

SENATE BILL 412

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1998 Regular Session  
8lr2283  
CF 8lr1377

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By: **Senator Bromwell**

Introduced and read first time: February 6, 1998

Assigned to: Economic and Environmental Affairs

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A BILL ENTITLED

1 AN ACT concerning

2 **Consumer Protection - Drug Storage and Shipment Safety Act**

3 FOR the purpose of authorizing the State Board of Pharmacy to adopt certain  
4 regulations concerning the delivery by certain means into the State of  
5 prescription drug orders to patients or their agents at certain places; requiring  
6 certain distribution permit holders to maintain adequate storage or shipment  
7 containers, including proper packaging materials, for certain purposes and to  
8 place certain notices into certain shipments of prescription drugs; and generally  
9 relating to the authority of the State Board of Pharmacy concerning the delivery  
10 and shipment of certain drugs into the State.

11 BY repealing and reenacting, with amendments,  
12 Article - Health Occupations  
13 Section 12-602  
14 Annotated Code of Maryland  
15 (1994 Replacement Volume and 1997 Supplement)

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

18 **Article - Health Occupations**

19 12-602.

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

21 (2) "Distribution permit" means a permit issued by the Board under this  
22 section to distribute prescription drugs or devices into, out of, or within the State as a  
23 distributor, jobber, manufacturer, or wholesaler, wherever located.

24 (3) "Prescription drugs or devices" means any drug or device that,  
25 because of its toxicity or other potential for harmful effect, the method of its use, or  
26 the collateral measures necessary for its use, is required by federal law to bear a  
27 cautionary label warning against dispensing without a prescription or is designated

1 by the Department as not safe for use except under the supervision of a practitioner  
2 licensed to administer drugs or devices of this nature.

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

4 (1) Feed for livestock or poultry;

5 (2) Fertilizers;

6 (3) Fungicides;

7 (4) Insecticide;

8 (5) Land plaster;

9 (6) Lime;

10 (7) Seeds; or

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

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

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

17 (1) Satisfy the Board that the applicant will distribute prescription  
18 drugs or devices in compliance with the restrictions specified in subsection (e) of this  
19 section; and

20 (2) Comply with any pertinent regulations adopted under subsection (i)  
21 of this section.

22 (e) A distribution permit holder may distribute prescription drugs or devices  
23 only:

24 (1) To the following persons:

25 (i) An authorized prescriber;

26 (ii) A pharmacy permit holder;

27 (iii) A distribution permit holder; or

28 (iv) Any other person approved by the Board; and

29 (2) In compliance with any rules and regulations adopted under this  
30 section.

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

2 (1) Submit an application to the Board on the form that the Board  
3 provides; and

4 (2) Pay to the Board an application fee set by the Board.

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

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

10 (i) To protect the public health and safety, the Board may adopt rules and  
11 regulations regarding the distribution of prescription drugs or devices including  
12 regulations regarding:

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

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

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

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

26 (5) WITH REGARD TO A PRESCRIPTION DRUG ORDER THAT IS  
27 DELIVERED IN THIS STATE BY THE UNITED STATES MAIL, A COMMON CARRIER, OR A  
28 DELIVERY SERVICE TO A PATIENT OR TO THE AGENT OF THE PATIENT, AT THE  
29 RESIDENCE OF THE PATIENT OR AT ANOTHER LOCATION DESIGNATED BY THE  
30 PATIENT, THE OBLIGATION OF A DISTRIBUTION PERMIT HOLDER TO:

31 (I) MAINTAIN ADEQUATE STORAGE OR SHIPMENT CONTAINERS TO  
32 ENSURE DRUG STABILITY AND POTENCY, INCLUDING THE USE OF PROPER  
33 PACKAGING MATERIALS TO ENSURE THAT THROUGHOUT THE DELIVERY PROCESS  
34 THE PRESCRIPTION DRUG IS MAINTAINED AT A STORAGE TEMPERATURE AS  
35 DEFINED IN THE GENERAL NOTICES SECTION OF THE UNITED STATES  
36 PHARMACOPEIA FOR RECOMMENDED CONDITIONS COMMONLY SPECIFIED ON  
37 PRODUCT LABELS;

1 (II) PROVIDE A GENERAL WRITTEN NOTICE, TO BE PLACED INTO  
2 EACH SHIPMENT OF A PRESCRIPTION DRUG, WHICH ALERTS CONSUMERS THAT  
3 UNDER CERTAIN CIRCUMSTANCES CHEMICAL DEGRADATION OF THE PRESCRIPTION  
4 DRUG MAY OCCUR;

5 (III) PROVIDE A SPECIFIC WRITTEN NOTICE, TO BE PLACED INTO  
6 EACH SHIPMENT OF A PRESCRIPTION DRUG, WHICH CONTAINS AN INDIVIDUAL DRUG  
7 SENSORY WARNING THAT IDENTIFIES INDICATORS OF A CHEMICAL DEGRADATION  
8 OF THE PRESCRIPTION DRUG BEING SHIPPED; AND

9 (IV) PROVIDE A WRITTEN NOTICE, TO BE PLACED INTO EACH  
10 SHIPMENT OF A PRESCRIPTION DRUG, WHICH PROVIDES A TOLL FREE CONSUMER  
11 ACCESS TELEPHONE NUMBER DEDICATED SOLELY TO ANSWERING QUESTIONS  
12 FROM CONSUMERS ABOUT THE CHEMICAL DEGRADATION OF PRESCRIPTION DRUGS.

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

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

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

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

23 (iii) The amount of the renewal fee.

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

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

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

29 (iii) Submits to the Board a renewal application on the form that the  
30 Board requires.

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

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

36 (l) A distribution permit is not transferable.

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

5 (n) A person may not violate any rule or regulation adopted under this section.

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

8 (1) This section; or

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

10 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
11 October 1, 1998.