

1 ENGROSSED HOUSE AMENDMENT
TO
2 ENGROSSED SENATE BILL NO. 131 By: Garvin of the Senate
3 and
4 McEntire of the House
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7 An Act relating to pharmacy; amending 59 O.S. 2011,
8 Section 353.18, as last amended by Section 4, Chapter
9 285, O.S.L. 2016 (59 O.S. Supp. 2020, Section
10 353.18), which relates to the sale, manufacturing or
11 packaging of dangerous drugs; providing licensure
12 exception; providing exception to pharmacy
13 requirements for facilities distributing or
14 dispensing dialysate or devices necessary for
15 peritoneal dialysis; amending 59 O.S. 2011, Section
16 353.24, as last amended by Section 6, Chapter 106,
17 O.S.L. 2018 (59 O.S. Supp. 2020, Section 353.24),
18 which relates to unlawful acts; providing certain
19 construction; providing certification exception; and
20 providing an effective date.

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1 the Oklahoma Health Care Authority to promulgate
2 rules; and declaring an emergency.

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

5 SECTION 1. NEW LAW A new section of law to be codified
6 in the Oklahoma Statutes as Section 1010.14 of Title 56, unless
7 there is created a duplication in numbering, reads as follows:

8 This act shall be known and may be cited as the "Oklahomans
9 Caring for Oklahomans Act".

10 SECTION 2. NEW LAW A new section of law to be codified
11 in the Oklahoma Statutes as Section 1010.15 of Title 56, unless
12 there is created a duplication in numbering, reads as follows:

13 A. The Oklahoma Health Care Authority shall implement the
14 Oklahomans Caring for Oklahomans Act by developing a program that
15 controls costs and improves health outcomes for Medicaid
16 beneficiaries. The plan shall contain new or improve upon existing
17 programs of the Authority and shall include, but not be limited to,
18 the following elements:

19 1. Prevention. Medicaid beneficiaries shall enroll in the
20 program and renew annually at their wellness visits to their primary
21 provider clinics. Enrollment and renewal shall include a standard
22 baseline risk assessment following the Centers for Medicare and
23 Medicaid Services' guidelines for substance abuse, mental health,
24 and physical health. The assessment shall identify social health

1 risks including, but not limited to, smoking, sedentary lifestyle,
2 obesity, social factors such as domestic violence, and food
3 insecurity.

4 2. Chronic care management. The Authority shall develop and
5 carry out a plan for chronic care coordination that shall include,
6 but not be limited to, the following components:

- 7 a. medication therapy management,
- 8 b. patient education,
- 9 c. frequent interaction between the Authority and
10 beneficiaries to identify potential health needs and
11 decrease emergency department and hospital
12 utilization, and
- 13 d. development of a long-term plan of wellness for each
14 beneficiary.

15 3. Payment reform. Building upon the success of primary care
16 medical homes, the Authority shall develop a transition care
17 management plan to incentivize compliance behaviors by patients
18 following inpatient treatment to decrease rehospitalizations and
19 emergency department utilization. The Authority shall establish
20 value-based payments for providers that incentivize providers with
21 improved quality metrics and health outcomes. If the Authority adds
22 to the covered benefit plan any new benefits that cost more than
23 Five Hundred Thousand Dollars (\$500,000.00), the new benefits must
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1 be approved by the Legislature unless a corresponding budget offset
2 can be found within the Authority's existing agency budget.

3 B. Health information exchange. In order to reduce redundancy
4 for medical services, the Authority shall maximize the sharing of
5 health information among providers. Any program for sharing data
6 shall also have the ability to screen for social determinants of
7 health.

8 C. Partnerships with tribal nations shall be maintained and
9 enhanced by the Authority in implementation of the Oklahomans Caring
10 for Oklahomans Act.

11 D. The Oklahoma Health Care Authority shall promulgate rules as
12 necessary to implement this act.

13 SECTION 3. It being immediately necessary for the preservation
14 of the public peace, health or safety, an emergency is hereby
15 declared to exist, by reason whereof this act shall take effect and
16 be in full force from and after its passage and approval."

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1 ENGROSSED SENATE
2 BILL NO. 131

By: Garvin of the Senate

and

McEntire of the House

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

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

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

24 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

1 State Board of Pharmacy. This licensure requirement applies whether
2 such sale, offer for sale or acceptance of prescriptions occurs in
3 this state, or such sale, offer for sale, or acceptance of
4 ~~prescription~~ prescriptions occurs out of state and the dangerous
5 drug, medicine, chemical or poison is to be delivered, distributed
6 or dispensed to patients or customers in this state. This licensure
7 requirement shall not apply to the distribution or dispensing of
8 dialysate or peritoneal dialysis devices to patients with end-stage
9 renal disease (ESRD) consistent with subsection F of this section.

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

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

1 of this subparagraph shall not apply to hospital drug
2 rooms.

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

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

7 (2) contain the name or names of persons owning the
8 pharmacy, and

9 (3) provide other such information deemed relevant by
10 the Board.

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

23 c. A license issued pursuant to the provisions of this
24 subsection shall be valid for a period set by the

1 Board and shall contain the name of the licensee and
2 the address of the place at which such business shall
3 be conducted.

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

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

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

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

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

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

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

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

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

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

23 (2) contain the name or names of the owners or the
24 applicants, and

1 (3) provide such other information deemed relevant by
2 the Board.

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

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

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

21 D. 1. The Board shall promulgate rules regarding the issuance
22 and renewal of licenses and permits pursuant to the Oklahoma
23 Pharmacy Act which shall include, but need not be limited to, l
24 provisions for new or renewal application requirements for its

1 licensees and permit holders. Requirements for new and renewal
2 applications may include, but need not be limited to, the following:

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

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

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

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

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

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

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

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

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

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

- 1 a. a patient with ESRD or the patient's designee for the
2 patient's self-administration of the dialysis therapy,
3 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 5. 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 2020, 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~~ end-stage renal disease
20 (ESRD) may be delivered or shipped to a prescriber's
21 clinic for administration or final delivery to the
22 patient,

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- 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
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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
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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 6. This act shall become effective November 1, 2021.

15 Passed the Senate the 2nd day of March, 2021.

16

17

Presiding Officer of the Senate

18

19 Passed the House of Representatives the ____ day of _____,

20 2021.

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Presiding Officer of the House
of Representatives

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