

STATE OF OKLAHOMA

1st Session of the 48th Legislature (2001)

CONFERENCE COMMITTEE
SUBSTITUTE FOR ENGROSSED
HOUSE BILL NO. 1297

By: Gilbert, Peters, Rice,
Adkins, Balkman, Bengel,
Cargill, Covey, Easley,
Ericson, Lindley, Liotta,
Miller (Ray), O'Neal,
Peterson, Roggow, Smaligo,
Sweeden and Tibbs of the
House

and

Cain of the Senate

CONFERENCE COMMITTEE SUBSTITUTE

An Act relating to public health; creating the Utilization of Unused Prescription Medications Act; directing the State Board of Health, the Oklahoma Board of Pharmacy and the Oklahoma Health Care Authority to develop and implement certain program; providing for certain rules and procedures; providing for evaluation; authorizing certain donations; providing for certain liability; providing for definition; amending 59 O.S. 1991, Sections 353.1, as last amended by Section 1, Chapter 128, O.S.L. 1998, 353.7, as last amended by Section 3, Chapter 250, O.S.L. 1997 and 353.24, as amended by Section 18, Chapter 199, O.S.L. 1993 (59 O.S. Supp. 2000, Sections 353.1, 353.7 and 353.24), which relate to the Oklahoma Pharmacy Act; modifying definition and term; expanding exception for certain action; 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 the Oklahoma Statutes as Section 1-1918.2 of Title 63, unless there is created a duplication in numbering, reads as follows:

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 Oklahoma 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 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. The State Board of Health, the Oklahoma 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 eighteen (18) 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. The State Board of Health, the Oklahoma 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 or which remain in intact packaging;

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 Title 63 of the Oklahoma Statutes, for dispensation to medically indigent persons.

F. Physicians, pharmacists and other health care professionals shall not be subject to liability for participation in the program established by this 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 2. AMENDATORY 59 O.S. 1991, Section 353.1, as last amended by Section 1, Chapter 128, O.S.L. 1998 (59 O.S. Supp. 2000, Section 353.1), is amended to read as follows:

Section 353.1 For the purposes of the Oklahoma Pharmacy Act, Section 353 et seq. of this title:

1. "Pharmacy" means a place regularly licensed by the Oklahoma State Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded or dispensed;

2. ~~"Pharmacist"~~ "Doctor of Pharmacy" means a person registered by the Oklahoma State Board of Pharmacy to engage in the practice of pharmacy. The terms "pharmacist" and "Doctor of Pharmacy" shall be interchangeable and shall have the same meaning wherever they appear

in the Oklahoma Statutes and the rules promulgated by the Board of Pharmacy;

3. "Drugs" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment or prevention of disease in humans and all substances and preparations, other than food, intended to affect the structure or any function of the body of a human;

4. "Medicine" means any drug or combination of drugs which has the property of curing, preventing, treating, diagnosing or mitigating diseases, or which is used for that purpose;

5. "Poison" means any substance which when introduced into the system, either directly or by absorption, produces violent, morbid or fatal changes, or which destroys living tissue with which such substance comes into contact;

6. "Chemical" means any medicinal substance, whether simple or compound or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin;

7. "Prescription" means and includes any order for drug or medical supplies written or signed, or transmitted by word of mouth, telephone or other means of communication by a licensed practitioner of allopathic or osteopathic medicine, including physician assistants under the supervision of a licensed physician, dentistry, optometry certified by the Board of Examiners in Optometry, podiatry, or veterinary medicine, licensed by law to prescribe such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist;

8. "Filled prescription" means a packaged prescription medication to which a label has been affixed, which shall contain such information as is required by the Oklahoma Pharmacy Act;

9. "Nonprescription drugs" means medicines or drugs which are sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government. Such items shall also include medical and dental supplies, and bottled or nonbulk chemicals which are sold or offered for sale to the general public, if such articles or preparations meet the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Section 321 et seq.;

10. "Hospital" means any institution licensed by this state for the care and treatment of patients;

11. "Person" means every individual, copartnership, corporation or association, unless the context otherwise requires;

12. "Board" or "State Board" means the Oklahoma State Board of Pharmacy;

13. "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient;

14. "Dispense" includes sell, distribute, leave with, give away, dispose of, deliver, or supply;

15. "Wholesaler" or "Distributor" means a person engaged in the business of distributing dangerous drugs or medicines at wholesale to pharmacies, hospitals, practitioners, government agencies, or other lawful drug outlets permitted to sell or use drugs or medicines;

16. "Dangerous drug", "legend drug" or "prescription drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (i) "Caution: Federal law prohibits dispensing without prescription", or (ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian", or a drug which is required by any applicable federal or state law or regulation to

be dispensed on prescription only or is restricted to use by practitioners only;

17. "Manufacturer" means a person engaged in the manufacturing of drugs;

18. "Practice of pharmacy" means:

- a. the interpretation and evaluation of prescription orders,
- b. the compounding, dispensing, and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices,
- c. the participation in drug selection and drug utilization reviews,
- d. the proper and safe storage of drugs and devices and the maintenance of proper records thereof,
- e. the responsibility for advising by counseling and providing information, where professionally necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices,
- f. the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy, and
- g. the provision of those acts or services that are necessary to provide pharmaceutical care;

19. "Drug outlet" means all pharmacies, wholesalers, manufacturers, or wherever dangerous drugs are stored, and facilities which are engaged in dispensing, delivery or distribution of dangerous drugs;

20. "Manufacturing" means the production, preparation, propagation, compounding, conversion, or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological

synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. The term "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons;

21. "Assistant pharmacist" means any person presently licensed as an assistant pharmacist in the State of Oklahoma by the Board pursuant to Section 353.10 of this title and for the purposes of this act shall be considered the same as a pharmacist, except where otherwise specified;

22. "Packager" means any person, firm, or corporation, except a pharmacy, who transfers dangerous drugs including but not limited to compressed medical gases from one container to another of any type;

23. "Continuing professional education" means professional, pharmaceutical education in the general areas of the socioeconomic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the diseased state;

24. "Accredited program" means those seminars, classes, meetings, work projects and other educational courses approved by the Board for purposes of continuing professional education;

25. "Supervising physician" means an individual holding a current license to practice as a physician from the State Board of Medical Licensure and Supervision, pursuant to the provisions of Section 481 et seq. of this title, or the State Board of Osteopathic Examiners, pursuant to the provisions of Section 620 et seq. of this title, who supervises an advanced practice nurse as defined in Section 567.3a of this title, and who is not in training as an intern, resident, or fellow. To be eligible to supervise an advanced practice nurse, such physician shall remain in compliance

with the rules promulgated by the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners; and

26. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

- a. as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or
- b. for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing.

Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

SECTION 3. AMENDATORY 59 O.S. 1991, Section 353.7, as last amended by Section 3, Chapter 250, O.S.L. 1997 (59 O.S. Supp. 2000, Section 353.7), is amended to read as follows:

Section 353.7 The State Board of Pharmacy shall have the powers and duties to:

1. Regulate the practice of pharmacy;
2. Regulate the sale of drugs, medicines, chemicals and poisons;
3. Regulate the dispensing of drugs and medicines in all places where drugs and medicines are compounded or dispensed;
4. Enter and inspect, by its members or by its duly authorized representatives, any and all places, including premises, equipment, contents and records, where drugs, medicines, chemicals or poisons are stored, sold, vended, given away, compounded, dispensed or manufactured;
5. Employ the number of inspectors necessary to carry out the provisions of the Oklahoma Pharmacy Act at an annual salary to be fixed by the Board, and to authorize necessary expenses. Such

inspectors shall have the same powers and authority as that granted to peace officers by the laws of this state for the purpose of enforcing the Oklahoma Pharmacy Act. In addition, such inspectors shall have the authority and the duty to confiscate all drugs, medicines, chemicals or poisons found to be stored, sold, vended, given away, compounded, dispensed or manufactured contrary to the provisions of the Oklahoma Pharmacy Act;

6. Prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies, as may be reasonably necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public, and to refuse the issuance of new or renewal licenses for failure to comply with such standards;

7. Examine and issue appropriate certificates of registration as ~~pharmacists~~ Doctor of Pharmacy to all applicants whom it shall deem qualified to be such under the provisions of the Oklahoma Pharmacy Act;

8. Investigate complaints, hold hearings and subpoena witnesses and records;

9. Initiate prosecution;

10. Reprimand or place on probation any holder of a certificate, license or permit; suspend or revoke certificates, licenses or permits, and levy fines not to exceed Five Hundred Dollars (\$500.00) for each count for which any holder of a certificate, license or permit has been convicted in Board hearings;

11. Adopt and establish rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy. Such rules shall be subject to amendment or repeal by the Board as the need may arise;

12. Perform such other duties, exercise such other powers and employ such other personnel as the provisions and enforcement of the Oklahoma Pharmacy Act may require; and

13. Make and publish uniform rules such as may be necessary for carrying out and enforcing the provisions of the Oklahoma Pharmacy Act, Oklahoma drug laws and rules, federal drug laws and regulations, and such other areas as in its discretion may be necessary to protect the health, safety and welfare of the public.

SECTION 4. AMENDATORY 59 O.S. 1991, Section 353.24, as amended by Section 18, Chapter 199, O.S.L. 1993 (59 O.S. Supp. 2000, 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 ~~his~~ 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; ~~or~~

5. Sell, offer for sale or barter or buy any professional samples. 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 ~~his~~ 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.

SECTION 5. This act shall become effective November 1, 2001.

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