

STATE OF OKLAHOMA

2nd Session of the 57th Legislature (2020)

HOUSE BILL 3418

By: McEntire

AS INTRODUCED

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 drugs 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 exception; 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

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

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

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

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 repackaged, 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.

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 drugs or devices necessary to perform home peritoneal dialysis,
11 provided the following criteria are met:

12 1. The drugs or devices are approved or cleared by the United
13 States Food and Drug Administration;

14 2. The drugs or devices are lawfully held by a manufacturer or
15 the manufacturer's agent who is properly licensed by the Board as a
16 manufacturer, wholesaler or distributor;

17 3. The drugs or devices are held and delivered in their
18 original, sealed packaging from the manufacturing facility;

19 4. The drugs or devices are delivered only upon receipt of a
20 physician's prescription by a licensed pharmacy, and the transmittal
21 of an order from the licensed pharmacy to the manufacturer or the
22 manufacturer's agent; and

23 5. The manufacturer, or agent of the manufacturer, delivers the
24 drugs or devices directly to:

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

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

7 SECTION 2. AMENDATORY 59 O.S. 2011, Section 353.24, as
8 last amended by Section 6, Chapter 106, O.S.L. 2018 (59 O.S. Supp.
9 2019, Section 353.24), is amended to read as follows:

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

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

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

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

23 4. No person, firm or business establishment shall offer to the
24 public, in any manner, their services as a "pick-up station" or

1 intermediary for the purpose of having prescriptions filled or
2 delivered, whether for profit or gratuitously. Nor may the owner of
3 any pharmacy or drug store authorize any person, firm or business
4 establishment to act for them in this manner with these exceptions:

- 5 a. patient-specific filled prescriptions may be delivered
6 or shipped to a prescriber's clinic for pick-up by
7 those patients whom the prescriber has individually
8 determined and documented do not have a permanent or
9 secure mailing address,
- 10 b. patient-specific filled prescriptions for drugs which
11 require special handling written by a prescriber may
12 be delivered or shipped to the prescriber's clinic for
13 administration or pick-up at the prescriber's office,
- 14 c. patient-specific filled prescriptions, including
15 sterile compounded drugs, may be delivered or shipped
16 to a prescriber's clinic where they shall be
17 administered,
- 18 d. patient-specific filled prescriptions for patients
19 with end-stage renal disease (ESRD) may be delivered
20 or shipped to a prescriber's clinic for administration
21 or final delivery to the patient,
- 22 e. patient-specific filled prescriptions for
23 radiopharmaceuticals may be delivered or shipped to a
24 prescriber's clinic for administration or pick-up, or

1 f. patient-specific filled prescriptions may be delivered
2 or shipped by an Indian Health Services (IHS) or
3 federally recognized tribal health organization
4 operating under the IHS in the delivery of the
5 prescriptions to a pharmacy operated by the IHS or a
6 federally recognized tribal health organization for
7 pick_up by an IHS or tribal patient.

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

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

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

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

13 8. Possess dangerous drugs without a valid prescription or a
14 valid license to possess such drugs; provided, however, this
15 provision shall not apply to any Department of Mental Health and
16 Substance Abuse Services employee or any person whose facility
17 contracts with the Department of Mental Health and Substance Abuse
18 Services whose possession of any dangerous drug, as defined in
19 Section 353.1 of this title, is for the purpose of delivery of a
20 mental health consumer's medicine to the consumer's home or
21 residence;

22 9. Fail to establish and maintain effective controls against
23 the diversion of drugs for any other purpose than legitimate
24

1 medical, scientific or industrial uses as provided by state, federal
2 and local law;

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

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

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

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

20 12. Violate a Board order or agreed order;

21 13. Compromise the security of licensure examination materials;
22 or

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

1 B. 1. It shall be unlawful for any person other than a
2 licensed pharmacist or physician to certify a prescription before
3 delivery to the patient or the patient's representative or
4 caregiver.

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

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

10 4. No pharmacist being requested to sell, furnish or compound
11 any drug, medicine, chemical or other pharmaceutical preparation, by
12 prescription or otherwise, shall substitute or cause to be
13 substituted for it, without authority of the prescriber or
14 purchaser, any like drug, medicine, chemical or pharmaceutical
15 preparation. Nothing in this paragraph shall prevent peritoneal
16 dialysis drugs or devices from being shipped directly from an
17 Oklahoma licensed manufacturer, wholesaler or distributor to an end-
18 stage renal disease (ESRD) patient or patient's designee, consistent
19 with the requirements of Section 353.18 of this title.

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

23 6. No person shall subvert the authority of the pharmacist-in-
24 charge of the pharmacy by impeding the management of the

1 prescription department to act in compliance with federal and state
2 law.

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

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

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

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