

STATE OF OKLAHOMA

1st Session of the 58th Legislature (2021)

COMMITTEE SUBSTITUTE
FOR

SENATE BILL 638

By: McCortney

COMMITTEE SUBSTITUTE

An Act relating to pharmacy; amending 59 O.S. 2011, Section 367.2, which relates to definitions used in the Utilization of Unused Prescription Medications Act; adding definition; amending 59 O.S. 2011, Section 367.3, as amended by Section 45, Chapter 475, O.S.L. 2019 (59 O.S. Supp. 2020, Section 367.3), which relates to program for utilization of unused prescription drugs; deleting procedure for transfer of certain prescription drugs; providing for donation or return of unused prescription medications for credit or reimbursement; excluding certain drugs; amending 59 O.S. 2011, Section 367.4, which relates to criteria for accepting unused prescription drugs; broadening criteria to apply to returned drugs; amending 59 O.S. 2011, Section 367.5, which relates to participation in program; clarifying inclusion of certain facilities; specifying ability to refuse individual returns; authorizing pharmacy to restock and redistribute returned prescription drugs after credit or reimbursement; amending 59 O.S. 2011, Section 367.6, which relates to liability of participating organizations and manufacturers; broadening criteria to apply to returned drugs; removing certain pharmacies from program; clarifying inclusion of certain facilities; amending 59 O.S. 2011, Section 367.7, which relates to promulgation of rules; directing promulgation of certain rules; and providing an effective date.

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

1 SECTION 1. AMENDATORY 59 O.S. 2011, Section 367.2, is
2 amended to read as follows:

3 Section 367.2. As used in the Utilization of Unused
4 Prescription Medications Act:

5 1. "Assisted living center" has the same meaning as such term
6 is defined in Section 1-890.2 of Title 63 of the Oklahoma Statutes;

7 2. "Cancer drugs" means any of several drugs that control or
8 kill neoplastic cells, commonly referred to as "cancer-fighting
9 drugs"; and includes, but is not limited to, drugs used in
10 chemotherapy to destroy cancer cells;

11 3. "Charitable clinic" means a charitable nonprofit corporation
12 or a facility organized as a not-for-profit organization pursuant to
13 the provisions of the Oklahoma General Corporation Act that:

14 a. holds a valid exemption from federal income taxation
15 issued pursuant to Section 501(a) of the Internal
16 Revenue Code (26 U.S.C., Section 501(a)),

17 b. is listed as an exempt organization under 501(c) of
18 the Internal Revenue Code (26 U.S.C., Section 501(c)),

19 c. provides on an outpatient basis for a period of less
20 than twenty-four (24) consecutive hours to persons not
21 residing or confined at such facility advice,
22 counseling, diagnosis, treatment, surgery, care or
23 services relating to the preservation or maintenance
24 of health, and

1 d. has a licensed outpatient pharmacy;

2 4. "Health care professional" means any of the following
3 persons licensed and authorized to prescribe and dispense drugs or
4 to provide medical, dental, or other health-related diagnoses, care
5 or treatment within the scope of their professional license:

6 a. a physician holding a current license to practice
7 medicine pursuant to Chapter 11 or Chapter 14 of ~~Title~~
8 ~~59 of the Oklahoma Statutes~~ this title,

9 b. an advanced practice nurse licensed pursuant to
10 Chapter 12 of ~~Title 59 of the Oklahoma Statutes~~ this
11 title,

12 c. a physician assistant licensed pursuant to Chapter 11
13 of ~~Title 59 of the Oklahoma Statutes~~ this title,

14 d. a dentist licensed pursuant to Chapter 7 of ~~Title 59~~
15 ~~of the Oklahoma Statutes~~ this title,

16 e. an optometrist licensed pursuant to Chapter 13 of
17 ~~Title 59 of the Oklahoma Statutes~~ this title, and

18 f. a pharmacist licensed pursuant to Chapter 8 of ~~Title~~
19 ~~59 of the Oklahoma Statutes~~ this title;

20 ~~4.~~ 5. "Medically indigent" means a person eligible to receive
21 Medicaid or Medicare or a person who has no health insurance and who
22 otherwise lacks reasonable means to purchase prescribed medications;
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24

1 ~~5. "Charitable clinic" means a charitable nonprofit corporation~~
2 ~~or a facility organized as a not-for-profit pursuant to the~~
3 ~~provisions of the Oklahoma General Corporation Act that:~~

4 ~~a. holds a valid exemption from federal income taxation~~
5 ~~issued pursuant to Section 501(a) of the Internal~~
6 ~~Revenue Code (26 U.S.C., Section 501(a)),~~

7 ~~b. is listed as an exempt organization under 501(c) of~~
8 ~~the Internal Revenue Code (26 U.S.C., Section 501(c)),~~

9 ~~c. provides on an outpatient basis for a period of less~~
10 ~~than twenty-four (24) consecutive hours to persons not~~
11 ~~residing or confined at such facility advice,~~
12 ~~counseling, diagnosis, treatment, surgery, care or~~
13 ~~services relating to the preservation or maintenance~~
14 ~~of health, and~~

15 ~~d. has a licensed outpatient pharmacy; and~~

16 6. "Nursing facility" has the same meaning as such term is
17 defined in Section 1-1902 of Title 63 of the Oklahoma Statutes; and

18 7. "Prescription drug" means a drug which may be dispensed only
19 upon prescription by a health care professional authorized by his or
20 her licensing authority and which is approved for safety and
21 effectiveness as a prescription drug under Section 505 or 507 of the
22 Federal Food, Drug and Cosmetic Act (52 Stat. 1040 (1938), 21
23 U.S.C.A., Section 301).

1 SECTION 2. AMENDATORY 59 O.S. 2011, Section 367.3, as
2 amended by Section 45, Chapter 475, O.S.L. 2019 (59 O.S. Supp. 2020,
3 Section 367.3), is amended to read as follows:

4 Section 367.3. A. The State Board of Pharmacy shall implement
5 statewide a program consistent with public health and safety through
6 which unused prescription drugs, other than prescription drugs
7 defined as controlled dangerous substances in Section 2-101 of Title
8 63 of the Oklahoma Statutes, may be ~~transferred from residential~~
9 ~~care homes, nursing facilities, assisted living centers, public~~
10 ~~intermediate care facilities for individuals with intellectual~~
11 ~~disabilities (ICFs/IID) or pharmaceutical manufacturers to~~
12 ~~pharmacies operated by a county. If no county pharmacy exists, or~~
13 ~~if a county pharmacy chooses not to participate, such unused~~
14 ~~prescription medications may be transferred to a pharmacy operated~~
15 ~~by a city-county health department or a pharmacy under contract with~~
16 ~~a city-county health department, a pharmacy operated by the~~
17 ~~Department of Mental Health and Substance Abuse Services or:~~

18 1. Donated by a residential care home, a nursing facility, an
19 assisted living center, an intermediate care facility for
20 individuals with intellectual disabilities (ICF/IID) or a
21 pharmaceutical manufacturer to a charitable clinic for the purpose
22 of distributing the unused prescription medications to Oklahoma
23 residents who are medically indigent; or
24

1 2. Returned by a residential care home, a nursing facility, an
2 assisted living center or an intermediate care facility for
3 individuals with intellectual disabilities (ICF/IID) to the pharmacy
4 where the unused prescription medications were purchased in exchange
5 for credit or reimbursement. Returns under this paragraph shall not
6 be available for drugs purchased by the state Medicaid program.

7 B. The Board ~~of Pharmacy~~ shall promulgate rules and establish
8 procedures necessary to implement the program established by the
9 Utilization of Unused Prescription Medications Act.

10 C. The Board ~~of Pharmacy~~ shall provide technical assistance to
11 entities who may wish to participate in the program.

12 SECTION 3. AMENDATORY 59 O.S. 2011, Section 367.4, is
13 amended to read as follows:

14 Section 367.4. The following criteria shall be used in
15 accepting unused prescription drugs for use under the Utilization of
16 Unused Prescription Medications Act:

17 1. Only prescription drugs in their original sealed unit dose
18 packaging or unused injectables shall be accepted and dispensed
19 pursuant to the Utilization of Unused Prescription Medications Act;

20 2. The packaging must be unopened, except that cancer drugs
21 packaged in single-unit doses may be accepted and dispensed when the
22 outside packaging is opened if the single-unit-dose packaging has
23 not been opened;

24 3. Expired prescription drugs shall not be accepted;

1 4. A prescription drug shall not be accepted or dispensed if
2 the person accepting or dispensing the drug has reason to believe
3 that the drug is adulterated;

4 5. No controlled dangerous substances shall be accepted; and

5 6. Subject to the limitation specified in this section, unused
6 prescription drugs dispensed for purposes of a medical assistance
7 program or drug product donation program, or unused prescription
8 drugs returned by a facility listed in Section 367.3 of this title
9 in exchange for credit or reimbursement, may be accepted and
10 dispensed under the Utilization of Unused Prescription Medications
11 Act.

12 SECTION 4. AMENDATORY 59 O.S. 2011, Section 367.5, is
13 amended to read as follows:

14 Section 367.5. A. Participation in the Utilization of Unused
15 Prescription Medications Act by pharmacies, nursing ~~homes~~
16 facilities, assisted living centers, intermediate care facilities
17 for individuals with intellectual disabilities (ICF/IID), charitable
18 clinics or prescription drug manufacturers shall be voluntary.
19 Nothing in the Utilization of Unused Prescription Medications Act
20 shall require any pharmacy, nursing ~~home~~ facility, assisted living
21 center, intermediate care facility for individuals with intellectual
22 disabilities (ICF/IID), charitable clinic or prescription drug
23 manufacturer to participate in the program. Furthermore, a pharmacy
24

1 that participates in the program shall have the right to refuse
2 individual returns of unused prescription medications.

3 B. A ~~pharmacy or~~ charitable clinic which meets the eligibility
4 requirements established in the Utilization of Unused Prescription
5 Medications Act may:

6 1. ~~Dispense~~ dispense prescription drugs donated under the
7 Utilization of Unused Prescription Medications Act to persons who
8 are medically indigent residents of Oklahoma as established in rules
9 by the State Board of Pharmacy; ~~and~~

10 2. ~~Charge.~~ Such drugs shall not be resold. However, the
11 charitable clinic may charge persons receiving donated prescription
12 drugs a handling fee established by rule by the Board ~~of Pharmacy~~.

13 C. A pharmacy which meets the eligibility requirements
14 established in the Utilization of Unused Prescription Medications
15 Act may restock and redistribute prescription drugs returned to the
16 pharmacy after the pharmacy has issued the credit or reimbursement
17 to the facility or entity who purchased the prescription drugs.

18 D. A pharmacy or charitable clinic which meets the eligibility
19 requirements established and authorized by the Utilization of Unused
20 Prescription Medications Act which accepts donated prescription
21 drugs shall:

22 1. Comply with all applicable federal and state laws related to
23 the storage and distribution of dangerous drugs;

1 2. Inspect all prescription drugs prior to dispensing the
2 prescription drugs to determine that such drugs are not adulterated;
3 and

4 3. Dispense prescription drugs only pursuant to a prescription
5 issued by a health care professional.

6 ~~D. Prescription drugs donated under the Utilization of Unused~~
7 ~~Prescription Medications Act shall not be resold.~~

8 E. For purposes of the Utilization of Unused Prescription
9 Medications Act, reimbursement from governmental agencies to
10 charitable clinics shall not be considered resale of prescription
11 drugs.

12 SECTION 5. AMENDATORY 59 O.S. 2011, Section 367.6, is
13 amended to read as follows:

14 Section 367.6. A. For matters related only to the lawful
15 donation, return, acceptance, or dispensing of prescription drugs
16 under the Utilization of Unused Prescription Medications Act, the
17 following persons and entities, in compliance with the Utilization
18 of Unused Prescription Medications Act, in the absence of bad faith
19 or gross negligence, shall not be subject to criminal or civil
20 liability for injury other than death, or loss to person or
21 property, or professional disciplinary action:

22 1. The State Board of Pharmacy;

23 2. The Department of Mental Health and Substance Abuse
24 Services;

1 3. Any ~~prescription drug manufacturer~~, governmental entity,
2 nursing ~~home~~ facility, or assisted living center, intermediate care
3 facility for individuals with intellectual disabilities (ICF/IID)
4 donating or returning prescription drugs under the Utilization of
5 Unused Prescription Medications Act;

6 4. Any prescription drug manufacturer or its representative
7 that directly donates prescription drugs in professional samples to
8 a charitable clinic or a pharmacy under the Utilization of Unused
9 Prescription Medications Act;

10 5. Any pharmacy, charitable clinic or health care professional
11 that accepts or dispenses prescription drugs under the Utilization
12 of Unused Prescription Medications Act; and

13 6. Any pharmacy, or charitable clinic, ~~city-county pharmacy or~~
14 ~~other state-contracted pharmacy~~ that employs a health care
15 professional who accepts or can legally dispense prescription drugs
16 under the Utilization of Unused Prescription Medications Act and the
17 Oklahoma Pharmacy Act.

18 B. For matters related to the donation, return, acceptance, ~~or~~
19 dispensing of a prescription drug manufactured by the prescription
20 drug manufacturer that is donated by any entity under the
21 Utilization of Unused Prescription Medications Act, a prescription
22 drug manufacturer shall not, in the absence of bad faith or gross
23 negligence, be subject to criminal or civil liability for injury
24 other than for death, or loss to person or property including, but

1 not limited to, liability for failure to transfer or communicate
2 product or consumer information or the expiration date of the
3 donated prescription drug.

4 SECTION 6. AMENDATORY 59 O.S. 2011, Section 367.7, is
5 amended to read as follows:

6 Section 367.7. A. The State Board of Pharmacy shall promulgate
7 emergency rules by December 1, 2004, to implement the Utilization of
8 Unused Prescription Medications Act. Permanent rules shall be
9 promulgated pursuant to the Administrative Procedures Act. Such
10 rules shall include:

11 1. Eligibility criteria for pharmacies and charitable clinics
12 authorized to receive and dispense donated prescription drugs under
13 the Utilization of Unused Prescription Medications Act;

14 2. Establishment of a formulary which shall include all
15 prescription drugs approved by the federal Food and Drug
16 Administration;

17 3. Standards and procedures for transfer, acceptance, safe
18 storage, security, and dispensing of donated prescription drugs;

19 4. A process for seeking input from the State Department of
20 Health in establishing provisions which affect nursing ~~homes~~
21 facilities and assisted living centers;

22 5. A process for seeking input from the Department of Mental
23 Health and Substance Abuse Services in establishing provisions which
24 affect mental health and substance abuse clients;

1 6. Standards and procedures for inspecting donated prescription
2 drugs to ensure that the drugs are in compliance with the
3 Utilization of Unused Prescription Medications Act and to ensure
4 that, in the professional judgment of the pharmacist, the
5 medications meet all federal and state standards for product
6 integrity;

7 7. Procedures for destruction of medications that are donated
8 which are controlled substances;

9 8. Procedures for verifying whether the pharmacy and
10 responsible pharmacist participating in the program are licensed and
11 in good standing with the Board ~~of Pharmacy~~;

12 9. Establishment of standards for acceptance of unused
13 prescription medications from assisted living centers; ~~and~~

14 10. Procedures for credit and reimbursement for returns of
15 unused prescription medications; and

16 11. Any other standards and procedures the Board ~~of Pharmacy~~
17 deems appropriate or necessary to implement the provisions of the
18 Utilization of Unused Prescription Medications Act.

19 B. In accordance with the rules and procedures of the program
20 established pursuant to this section, a resident of a nursing
21 facility or assisted living center, or the representative or
22 guardian of a resident may donate unused prescription medications,
23 other than prescription drugs defined as controlled dangerous
24

1 substances by Section 2-101 of Title 63 of the Oklahoma Statutes,
2 for dispensation to medically indigent persons.

3 SECTION 7. This act shall become effective November 1, 2021.

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