

STATE OF OKLAHOMA

2nd Session of the 49th Legislature (2004)

CONFERENCE COMMITTEE
SUBSTITUTE
FOR ENGROSSED
HOUSE BILL NO. 1866

By: Gilbert, Peters, Balkman,
Lindley, Adkins, Dorman,
Ellis, Harrison, Liotta,
McClain, Morgan (Danny) and
Smithson of the House

and

Cain, Rabon, Fair, Lawler,
Williams and Gumm of the
Senate

CONFERENCE COMMITTEE SUBSTITUTE

An Act relating to prescription drugs; providing short title; defining terms; amending 63 O.S. 2001, Section 1-1918.2, as last amended by Section 1, Chapter 167, O.S.L. 2003 (63 O.S. Supp. 2003, Section 1-1918.2), which relates to the Utilization of Unused Prescription Medications Act; expanding scope of pilot program; establishing program at the Board of Pharmacy; setting parameters for participation; defining criteria; expanding program to residents of assisted living centers; providing exemption from criminal or civil liability under certain circumstances; requiring promulgation of certain rules and stating contents of rules; amending 59 O.S. 2001, Section 353.24, as amended by Section 20, Chapter 22, O.S.L. 2002 (59 O.S. Supp. 2003, Section 353.24), which relates to the Oklahoma Pharmacy Act; expanding and modifying unlawful acts pursuant to the Oklahoma Pharmacy Act; prohibiting resale and clarifying what constitutes resale of prescription drugs; providing for codification; providing for recodification; and declaring an emergency.

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

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.1 of Title 59, unless there is created a duplication in numbering, reads as follows:

Sections 1 through 7 of this act shall be known and may be cited as the "Utilization of Unused Prescription Medications Act".

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.2 of Title 59, unless there is created a duplication in numbering, reads as follows:

As used in the Utilization of Unused Prescription Medications Act:

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

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

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

- a. a physician holding a current license to practice medicine pursuant to Chapter 11 or Chapter 14 of Title 63 of the Oklahoma Statutes,
- b. an advanced practice nurse licensed pursuant to Chapter 12 of Title 63 of the Oklahoma Statutes,
- c. a physician assistant licensed pursuant to Chapter 11 of Title 63 of the Oklahoma Statutes,
- d. a dentist licensed pursuant to Chapter 7 of Title 63 of the Oklahoma Statutes,
- e. an optometrist licensed pursuant to Chapter 13 of Title 63 of the Oklahoma Statutes, and
- f. a pharmacist licensed pursuant to Chapter 8 of Title 63 of the Oklahoma Statutes;

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

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

- a. holds a valid exemption from federal income taxation issued pursuant to Section 501(a) of the Internal Revenue Code (26 U.S.C., Section 501(a)),
- b. is listed as an exempt organization under 501(c) of the Internal Revenue Code (26 U.S.C., Section 501(c)),
- c. provides on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at such facility advice, counseling, diagnosis, treatment, surgery, care or services relating to the preservation or maintenance of health, and
- d. has a licensed outpatient pharmacy; and

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

SECTION 3. AMENDATORY 63 O.S. 2001, Section 1-1918.2, as last amended by Section 1, Chapter 167, O.S.L. 2003 (63 O.S. Supp. 2003, Section 1-1918.2), is amended to read as follows:

Section 1-1918.2 A. ~~This section shall be known and may be cited as the "Utilization of Unused Prescription Medications Act".~~

~~B.~~ 1. The State Board of Health, the Board of Pharmacy and the Oklahoma Health Care Authority shall jointly develop and implement a pilot program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances by Section 2-101 of ~~this title~~ Title 63 of the Oklahoma Statutes, may be transferred from nursing

facilities to pharmacies operated by city-county health departments or county pharmacies for the purpose of distributing the medication to Oklahoma residents who are medically indigent.

C. 2. The pilot program established pursuant to the provisions of paragraph 1 of this subsection shall conform to the requirements established in rules promulgated by the State Board of Health, the Board of Pharmacy and the Oklahoma Health Care Authority prior to the effective date of this act, and shall remain in effect until January 1, 2005.

B. The State Board of Health, the Board of Pharmacy, the Oklahoma Health Care Authority, the State Board of Medical Licensure and Supervision, and the State Board of Osteopathic Examiners shall review and evaluate the pilot program no later than twenty-four (24) months after its implementation and shall submit a report and any recommendations to the Governor, the Speaker of the Oklahoma House of Representatives, the President Pro Tempore of the State Senate, and the Chairs of the appropriate legislative committees on or before January 1, 2005.

C. 1. Beginning January 1, 2005, the 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 nursing facilities, assisted living centers 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 a charitable clinic for the purpose of

distributing the unused prescription medications to Oklahoma residents who are medically indigent

2. The Board of Pharmacy shall promulgate rules and establish procedures necessary to implement the program established by the Utilization of Unused Prescription Medications Act.

3. The Board of Pharmacy shall provide technical assistance to entities who may wish to participate in the program.

~~D. The State Board of Health, the Board of Pharmacy and the Oklahoma Health Care Authority shall promulgate rules and establish procedures necessary to implement the program established by this section. The rules and procedures shall provide:~~

~~1. For a formulary for the medications to be distributed pursuant to the program;~~

~~2. For the protection of the privacy of the individual for whom the medication was originally prescribed;~~

~~3. For the integrity and safe storage and safe transfer of the medication, which may include, but shall not be limited to, limiting the drugs made available through the program to those that were originally dispensed by unit dose or an individually sealed dose and that remain in intact packaging; provided, however, the rules shall authorize the use of any remaining medications;~~

~~4. For the tracking of and accountability for the medications;~~
and

~~5. For other matters necessary for the implementation of the program.~~

~~E. In accordance with the rules and procedures of a program established pursuant to this section, the resident of a nursing facility, or the representative or guardian of a resident may donate unused prescription medications, other than prescription drugs defined as controlled dangerous substances by Section 2-101 of this title, for dispensation to medically indigent persons.~~

~~F. Physicians, pharmacists, pharmacies, other health care professionals, and nursing facilities shall not be subject to liability for participation in the program established by the Utilization of Unused Prescription Medications Act when acting within the scope of practice of their license and in good faith compliance with the rules promulgated pursuant to the Utilization of Unused Prescription Medications Act.~~

~~G. For purposes of this section, "medically indigent" means a person who has no health insurance or who otherwise lacks reasonable means to purchase prescribed medications.~~

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.4 of Title 59, unless there is created a duplication in numbering, reads as follows:

The following criteria shall be used in accepting unused prescription drugs for use under the Utilization of Unused Prescription Medications Act:

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

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

3. Expired prescription drugs shall not be accepted;

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

5. No controlled dangerous substances shall be accepted; and

6. Subject to the limitation specified in this section, unused prescription drugs dispensed for purposes of a medical assistance program or drug product donation program may be accepted and

dispensed under the Utilization of Unused Prescription Medications Act.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.5 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. Participation in the Utilization of Unused Prescription Medications Act by pharmacies, nursing homes, assisted living centers, charitable clinics or prescription drug manufacturers shall be voluntary. Nothing in the Utilization of Unused Prescription Medications Act shall require any pharmacy, nursing home, assisted living center, charitable clinic or prescription drug manufacturer to participate in the program.

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

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

2. Charge persons receiving donated prescription drugs a handling fee established by rule by the Board of Pharmacy.

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

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

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

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

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

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

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.6 of Title 59, unless there is created a duplication in numbering, reads as follows:

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

1. The Board of Pharmacy;

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

3. Any prescription drug manufacturer, governmental entity, nursing home, or assisted living center donating prescription drugs under the Utilization of Unused Prescription Medications Act;

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

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

6. Any pharmacy, charitable clinic, city-county pharmacy or other state-contracted pharmacy that employs a health care professional who accepts or can legally dispense prescription drugs

under the Utilization of Unused Prescription Medications Act and the Oklahoma Pharmacy Act.

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

SECTION 7. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 367.7 of Title 59, unless there is created a duplication in numbering, reads as follows:

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

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

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

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

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

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

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

7. A maximum handling fee not to exceed Ten Dollars (\$10.00) per visit that pharmacies and charitable clinics may charge to drug recipients to cover restocking and dispensing costs;

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

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

10. Establishment of standards for acceptance of unused prescription medications from assisted living centers; and

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

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

SECTION 8. AMENDATORY 59 O.S. 2001, Section 353.24, as amended by Section 20, Chapter 22, O.S.L. 2002 (59 O.S. Supp. 2003, Section 353.24), is amended to read as follows:

Section 353.24 It shall be unlawful for any person, firm or corporation to:

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

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

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

4. Enter into any arrangement whereby prescription orders are received, or prescriptions delivered at a place other than the pharmacy in which they are compounded and dispensed. However, nothing in this paragraph shall prevent a pharmacist or an employee of the pharmacy from personally receiving a prescription or delivering a legally filled prescription at a residence, office or place of employment of the patient for whom the prescription was written. Nothing in this paragraph shall prevent veterinary prescription drugs from being shipped directly from a wholesaler or distributor to a client; provided, such drugs may be dispensed only on prescription of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists;

5. Sell, offer for sale or barter or buy any professional samples except through a program pursuant to the Utilization of Unused Prescription Medications Act. For purpose of this paragraph, "professional samples" means complimentary drugs packaged in accordance with federal and state statutes and regulations and provided to a licensed practitioner free of charge by manufacturers

or distributors for the purpose of being distributed free of charge in such package by the licensed practitioner to a patient; ~~or~~

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

7. Possess dangerous drugs without a valid prescription or a valid license to possess such drugs.

SECTION 9. RECODIFICATION 63 O.S. 2001, Section 1-1918.2, as last amended by Section 3 of this act, shall be recodified as Section 367.3 of Title 59 of the Oklahoma Statutes, unless there is created a duplication in numbering.

SECTION 10. It being immediately necessary for the preservation of the public peace, health and safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

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