

ENGROSSED HOUSE
BILL NO. 2715

By: Stanley, Glover and Piatt
of the House

and

Robinson of the Senate

(professions and occupations - amending four sections
in Title 59 - Oklahoma Pharmacy Act - renewal
procedures - license violations - repealing 59 O.S.,
Section 353.1 - duplicate section - emergency)

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

SECTION 1. AMENDATORY 59 O.S. 2001, Section 353.1

(Section 6, Chapter 400, O.S.L. 2001), 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, or as authorized in subsection G of Section 353.13 of this title;

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 and administering of drugs and devices, pursuant to a prescription and/or an agreed standing order by a physician authorized to practice medicine pursuant to the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act or the Oklahoma Osteopathic Medicine Act 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; and

27. "Standing orders" means an order that sets out parameters for a patient drug regimen issued by a physician authorized to practice medicine pursuant to the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act or the Oklahoma Osteopathic Medicine Act.

SECTION 2. AMENDATORY 59 O.S. 2001, 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. Administer oaths in all matters pertaining to the affairs of the Board and to take evidence and compel the attendance of witnesses

on questions pertaining to the enforcement of the Oklahoma Pharmacy Act;

6. 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.~~ 7. 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.~~ 8. Examine and issue appropriate certificates of registration as Doctor of Pharmacy to all applicants whom it shall deem qualified to be such under the provisions of the Oklahoma Pharmacy Act;

~~8.~~ 9. Investigate complaints, hold hearings and subpoena witnesses and records;

~~9.~~ 10. Initiate prosecution;

~~10.~~ 11. 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)~~ One Thousand Dollars (\$1,000.00) for each count for which any holder of a certificate, license or permit has been convicted in Board hearings. Provided, as a condition of corrective disciplinary sanctions, the Board may require extra continuing education or attendance at a live continuing education program and

may require participation in an rehabilitation program for the impaired. The Board may take such actions singly or in combination as the nature of the violation requires;

~~11.~~ 12. 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.~~ 13. 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.~~ 14. 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 3. AMENDATORY 59 O.S. 2001, Section 353.11, is amended to read as follows:

Section 353.11 A. Every registered pharmacist and assistant pharmacist who desires to continue in the profession of pharmacy in this state shall annually, after the expiration of the ~~first year of~~ registration, and on or before the ~~first day of July of~~ expiration date each year, ~~pay~~ complete a renewal form and remit to the Board a renewal fee to be fixed by the Board. ~~Such renewal fee shall not exceed Seventy-five Dollars (\$75.00).~~ Upon compliance with the provisions of the Oklahoma Pharmacy Act and payment of such renewal fee, a renewal certificate of registration shall be issued.

B. If any person fails or neglects to procure his annual registration or permit, as herein required, notice of such failure having been mailed to his post office address, the Board may, after the expiration of thirty (30) days following the issue of said notice, deprive him of his registration and all other privileges conferred by

the Oklahoma Pharmacy Act. In order to regain registration, it shall be necessary for such person to make application in writing to the Board requesting reinstatement. The Board may require such person to appear before the Board at a regular meeting.

SECTION 4. AMENDATORY 59 O.S. 2001, Section 353.26, is amended to read as follows:

Section 353.26 A. The Board of Pharmacy is specifically granted the power to:

1. Revoke or suspend any certificate, license or permit issued pursuant to the Oklahoma Pharmacy Act or reprimand or place on probation any holder of a certificate, license, or permit who:
 - a. violates any provision of the Oklahoma Pharmacy Act,
 - b. violates any of the provisions of Sections 2-101 et seq. of Title 63 of the Oklahoma Statutes or the Uniform Controlled Dangerous Substances Act,
 - c. has been convicted of a felony,
 - d. engages in the practice of pharmacy while incapacitated or abuses intoxicating liquors or other chemical substances,
 - e. conducts himself in a manner likely to lower public esteem for the profession of pharmacy,
 - f. has had his license placed on probation, suspended, or revoked or has been reprimanded by another State Board of Pharmacy,
 - g. has been legally adjudged to be not mentally competent, or
 - h. exercises conduct and habits inconsistent with the rules of professional conduct established by the Board; and
2. Levy administrative fines not to exceed ~~Five Hundred Dollars~~ One Thousand Dollars (\$1,000.00) for each count of which ~~(\$500.00)~~

any holder of a certificate, license, or permit has been convicted in Board hearings.

B. The Board, its employees, or other agents shall keep confidential information obtained during an investigation into violations of the Oklahoma Pharmacy Act, except such information may be introduced by the state in administrative proceedings before the Board.

C. To ensure the confidentiality of such information for the protection of the affected individual or entity, the information obtained shall not be deemed to be a record as that term is defined in the Oklahoma Open Records Act.

D. 1. The Board, upon a sworn complaint filed with its Director, and after giving at least ten (10) days' written notice by registered or certified mail of the filing of such complaint to the person accused therein of the date and place of a hearing thereon, to which notice shall be attached a statement of the charges contained in the complaint, is hereby authorized and empowered, if ~~it~~ the Board finds that the allegations of the complaint are supported by the evidence rendered at the hearing to, by written order, revoke permanently or suspend for a designated period, the certificate, license or permit of the person charged in the complaint or reprimand or place on probation said person.

2. The Board may, upon written application therefor and in the exercise of its official discretion, cancel ~~said~~ the order.

3. A person whose certificate, license or permit has been revoked or suspended or who has been reprimanded or placed on probation or fined may appeal such Board order pursuant to the Administrative Procedures Act.

SECTION 5. REPEALER 59 O.S. 2001, Section 353.1 (Section 2, Chapter 281, O.S.L. 2001), is hereby repealed.

SECTION 6. 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.

Passed the House of Representatives the 6th day of March, 2002.

Presiding Officer of the House of
Representatives

Passed the Senate the ____ day of _____, 2002.

Presiding Officer of the Senate