STATE OF OKLAHOMA

2nd Session of the 56th Legislature (2018)

HOUSE BILL 2971 By: Frix

AS INTRODUCED

An Act relating to the Oklahoma Pharmacy Act; amending 59 O.S. 2011, Section 353.18, as last amended by Section 4, Chapter 285, O.S.L. 2016 (59 O.S. Supp. 2017, Section 353.18), which relates to licensing requirements for the sale, manufacture or packaging of items regulated pursuant to the Oklahoma Pharmacy Act; expanding scope of licensing requirement; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 59 O.S. 2011, Section 353.18, as last amended by Section 4, Chapter 285, O.S.L. 2016 (59 O.S. Supp. 2017, Section 353.18), is amended to read as follows:

Section 353.18 A. 1. It shall be unlawful for any person, including, but not limited to, out-of-state, Internet, website or online pharmacies, to sell at retail or to offer for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and drugs, or to accept prescriptions for same, without first procuring a license from the State Board of Pharmacy. This licensure requirement applies whether

such sale, offer for sale or acceptance of prescriptions occurs in this state, or such sale, offer for sale, or acceptance of prescription occurs out of state and the dangerous drug, medicine, chemical or poison is to be delivered, distributed or dispensed to patients or customers in this state.

2. A pharmacy license shall be issued to such person as the Board shall deem qualified upon evidence satisfactory to the Board that:

a. the place for which the license is sought will be conducted in full compliance with the law and the rules of the Board,

b. the location and physical characteristics of the place are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to the public health and safety,

c. the place will be under the management and control of a licensed pharmacist or pharmacist-in-charge who shall be licensed as a pharmacist in Oklahoma, and

d. a licensed pharmacist shall be present and on duty at all business hours; provided, however, the provisions of this subparagraph shall not apply to hospital drug rooms.

3. a. An application for an initial or renewal license issued pursuant to the provisions of this subsection shall:

(1) be submitted to the Board in writing,

(2) contain the name or names of persons owning the pharmacy, and

(3) provide other such information deemed relevant by the Board.

b. An application for an initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year. Prior to opening for business, all applicants for an initial license or permit shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00); provided, however, that no charge shall be made for the licensing of any Federal Veterans Hospital in the State of Oklahoma. Non-resident pharmacies shall reimburse the Board for any actual expenses incurred for inspections.

c. A license issued pursuant to the provisions of this subsection shall be valid for a period set by the Board and shall contain the name of the licensee and

the address of the place at which such business shall be conducted.

4. A retail pharmacy that prepares sterile drugs shall obtain a pharmacy license, and shall also obtain a sterile compounding permit at a fee set by the Board, not to exceed Seventy-five Dollars ($75.00). Such pharmacy shall meet requirements set by the Board by rule for sterile compounding permits.

5. An outsourcing facility desiring to dispense prescriptions to patients must additionally license and meet the requirements of a pharmacy.

B. 1. It shall be unlawful for any person to manufacture, repackage, distribute, outsource, warehouse or be a third-party logistics provider of any dangerous drugs, medicines, medical gases, chemicals, or poisons for the treatment of disease, excluding agricultural chemicals without first procuring a license from the Board. It shall be unlawful to sell or offer for sale at retail or wholesale dangerous drugs, medicines, medical gases, chemicals or poisons without first procuring a license from the Board. This licensure requirement shall apply when the manufacturing, repackaging, distributing, outsourcing, warehousing, or provision of third-party logistics occurs in this state or out of state for delivery, distribution, or dispensing to patients or customers in this state.

2. A license shall be issued to such person as the Board shall deem qualified upon satisfactory evidence to the Board that:

a. the place for which the license is sought will be conducted in full compliance with the laws of this state and the administrative rules of the Board,

b. the location and physical characteristics of the place of business are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to public health and safety,

c. the place shall be under the management and control of such persons as may be approved by the Board after a review and determination of the persons' qualifications, and

d. an outsourcing facility shall designate in writing on a Board-approved form a person to serve as the pharmacist-in-charge who is a pharmacist licensed by the Board.

3. a. An application for an initial or renewal license issued pursuant to the provisions of this subsection shall:

(1) be submitted to the Board in writing,

(2) contain the name or names of the owners or the applicants, and

(3) provide such other information deemed relevant by the Board.

b. An application for an initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year. Prior to opening for business, all applicants for initial or renewal license shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00). Non-resident applicants shall reimburse the Board for any actual expenses incurred for inspections.

c. A license issued pursuant to the provisions of this subsection shall contain the name of the licensee and the address of the place at which such business shall be conducted and shall be valid for a period of time set by the Board.

C. A licensee or permit holder who, pursuant to the provisions of this section, fails to complete an application for a renewal license or permit by the fifteenth day after the expiration of the license or permit shall pay a late fee to be fixed by the Board.

D. 1. The Board shall promulgate rules regarding the issuance and renewal of licenses and permits pursuant to the Oklahoma Pharmacy Act which shall include, but need not be limited to provisions for new or renewal application requirements for its

licensees and permit holders. Requirements for new and renewal applications may include, but need not be limited to, the following:

a. type of ownership, whether individual, partnership, limited liability company or corporation,

b. names and addresses of principal owners or officers and their Social Security numbers, including applicant's full name, all trade or business names used, full business address, telephone numbers, and email addresses,

c. names of designated representatives and facility managers and their Social Security numbers and dates of birth,

d. evidence of a criminal background check and fingerprinting of the applicant, if a person, and all of the applicant's designated representatives and facility managers,

e. a copy of the license from the applicant's home state, and if applicable, from the federal government,

f. bond requirements, and

g. any other information deemed by the Board to be necessary to protect the public health and safety.

2. The Board shall be authorized to use an outside agency, such as the National Association of Boards of Pharmacy (NABP) or the

Verified-Accredited Wholesale Distributors (VAWD), to accredit wholesale distributors and repackagers.

E. The Oklahoma Pharmacy Act shall not be construed to prevent the sale of nonprescription drugs in original manufacturer packages by any merchant or dealer.

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