State of Arkansas
78th General Assembly
Regular Session, 1991
By: Senator Ross

A BillACT 739 OF 1991
SENATE BILL 589

For An Act To Be Entitled

"AN ACT TO AMEND VARIOUS SECTIONS OF AND ADD NEW SECTIONS TO SUBCHAPTER 5 OF TITLE 20, CHAPTER 64 RELATING TO THE LICENSING OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS BY THE ARKANSAS STATE BOARD OF PHARMACY; AND FOR OTHER PURPOSES."

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 20-64-501 is hereby amended to read as follows:

"20-64-501. Applicability. Nothing in this subchapter shall apply to the sale of chemicals or poisons for use for nonmedical purposes or for uses as insecticides or biologics or medicine used for the cure, mitigation, or prevention of disease of animals or fowl and uses for agricultural use which comply with the requirements of the federal Food, Drug, and Cosmetic Act and all amendments thereto unless those products are prescription drugs under this subchapter."

SECTION 2. Arkansas Code § 20-64-503 is hereby amended to read as follows:

"20-64-503. Definitions. As used in this subchapter, unless the context otherwise requires:

(1) 'Board' means the Arkansas State Board of Pharmacy;

(2) 'Person' includes individual, partnership, corporation, business firm and association;

(3) 'Controlled substance' means those substances, drugs, or immediate precursors listed in Schedules I through VI of the Uniform Controlled Substances Act, 5-64-101 et seq., and revised by the coordinator pursuant to his authority under 5-64-214 - 5-64-216;

(4)(A) 'Legend drug' means a drug limited by 503(b)(1) of the federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is:

(i) Habit-forming;

(ii) Toxic or having potential for harm;

(iii) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(B) The product label of a legend drug is required to contain the statement 'CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.'

(C) A legend drug includes prescription drugs subject to the requirement of 503(b)(1) of the federal Food, Drug, and Cosmetic Act which shall be exempt from 502(F)(1) if certain specified conditions are met.

(5) 'Prescription drug' means controlled substances legend drugs and veterinary legend drugs as defined herein.

(6) 'Blood' means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(7) 'Blood component' means that part of blood separated by physical or mechanical means.

(8) 'Manufacturer' means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(9) 'Wholesale distribution' means the distribution of prescription drugs to persons other than consumers or patients, but does not include:

(A) Intracompany sales;

(B) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(C) The sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the federal Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(D) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for the purposes of this section 'common control'

means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock or voting rights, by contract or otherwise;

(E) The sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, 'emergency medical reasons' includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(F) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(G) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(H) The sale, purchase or trade of blood components intended for transfusion.

(10) 'Wholesale distributor' means any person engaged in wholesale distribution of prescription drugs, including but not limited to manufacturers; repackers' own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. A wholesale drug distributor shall not include any for-hire carrier or person or entity hired solely to transport prescription drugs.

(11) 'Drug sample' means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(12) 'Veterinary legend drugs' means drugs defined in 21 CFR §201.105 and bearing a label required to bear the cautionary statement, 'CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF A LICENSED VETERINARIAN'."

SECTION 3. Arkansas Code § 20-64-504 is hereby amended to read as

follows:

"20-64-504. Sales - Permit required. It shall be unlawful for any person to sell or offer for sale by advertisement, circular, letter, sign, or oral solicitation or any other means any prescription drug unless the person holds and possesses a permit authorizing such sale as provided by this subchapter."

SECTION 4. Arkansas Code § 20-64-505 is hereby amended to read as follows:

"20-64-505. Wholesale distributor - Permit required.

(a) Every wholesale distributor who shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, shipping into this state or selling or offering to sell in this state, shall register annually with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the Board and accompanied by a fee of two hundred dollars ($200). The Board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.

(b)(1) The permit may be renewed annually at a renewal permit fee of one hundred dollars ($100).

(2) All permits issued under this section shall expire on December 31 of each calendar year.

(3) Each application for the renewal of the permit must be made on or before December 31 of each year, at which time the previous permits shall become null and void.

(c) Each permit issued hereunder shall be displayed by the holder thereof in a conspicuous place."

SECTION 5. Arkansas Code § 20-64-506 is hereby amended to read as follows:

"20-64-506. Wholesale distributors - Shipment to certain licensed professionals.

(a) All wholesale distributors must, before shipping to a recipient in this state any prescription drug as defined in this subchapter, ascertain that the person to whom shipment is made is either a licensed physician licensed by the Arkansas State Medical Board, a licensed Doctor of Dentistry, a licensed Doctor of Veterinary Medicine, a licensed Doctor of Podiatry Medicine, a hospital licensed by the State Board of Health, a licensed wholesale distributor as defined in this subchapter, a licensed pharmacy licensed by the Arkansas State Board of Pharmacy, or other entity authorized by law to purchase or possess prescription drugs.

(b) No wholesale distributor shall ship any prescription drug to any person after receiving written notice from the board that the person no longer holds a registered pharmacy permit or is not a licensed physician, dentist, veterinarian or hospital."

SECTION 6. Arkansas Code § 20-64-507 is hereby amended to read as follows:

"20-64-507. Regulations.

(a) The board shall adopt regulations for the wholesale distribution of prescription drugs which promote the public health and welfare and which comply with the minimum standards, terms and conditions of the federal Prescription Drug Marketing Act (PDMA) and federal regulations, including without limitations 21 CFR §205, for licensing by state authorities of persons who engage in the wholesale distribution in interstate commerce of prescription drugs. The regulations shall include, without limitation:

(1) minimum information from each wholesale distributor required for licensing and renewal of licenses;

(2) minimum qualifications of persons who engage in the wholesale distribution of prescription drugs;

(3) appropriate education or experience, or both, of persons employed in wholesale distribution of prescription drugs who assume responsibility for positions related to compliance with state licensing requirements;

(4) minimum requirements for the storage and handling of prescription drugs; and

(5) minimum requirements for the establishment and maintenance of

prescription drug distribution records.

(b) In the event that this subchapter or regulations promulgated hereunder conflict with the PDMA or federal regulations, the PDMA or federal regulations shall control.

(c) The Board of Pharmacy shall appoint an advisory committee composed of seven (7) members, one (1) of whom shall be a representative of pharmacy but who shall not be a member of the board, three (3) of whom shall be representatives of wholesale drug distributors, and three (3) of whom shall be representatives of drug manufacturers. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributions and drug manufacturers which are proposed by the board."

SECTION 7. Arkansas Code § 20-64-508 is hereby amended to read as follows:

"20-64-508. Revocation or suspension of licenses. The board may revoke or suspend an existing license or may refuse to issue a license under this subchapter if the holder or applicant has committed or is found guilty by the board of any of the following:

(1) Violation of any federal, state or local law or regulation relating to drugs;

(2) Violation of any provisions of this subchapter or any regulation promulgated hereunder;

(3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety."

SECTION 8. Subchapter 5 of Title 20, Chapter 64 of the Arkansas Code of 1987, Annotated is hereby amended to add a new § 20-64-509 to read as follows:

"20-64-509. Penalties.

(a) After notice and hearing, whenever the board has found a licensee to have committed any act enumerated in Arkansas Code § 20-64-508, the board shall have the power to impose a civil penalty and may order the license be suspended until the penalty is paid.

(b) Before imposing any civil penalty, the board shall determine that the public health and welfare would not be impaired by the imposition of the

penalty and payment of the penalty will achieve the desired disciplinary purposes.

(c) No penalty imposed by the board shall exceed one thousand dollars ($1,000) per violation, nor shall the board impose a penalty on a licensee where the license has been revoked by the board for such violation.

(d) Each instance where a federal, state or local law or regulation is violated shall constitute a separate violation.

(e) The power and authority of the board to impose penalties is not to be affected by any other civil or criminal proceeding concerning the same violation, nor shall the imposition of a penalty preclude the board from imposing other sanctions short of revocation."

SECTION 9. Subchapter 5 of Title 20, Chapter 64 of the Arkansas Code of 1987, Annotated is hereby amended to add a new § 20-64-510 to read as follows:

"20-64-510. Hearing procedures. The procedure for notice, hearing and appeals therefrom shall be that of the Arkansas State Board of Pharmacy set forth in Arkansas Code § 17-91-313 and that of the Arkansas Administrative Procedure Act, § 25-15-201 et seq."

SECTION 10. Subchapter 5 of Title 20, Chapter 64 of the Arkansas Code of 1987, Annotated is hereby amended to add a new § 20-64-511 to read as follows:

"20-64-511. Violations. A person violating any provision of this subchapter shall be guilty of a Class A misdemeanor."

SECTION 11. Subchapter 5 of Title 20, Chapter 64 of the Arkansas Code of 1987, Annotated is hereby amended to add a new § 20-64-512 to read as follows:

"20-64-512. Records and inspection of records. The board may conduct inspections upon all premises purporting or appearing to be used by a person licensed under this subchapter. The board in its discretion may accept a satisfactory inspection by the United States Food and Drug Administration (USFDA) or a state agency of another state which the board determines to be comparable to that made by USFDA or the board. A licensed person may keep records at a central location apart from the principal office of the licensee

or the location at which the drugs were stored and from which they are distributed."

SECTION 12. Subchapter 5 of Title 20, Chapter 64 of the Arkansas Code of 1987, Annotated is hereby amended to add a new § 20-64-513 to read as follows:

"20-64-513. Injunctive powers. The board may in its discretion and in addition to various remedies provided by law under this subchapter apply to a court having competent jurisdiction over the parties and subject matter for a writ of injunction to restrain violations of this act or of any conduct which constitutes a clear and present danger to the public health and safety."

SECTION 13. All provisions of this act of general and permanent nature are amendatory to the Arkansas Code of 1987 Annotated and the Arkansas Code Revision Commission shall incorporate the same in the Code.

SECTION 14. If any provisions of this act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provisions or application, and to this end the provisions of this act are declared to be severable.

SECTION 15. All laws and parts of laws in conflict with this act are hereby repealed.

APPROVED: 3-25-91