ENGROSSED HOUSE
BILL NO. 3418

By: McEntire and Sanders of the House

and

McCortney and Scott of the Senate

An Act relating to pharmacy; amending 59 O.S. 2011, Section 353.18, as last amended by Section 4, Chapter 285, O.S.L. 2016 (59 O.S. Supp. 2019, Section 353.18), which relates to the sale, manufacturing or packaging of dangerous drugs; providing licensure exception; providing exception to pharmacy requirements for facilities distributing or dispensing dialysate or devices necessary for peritoneal dialysis; amending 59 O.S. 2011, Section 353.24, as last amended by Section 6, Chapter 106, O.S.L. 2018 (59 O.S. Supp. 2019, Section 353.24), which relates to unlawful acts; providing exceptions; 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. 2019, 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, 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~~ prescriptions 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. This licensure requirement shall not apply to the distribution or dispensing of dialysate or peritoneal dialysis devices to patients with end-stage renal disease (ESRD) consistent with subsection F of this section.

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.

F. The Oklahoma Pharmacy Act shall not be construed to apply to a facility engaged in the distribution or dispensing to patients of dialysate or peritoneal dialysis devices necessary to perform home peritoneal dialysis, provided the following criteria are met:

1. The dialysate is comprised of dextrose or icodextrin;

2. The dialysate or peritoneal dialysis devices are approved or cleared by the United States Food and Drug Administration;

3. The dialysate or peritoneal dialysis devices are lawfully held by a manufacturer, or the manufacturer's agent, who is properly licensed by the Board as a manufacturer, wholesaler or distributor;

4. The dialysate or peritoneal dialysis devices are held and delivered in their original, sealed packaging from the manufacturing facility;

5. The dialysate or peritoneal dialysis devices are delivered only upon receipt of a physician's prescription by a licensed pharmacy, and the transmittal of an order from the licensed pharmacy to the manufacturer or the manufacturer's agent; and

6. The manufacturer, or agent of the manufacturer, delivers the dialysate or peritoneal dialysis devices directly to:

a. a patient with ESRD, or the patient's designee, for the patient's self-administration of the dialysis therapy, or

b. a health care provider or institution for administration or delivery of the dialysis therapy to the patient with ESRD.

SECTION 2. AMENDATORY 59 O.S. 2011, Section 353.24, as last amended by Section 6, Chapter 106, O.S.L. 2018 (59 O.S. Supp. 2019, Section 353.24), is amended to read as follows:

Section 353.24 A. It shall be unlawful for any licensee or other person to:

1. Forge or increase the quantity of drug in any prescription, or to present a prescription bearing forged, fictitious or altered information or to possess any drug secured by such forged, fictitious or altered prescription;

2. Sell, offer for sale, barter or give away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act or as otherwise provided by the State Board of Pharmacy;

3. Sell, offer for sale, barter or give away any drugs damaged by fire, water, or other causes without first obtaining the written approval of the Board or the State Department of Health;

4. No person, firm or business establishment shall offer to the public, in any manner, their services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Nor may the owner of any pharmacy or drug store authorize any person, firm or business establishment to act for them in this manner with these exceptions:

a. patient-specific filled prescriptions may be delivered or shipped to a prescriber's clinic for pick-up by those patients whom the prescriber has individually determined and documented do not have a permanent or secure mailing address,

b. patient-specific filled prescriptions for drugs which require special handling written by a prescriber may be delivered or shipped to the prescriber's clinic for administration or pick-up at the prescriber's office,

c. patient-specific filled prescriptions, including sterile compounded drugs, may be delivered or shipped to a prescriber's clinic where they shall be administered,

d. patient-specific filled prescriptions for patients with end-stage renal disease (ESRD) may be delivered or shipped to a prescriber's clinic for administration or final delivery to the patient,

e. patient-specific filled prescriptions for radiopharmaceuticals may be delivered or shipped to a prescriber's clinic for administration or pick-up, or

f. patient-specific filled prescriptions may be delivered or shipped by an Indian Health Services (IHS) or federally recognized tribal health organization operating under the IHS in the delivery of the prescriptions to a pharmacy operated by the IHS or a federally recognized tribal health organization for pick-up by an IHS or tribal patient.

However, nothing in this paragraph shall prevent a pharmacist or an employee of the pharmacy from personally receiving a prescription or delivering a legally filled prescription to a residence, office or place of employment of the patient for whom the prescription was written. Provided further, the provisions of this paragraph shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substance Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence. Nothing in this paragraph shall prevent veterinary prescription drugs from being shipped directly from an Oklahoma licensed wholesaler or distributor registered with the Oklahoma Board of Veterinary Medical

Examiners to a client; provided, such drugs may be dispensed only on prescription of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists. Nothing in this paragraph shall prevent dialysate and peritoneal dialysis devices from being shipped directly from an Oklahoma licensed manufacturer, wholesaler or distributor to an ESRD patient or patient's designee, consistent with subsection F of Section 353.18 of this title;

5. Sell, offer for sale or barter or buy any professional samples except through a program pursuant to the Utilization of Unused Prescription Medications Act;

6. Refuse to permit or otherwise prevent members of the Board or such representatives thereof from entering and inspecting any and all places, including premises, vehicles, equipment, contents, and records, where drugs, medicine, chemicals or poisons are stored, sold, vended, given away, compounded, dispensed, repackaged, transported, or manufactured;

7. Interfere, refuse to participate in, impede or otherwise obstruct any inspection, investigation or disciplinary proceeding authorized by the Oklahoma Pharmacy Act;

8. Possess dangerous drugs without a valid prescription or a valid license to possess such drugs; provided, however, this provision shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substance Abuse

Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence;

9. Fail to establish and maintain effective controls against the diversion of drugs for any other purpose than legitimate medical, scientific or industrial uses as provided by state, federal and local law;

10. Fail to have a written drug diversion detection and prevention policy;

11. Possess, sell, offer for sale, barter or give away any quantity of dangerous drugs not listed as a scheduled drug pursuant to Sections 2-201 through 2-212 of Title 63 of the Oklahoma Statutes when obtained by prescription bearing forged, fictitious or altered information.

a. A first violation of this section shall constitute a misdemeanor and upon conviction shall be punishable by imprisonment in the county jail for a term not more than one (1) year and a fine in an amount not more than One Thousand Dollars ($1,000.00).

b. A second violation of this section shall constitute a felony and upon conviction shall be punishable by imprisonment in the Department of Corrections for a

term not exceeding five (5) years and a fine in an amount not more than Two Thousand Dollars ($2,000.00);

12. Violate a Board order or agreed order;

13. Compromise the security of licensure examination materials; or

14. Fail to notify the Board, in writing, within ten (10) days of a licensee or permit holder's address change.

B. 1. It shall be unlawful for any person other than a licensed pharmacist or physician to certify a prescription before delivery to the patient or the patient's representative or caregiver. Dialysate and peritoneal dialysis devices supplied pursuant to the provisions of subsection F of Section 353.18 of this title shall not be required to be certified by a pharmacist prior to being supplied by a manufacturer, wholesaler or distributor.

2. It shall be unlawful for any person to institute or manage a pharmacy unless such person is a licensed pharmacist or has placed a licensed pharmacist in charge of such pharmacy.

3. No licensed pharmacist shall manage, supervise or be in charge of more than one pharmacy.

4. No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted for it, without authority of the prescriber or

purchaser, any like drug, medicine, chemical or pharmaceutical preparation.

5. No pharmacy, pharmacist-in-charge or other person shall permit the practice of pharmacy except by a licensed pharmacist or assistant pharmacist.

6. No person shall subvert the authority of the pharmacist-in-charge of the pharmacy by impeding the management of the prescription department to act in compliance with federal and state law.

C. 1. It shall be unlawful for a pharmacy to resell dangerous drugs to any wholesale distributor.

2. It shall be unlawful for a wholesale distributor to purchase drugs from a pharmacy.

SECTION 3. This act shall become effective November 1, 2020.

Passed the House of Representatives the 9th day of March, 2020.

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Presiding Officer of the House of Representatives

Passed the Senate the ___ day of _____, 2020.

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Presiding Officer of the Senate