

1 **SENATE FLOOR VERSION**

2 February 8, 2021

3 SENATE BILL NO. 131

By: Garvin of the Senate

4 and

5 McEntire of the House

6  
7  
8 An Act relating to pharmacy; amending 59 O.S. 2011,  
9 Section 353.18, as last amended by Section 4, Chapter  
10 285, O.S.L. 2016 (59 O.S. Supp. 2020, Section  
11 353.18), which relates to the sale, manufacturing or  
12 packaging of dangerous drugs; providing licensure  
13 exception; providing exception to pharmacy  
14 requirements for facilities distributing or  
15 dispensing dialysate or devices necessary for  
16 peritoneal dialysis; amending 59 O.S. 2011, Section  
17 353.24, as last amended by Section 6, Chapter 106,  
18 O.S.L. 2018 (59 O.S. Supp. 2020, Section 353.24),  
19 which relates to unlawful acts; providing certain  
20 construction; providing certification exception; and  
21 providing an effective date.

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

23 SECTION 1. AMENDATORY 59 O.S. 2011, Section 353.18, as  
24 last amended by Section 4, Chapter 285, O.S.L. 2016 (59 O.S. Supp.  
2020, Section 353.18), is amended to read as follows:

25 Section 353.18. A. 1. It shall be unlawful for any person,  
26 including, but not limited to, Internet, website or online  
27 pharmacies, to sell at retail or to offer for sale, dangerous drugs,  
28 medicines, chemicals or poisons for the treatment of disease,

1 excluding agricultural chemicals and drugs, or to accept  
2 prescriptions for same, without first procuring a license from the  
3 State Board of Pharmacy. This licensure requirement applies whether  
4 such sale, offer for sale or acceptance of prescriptions occurs in  
5 this state, or such sale, offer for sale, or acceptance of  
6 ~~prescription~~ prescriptions occurs out of state and the dangerous  
7 drug, medicine, chemical or poison is to be delivered, distributed  
8 or dispensed to patients or customers in this state. This licensure  
9 requirement shall not apply to the distribution or dispensing of  
10 dialysate or peritoneal dialysis devices to patients with end-stage  
11 renal disease (ESRD) consistent with subsection F of this section.

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

- 15 a. the place for which the license is sought will be  
16 conducted in full compliance with the law and the  
17 rules of the Board,
- 18 b. the location and physical characteristics of the place  
19 are reasonably consistent with the maintenance of  
20 professional surroundings and constitute no known  
21 danger to the public health and safety,
- 22 c. the place will be under the management and control of  
23 a licensed pharmacist or pharmacist-in-charge who  
24 shall be licensed as a pharmacist in Oklahoma, and

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

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

8                   (1)  be submitted to the Board in writing,

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

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

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

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

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

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

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

1 delivery, distribution, or dispensing to patients or customers in  
2 this state.

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

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

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

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

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

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

24 (1) be submitted to the Board in writing,

- 1 (2) contain the name or names of the owners or the  
2 applicants, and  
3 (3) provide such other information deemed relevant by  
4 the Board.

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

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

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

23 D. 1. The Board shall promulgate rules regarding the issuance  
24 and renewal of licenses and permits pursuant to the Oklahoma

1 Pharmacy Act which shall include, but need not be limited to,  
2 provisions for new or renewal application requirements for its  
3 licensees and permit holders. Requirements for new and renewal  
4 applications may include, but need not be limited to, the following:

- 5 a. type of ownership, whether individual, partnership,  
6 limited liability company or corporation,
- 7 b. names and addresses of principal owners or officers  
8 and their Social Security numbers, including  
9 applicant's full name, all trade or business names  
10 used, full business address, telephone numbers, and  
11 email addresses,
- 12 c. names of designated representatives and facility  
13 managers and their Social Security numbers and dates  
14 of birth,
- 15 d. evidence of a criminal background check and  
16 fingerprinting of the applicant, if a person, and all  
17 of the applicant's designated representatives and  
18 facility managers,
- 19 e. a copy of the license from the applicant's home state,  
20 and if applicable, from the federal government,
- 21 f. bond requirements, and
- 22 g. any other information deemed by the Board to be  
23 necessary to protect the public health and safety.

24

1           2. The Board shall be authorized to use an outside agency, such  
2 as the National Association of Boards of Pharmacy (NABP) or the  
3 Verified-Accredited Wholesale Distributors (VAWD), to accredit  
4 wholesale distributors and repackagers.

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

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

12           1. The dialysate is comprised of dextrose or icodextrin;

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

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

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

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



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

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

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

9       SECTION 2.       AMENDATORY       59 O.S. 2011, Section 353.24, as  
10 last amended by Section 6, Chapter 106, O.S.L. 2018 (59 O.S. Supp.  
11 2020, Section 353.24), is amended to read as follows:

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

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

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

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

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

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

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

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

20 d. patient-specific filled prescriptions for patients  
21 with ~~End Stage Renal Disease~~ end-stage renal disease  
22 (ESRD) may be delivered or shipped to a prescriber's  
23 clinic for administration or final delivery to the  
24 patient,

- 1 e. patient-specific filled prescriptions for  
2 radiopharmaceuticals may be delivered or shipped to a  
3 prescriber's clinic for administration or pick-up, or  
4 f. patient-specific filled prescriptions may be delivered  
5 or shipped by an Indian Health Services (IHS) or  
6 federally recognized tribal health organization  
7 operating under the IHS in the delivery of the  
8 prescriptions to a pharmacy operated by the IHS or a  
9 federally recognized tribal health organization for  
10 pick\_up by an IHS or tribal patient.

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

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

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

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

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

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

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

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

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

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

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

21 b. A second violation of this section shall constitute a  
22 felony and upon conviction shall be punishable by  
23 imprisonment in the Department of Corrections for a  
24

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

3 12. Violate a Board order or agreed order;

4 13. Compromise the security of licensure examination materials;

5 or

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

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

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

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

20 4. No pharmacist being requested to sell, furnish or compound  
21 any drug, medicine, chemical or other pharmaceutical preparation, by  
22 prescription or otherwise, shall substitute or cause to be  
23 substituted for it, without authority of the prescriber or  
24

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

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

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

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

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

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

15 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES  
16 February 8, 2021 - DO PASS

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