

1 **HOUSE OF REPRESENTATIVES - FLOOR VERSION**

2 STATE OF OKLAHOMA

3 2nd Session of the 57th Legislature (2020)

4 COMMITTEE SUBSTITUTE
5 FOR
6 HOUSE BILL NO. 3418

By: McEntire of the House

and

McCortney of the Senate

7
8
9 COMMITTEE SUBSTITUTE

10 An Act relating to pharmacy; amending 59 O.S. 2011,
11 Section 353.18, as last amended by Section 4, Chapter
12 285, O.S.L. 2016 (59 O.S. Supp. 2019, Section
13 353.18), which relates to the sale, manufacturing or
14 packaging of dangerous drugs; providing licensure
15 exception; providing exception to pharmacy
16 requirements for facilities distributing or
17 dispensing dialysate or devices necessary for
18 peritoneal dialysis; amending 59 O.S. 2011, Section
19 353.24, as last amended by Section 6, Chapter 106,
20 O.S.L. 2018 (59 O.S. Supp. 2019, Section 353.24),
21 which relates to unlawful acts; providing exceptions;
22 and providing an effective date.

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

24 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

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
6 such sale, offer for sale or acceptance of prescriptions occurs in
7 this state, or such sale, offer for sale, or acceptance of
8 ~~prescription~~ prescriptions occurs out of state and the dangerous
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 a. the place for which the license is sought will be
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,

1 c. the place will be under the management and control of
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
6 of this subparagraph shall not apply to hospital drug
7 rooms.

8 3. a. An application for an initial or renewal license
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 b. An application for an initial or renewal license shall
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

1 State of Oklahoma. Non-resident pharmacies shall
2 reimburse the Board for any actual expenses incurred
3 for 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 B. 1. It shall be unlawful for any person to manufacture,
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

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 shall
7 deem qualified upon satisfactory evidence to the Board that:

8 a. the place for which the license is sought will be
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 qualifications, and

20 d. an outsourcing facility shall designate in writing on
21 a Board-approved form a person to serve as the
22 pharmacist-in-charge who is a pharmacist licensed by
23 the Board.
24

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

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

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

7 (3) provide such other information deemed relevant by
8 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.

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

23 C. A licensee or permit holder who, pursuant to the provisions
24 of this section, fails to complete an application for a renewal

1 license or permit by the fifteenth day after the expiration of the
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,
6 provisions for new or renewal application requirements for its
7 licensees and permit holders. Requirements for new and renewal
8 applications may include, but need not be limited to, the following:

- 9 a. type of ownership, whether individual, partnership,
10 limited liability company or corporation,
- 11 b. names and addresses of principal owners or officers
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 c. names of designated representatives and facility
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 e. a copy of the license from the applicant's home state,
24 and if applicable, from the federal government,

1 f. bond requirements, and

2 g. any other information deemed by the Board to be
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 E. The Oklahoma Pharmacy Act shall not be construed to prevent
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;

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
8 the patient's self-administration of the dialysis
9 therapy, 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 2019, 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
24

1 pursuant to the Utilization of Unused Prescription Medications Act
2 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;

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

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

- 1 d. patient-specific filled prescriptions for patients
2 with end-stage renal disease (ESRD) may be delivered
3 or shipped to a prescriber's clinic for administration
4 or final delivery to the patient,
- 5 e. patient-specific filled prescriptions for
6 radiopharmaceuticals may be delivered or shipped to a
7 prescriber's clinic for administration or pick-up, or
- 8 f. patient-specific filled prescriptions may be delivered
9 or shipped by an Indian Health Services (IHS) or
10 federally recognized tribal health organization
11 operating under the IHS in the delivery of the
12 prescriptions to a pharmacy operated by the IHS or a
13 federally recognized tribal health organization for
14 pick-up by an IHS or tribal patient.

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

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

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

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

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

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

10 9. Fail to establish and maintain effective controls against
11 the diversion of drugs for any other purpose than legitimate
12 medical, scientific or industrial uses as provided by state, federal
13 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.

21 a. A first violation of this section shall constitute a
22 misdemeanor and upon conviction shall be punishable by
23 imprisonment in the county jail for a term not more
24

1 than one (1) year and a fine in an amount not more
2 than One Thousand Dollars (\$1,000.00).

3 b. A second violation of this section shall constitute a
4 felony and upon conviction shall be punishable by
5 imprisonment in the Department of Corrections for a
6 term not exceeding five (5) years and a fine in an
7 amount not more than Two Thousand Dollars (\$2,000.00);

8 12. Violate a Board order or agreed order;

9 13. Compromise the security of licensure examination materials;

10 or

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

13 B. 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 caregiver. Dialysate and peritoneal dialysis devices supplied
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.

1 4. No pharmacist being requested to sell, furnish or compound
2 any drug, medicine, chemical or other pharmaceutical preparation, by
3 prescription or otherwise, shall substitute or cause to be
4 substituted for it, without authority of the prescriber or
5 purchaser, any like drug, medicine, chemical or pharmaceutical
6 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.

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

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

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

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

19
20 COMMITTEE REPORT BY: COMMITTEE ON APPROPRIATIONS AND BUDGET, dated
21 02/26/2020 - DO PASS, As Amended and Coauthored.