ENGROSSED SENATE
BILL NO. 412

By: Anderson of the Senate

and

Armes of the House

An Act relating to professions and occupations; amending 59 O.S. 2001, Sections 353.1, as last amended by Section 16, Chapter 523, O.S.L. 2004 and 353.13 (59 O.S. Supp. 2004, Section 353.1), which relate to the Oklahoma Pharmacy Act; modifying definitions; clarifying language; exempting certain prescriptions from specified requirement; clarifying requirements regarding supply and dispensing of shipped veterinary prescription drugs; stating certain violations; requiring 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. 2001, Section 353.1, as last amended by Section 16, Chapter 523, O.S.L. 2004 (59 O.S. Supp. 2004, Section 353.1), is amended to read as follows:

Section 353.1 For the purposes of the Oklahoma Pharmacy Act:

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

2. "Doctor of Pharmacy" means a person registered by the 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, or by a wholesaler or distributor as authorized in subsection G of Section 353.13 of this title;

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 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", "prescription drug" or "Rx Only" means a drug which:

a. under federal law, is required, prior to being dispensed or delivered, to be labeled with one of the following statements:

(1) "Caution: Federal law prohibits dispensing without prescription",

(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian", or

(3) "Rx Only", or

b. 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, administering 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 the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or the State Board of Osteopathic Examiners, pursuant to the provisions of the Oklahoma Osteopathic Medicine Act, 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;

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;

27. “Medical gas” means those gases and liquid oxygen upon which the manufacturer or distributor has placed one of several cautions, such as “Rx Only”, in compliance with federal law;

28. “Medical gas order” means an order for medical gas issued by a licensed medical practitioner;

29. “Medical gas distributor” means a person who distributes, transfers, wholesales, delivers or sells medical gases to a person and may also include a patient or ultimate user;

30. “Medical gas supplier” means a person who dispenses medical gases only to a patient or ultimate user; and

31. “Supportive personnel” means technicians and auxiliary supportive persons who are regularly paid employees of a pharmacy who work and perform tasks in the pharmacy as authorized by Section 353.29 of this title.

SECTION 2. AMENDATORY 59 O.S. 2001, Section 353.13, is amended to read as follows:

Section 353.13 A. It shall be unlawful for any person, other than a registered pharmacist or assistant pharmacist, to certify the

finished prescription, as defined by the Board, before delivery to the patient or the patient's agent or care giver.

B. It shall be unlawful for any person to institute or manage a pharmacy unless such person shall be a registered pharmacist, or shall place in charge of said pharmacy a registered pharmacist.

C. No registered pharmacist shall manage, supervise nor be in charge of more than one pharmacy.

D. No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted therefor, without authority of the prescriber or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.

E. No proprietor of a pharmacy, or other person, shall permit the practice of pharmacy except by a registered pharmacist or assistant pharmacist.

F. No proprietor of a pharmacy, or other person, shall subvert the authority of the pharmacist in charge of the pharmacy by impeding the management of the prescription department in compliance with federal and state pharmacy laws and regulations.

G. Nothing in the Oklahoma Pharmacy Act 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~~ supplied to the client on the order of ~~a~~ an Oklahoma licensed veterinarian and only when ~~an existing veterinary~~ a valid veterinarian-client-patient relationship exists.

1. Prescriptions dispensed pursuant to the provisions of this subsection shall not be required to be certified by a pharmacist prior to being dispensed by a wholesaler or distributor.

2. It shall be a violation of state law for an owner or their authorized agent to acquire or use any prescription drug other than

according to the label and/or outside of a valid veterinarian-client-patient relationship (VCPR);

3. It shall be a violation of state law for a wholesaler or distributor to sell a prescription labeled drug to an owner or their authorized agent without a valid VCPR in place; and

4. Compliance of this act as it relates to veterinary prescription labeled drugs shall be done in accordance with and pursuant to rules that shall be promulgated by the Oklahoma State Board of Veterinary Medical Examiners and in consultation with the State Veterinarian in accordance with state law.

SECTION 3. This act shall become effective November 1, 2005.

Passed the Senate the 9th day of March, 2005.

_____
Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2005.

_____
Presiding Officer of the House
of Representatives