

STATE OF OKLAHOMA

1st Session of the 58th Legislature (2021)

SENATE BILL 638

By: Garvin

AS INTRODUCED

An Act relating to pharmacy; 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; requiring certain credit or reimbursement to state Medicaid program under certain conditions; 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; excluding Medicaid copayments from certain requirement; 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:

SECTION 1. AMENDATORY 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), is amended to read as follows:

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

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

1 2. Returned by a residential care home, an assisted living
2 center or an intermediate care facility for individuals with
3 intellectual disabilities (ICF/IID) to the pharmacy where the unused
4 prescription medications were purchased in exchange for credit or
5 reimbursement. If the pharmacy accepts a return of unused
6 prescription medications that were purchased by the state Medicaid
7 program, the pharmacy shall credit or reimburse the state Medicaid
8 program for the medications; provided that, the pharmacy may keep
9 any dispensing fee paid to the pharmacy by the state Medicaid
10 program for dispensation of the medications.

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

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

16 SECTION 2. AMENDATORY 59 O.S. 2011, Section 367.4, is
17 amended to read as follows:

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

21 1. Only prescription drugs in their original sealed unit dose
22 packaging or unused injectables shall be accepted and dispensed
23 pursuant to the Utilization of Unused Prescription Medications Act;
24

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

5 3. Expired prescription drugs shall not be accepted;

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

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

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

17 SECTION 3. AMENDATORY 59 O.S. 2011, Section 367.5, is
18 amended to read as follows:

19 Section 367.5. A. Participation in the Utilization of Unused
20 Prescription Medications Act by pharmacies, nursing homes, assisted
21 living centers, intermediate care facilities for individuals with
22 intellectual disabilities (ICF/IID), charitable clinics or
23 prescription drug manufacturers shall be voluntary. Nothing in the
24 Utilization of Unused Prescription Medications Act shall require any

1 pharmacy, nursing home, assisted living center, intermediate care
2 facility for individuals with intellectual disabilities (ICF/IID),
3 charitable clinic or prescription drug manufacturer to participate
4 in the program. Furthermore, a pharmacy that participates in the
5 program shall have the right to refuse individual returns of unused
6 prescription medications including, but not limited to, medications
7 that were purchased by the state Medicaid program.

8 B. A ~~pharmacy or~~ charitable clinic which meets the eligibility
9 requirements established in the Utilization of Unused Prescription
10 Medications Act may:

11 ~~1. Dispense~~ dispense prescription drugs donated under the
12 Utilization of Unused Prescription Medications Act to persons who
13 are medically indigent residents of Oklahoma as established in rules
14 by the State Board of Pharmacy, ~~and~~

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

18 C. A pharmacy which meets the eligibility requirements
19 established in the Utilization of Unused Prescription Medications
20 Act may restock and redistribute prescription drugs returned to the
21 pharmacy after the pharmacy has issued the credit or reimbursement
22 to the facility or entity who purchased the prescription drugs. The
23 pharmacy shall not be required to reimburse Medicaid beneficiaries
24 for prescription copayments.

1 D. A pharmacy or charitable clinic which meets the eligibility
2 requirements established and authorized by the Utilization of Unused
3 Prescription Medications Act which accepts donated prescription
4 drugs shall:

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

7 2. Inspect all prescription drugs prior to dispensing the
8 prescription drugs to determine that such drugs are not adulterated;
9 and

10 3. Dispense prescription drugs only pursuant to a prescription
11 issued by a health care professional.

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

14 E. For purposes of the Utilization of Unused Prescription
15 Medications Act, reimbursement from governmental agencies to
16 charitable clinics shall not be considered resale of prescription
17 drugs.

18 SECTION 4. AMENDATORY 59 O.S. 2011, Section 367.6, is
19 amended to read as follows:

20 Section 367.6. A. For matters related only to the lawful
21 donation, return, acceptance, or dispensing of prescription drugs
22 under the Utilization of Unused Prescription Medications Act, the
23 following persons and entities, in compliance with the Utilization
24 of Unused Prescription Medications Act, in the absence of bad faith

1 or gross negligence, shall not be subject to criminal or civil
2 liability for injury other than death, or loss to person or
3 property, or professional disciplinary action:

4 1. The State Board of Pharmacy;

5 2. The Department of Mental Health and Substance Abuse
6 Services;

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

12 4. Any prescription drug manufacturer or its representative
13 that directly donates prescription drugs in professional samples to
14 a charitable clinic or a pharmacy under the Utilization of Unused
15 Prescription Medications Act;

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

19 6. Any pharmacy, or charitable clinic, ~~city-county pharmacy or~~
20 ~~other state-contracted pharmacy~~ that employs a health care
21 professional who accepts or can legally dispense prescription drugs
22 under the Utilization of Unused Prescription Medications Act and the
23 Oklahoma Pharmacy Act.

1 B. For matters related to the donation, return, acceptance, or
2 dispensing of a prescription drug manufactured by the prescription
3 drug manufacturer that is donated by any entity under the
4 Utilization of Unused Prescription Medications Act, a prescription
5 drug manufacturer shall not, in the absence of bad faith or gross
6 negligence, be subject to criminal or civil liability for injury
7 other than for death, or loss to person or property including, but
8 not limited to, liability for failure to transfer or communicate
9 product or consumer information or the expiration date of the
10 donated prescription drug.

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

13 Section 367.7. A. The State Board of Pharmacy shall promulgate
14 emergency rules by December 1, 2004, to implement the Utilization of
15 Unused Prescription Medications Act. Permanent rules shall be
16 promulgated pursuant to the Administrative Procedures Act. Such
17 rules shall include:

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

21 2. Establishment of a formulary which shall include all
22 prescription drugs approved by the federal Food and Drug
23 Administration;

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

3 4. A process for seeking input from the State Department of
4 Health in establishing provisions which affect nursing homes and
5 assisted living centers;

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

9 6. Standards and procedures for inspecting donated prescription
10 drugs to ensure that the drugs are in compliance with the
11 Utilization of Unused Prescription Medications Act and to ensure
12 that, in the professional judgment of the pharmacist, the
13 medications meet all federal and state standards for product
14 integrity;

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

17 8. Procedures for verifying whether the pharmacy and
18 responsible pharmacist participating in the program are licensed and
19 in good standing with the Board of Pharmacy;

20 9. Establishment of standards for acceptance of unused
21 prescription medications from assisted living centers; and

22 10. Procedures for credit and reimbursement for returns of
23 unused prescription medications; and
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1 11. Any other standards and procedures the Board ~~of Pharmacy~~
2 deems appropriate or necessary to implement the provisions of the
3 Utilization of Unused Prescription Medications Act.

4 B. In accordance with the rules and procedures of the program
5 established pursuant to this section, a resident of a nursing
6 facility or assisted living center, or the representative or
7 guardian of a resident may donate unused prescription medications,
8 other than prescription drugs defined as controlled dangerous
9 substances by Section 2-101 of Title 63 of the Oklahoma Statutes,
10 for dispensation to medically indigent persons.

11 SECTION 6. This act shall become effective November 1, 2021.

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