

STATE OF OKLAHOMA

2nd Session of the 49th Legislature (2004)

COMMITTEE SUBSTITUTE  
FOR  
HOUSE BILL NO. 1866

By: Gilbert

COMMITTEE SUBSTITUTE

An Act relating to public health and safety; creating Utilization of Unused Prescription Medications Act; 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; defining terms; establishing Program at Department of Health; defining criteria; providing exemption from criminal or civil liability under certain circumstances; requiring promulgation of certain rules; providing for codification; and providing an effective date.

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 1-1918.1a of Title 63, unless there is created a duplication in numbering, reads as follows:

This act shall be known and may be cited as the "Utilization of Unused Prescription Medications Act".

SECTION 2. 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.~~ 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, may be transferred from nursing facilities to pharmacies operated by

city-county health departments ~~or~~, county pharmacies, nonprofit health care clinics, or pharmacies under contract with the county health department or the State Department of Health for the purpose of distributing the medication to Oklahoma residents who are medically indigent.

~~C.~~ 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 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.

~~D.~~ C. 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~~ an inclusionary 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.~~ D. 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.~~ E. 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.~~ F. 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 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-1918.3 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in the Utilization of Unused Prescription Medications Act:

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

- a. a licensed physician,
- b. a registered nurse practitioner,
- c. a physician assistant,
- d. a dentist,
- e. an optometrist, and
- f. a pharmacist;

2. "Hospital" has the same meaning as such term is defined in Section 1-701 of Title 63 of the Oklahoma Statutes;

3. "Nonprofit clinic" means a charitable nonprofit corporation or a facility organized not-for-profit pursuant to the provisions of the Oklahoma General Corporation Act and that 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)) and is listed as an exempt organization under 501(c) of the Internal Revenue Code (26 U.S.C. 501(c)) in which advice, counseling, diagnosis, treatment, surgery, care or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at such facility; and

4. "Prescription drug" means a drug which may be dispensed only upon prescription by a person authorized by their 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. 301).

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-1918.4 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. By January 1, 2005, the Oklahoma State Department of Health shall establish the "Utilization of Unused Prescription Medications Program" to accept or dispense prescription drugs donated for the purpose of being dispensed to persons who are residents of Oklahoma and who meet eligibility requirements.

B. The following criteria shall be used in accepting drugs for use in the Program:

1. Only prescription drugs in their original sealed unit dose packaging shall be accepted and dispensed pursuant to the Program;

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. Prescription drugs that are unexpired shall be accepted;

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

5. No controlled dangerous substances shall be accepted from individuals; and

6. Subject to the limitation specified in this section, unused prescription drugs dispensed for purposes of a medical assistance program may be accepted and dispensed under the Utilization of Unused Prescription Medications Program.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-1918.5 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Any person, including but not limited to a prescription drug manufacturer or health care facility, may donate prescription drugs to the Utilization of Unused Prescription Medications Program. The drugs shall be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the Utilization of Unused Prescription Medications Program and meets the criteria for participation established by rule of the Department. Participation in the Program by pharmacies, hospitals, and nonprofit clinics shall be voluntary. Nothing in the Utilization of Unused Prescription Medications Act shall require any pharmacy, hospital, or nonprofit clinic to participate in the Program.

B. 1. A pharmacy, hospital, or nonprofit clinic which meets the eligibility requirements established in the Utilization of Unused Prescription Medications Act may dispense prescription drugs donated under the Program to persons who are residents of Oklahoma and who meet the eligibility requirements established in rules by the Oklahoma Board of Health of the Program, or to other governmental entities and nonprofit private entities who dispense

prescription drugs to persons who meet the eligibility requirements established in rules by the Oklahoma Board of Health.

2. A prescription drug shall be dispensed only pursuant to a prescription issued by a health care professional.

3. A pharmacy, hospital, or nonprofit clinic which accepts donated prescription drugs shall comply with all applicable federal and state laws dealing with the storage and distribution of dangerous drugs and shall inspect all prescription drugs prior to dispensing the prescription drugs to determine that they are not adulterated.

4. The pharmacy, hospital, or nonprofit clinic may charge persons receiving donated prescription drugs a handling fee established by rule by the State Board of Health.

5. Prescription drugs donated to the Program shall not be resold. For purposes of the Utilization of Unused Prescription Medications Act, reimbursement from governmental agencies to nonprofit 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 1-1918.6 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The following persons and entities when acting in good faith and in compliance with the Utilization of Unused Prescription Medications Act shall not be subject to criminal or civil liability for injury, or loss to person or property, or professional disciplinary action for matters related to donating, accepting, or dispensing prescription drugs under the Utilization of Unused Prescription Medications Program:

1. The Oklahoma State Board of Health;
2. The Commissioner of Health;
3. Any governmental entity or person donating prescription drugs to the Program;

4. Any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses prescription drugs under the Program; and

5. Any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses prescription drugs under the Program.

B. A prescription drug manufacturer shall not, in the absence of bad faith, be subject to criminal or civil liability for injury, or loss to person or property for matter related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any person under the Program, 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 1-1918.7 of Title 63, unless there is created a duplication in numbering, reads as follows:

In consultation with the Board of Pharmacy, the State Board of Health shall adopt and promulgate rules to implement the Utilization of Unused Prescription Medications Act. Such rules shall include:

1. Eligibility criteria for pharmacies, hospitals and nonprofit clinics to receive and dispense donated prescription drugs under the Program;

2. Standards and procedures for transfer, receipt, safely storing, security, and dispensing donated prescription drugs;

3. Standards and procedures for inspecting donated prescription drugs to determine that the original single-unit-dose packaging is sealed and that the prescription drugs are in the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity;

4. Eligibility requirements for recipients in the Program based on the economic need of persons who will receive prescription drugs under the Program;

5. An identification card by which a person who is eligible to receive donated prescription drugs under the Program, may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

6. A form that a person receiving a prescription drug from the Program must sign before receiving the drug in order to confirm that such person understands the criminal and civil immunity from liability provisions of the Program;

7. A maximum handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

8. For prescription drugs donated to the Program by individuals:

- a. a list of prescription drugs, arranged by category or by individual drug, that the Program will and will not accept from individuals.
- b. a list of prescription drugs, arranged by category or by individual drug, that the Program will not accept from individuals. If a drug is ineligible for donation, the list must include a statement as to the reason the drug is ineligible for donation, and a form each donor must sign stating that the donor is the owner of the prescription drugs and intends to voluntarily donate such drugs to the Program;

9. For prescription drugs donated to the Program by health care facilities:

- a. a list of prescription drugs, arranged by category or by individual drug, that the Program will accept from health care facilities.

b. a list of prescription drugs, arranged by category or by individual drug, that the Program will not accept from health care facilities. If a drug is ineligible for donation, the list must include a statement as to the reason the drug is ineligible for donation;

10. Destruction of medications that are donated which are controlled substances;

11. System is in place to track restocking and reuse to allow medications to be recalled if required;

12. Mechanism is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source;

13. The pharmacy and responsible pharmacist are licensed and in good standing with the Oklahoma Board of Pharmacy; and

14. Any other standards and procedures the Department deems appropriate or necessary to implement the provisions of this act.

SECTION 8. This act shall become effective November 1, 2004.

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