SHORT TITLE: Prescription labels; requiring drug expiration date be included on certain labels; effective date.

STATE OF OKLAHOMA

1st Session of the 44th Legislature (1993)

SENATE BILL NO. 34 By: Hooper

AS INTRODUCED

An Act relating to prescription labels; amending 59 O.S. 1991, Sections 353.1 and 355.1, which relate to definitions and dispensing dangerous drugs; requiring drug expiration date be included on certain labels; and providing an effective date.

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

SECTION 1. AMENDATORY 59 O.S. 1991, Section 353.1, is amended to read as follows:

Section 353.1 For the purposes of Sections 353.1 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" means a person registered by the Oklahoma State Board of Pharmacy to prepare, compound and dispense drugs, medicines, chemicals and poisons.

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 man and all substances and preparations, other than food, intended to affect the structure or any function of the body of man.

4. "Medicine" means any drug or combination of drugs which has the property of curing, preventing, treating 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. a. "Prescription" means and includes any order for drug or medical supplies written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication by a legally competent practitioner of medicine, dentistry, osteopathy, optometry certified by the Board of Examiners in Optometry to administer ocular pharmaceutical agents as authorized by Sections 581 and 584 of this title, podiatry, or veterinary medicine, licensed by law to prescribe and administer such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist. Such prescription received by other than written communication shall be promptly recorded in writing by the pharmacist. The record made by the pharmacist shall constitute the original prescription to be filed by the pharmacist.

b. For purposes of Sections 353.1 et seq. of this title, pharmacists may dispense ocular topical pharmaceutical agents for qualified optometrist certified by the Board of Examiners in Optometry to use such ocular topical pharmaceutical agents. Nothing in this subsection shall provide for optometrists to be

authorized in any way to manufacture, distribute, dispense, prescribe, administer or use for scientific purposes any controlled dangerous substance as defined in paragraph 8 of Section 2-101 of Title 63 of the Oklahoma Statutes. All prescriptions issued by certified optometrists shall include the certification number of the optometrist as assigned by the Board of Examiners in Optometry. The Board of Examiners in Optometry shall provide an annual list of all certified optometrists directly to each pharmacy licensed by the Oklahoma State Board of Pharmacy. Any additions or deletions in certification shall be mailed to all pharmacies in this state within thirty (30) days of such change.

c. "Filled prescription" means a packaged prescription medication to which a label has been affixed, which label includes the name and address of the pharmacy of origin, date of filling, the date after which the drug is no longer effective, name of patient, name of prescriber, directions for administration and prescription number. When directed by the prescriber, such label shall legibly state, in addition to any other information, the trade or generic name, and the quantity and strength, not meaning ingredients, of the drug therein contained. This requirement shall not apply to compounded prescriptions or medicines and drugs supplied or delivered directly to patients for consumption on the premises while admitted to any hospital or mental institution.

8. "Patent or proprietary medicines" means and includes packaged medicines, drugs, medical and dental supplies, and bottled or nonbulk chemicals identified by and sold pursuant to a trademark,

trade name or other trade symbol, privately owned or registered in the United States Patent Office, 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.

9. "Hospital" means any institution for the care and treatment of the sick and injured approved and licensed by this state.

10. Masculine words shall include the feminine and neuter, and the singular includes the plural.

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

12. "The Board" or "The 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. A "Wholesaler" or "Distributor" means a person engaged in the business of distributing drugs or medicines at wholesale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell or use drugs or medicines.

16. "Dangerous drugs" shall mean and include any drug intended for use by man which, because of its toxicity or other potentiality for harmful effects, or the method of its use, or the collateral measures necessary for its use, is not safe for use except pursuant to the supervision of a practitioner licensed by law to administer such drugs. This shall include all drugs upon which the manufacturer or distributor has, in compliance with federal law and regulations, placed the following - "Caution - Federal Law prohibits dispensing without prescription".

17. "Manufacturer" means and includes a person, except a pharmacy, who prepares, derives, produces, compounds, or repackages any drug.

SECTION 2. AMENDATORY 59 O.S. 1991, Section 355.1, is amended to read as follows:

Section 355.1 A. Except as provided for in Section 353.1 et seq. of ~~Title 59 of the Oklahoma Statutes~~ this title, only a licensed practitioner may dispense dangerous drugs to his patients, and only for the expressed purpose of serving the best interests and promoting the welfare of his patients. The dangerous drugs shall be dispensed in an appropriate container to which a label has been affixed, such label to include the name and office address of the licensed practitioner, date dispensed, the date after which the drug is no longer effective, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength, not meaning ingredients, of the drug therein contained; provided, this requirement shall not apply to compounded medicines. The licensed practitioner shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years a record of every dangerous drug compounded or dispensed by the licensed practitioner.

B. A licensed practitioner desiring to dispense dangerous drugs pursuant to this section shall register annually with his licensing board as a dispenser, through a regulatory procedure adopted and prescribed by his licensing board.

C. A licensed practitioner who dispenses professional samples to his patients shall be exempt from the requirement of subsection B of this section if:

1. The licensed practitioner furnishes the professional samples to the patient in the package provided by the manufacturer;

2. No charge is made to the patient; and

3. An appropriate record is entered in the patient's chart.

D. This section shall not apply to the services provided through the State Department of Health or the Department of Mental Health and Substance Abuse Services.

E. This section shall not apply to organizations and services incorporated as state or federal tax-exempt charitable nonprofit entities and/or organizations and services receiving all or part of their operating funds from a local, state or federal governmental entity; provided, such organizations and services shall comply with the labeling and recordkeeping requirements set out in subsection A of this section.

SECTION 3. This act shall become effective September 1, 1993.

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