SB718 FULLPCS1 Marcus McEntire-AB 4/6/2021 4:02:38 pm

COMMITTEE AMENDMENT HOUSE OF REPRESENTATIVES State of Oklahoma

SPEAKER:

CHAIR:

I move to amend <u>SB718</u> Of the printed Bill Page Section Lines Of the Engrossed Bill

By striking the Title, the Enacting Clause, the entire bill, and by inserting in lieu thereof the following language:

AMEND TITLE TO CONFORM TO AMENDMENTS

Amendment submitted by: Marcus McEntire

Adopted:

Reading Clerk

1	STATE OF OKLAHOMA
2	1st Session of the 58th Legislature (2021)
З	PROPOSED COMMITTEE SUBSTITUTE
4	FOR ENGROSSED SENATE BILL NO. 718 By: McCortney of the Senate
5	and
6	
7	McEntire of the House
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9	PROPOSED COMMITTEE SUBSTITUTE
10	An Act relating to pharmacy; amending 59 O.S. 2011, Section 353.18, as last amended by Section 4, Chapter
11	285, O.S.L. 2016 (59 O.S. Supp. 2020, Section 353.18), which relates to the sale, manufacturing or
12	packaging of dangerous drugs; providing licensure exception; providing exception to pharmacy
13	requirements for facilities distributing or dispensing dialysate or devices necessary for
14	peritoneal dialysis; amending 59 O.S. 2011, Section 353.24, as last amended by Section 6, Chapter 106,
15	O.S.L. 2018 (59 O.S. Supp. 2020, Section 353.24), which relates to unlawful acts; providing certain
16	construction; providing certification exception; and providing an effective date.
17	providing an effective date.
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19	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
20	SECTION 1. AMENDATORY 59 O.S. 2011, Section 353.18, as
21	last amended by Section 4, Chapter 285, O.S.L. 2016 (59 O.S. Supp.
22	2020, Section 353.18), is amended to read as follows:
23	Section 353.18 A. 1. It shall be unlawful for any person,
24	including, but not limited to, Internet, website or online

1 pharmacies, to sell at retail or to offer for sale, dangerous drugs, 2 medicines, chemicals or poisons for the treatment of disease, 3 excluding agricultural chemicals and drugs, or to accept 4 prescriptions for same, without first procuring a license from the 5 State Board of Pharmacy. This licensure requirement applies whether such sale, offer for sale or acceptance of prescriptions occurs in 6 7 this state, or such sale, offer for sale, or acceptance of prescription prescriptions occurs out of state and the dangerous 8 9 drug, medicine, chemical or poison is to be delivered, distributed 10 or dispensed to patients or customers in this state. This licensure 11 requirement shall not apply to the distribution or dispensing of 12 dialysate or peritoneal dialysis devices to patients with end-stage 13 renal disease (ESRD) consistent with subsection F of this section. 14 2. A pharmacy license shall be issued to such person as the 15 Board shall deem qualified upon evidence satisfactory to the Board 16 that: 17 the place for which the license is sought will be a. 18 conducted in full compliance with the law and the 19 rules of the Board, 20 b. the location and physical characteristics of the place 21 are reasonably consistent with the maintenance of 22 professional surroundings and constitute no known 23 danger to the public health and safety, 24

1 the place will be under the management and control of с. 2 a licensed pharmacist or pharmacist-in-charge who 3 shall be licensed as a pharmacist in Oklahoma, and 4 d. a licensed pharmacist shall be present and on duty at 5 all business hours; provided, however, the provisions of this subparagraph shall not apply to hospital drug 6 7 rooms. 3. An application for an initial or renewal license 8 a. 9 issued pursuant to the provisions of this subsection 10 shall: 11 (1)be submitted to the Board in writing, 12 (2) contain the name or names of persons owning the 13 pharmacy, and 14 (3) provide other such information deemed relevant by 15 the Board. 16 An application for an initial or renewal license shall b. 17 be accompanied by a licensing fee not to exceed Three 18 Hundred Dollars (\$300.00) for each period of one (1) 19 year. Prior to opening for business, all applicants 20 for an initial license or permit shall be inspected. 21 An initial licensure applicant shall pay an inspection 22 fee not to exceed Two Hundred Dollars (\$200.00); 23 provided, however, that no charge shall be made for 24 the licensing of any Federal Veterans Hospital in the

1State of Oklahoma. Non-resident pharmacies shall2reimburse the Board for any actual expenses incurred3for inspections.

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

9 4. A retail pharmacy that prepares sterile drugs shall obtain a 10 pharmacy license, and shall also obtain a sterile compounding permit 11 at a fee set by the Board, not to exceed Seventy-five Dollars 12 (\$75.00). Such pharmacy shall meet requirements set by the Board by 13 rule for sterile compounding permits.

14 5. An outsourcing facility desiring to dispense prescriptions 15 to patients must additionally license and meet the requirements of a 16 pharmacy.

17 1. It shall be unlawful for any person to manufacture, Β. 18 repackage, distribute, outsource, warehouse or be a third-party 19 logistics provider of any dangerous drugs, medicines, medical gases, 20 chemicals, or poisons for the treatment of disease, excluding 21 agricultural chemicals, without first procuring a license from the 22 Board. It shall be unlawful to sell or offer for sale at retail or 23 wholesale dangerous drugs, medicines, medical gases, chemicals or 24 poisons without first procuring a license from the Board. This

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1 licensure requirement shall apply when the manufacturing,

2 repackaging, distributing, outsourcing, warehousing, or provision of 3 third-party logistics occurs in this state or out of state for 4 delivery, distribution, or dispensing to patients or customers in 5 this state.

6 2. A license shall be issued to such person as the Board shall7 deem qualified upon satisfactory evidence to the Board that:

- the place for which the license is sought will be 8 a. 9 conducted in full compliance with the laws of this 10 state and the administrative rules of the Board, 11 b. the location and physical characteristics of the place 12 of business are reasonably consistent with the 13 maintenance of professional surroundings and 14 constitute no known danger to public health and 15 safety,
- 16 c. the place shall be under the management and control of 17 such persons as may be approved by the Board after a 18 review and determination of the persons' 19 gualifications, and

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.

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- 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.
- 9 b. An application for an initial or renewal license shall 10 be accompanied by a licensing fee not to exceed Three 11 Hundred Dollars (\$300.00) for each period of one (1) 12 year. Prior to opening for business, all applicants 13 for initial or renewal license shall be inspected. An 14 initial licensure applicant shall pay an inspection 15 fee not to exceed Two Hundred Dollars (\$200.00). Non-16 resident applicants shall reimburse the Board for any 17 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

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license or permit by the fifteenth day after the expiration of the 1 2 license or permit shall pay a late fee to be fixed by the Board. 3 D. 1. The Board shall promulgate rules regarding the issuance 4 and renewal of licenses and permits pursuant to the Oklahoma 5 Pharmacy Act which shall include, but need not be limited to, provisions for new or renewal application requirements for its 6 7 licensees and permit holders. Requirements for new and renewal applications may include, but need not be limited to, the following: 8 9 a. type of ownership, whether individual, partnership, 10 limited liability company or corporation, names and addresses of principal owners or officers 11 b. 12 and their Social Security numbers, including 13 applicant's full name, all trade or business names 14 used, full business address, telephone numbers, and 15 email addresses, 16 names of designated representatives and facility с. 17 managers and their Social Security numbers and dates 18 of birth, 19 d. evidence of a criminal background check and 20 fingerprinting of the applicant, if a person, and all 21 of the applicant's designated representatives and 22 facility managers, 23 a copy of the license from the applicant's home state, e. 24 and if applicable, from the federal government,

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- f. bond requirements, and
- 2 any other information deemed by the Board to be q. 3 necessary to protect the public health and safety. 4 2. The Board shall be authorized to use an outside agency, such 5 as the National Association of Boards of Pharmacy (NABP) or the 6 Verified-Accredited Wholesale Distributors (VAWD), to accredit 7 wholesale distributors and repackagers. 8 The Oklahoma Pharmacy Act shall not be construed to prevent Ε. 9 the sale of nonprescription drugs in original manufacturer packages 10 by any merchant or dealer. 11 F. The Oklahoma Pharmacy Act shall not be construed to apply to 12 a facility engaged in the distribution or dispensing to patients of 13 dialysate or peritoneal dialysis devices necessary to perform home 14 peritoneal dialysis, provided the following criteria are met: 15 1. The dialysate is comprised of dextrose or icodextrin; 16 2. The dialysate or peritoneal dialysis devices are approved or 17 cleared by the United States Food and Drug Administration; 18 3. The dialysate or peritoneal dialysis devices are lawfully 19 held by a manufacturer, or the manufacturer's agent, who is properly 20 licensed by the Board as a manufacturer, wholesaler or distributor; 21 4. The dialysate or peritoneal dialysis devices are held and 22 delivered in their original, sealed packaging from the manufacturing 23 facility;
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1	5. The dialysate or peritoneal dialysis devices are delivered
2	only upon receipt of a physician's prescription by a licensed
3	pharmacy, and the transmittal of an order from the licensed pharmacy
4	to the manufacturer or the manufacturer's agent; and
5	6. The manufacturer or agent of the manufacturer delivers the
6	dialysate or peritoneal dialysis devices directly to:
7	a. a patient with ESRD or the patient's designee for the
8	patient's self-administration of the dialysis therapy,
9	or
10	b. a health care provider or institution for
11	administration or delivery of the dialysis therapy to
12	the patient with ESRD.
13	SECTION 2. AMENDATORY 59 O.S. 2011, Section 353.24, as
14	last amended by Section 6, Chapter 106, O.S.L. 2018 (59 O.S. Supp.
15	2020, Section 353.24), is amended to read as follows:
16	Section 353.24 A. It shall be unlawful for any licensee or
17	other person to:
18	1. Forge or increase the quantity of drug in any prescription,
19	or to present a prescription bearing forged, fictitious or altered
20	information or to possess any drug secured by such forged,
21	fictitious or altered prescription;
22	2. Sell, offer for sale, barter or give away any unused
23	quantity of drugs obtained by prescription, except through a program
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pursuant to the Utilization of Unused Prescription Medications Act
 or as otherwise provided by the State Board of Pharmacy;

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

A. 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:

12a.patient-specific filled prescriptions may be delivered13or shipped to a prescriber's clinic for pick-up by14those patients whom the prescriber has individually15determined and documented do not have a permanent or16secure mailing address,

17 b. patient-specific filled prescriptions for drugs which 18 require special handling written by a prescriber may 19 be delivered or shipped to the prescriber's clinic for 20 administration or pick-up at the prescriber's office, 21 с. patient-specific filled prescriptions, including 22 sterile compounded drugs, may be delivered or shipped 23 to a prescriber's clinic where they shall be 24 administered,

- 1d.patient-specific filled prescriptions for patients2with End Stage Renal Disease end-stage renal disease3(ESRD) may be delivered or shipped to a prescriber's4clinic for administration or final delivery to the5patient,
- patient-specific filled prescriptions for 6 e. 7 radiopharmaceuticals may be delivered or shipped to a prescriber's clinic for administration or pick-up, or 8 9 f. patient-specific filled prescriptions may be delivered 10 or shipped by an Indian Health Services (IHS) or federally recognized tribal health organization 11 operating under the IHS in the delivery of the 12 13 prescriptions to a pharmacy operated by the IHS or a 14 federally recognized tribal health organization for 15 pick-up by an IHS or tribal patient.

16 However, nothing in this paragraph shall prevent a pharmacist or 17 an employee of the pharmacy from personally receiving a prescription 18 or delivering a legally filled prescription to a residence, office 19 or place of employment of the patient for whom the prescription was 20 written. Provided further, the provisions of this paragraph shall 21 not apply to any Department of Mental Health and Substance Abuse 22 Services employee or any person whose facility contracts with the 23 Department of Mental Health and Substance Abuse Services whose 24 possession of any dangerous drug, as defined in Section 353.1 of

1 this title, is for the purpose of delivery of a mental health 2 consumer's medicine to the consumer's home or residence. Nothing in 3 this paragraph shall prevent veterinary prescription drugs from 4 being shipped directly from an Oklahoma licensed wholesaler or 5 distributor registered with the Oklahoma Board of Veterinary Medical Examiners to a client; provided, such drugs may be dispensed only on 6 7 prescription of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists. Nothing in this 8 9 paragraph shall prevent dialysate and peritoneal dialysis devices 10 from being shipped directly from an Oklahoma licensed manufacturer, 11 wholesaler or distributor to an ESRD patient or patient's designee, 12 consistent with subsection F of Section 353.18 of this title;

13 5. Sell, offer for sale or barter or buy any professional 14 samples except through a program pursuant to the Utilization of 15 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;

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1 8. Possess dangerous drugs without a valid prescription or a 2 valid license to possess such drugs; provided, however, this 3 provision shall not apply to any Department of Mental Health and 4 Substance Abuse Services employee or any person whose facility 5 contracts with the Department of Mental Health and Substance Abuse Services whose possession of any dangerous drug, as defined in 6 Section 353.1 of this title, is for the purpose of delivery of a 7 mental health consumer's medicine to the consumer's home or 8 9 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;

14 10. Fail to have a written drug diversion detection and 15 prevention policy;

16 11. Possess, sell, offer for sale, barter or give away any 17 quantity of dangerous drugs not listed as a scheduled drug pursuant 18 to Sections 2-201 through 2-212 of Title 63 of the Oklahoma Statutes 19 when obtained by prescription bearing forged, fictitious or altered 20 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

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1 than one (1) year and a fine in an amount not more 2 than One Thousand Dollars (\$1,000.00). A second violation of this section shall constitute a 3 b. 4 felony and upon conviction shall be punishable by 5 imprisonment in the Department of Corrections for a term not exceeding five (5) years and a fine in an 6 7 amount not more than Two Thousand Dollars (\$2,000.00); 12. Violate a Board order or agreed order; 8 9 13. Compromise the security of licensure examination materials; 10 or 11 Fail to notify the Board, in writing, within ten (10) days 14. of a licensee or permit holder's address change. 12 13 Β. 1. It shall be unlawful for any person other than a 14 licensed pharmacist or physician to certify a prescription before 15 delivery to the patient or the patient's representative or 16 Dialysate and peritoneal dialysis devices supplied caregiver. 17 pursuant to the provisions of subsection F of Section 353.18 of this 18 title shall not be required to be certified by a pharmacist prior to 19 being supplied by a manufacturer, wholesaler or distributor. 20 2. It shall be unlawful for any person to institute or manage a 21 pharmacy unless such person is a licensed pharmacist or has placed a 22 licensed pharmacist in charge of such pharmacy. 23 3. No licensed pharmacist shall manage, supervise or be in 24 charge of more than one pharmacy.

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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.

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

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.

14 C. 1. It shall be unlawful for a pharmacy to resell dangerous 15 drugs to any wholesale distributor.

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

SECTION 3. This act shall become effective November 1, 2021.

20 58-1-8077 AB 04/06/21 21 22 23 24