

SHORT TITLE: Uniform Controlled Dangerous Substances Act; expanding ephedrine; naming products for exception; emergency.

STATE OF OKLAHOMA

2nd Session of the 45th Legislature (1996)

SENATE BILL NO. 1123

By: Helton

AS INTRODUCED

An Act relating to the Uniform Controlled Dangerous Substances Act; amending 63 O.S. 1991, Sections 2-210, as amended by Section 1, Chapter 147, O.S.L. 1995, 2-309, and 2-407 (63 O.S. Supp. 1995, Section 2-210), which relate to Schedule IV drugs, written prescriptions for Schedule II drugs, and attempt to obtain prescription; expanding ephedrine; naming products for exemption; authorizing Director to exempt other drug products; requiring certain considerations; requiring certain hearing; providing certain listing; authorizing certain facsimile of prescription; stating applicable conditions for facsimile; prohibiting certain acts regarding prescription forms; providing penalties; and declaring an emergency.

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

SECTION 1. AMENDATORY 63 O.S. 1991, Section 2-210, as amended by Section 1, Chapter 147, O.S.L. 1995 (63 O.S. Supp. 1995, Section 2-210), is amended to read as follows:

Section 2-210. The controlled substances listed in this section are included in Schedule IV.

A. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant or depressant effect on the central nervous system:

1. Chloral betaine-; i
2. Chloral hydrate-; i
3. Ethchlorvynol-; i
4. Ethinamate-; i
5. Meprobamate-; i

6. Paraldehyde;i
7. Petrichloral;i
8. Diethylpropion;i
9. Phentermine;i
10. Pemoline;i
11. Chlordiazepoxide;i
12. Chlordiazepoxide and its salts, but not including chlordiazepoxide hydrochloride and clidinium bromide or chlordiazepoxide and water-soluble esterified estrogens;i
13. Diazepam;i
14. Oxazepam;i
15. Clorazepate;i
16. Flurazepam and its salts;i
17. Clonazepam;i
18. Barbital;i
19. Mebutamate;i
20. Methohexital;i
21. Methylphenobarbital;i
22. Phenobarbital;i
23. Fenfluramine;i
24. Pentazocine;i
25. Dextropropoxyphene;i
26. Butorphanol;i
27. Alprazolam;i
28. Halazepam;i
29. Lorazepam;i
30. Prazepam;i
31. Temazepam;i
32. Triazolam;i
33. Carisoprodol;i or

34. Ephedrine, its salts, optical isomers, and salts of optical isomers as the only active ingredient, or in combination with other active ingredients ~~unless the combination product is:~~

- ~~a. in compliance with the pertinent federal OTC Tentative Final Monograph or Final Monograph as to dosage, labeling, and ingredient formulation, or~~
- ~~b. the drug product is marketed pursuant to a federal Food and Drug Administration-approved new drug application or its equivalent.~~

B. 1. The following nonnarcotic substances, which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C., Section 301), be lawfully sold over the counter without a prescription, are excluded from all schedules of controlled substances under this title:

- a. Breathe-Aid,
- b. BronCare,
- c. Bronchial Congestion,
- d. Bronkaid Tablets,
- e. Bronkaid Dual Action Caplets,
- f. Bronkotabs,
- g. Bronkolixir,
- h. NeoRespin,
- i. Pazo Hemorrhoid Ointment and Suppositories;
- j. Primatene Tablets,
- k. Primatene "Dual Action" Formula,
- l. Quelidrine,
- m. Resp, and
- n. Vatronal Nose Drops.

2. At the request of any person, the Director may exempt any other drug product containing ephedrine from being included as a Schedule IV controlled substance if such product:

- a. is labeled and marketed in a manner consistent with the pertinent OTC tentative final or final monograph issued by the FDA, and
- b. is manufactured and distributed for legitimate medicinal use and in a manner that reduces or eliminates the likelihood of abuse.

3. In making a determination regarding a drug product, the Director, after notice and hearing, shall consider the following:

- a. the history and current pattern of abuse,
- b. the name and labeling of the product,
- c. the intended manner of distribution, advertising and promotion of the product, and
- d. other factors as may be relevant to and consistent with the public health and safety.

4. The hearing shall be held in accordance with the Oklahoma Administrative Procedures Act.

5. A list of current drug products meeting exemption requirements under this subsection may be obtained from the Bureau upon written request.

C. The Board of Pharmacy may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection A of this section from the application of all or any part of the Uniform Controlled Dangerous Substances Act, Section 2-101 et seq. of this title, if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity,

proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

SECTION 2. AMENDATORY 63 O.S. 1991, Section 2-309, is amended to read as follows:

Section 2-309. A. 1. Except for dosages medically required for a period not to exceed forty-eight (48) hours which are administered by or on direction of a practitioner, other than a pharmacist, or medication dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled dangerous substance included in Schedule II, which is a prescription drug as determined under regulation promulgated by the Board of Pharmacy, may be dispensed without the written prescription of a practitioner; provided, that, in emergency situations, as prescribed by the Board of Pharmacy by regulation, such drug may be dispensed upon oral prescription reduced promptly to writing and filed by the pharmacist in a manner to be prescribed by rules and regulations of the Director.

2. The transmission of written prescription by practitioner to dispensing pharmacy by facsimile is permitted only under the following conditions:

- a. for Schedule II drugs, the original prescription must be presented and verified against the facsimile at the time the substances are actually dispensed, and the original document must be properly annotated and retained for filing, and
- b. for drugs in Schedules III and IV, a facsimile copy of a written, signed prescription transmitted directly by the prescribing practitioner to the pharmacy can serve as an original prescription except:

(1) home infusion pharmacy may consider the facsimile to be a "written prescription" as required by this Act and as required by Title 21 U.S.C., Section 829(a). The facsimile copy of the prescription shall be retained as an original prescription, and it must contain all the information required by this act and 21 CFR, Section 1306.05(a), including date issued, the patient's full name and address, and the practitioner's name, address, DEA registration number, and signature. The exception to the regulations for home infusion/IV therapy is intended to facilitate the means by which home infusion pharmacies obtain prescriptions for patient's requiring the frequently modified parenteral controlled release administration of narcotic substances, but does not extend to the dispensing of oral dosage units of controlled substances, and

(2) the same exception is granted to patients in Long Term Care facilities (LTCF), which are filled by and delivered to the facility by a dispensing pharmacy.

3. Prescriptions shall be retained in conformity with the requirements of this section and Section 2-307 of this title. No prescription for a Schedule II substance may be refilled.

B. 1. Except for dosages medically required for a period not to exceed forty-eight (48) hours which are administered by or on direction of a practitioner, other than a pharmacist, or medication dispensed directly by a practitioner, other than a pharmacist, to an

ultimate user, no controlled dangerous substance included in Schedule III or IV, which is a prescription drug as determined under regulation promulgated by the Board of Pharmacy, may be dispensed without a written or oral prescription.

2. A written or oral prescription for a controlled dangerous substance in Schedule III or IV may not be filled or refilled more than six (6) months after the date thereof or be refilled more than five times after the date of the prescription, unless renewed by the practitioner.

C. No controlled dangerous substance included in Schedule V may be distributed or dispensed other than for a legitimate medical or scientific purpose.

D. Except for dosages medically required for a period not to exceed forty-eight (48) hours which are administered by or on direction of a practitioner, other than a pharmacist, or medication dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, tincture opium camphorated, commonly known as paregoric, may not be dispensed without a written or oral prescription. The refilling of a prescription for paregoric shall be unlawful unless permission is granted by the prescriber, either written or oral.

E. Whenever it appears to the Director that a drug not considered to be a prescription drug under existing state law or regulation of the Board of Pharmacy should be so considered because of its abuse potential, he shall so advise the Board of Pharmacy and furnish to him all available data relevant thereto.

F. "Prescription", as used herein, means a written or oral order by a practitioner to a pharmacist for a controlled dangerous substance for a particular patient, which specifies the date of its issue, and the full name and address of the patient; if the

controlled dangerous substance is prescribed for an animal, the species of the animal; the name and quantity of the controlled dangerous substance prescribed; the directions for use; the name and address of the owner of the animal and, if written, the signature of the practitioner.

G. No person shall solicit, dispense, receive or deliver any controlled dangerous substance through the mail, unless the ultimate user is personally known to the practitioner and circumstances clearly indicate such method of delivery is in the best interest of the health and welfare of the ultimate user.

SECTION 3. AMENDATORY 63 O.S. 1991, Section 2-407, is amended to read as follows:

Section 2-407. A. No person shall obtain or attempt to obtain any preparation excepted from the provisions of the Uniform Controlled Dangerous Substances Act pursuant to Section 2-313 of this title in a manner inconsistent with the provisions of paragraph 1 of subsection B of Section 2-313 of this title, or a controlled dangerous substance or procure or attempt to procure the administration of a controlled dangerous substance:

1. By fraud, deceit, misrepresentation, or subterfuge;

2. By the forgery ~~or~~ of, alteration of, adding any information to or changing any information on a prescription or of any written order;

3. By the concealment of a material fact; or

4. By the use of a false name or the giving of a false address.

B. Except as authorized by this act, a person shall not manufacture, create, deliver, or possess with intent to manufacture, create, or deliver or possess a prescription form, an original prescription form, or a counterfeit prescription form. This shall not apply to the legitimate manufacture or delivery of prescription

forms, or a person acting as an authorized agent of the practitioner.

C. Information communicated to a physician in an effort unlawfully to procure a controlled dangerous substance, or unlawfully to procure the administration of any such drug, shall not be deemed a privileged communication.

~~C.~~ D. Any person who violates this section is guilty of a felony punishable by imprisonment for not more than ten (10) years, by a fine of not more than Ten Thousand Dollars (\$10,000.00) or both such fine and imprisonment. A second or subsequent offense under this section is a felony punishable by imprisonment for not less than four (4) nor more than twenty (20) years, by a fine of not more than Twenty Thousand Dollars (\$20,000.00) or both such fine and imprisonment.

~~D.~~ E. Convictions for second or subsequent violations of this section shall not be subject to statutory provisions for suspended sentences, deferred sentences, or probation.

SECTION 4. 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.

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