SENATE BILL No. 315

Introduced by Senator Wright

February 14, 2011

An act to amend Sections 11100 and 11106 of, and to add Section 11375.5 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 315, as introduced, Wright. Ephedrine and pseudoephedrine.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, and specified related drugs within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified.

This bill would provide, in addition, that any person who obtains ephedrine, pseudoephedrine, phenylpropanolamine, and specified related drugs without a prescription, as specified, shall be guilty of an infraction or a misdemeanor. The bill would make conforming changes to related provisions. By creating new crimes or revising the penalties for existing crimes involving ephedrine, pseudoephedrine, and specified related drugs, this bill would impose a state-mandated local program.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11100 of the Health and Safety Code is amended to read:

11100. (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.
(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.

(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.
(37) Iodine or tincture of iodine.
(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).
(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.
(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to

any person or business entity in this state or any other state, shall require (A) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (B) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the ~~California Department of Health Services~~ *State Department of Public Health*; registration number issued by the ~~Federal~~ *federal* Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the ~~California~~ Department of Justice; driver's license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) Any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

~~(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.~~

~~(B)~~

(6) Any ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product~~ *sale, transfer, furnishing, or receipt of a product specified in Section 11375.5 pursuant to prescription shall not be subject to the reporting or permitting requirements of this section, unless a product is* subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States ~~Code~~ *Code, in which case the product* shall similarly no longer be exempt from any state reporting or permitting ~~requirement,~~ *requirement* unless otherwise reinstated pursuant to subdivision (d) ~~or (e)~~ of Section 814 of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) ~~Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it~~ *It* is unlawful for any manufacturer, wholesaler, retailer, or other person *or entity in this state* to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) ~~Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it~~ *It* is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

~~(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.~~

~~(4)~~

(3) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of ~~phenylpropanolamine or pseudoephedrine~~ *any product specified in Section 11375.5* per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of ~~which, as~~ *which include being* a distributor of ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales,~~ *any product specified in Section 11375.5 upon prescription only, except for pediatric liquids*, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

~~(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.~~

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

SEC. 2. Section 11106 of the Health and Safety Code is amended to read:

11106. (a) (1) (A) Any manufacturer, wholesaler, retailer, or ~~any~~ other person or entity in this state that sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. For any substance added to the list set forth in subdivision (a) of Section 11100 on or after January 1, 2002, the Department of Justice may postpone the effective date of the requirement for a permit for a period not to exceed six months from the listing date of the substance.

(B) An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1.

(C) This paragraph shall not apply to any manufacturer, wholesaler, or wholesale distributor who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice; any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian; any state-licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food-animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(D) This paragraph shall not apply to the sale, transfer, furnishing, or receipt of any betadine or povidone solution with

an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

~~(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.~~

~~(3)~~

(2) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).~~ *any product as specified in Section 11375.5.*

(b) (1) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department.

(2) The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require applicants or permittees to reveal

their chemical processes that are typically considered trade secrets and proprietary business information.

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

(d) An application may be denied, or a permit may be revoked or suspended, for reasons which include, but are not limited to, the following:

(1) Materially falsifying an application for a permit or an application for the renewal of a permit.

(2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision (a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States.

(3) Failure to maintain effective controls against the diversion of precursors to unauthorized persons or entities.

(4) Failure to comply with this article or any regulations of the department adopted thereunder.

(5) Failure to provide the department, or any duly authorized federal or state official, with access to any place for which a permit has been issued, or for which an application for a permit has been submitted, in the course of conducting a site investigation, inspection, or audit; or failure to promptly produce for the official conducting the site investigation, inspection, or audit any book, record, or document requested by the official.

(6) Failure to provide adequate documentation of a legitimate business purpose involving the applicant’s or permittee’s use of any substance listed in subdivision (a) of Section 11100.

(7) Commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions, or duties of a permitholder.

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management,

or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

(e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged pursuant to Section 1203.4 of the Penal Code, and any arrests pending adjudication.

(f) The department may retain jurisdiction of a canceled or expired permit in order to proceed with any investigation or disciplinary action relating to a permittee.

(g) The department may grant permits on forms prescribed by it, which shall be effective for not more than one year from the date of issuance and which shall not be transferable. Applications and permits shall be uniform throughout the state, on forms prescribed by the department.

(h) Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department.

(i) A permit granted pursuant to this article may be renewed one year from the date of issuance, and annually thereafter, following the timely filing of a complete renewal application with all supporting documents, the payment of a permit renewal fee not to exceed the application processing costs of the department, and a review of the application by the department.

(j) Selling, transferring, or otherwise furnishing or obtaining any substance specified in subdivision (a) of Section 11100 without a permit is a misdemeanor or a felony.

(k) (1) No person under 18 years of age shall be eligible for a permit under this section.

(2) No business for which a permit has been issued shall employ a person under 18 years of age in the capacity of a manager, agent, or representative.

(*l*) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

(2) In the event of subsequent changes in ownership, management, or employment, the permittee shall notify the department in writing within 15 calendar days of the changes, and shall submit one set of 10-print fingerprints for each individual not previously fingerprinted under this section.

SEC. 3. Section 11375.5 is added to the Health and Safety Code, to read:

11375.5. (a) Any person who obtains any substance specified in subdivision (b), unless upon the prescription of a physician, dentist, podiatrist, or veterinarian, licensed to practice in this state, shall be guilty of an infraction or a misdemeanor.

(b) This section shall apply to any material, compound, mixture, or preparation containing ephedrine, pseudoephedrine, norpseudoephedrine, phenylpropanolamine, N-methylephedrine, N-ethylephedrine, N-methylpseudoephedrine, N-ethylpseudoephedrine, chloroephedrine, or chloropseudoephedrine, except for pediatric liquid forms as specified in subdivision (h) of Section 11100.

(c) This section shall not be construed to prevent prosecution under any other applicable law.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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