAW ENFORCEMENT
4 OFFICERS IN ACCORDANCE WITH A VALID WARRANT.

5 (E) A PERSON MAY NOT HINDER AN INSPECTION OR INVESTIGATION
6 CONDUCTED UNDER THIS SECTION.

7 **12-6D-11.**

8 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
9 MEANINGS INDICATED.

10 (2) "PERSONALLY PREPARE AND DISPENSE" MEANS THAT A
11 DENTIST, PHYSICIAN, OR PODIATRIST:

12 (I) IS PHYSICALLY PRESENT ON THE PREMISES WHERE THE
13 PRESCRIPTION IS FILLED; AND

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

16 (3) "STARTER DOSAGE" MEANS AN AMOUNT OF DRUG SUFFICIENT
17 TO BEGIN THERAPY:

18 (I) OF SHORT DURATION OF 72 HOURS OR LESS; OR

19 (II) PRIOR TO OBTAINING A LARGER QUANTITY OF THE
20 DRUG TO COMPLETE THERAPY.

21 (B) A DENTIST, PHYSICIAN, OR PODIATRIST MAY PERSONALLY PREPARE
22 AND DISPENSE A STARTER DOSAGE OF ANY DRUG THE DENTIST, PHYSICIAN, OR
23 PODIATRIST IS AUTHORIZED TO PRESCRIBE TO A PATIENT OF THE DENTIST,
24 PHYSICIAN, OR PODIATRIST IF:

25 (1) THE DENTIST, PHYSICIAN, OR PODIATRIST HAS BEEN ISSUED
26 A PERMIT BY THE BOARD UNDER § 12-6D-06 OF THIS SUBTITLE;

27 (2) THE STARTER DOSAGE COMPLIES WITH THE LABELING
28 REQUIREMENTS OF § 12-509 OF THIS TITLE;

29 (3) NO CHARGE:

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A (II) FOR THE STARTER DOSAGE IS INCORPORATED IN FLAT
FEE FOR AN OFFICE VISIT; AND

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3

(4) THE DENTIST, PHYSICIAN, OR PODIATRIST ENTERS AN
APPROPRIATE RECORD IN THE PATIENT'S MEDICAL RECORD.

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5

6 (C) IN ACCORDANCE WITH THE PROVISIONS OF SUBSECTION (D) OF
7 THIS SECTION, A DENTIST, PHYSICIAN, OR PODIATRIST MAY PERSONALLY
8 PREPARE AND DISPENSE ANY DRUG THAT A DENTIST, PHYSICIAN, OR
9 PODIATRIST MAY PRESCRIBE TO THE EXTENT PERMITTED BY LAW IN THE
10 COURSE OF TREATING A PATIENT IN THE OFFICE OF THE DENTIST, PHYSICIAN,
11 OR PODIATRIST, IF THE DENTIST, PHYSICIAN, OR PODIATRIST HAS BEEN ISSUED
12 A PERMIT BY THE BOARD UNDER § 12-6D-06 OF THIS SUBTITLE.

13 (D) A DENTIST, PHYSICIAN, OR PODIATRIST WHO PERSONALLY
14 PREPARES AND DISPENSES A DRUG IN THE COURSE OF TREATING A PATIENT AS
15 AUTHORIZED UNDER SUBSECTION (C) OF THIS SECTION SHALL:

16 (1) COMPLY WITH THE LABELING REQUIREMENTS OF § 12-509 OF
17 THIS TITLE;

18 (2) RECORD THE DISPENSING OF THE PRESCRIPTION DRUG IN
19 THE PATIENT'S MEDICAL RECORD;

20 (3) EXCEPT FOR STARTER DOSAGES OR SAMPLES DISPENSED
21 WITHOUT CHARGE, PROVIDE THE PATIENT WITH A WRITTEN PRESCRIPTION;
22 AND

23 (4) MAINTAIN A SINGLE FORM IN THE PATIENT'S MEDICAL
24 RECORD INDICATING THAT A PHARMACY IS NOT CONVENIENTLY AVAILABLE TO
25 THE PATIENT.

26 (E) A PERMIT HOLDER MAY NOT HAVE A SUBSTANTIAL FINANCIAL
27 INTEREST IN A PHARMACY.

28 12-6D-12.

29 (A) SUBJECT TO THE HEARING PROVISIONS OF § 12-315 OF THIS TITLE,
30 FOR A VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER
31 THIS SUBTITLE, THE BOARD MAY:

32 (1) DENY A PERMIT TO AN APPLICANT;

1

REPRIMAND A PERMIT HOLDER;

2

PLACE A PERMIT HOLDER ON PROBATION; OR

(2)

SUSPEND OR REVOKE A PERMIT.

(3)

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(4)

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(B) A PERSON AGGRIEVED BY A FINAL ACTION OF THE BOARD UNDER

5 THIS SUBTITLE MAY NOT APPEAL TO THE SECRETARY OR THE BOARD OF

6 REVIEW BUT MAY APPEAL AS PROVIDED UNDER TITLE 10, SUBTITLE 2 OF THE

7 STATE GOVERNMENT ARTICLE.

8

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect

9 October 1, 2011.