

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



1 (2009 Replacement Volume and 2010 Supplement)

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

4 **Article – Health Occupations**

5 12–315.

6 (a) Except as otherwise provided in the Administrative Procedure Act, before
7 the Board takes any action under § 12–313 of this subtitle or § 12–6B–09 **OR §**
8 **12–6D–12** of this title, it shall give the individual against whom the action is
9 contemplated an opportunity for a hearing before the Board.

10 (b) The Board shall give notice and hold the hearing in accordance with the
11 Administrative Procedure Act.

12 (c) The hearing notice to be given to the individual shall be sent by certified
13 mail, return receipt requested, bearing a postmark from the United States Postal
14 Service, to the last known address of the individual at least 20 days before the
15 hearing.

16 (d) The individual may be represented at the hearing by counsel.

17 (e) Over the signature of an officer or the executive director of the Board, the
18 Board may issue subpoenas and administer oaths in connection with any investigation
19 under this title and any hearings or proceedings before it.

20 (f) If, without lawful excuse, a person disobeys a subpoena from the Board or
21 an order by the Board to take an oath or to testify or answer a question, then, on
22 petition of the Board, a court of competent jurisdiction may punish the person as for
23 contempt of court.

24 (g) If after due notice the individual against whom the action is
25 contemplated fails or refuses to appear, nevertheless the Board may hear and
26 determine the matter.

27 (h) The hearing of charges against a person may not be stayed or challenged
28 by procedural defects alleged to have occurred prior to filing of the charges.

29 (i) (1) This subsection does not apply to a civil action brought by a party
30 to a proceeding before the Board who claims to be aggrieved by the decision of the
31 Board.

32 (2) Except by the express stipulation and consent of all parties to a
33 proceeding before the Board or any of its investigatory bodies, in a civil or criminal
34 action:

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 A PERMIT AUTHORIZES THE PERMIT HOLDER, WHILE THE PERMIT IS
2 EFFECTIVE, TO DISPENSE PRESCRIPTION DRUGS TO A PATIENT WHEN A
3 PHARMACY IS NOT CONVENIENTLY AVAILABLE TO THE PATIENT.

4 **12-6D-08.**

5 (A) A PERMIT EXPIRES 5 YEARS AFTER ITS EFFECTIVE DATE, UNLESS
6 THE PERMIT IS RENEWED FOR A 5-YEAR TERM AS PROVIDED IN THIS SECTION.

7 (B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS
8 SUBSECTION, ON OR BEFORE OCTOBER 1 OF THE YEAR THE PERMIT EXPIRES,
9 THE BOARD SHALL SEND TO EACH PERMIT HOLDER A RENEWAL NOTICE FOR
10 THE PERMIT BY FIRST-CLASS MAIL TO THE LAST KNOWN ADDRESS OF THE
11 PERMIT HOLDER.

12 (2) IF REQUESTED BY A PERMIT HOLDER, THE BOARD SHALL
13 SEND TO THE PERMIT HOLDER, AT LEAST TWO TIMES WITHIN THE MONTH
14 BEFORE A PERMIT EXPIRES, A RENEWAL NOTICE FOR THE PERMIT BY
15 ELECTRONIC MAIL TO THE LAST KNOWN ELECTRONIC ADDRESS OF THE PERMIT
16 HOLDER.

17 (3) IF A RENEWAL NOTICE SENT BY ELECTRONIC MAIL UNDER
18 PARAGRAPH (2) OF THIS SUBSECTION IS RETURNED TO THE BOARD AS
19 UNDELIVERABLE, THE BOARD SHALL SEND TO THE PERMIT HOLDER A
20 RENEWAL NOTICE FOR THE PERMIT BY FIRST-CLASS MAIL TO THE LAST KNOWN
21 ADDRESS OF THE PERMIT HOLDER.

22 (4) A RENEWAL NOTICE SENT UNDER THIS SUBSECTION SHALL
23 STATE:

24 (I) THE DATE ON WHICH THE CURRENT PERMIT EXPIRES;

25 (II) THE DATE BY WHICH THE RENEWAL APPLICATION MUST
26 BE RECEIVED BY THE BOARD FOR THE RENEWAL TO BE ISSUED AND MAILED
27 BEFORE THE PERMIT EXPIRES; AND

28 (III) THE AMOUNT OF THE RENEWAL FEE.

29 (C) BEFORE THE PERMIT EXPIRES, THE PERMIT HOLDER
30 PERIODICALLY MAY RENEW THE PERMIT FOR AN ADDITIONAL 5-YEAR TERM, IF
31 THE PERMIT HOLDER:

32 (1) OTHERWISE IS ENTITLED TO THE PERMIT;

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:**

1 (I) IS MADE FOR THE STARTER DOSAGE; OR

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

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

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 **(2) REPRIMAND A PERMIT HOLDER;**
2 **(3) PLACE A PERMIT HOLDER ON PROBATION; OR**
3 **(4) SUSPEND OR REVOKE A PERMIT.**

4 **(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.