HOUSE BILL 1062

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By: **Delegates Klausmeier, Elliott, D. Hughes, and Stull**
Introduced and read first time: February 13, 1998
Assigned to: Environmental Matters

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 26, 1998

CHAPTER_____

AN ACT concerning

Consumer Protection - Drug Storage and Shipment Safety Act

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

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section ~~12-602~~ 12-403(b)(15) and (16) and (f)(7) and (8)
Annotated Code of Maryland
(1994 Replacement Volume and 1997 Supplement)

BY adding to
Article - Health Occupations
Section 12-403(b)(17) and (f)(9)
Annotated Code of Maryland
(1994 Replacement Volume and 1997 Supplement)

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

Article - Health Occupations

~~12-602.~~

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

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

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

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

~~(1) Feed for livestock or poultry;~~

~~(2) Fertilizers;~~

~~(3) Fungicides;~~

~~(4) Insecticide;~~

~~(5) Land plaster;~~

~~(6) Lime;~~

~~(7) Seeds; or~~

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

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

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

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

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

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

~~(1) To the following persons:~~

~~(i) An authorized prescriber;~~

~~(ii) A pharmacy permit holder;~~

~~(iii) A distribution permit holder; or~~

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

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

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

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

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

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

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

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

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

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

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

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

~~(5) WITH REGARD TO A PRESCRIPTION DRUG ORDER THAT IS DELIVERED IN THIS STATE BY THE UNITED STATES MAIL, A COMMON CARRIER, OR A DELIVERY SERVICE TO A PATIENT OR TO THE AGENT OF THE PATIENT, AT THE~~

~~RESIDENCE OF THE PATIENT OR AT ANOTHER LOCATION DESIGNATED BY THE PATIENT, THE OBLIGATION OF A DISTRIBUTION PERMIT HOLDER TO:~~

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

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

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

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

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

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

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

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

~~(iii) The amount of the renewal fee.~~

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

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

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

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

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

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

~~(l) A distribution permit is not transferable.~~

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

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

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

~~(1) This section; or~~

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

12-403.

(b) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

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

(16) Shall provide such personnel, automation, and technology as are necessary to allow the licensed pharmacist employee to comply with the labeling requirements specified in § 12-505[.]; AND

(17) SHALL, WITH REGARD TO A PRESCRIPTION DRUG THAT IS DELIVERED IN THIS STATE BY THE UNITED STATES MAIL, A COMMON CARRIER, OR A DELIVERY SERVICE AND IS NOT PERSONALLY HAND DELIVERED DIRECTLY TO A PATIENT OR TO THE AGENT OF THE PATIENT AT THE RESIDENCE OF THE PATIENT OR AT ANOTHER LOCATION DESIGNATED BY THE PATIENT:

(I) PROVIDE A GENERAL WRITTEN NOTICE IN EACH SHIPMENT OF A PRESCRIPTION DRUG THAT ALERTS A CONSUMER THAT, UNDER CERTAIN CIRCUMSTANCES, A MEDICATION'S EFFECTIVENESS MAY BE AFFECTED BY EXPOSURE TO EXTREMES OF HEAT, COLD, OR HUMIDITY; AND

(II) PROVIDE A SPECIFIC WRITTEN NOTICE IN EACH SHIPMENT OF A PRESCRIPTION DRUG THAT PROVIDES A CONSUMER WITH A TOLL-FREE OR LOCAL CONSUMER ACCESS TELEPHONE NUMBER ACCESSIBLE DURING REGULAR HOURS OF OPERATION, WHICH IS DESIGNED TO RESPOND TO CONSUMER QUESTIONS PERTAINING TO MEDICATIONS.

(f) A nonresident pharmacy shall:

(7) Disclose its toll-free telephone number on a label affixed to each container of drug or devices; [and]

(8) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located[.]; AND

(9) COMPLY WITH THE REQUIREMENTS OF SUBSECTION (B)(17) OF THIS SECTION.

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