STATE OF OKLAHOMA

2nd Session of the 53rd Legislature (2012)

SENATE BILL 1281 By: Wyrick

AS INTRODUCED

An Act relating to pseudoephedrine; amending 63 O.S. 2011, Sections 2-208 and 2-212, which relate to the Uniform Controlled Dangerous Substances Act; adding pseudoephedrine to Schedule III; providing for certain exception; defining terms; deleting pseudoephedrine from Schedule V; deleting procedures for sale of certain products; amending 63 O.S. 2011, Sections 2-309C and 2-309D, which relate to the Anti-Drug Diversion Act; deleting reporting and monitoring requirements for dispensers and registrants who dispense certain product; and providing an effective date.

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

SECTION 1. AMENDATORY 63 O.S. 2011, Section 2-208, is amended to read as follows:

Section 2-208. The controlled substances listed in this section are included in Schedule III.

A. Unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following substances or any other substance having a potential for abuse associated with a stimulant or depressant effect on the central nervous system:

1. Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid unless specifically excepted or unless listed in another schedule;

2. Chlorhexadol;

3. Glutethimide;

4. Lysergic acid;

5. Lysergic acid amide;

6. Methyprylon;

7. Sulfondiethylmethane;

8. Sulfonethylmethane;

9. Sulfonmethane;

10. Benzephetamine and its salts;

11. Chlorphentermine and its salts;

12. Clortermine;

13. Mazindol;

14. Phendimetrazine;

15. Phenylacetone (P2P);

16. 1-Phenycyclohexylamine;

17. 1-Piperidinocychexanecarbo nitrile (PCC);

18. Ketamine, its salts, isomers, and salts of isomers;

19. Any material, compound, mixture, or preparation which contains any quantity of the following hormonal substances or steroids, including their salts, isomers, esters and salts of isomers and esters, when the existence of these salts, isomers,

esters, and salts of isomers and esters is possible within the specific chemical designation:

a. Boldenone,

b. Chlorotestosterone,

c. Clostebol,

d. Dehydrochlormethyltestosterone,

e. Dihydrotestosterone,

f. Drostanolone,

g. Ethylestrenol,

h. Fluoxymesterone,

i. Formebolone,

j. Mesterolone,

k. Methandienone,

l. Methandranone,

m. Methandriol,

n. Methandrostenolone,

o. Methenolone,

p. Methyltestosterone, except as provided in subsection E of this section,

q. Mibolerone,

r. Nandrolone,

s. Norethandrolone,

t. Oxandrolone,

u. Oxymesterone,

v. Oxymetholone,

w. Stanolone,

x. Stanozolol,

y. Testolactone,

z. Testosterone, except as provided in subsection E of this section, and

aa. Trenbolone;

20. Tetrahydrocannibinols;

21. Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act;

22. Buprenorphine; ~~or~~

23. Hydrocodone with another active ingredient; or

24. Any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers.

Livestock implants as regulated by the Federal Food and Drug Administration shall be exempt.

B. Nalorphine.

C. Unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

1. Not more than one and eight-tenths (1.8) grams of codeine or any of its salts, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

2. Not more than one and eight-tenths (1.8) grams of codeine or any of its salts, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

3. Not more than one and eight-tenths (1.8) grams of dihydrocodeine or any of its salts, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

4. Not more than three hundred (300) milligrams of ethylmorphine or any of its salts, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

5. Not more than five hundred (500) milligrams of opium per one hundred (100) milliliters or per one hundred (100) grams, or not more than twenty-five (25) milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; or

6. Not more than fifty (50) milligrams of morphine or any of its salts, per one hundred (100) milliliters or per one hundred

(100) grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

D. The Board of Pharmacy may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections A and B of this section from the application of all or any part of the Uniform Controlled Dangerous Substances Act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or 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 stimulant or depressant effect on the central nervous system.

E. The following hormonal substances or steroids are exempt from classification as Schedule III controlled dangerous substances:

1. Estratest, containing 1.25 mg esterified estrogens and 2.5 mg methyltestosterone;

2. Estratest HS, containing 0.625 mg esterified estrogens and 1.25 mg methyltestosterone;

3. Premarin with Methyltestosterone, containing 1.25 mg conjugated estrogens and 10.0 mg methyltestosterone;

4. Premarin with Methyltestosterone, containing 0.625 mg conjugated estrogens and 5.0 mg methyltestosterone;

5. Testosterone Cypionate - Estrodiol Cypionate injection, containing 50 mg/ml Testosterone Cypionate; and

6. Testosterone Enanthate - Estradiol Valerate injection, containing 90 mg/ml Testosterone Enanthate and 4 mg/ml Estradiol Valerate.

F. This section shall not apply to any compounds, mixtures, or preparations which are in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. For purposes of this section:

1. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension, which, in the case of pseudoephedrine, is suspended in a matrix of glycerin, polyethylene glycol, and propylene glycol, along with other liquid substances. Regardless of product manufacturer labeling, a gelatin-covered solid does not constitute a gel capsule under this definition; and

2. "Active ingredient" shall include the matrix of glycerin, polyethylene glycol, and propylene glycol that is found in liquid capsules.

SECTION 2. AMENDATORY 63 O.S. 2011, Section 2-212, is amended to read as follows:

Section 2-212. A. The controlled substances listed in this section are included in Schedule V.

~~1.~~ Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also

contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

~~a. not~~

1. Not more than two hundred (200) milligrams of codeine, or any of its salts, per one hundred (100) milliliters or per one hundred (100) grams~~,~~;

~~b. not~~

2. Not more than one hundred (100) milligrams of dihydrocodeine, or any of its salts, per one hundred (100) milliliters or per one hundred (100) grams~~,~~;

~~c. not~~

3. Not more than one hundred (100) milligrams of ethylmorphine, or any of its salts, per one hundred (100) milliliters or per one hundred (100) grams~~,~~;

~~d. not~~

4. Not more than two and five-tenths (2.5) milligrams of diphenoxylate and not less than twenty-five (25) micrograms of atropine sulfate per dosage unit~~, or~~;

~~e. not~~

5. Not more than one hundred (100) milligrams of opium per one hundred (100) milliliters or per one hundred (100) grams~~.~~; or

~~2. Any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers. If any compound, mixture, or preparation as specified in this paragraph is dispensed, sold, or distributed in a pharmacy:~~

~~a. it shall be dispensed, sold, or distributed only by, or under the supervision of, a licensed pharmacist or a registered pharmacy technician, and~~

~~b. any person purchasing, receiving, or otherwise acquiring any compound, mixture, or preparation shall produce a driver license, passport, military identification, or other state-issued identification card and shall sign a written log, receipt, or other program or mechanism approved by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, showing:~~

~~(1) the date of the transaction,~~

~~(2) name of the purchaser,~~

~~(3) driver license number, passport, military identification, or state-issued identification number and state of residence of the purchaser,~~

~~(4) name and initials of the pharmacist or pharmacy technician conducting the transaction,~~

~~(5) the product being sold, and~~

~~(6) total quantity, in grams or milligrams, of pseudoephedrine purchased.~~

~~No person shall purchase, receive, or otherwise acquire more than nine (9) grams of any product, mixture, or preparation within any thirty-day period. Provided, the requirements of this subsection shall not apply to any quantity of such product, mixture or preparation dispensed pursuant to a valid prescription.~~

~~3.~~ 6. Any compound, mixture, or preparation containing any detectable quantity of pregabalin.

B. ~~The Schedule, as specified in paragraph 2 of subsection A, shall not apply to any compounds, mixtures, or preparations which are in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient.~~

~~C.~~ The Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, by rule, may exempt other products from this Schedule which the Director finds are not used in the illegal manufacture of methamphetamine or other controlled dangerous substances. A manufacturer of a drug product may apply for removal of the product from the Schedule if the product is determined by the Director to have been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

~~D. As used in this section:~~

~~1. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension, which, in the case of pseudoephedrine, is suspended in a matrix of glycerin, polyethylene glycol, and propylene glycol, along with other liquid substances. Regardless of product manufacturer labeling, a gelatin-covered solid does not constitute a gel capsule under this definition; and~~

~~2. "Active ingredient" shall include the matrix of glycerin, polyethylene glycol, and propylene glycol that is found in liquid capsules.~~

SECTION 3. AMENDATORY 63 O.S. 2011, Section 2-309C, is amended to read as follows:

Section 2-309C. A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance including any compound mixture or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers when dispensed pursuant to a valid prescription shall transmit to a central repository designated by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control using the American Society for Automation in Pharmacy's (ASAP) Telecommunications Format for Controlled Substances version designated in rules by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, the following information for each dispensation:

1. Recipient's name;

2. Recipient's address;

3. Recipient's date of birth;

4. Recipient's identification number;

5. National Drug Code number of the substance dispensed;

6. Date of the dispensation;

7. Quantity of the substance dispensed;

8. Prescriber's United States Drug Enforcement Agency registration number;

9. Dispenser's registration number; and

10. Other information as required by administrative rule.

B. The information required by this section shall be transmitted:

1. In a format or other media designated acceptable by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control; and

2. Within twenty-four (24) hours of the time that the substance is dispensed. Beginning January 1, 2012, all information shall be submitted on a real-time log.

C. When a prescription is written or dispensed to a resident of a nursing home or a person who is under the care of a hospice program licensed pursuant to the provisions of the Oklahoma Hospice Licensing Act who does not have an identification card issued by the state or another form of a recipient identification number pursuant to Section 2-309B of this title, a Social Security number may be used for the purpose of complying with the reporting requirements provided for in this section.

D. The provisions of subsection B of this section shall not apply to a nonresident drug outlet registered pursuant to the Oklahoma Pharmacy Act or to a resident drug outlet as defined in Section 353.1 of Title 59 of the Oklahoma Statutes if the nonresident or resident drug outlet mails or delivers a controlled substance to a patient or client. Nonresident and resident drug outlets shall transmit the information required in this section within seven (7) days of the date that the controlled substance is dispensed.

E. Willful failure to transmit accurate information as required by this section shall be a misdemeanor punishable, upon conviction, by not more than one (1) year in the county jail, or by a fine of not more than One Thousand Dollars ($1,000.00), or by both such imprisonment and fine, or administrative action may be taken pursuant to Section 2-304 of this title.

F. The Director of the Bureau shall have the authority to allow paper submissions on a form designated by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, if the dispenser has an appropriate hardship.

~~G. The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control is authorized, by any funds available to it, to implement a real-time electronic logbook to monitor the sale of nonprescription Schedule V products containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical~~

~~isomers. Dispensers of such pseudoephedrine products shall report all such sales electronically pursuant to rules promulgated by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.~~

~~H. The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall have the authority to adopt rules for the reporting of sales of Schedule V product containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers.~~

SECTION 4. AMENDATORY 63 O.S. 2011, Section 2-309D, is amended to read as follows:

Section 2-309D. A. The information collected at the central repository pursuant to the Anti-Drug Diversion Act shall be confidential and shall not be open to the public. Access to the information shall be limited to:

1. Peace officers certified pursuant to Section 3311 of Title 70 of the Oklahoma Statutes who are employed as investigative agents of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

2. The United States Drug Enforcement Administration Diversion Group Supervisor;

3. The executive director or chief investigator, as designated by each board, of the following state boards:

a. Board of Podiatric Medical Examiners,

b. Board of Dentistry,

c. State Board of Pharmacy,

d. State Board of Medical Licensure and Supervision,

e. State Board of Osteopathic Examiners,

f. State Board of Veterinary Medical Examiners, and

g. Oklahoma Health Care Authority;

provided, however, that the executive director or chief investigator of each of these boards shall be limited to access to information relevant to licensees of the employing board of such executive director or chief investigator; and

4. A multicounty grand jury properly convened pursuant to the Multicounty Grand Jury Act~~, Sections 350 through 363 of Title 22 of the Oklahoma Statutes~~.

B. This section shall not prevent the disclosure, at the discretion of the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, of investigative information to peace officers and investigative agents of federal, state, county or municipal law enforcement agencies, district attorneys and the Attorney General in furtherance of criminal investigations or prosecutions within their respective jurisdictions, and to registrants in furtherance of efforts to guard against the diversion of controlled dangerous substances.

C. Any unauthorized disclosure of any information collected at the central repository provided by the Anti-Drug Diversion Act shall be a misdemeanor. Violation of the provisions of this section shall

be deemed willful neglect of duty and shall be grounds for removal from office.

D. Notwithstanding the provisions of subsection B, registrants shall have no requirement or obligation to access or check the information in the central repository prior to dispensing or administering medications or as part of their professional practices. Registrants shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central repository and no lawsuit may be predicated thereon. ~~Nothing herein shall be construed to relieve a registrant from any duty to monitor and report the sales of certain products pursuant to subsection E of Section 2-309C of this title.~~

E. Information regarding nonfatal overdoses, other than statistical information as required by Section 2-106 of this title, shall be completely confidential. Access to this information shall be strictly limited to the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or designee, the Chief Medical Examiner, and the registrant that enters the information. Registrants shall not be liable to any person for a claim of damages for information reported pursuant to the provisions of Section 2-105 of this title.

SECTION 5. This act shall become effective November 1, 2012.

53-2-2093 JM 1/17/2012 3:42:51 PM