

HOUSE BILL 1030

J2

71r2476
CF 71r2735

By: **Delegate Montgomery**

Introduced and read first time: February 9, 2007

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy – Wholesale Drug Distribution – Permit**
3 **Requirements**

4 FOR the purpose of altering the requirements for obtaining a wholesale distributor's
5 permit to include a certain inspection and the posting of a certain bond;
6 requiring a certain pedigree for prescription drugs or devices distributed in the
7 State; requiring the State Board of Pharmacy to adopt regulations regarding
8 certain pedigree and inspection requirements; defining a certain term; and
9 generally relating to permit requirements for wholesale drug distribution.

10 BY repealing and reenacting, with amendments,
11 Article – Health Occupations
12 Section 12–602
13 Annotated Code of Maryland
14 (2005 Replacement Volume and 2006 Supplement)

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

17 **Article – Health Occupations**

18 12–602.

19 (a) (1) In this section the following words have the meanings indicated.

20 (2) “Distribution permit” means a permit issued by the Board under

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 this section to distribute prescription drugs or devices into, out of, or within the State
2 as a distributor, jobber, manufacturer, or wholesaler, wherever located.

3 **(3) "PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE**
4 **CONTAINING INFORMATION THAT RECORDS EACH DISTRIBUTION OF A**
5 **PRESCRIPTION DRUG OR DEVICE.**

6 [(3)] (4) "Prescription drugs or devices" means any drug or device
7 that, because of its toxicity or other potential for harmful effect, the method of its use,
8 or the collateral measures necessary for its use, is required by federal law to bear a
9 cautionary label warning against dispensing without a prescription or is designated by
10 the Department as not safe for use except under the supervision of a practitioner
11 licensed to administer drugs or devices of this nature.

12 (b) This section does not affect any person while distributing:

13 (1) Feed for livestock or poultry;

14 (2) Fertilizers;

15 (3) Fungicides;

16 (4) Insecticide;

17 (5) Land plaster;

18 (6) Lime;

19 (7) Seeds; or

20 (8) Devices, drugs, or supplies of any kind for the treatment, care, or
21 cure of farm animals.

22 (c) A person shall hold a distribution permit issued by the Board before the
23 person may distribute prescription drugs or devices as a distributor, jobber,
24 manufacturer, or wholesaler.

25 (d) To qualify for a distribution permit, an applicant shall:

26 (1) Satisfy the Board that the applicant will distribute prescription
27 drugs or devices in compliance with the restrictions specified in subsection (e) of this
28 section; [and]

1 **(2) SUBMIT EVIDENCE OF AN INSPECTION PERFORMED:**

2 **(I) BY THE BOARD OR AN APPROVED AGENT OF THE**
3 **BOARD FOR EACH FACILITY OPERATED BY THE APPLICANT; AND**

4 **(II) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE**
5 **BOARD; AND**

6 **[(2)] (3)** Comply with any pertinent regulations adopted under
7 subsection (i) of this section.

8 (e) A distribution permit holder may distribute prescription drugs or devices
9 only:

10 (1) To the following persons:

11 (i) An authorized prescriber;

12 (ii) A pharmacy permit holder;

13 (iii) A distribution permit holder; or

14 (iv) Any other person approved by the Board; [and]

15 **(2) IF THE DISTRIBUTED PRESCRIPTION DRUGS OR DEVICES ARE**
16 **ACCOMPANIED BY A PEDIGREE ESTABLISHED IN ACCORDANCE WITH**
17 **REGULATIONS ADOPTED BY THE BOARD; AND**

18 **[(2)] (3)** In compliance with any rules and regulations adopted under
19 this section.

20 (f) To apply for a distribution permit, an applicant shall:

21 (1) Submit an application to the Board on the form that the Board
22 provides; [and]

23 **(2) SUBMIT TO THE BOARD, IN ACCORDANCE WITH REGULATIONS**
24 **ADOPTED BY THE BOARD, A BOND OF AT LEAST \$100,000, OR OTHER**
25 **EQUIVALENT MEANS OF SECURITY ACCEPTABLE TO THE BOARD, SUCH AS AN**
26 **IRREVOCABLE LETTER OF CREDIT OR A DEPOSIT IN A TRUST ACCOUNT OR**

1 **FINANCIAL INSTITUTION, PAYABLE TO AN ACCOUNT ESTABLISHED BY THE**
2 **BOARD; AND**

3 [(2)] (3) Pay to the Board an application fee set by the Board.

4 (g) The Board shall issue a distribution permit to any applicant who meets
5 the requirements of this section.

6 (h) A distribution permit issued under this section authorizes the
7 distribution permit holder to distribute prescription drugs or devices as a distributor,
8 jobber, manufacturer, or wholesaler while the distribution permit is effective.

9 (i) To protect the public health and safety, the Board:

10 (1) [may] **MAY** adopt rules and regulations regarding the distribution
11 of prescription drugs or devices including regulations regarding:

12 [(1)] (I) Qualifications and information required from an applicant
13 seeking issuance or renewal of a distribution permit;

14 [(2)] (II) Minimum requirements for the receipt, storage, and
15 handling of prescription drugs or devices, security precautions, quality control, record
16 keeping, and establishment of written procedures, policy, and responsibilities of
17 personnel;

18 [(3)] (III) The education and experience of personnel employed in
19 positions responsible for duties referenced in [paragraph (2)] **ITEM (II)** of this
20 [subsection] **ITEM** and generally responsible for carrying out those duties that are
21 subject to State licensure requirements under this subtitle; and

22 [(4)] (IV) Disciplinary action to be taken against a permit holder who
23 is convicted of or pleads guilty or nolo contendere to a violation of State, federal, or
24 local drug laws or who violates regulations promulgated by the Board under this
25 section; **AND**

26 (2) **SHALL ADOPT REGULATIONS SPECIFYING:**

27 (I) **PEDIGREE REQUIREMENTS; AND**

28 (II) **ROUTINE INSPECTION REQUIREMENTS.**

1 (j) (1) A distribution permit expires on the December 31 after its effective
2 date, unless the distribution permit is renewed for a 1-year term as provided in this
3 subsection.

4 (2) At least 1 month before a distribution permit expires, the Board
5 shall send to the distribution permit holder, by first-class mail to the last known
6 address of the distribution permit holder, a renewal notice that contains a statement
7 of:

8 (i) The date on which the current distribution permit expires;

9 (ii) The date by which the renewal application must be received
10 by the Board for the renewal to be issued and mailed before the distribution permit
11 expires; and

12 (iii) The amount of the renewal fee.

13 (3) Before a distribution permit expires, a distribution permit holder
14 periodically may renew it for an additional 1-year term, if the distribution permit
15 holder:

16 (i) Otherwise is entitled to a distribution permit;

17 (ii) Pays to the Board a renewal fee set by the Board; and

18 (iii) Submits to the Board a renewal application on the form that
19 the Board requires.

20 (4) The Board shall renew the distribution permit of each distribution
21 permit holder who meets the requirements of this section and any regulation adopted
22 under this section.

23 (k) Each distribution permit shall be displayed conspicuously in the place for
24 which it is issued.

25 (l) A distribution permit is not transferable.

26 (m) Subject to any other restriction provided by law, a person may not
27 purchase or obtain any prescription drugs or devices unless the drug or device is
28 obtained from a distribution permit holder, a licensed pharmacist, or an authorized
29 prescriber.

30 (n) A person may not violate any rule or regulation adopted under this

1 section.

2 (o) A distribution permit is void on conviction of the distribution permit
3 holder for any violation of:

4 (1) This section; or

5 (2) Any rule or regulation adopted by the Board under this section.

6 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
7 July 1, 2007.