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Legislation and Regulation Committee

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LEGISLATION AND REGULATION COMMITTEE

The Committee has not met in the past quarter.

PART 1: LEGISLATION REPORT

The California Legislature reconvened for the 2011-2012 Session on January 3, 2011.

a. Board Sponsored Legislation

1. 2011 Omnibus Proposal to Amend Section 4200 – Remove Obsolete Reference to Previous Pharmacist Licensing Requirement

ATTACHMENT 1

At the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code Section 4200. Staff has submitted language to the Senate Committee on Business, Professions and Economic Development for inclusion in the committee's omnibus bill. A copy of the language approved by the board is provided in **Attachment 1**.

2. Section 4362 – Entry Into the Pharmacists Recovery Program

ATTACHMENT 2

The board's Disciplinary Guidelines specify that a licensee who participates in the Pharmacists Recovery Program is responsible for the cost of that person's participation. At the October 2010 Board Meeting, the board voted to pursue a statutory change to specify that a participant shall pay to the Pharmacists Recovery Program a portion of the monthly administrative co-pay charged by the program. The language approved by the board is provided in Attachment 2.

3. Sections 4040.5, 4081, and 4126.5 – Proposal Regarding the Return of Medicine via Reverse Distributors

ATTACHMENT 3

Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. The board voted in January 2010 to pursue sponsorship of such legislation, to include the provisions below, but they were not picked up in the prior session. Board staff is working to secure an author to carry these provisions. A copy of the language approved by the board is provided in **Attachment 3**, as well as a Fact Sheet developed by the board**.**

a. Amend section 4040.5 – Reverse Distributor

   Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

b. Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

   Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

c. Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

   Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall.

4. Section 4104, 4105 and 4112 – Enforcement Enhancements

ATTACHMENT 4

In January 2010 the board voted to pursue statutory changes as outlined in Sections 4104 and 4112. Proposed amendments to § 4105 mirror those contained in proposed changes to § 4081, related to the production of records, when requested by the board.

A copy of the language approved by the board is provided in Attachment 4. Staff is working to secure an author to carry these provisions.

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

   Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

   Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board

c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

   Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

b. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

ATTACHMENT 5

1. <u>SB 41 (Yee) – Disposal of Hypodermic Needles and Syringes</u>

   Senate Bill 41 is a reintroduction of Senator Yee's (prior session) SB 1029. The Governor vetoed SB 1029 stating the bill would remove the ability of local officials to best determine policies in their jurisdiction. The board did not take a position on SB 1029.

   As introduced, SB 41 would allow a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 30 years of age or older. The bill addresses the storage of products to ensure they would be available only to authorized personnel, would require that disposal options are provided to consumers, and would require pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

   The bill has been double-referred to the Senate Committees on Health, and Public Safety. A copy of the bill and the author's Fact Sheet is provided in **Attachment 5**.

2. <u>AB 36 (Hill) – Retail Sale of Ephedrine; Transmission of Sale Data to NPLEx</u>

   Assembly Bill 36 would specify that it is a crime for any retail distributor to distribute specified amounts of nonprescription products containing ephedrine, except pursuant to a prescription. The bill would further require retail distributors to transmit sale data to the National Precursor Log Exchange (NPLEx), would require the California Department of Justice to enter into an MOU with the NPLEx, and would restrict the use of the information reported.

   In the prior session, Assembly Member Hill carried AB 1455 to implement similar provisions; the bill died in committee.

   AB 36 has been referred to the Assembly Committee on Public Safety. A copy of the bill is provided in Attachment 5.

Attachment 1

California State Board of Pharmacy
2011 – Omnibus Proposal
Senate Committee on Business, Professions & Economic Development

Proposal to Amend § 4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

§ 4200. (a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has ~~passed a written and practical examination given by the board prior to December 31, 2003, or has~~ passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Attachment 2

Proposal to amend §4362 to establish a co-pay

§ 4362. Entry into the Pharmacists Recovery Program

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of $125 monthly to cover a portion of the administrative costs borne by the board to contract for these services. This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

Attachment 3

§ 4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned **by the patient or the patient's agent** to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient **or a patient's agent** to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler **as defined in Health and Safety Code section (insert number here)**.

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

§ 4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(8) A licensed integrated waste hauler, as defined in Health and Safety Code section (insert section number), for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy.

§ 4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all drugs returned to a wholesaler or provided to a reverse distributor shall document the quantity **or weight** of **the** drugs returned, the date **the drugs were returned** and **the names of the reverse distributors or wholesalers** ~~entity~~ to **whom** the drugs were provided. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the date and name of the licensed **integrated** waste hauler. **For the purpose of this section, "licensed integrated waste hauler" means a person or entity as defined in Health and Safety Code section (insert number here)**.

CALIFORNIA STATE
BOARD OF PHARMACY

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CALIFORNIA STATE BOARD OF PHARMACY

DISPOSAL OF PRESCRIPTION DRUGS

SUMMARY

Californians need a safe, efficient and effective method of disposing of unwanted, expired, or unused prescription drugs (i.e., pharmaceutical waste). This is especially true when a drug recall is issued by the U.S. Food and Drug Administration or is voluntarily issued by a manufacturer

Without a safe and effective method for disposal, prescription drugs may be left indefinitely in medicine cabinets where they pose a threat of potential prescription drug misuse or abuse. As a matter of public protection, it is vital that unwanted or expired prescription drugs not be diverted to or used by unauthorized users, or re-enter the drug supply chain.

This proposal will authorize a pharmacy to utilize a licensed hazardous waste hauler for the purpose of disposing of pharmaceutical waste that is returned to the pharmacy, and also specifies records that must be maintained regarding the disposal of these drugs.

BACKGROUND

The Office of National Drug Control Policy, the Health and Human Services Agency and the Environmental Protection Agency urges American's to use pharmaceutical take-back locations to dispose of prescription drugs, yet few programs exist.

In California, several local governments, water districts, law enforcement agencies and non-profit organizations organize singular prescription take-back events.

The U.S. Drug Enforcement Agency also coordinates drug take-back events for controlled substances.

The U.S. Geological Survey conducted a study in 2002 resulting in measurable concentrations of prescription and non-prescription drugs, steroids, and reproductive hormones in a sampling of streams across 30 states.

In December 2008, the California Integrated Waste Management Board issued guidelines to establish minimum requirements for model disposal programs for waste pharmaceuticals, and modified guidelines were released in February 2009. These guidelines apply to facilities that wish to establish take-back programs.

Currently, a pharmacy can return dangerous drugs that have not yet been dispensed to a manufacturer or wholesaler – but a pharmacy cannot return drugs in this manner once they have been dispensed to a patient.

This proposal will specify the method by which a pharmacy can dispose of previously-dispensed pharmaceutical waste, and also establishes record keeping requirements for such disposal.

CONTACT

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Attachment 4

PROVISION 1:

Amend §4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures

Why Needed: when a pharmacy identifies a theft of drugs by an employee, the pharmacy would be required to provide the board with an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results. This would greatly aid the board in pursuing prosecution more quickly.

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report <u>and provide</u> to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. <u>As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board.</u>
(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

PROVISION 2:

Amend §4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(b) When requested by an inspector or authorized representative of the board, the owner, corporate officers, or manager of any entity licensed by the board shall provide the board with records as requested within 72 hours of the request. The entity may request an extension of this timeframe for a period up to 14 days. Such a request must be made in writing and is subject to approval.

~~(e)~~ (f) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

~~(f) This section shall become operative on January 1, 2006.~~

PROVISION 3:

Amend §4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Why Needed: To prevent an individual whose pharmacist license has been revoked in California from working in another state as a pharmacist to dispense medication mailed to patients in California. Mail order is one way many patients receive medication from their health plans. If California revokes a pharmacist from practicing in this state, it undermines the board's public protection efforts if the pharmacist can still dispense medication to California patients from outside the state.

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.

~~(d)~~ (e) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

~~(e)~~ (f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

~~(f)~~ (g) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~ (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~ (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~ (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

Attachment 5

SENATE BILL No. 41

Introduced by Senator Yee

December 7, 2010

An act to amend Sections 4145 and 4148 of, and to repeal Section 4140 of, the Business and Professions Code, and to amend Section 11364 of, to add Section 121281 to, and to repeal Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 41, as introduced, Yee. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes, and requires, with certain exceptions, a prescription to purchase a hypodermic needle or syringe for human use. Existing law prohibits any person from possessing or having under his or her control any hypodermic needle or syringe, except in accordance with those regulatory provisions.

This bill would delete the prohibition against any person possessing or having under his or her control any hypodermic needle or syringe, except in accordance with the aforementioned regulatory provisions.

Existing law, beginning January 1, 2011, and ending December 31, 2018, authorizes a county or city to authorize a licensed pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person 18 years of age or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with a local health department in the Disease Prevention Demonstration Project, established by law to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of bloodborne pathogens, including HIV and hepatitis C.

This bill would, instead, delete the December 31, 2018, repeal date and permit a physician or pharmacist, without a prescription or a permit, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older and would permit a person 18 years of age or older, without a prescription or license, to obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist. This bill would make conforming changes, including the elimination of the Disease Prevention Demonstration Project.

Under existing law, it is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking specified controlled substances.

Existing law, beginning January 1, 2011, and ending December 31, 2018, provides that the above-described provisions, pursuant to authorization from a city or county, shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes.

This bill would, instead, delete the December 31, 2018, repeal date and provide that the above-described provisions making it unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia for unlawfully injecting or smoking certain controlled substances shall not apply to possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

This bill would require the state Office of AIDS to develop and maintain information on its Internet Web site to educate consumers at risk of bloodborne infections of opportunities to improve and protect their health, and to protect the public health and would also require the California State Board of Pharmacy to post, or post a link to, this information on its Internet Web site.

The Pharmacy Law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes. Existing law makes it a crime to knowingly violate any provision relating to the Pharmacy Law.

This bill would amend the Pharmacy Law to require pharmacies that furnish nonprescription hypodermic needles and syringes to store the hypodermic needles and syringes in a manner that ensures that they are not accessible to unauthorized persons, and would require pharmacies to provide consumers with prescribed options for consumer disposal of

hypodermic needles and syringes. This bill would also require the pharmacies to provide written information or verbal counseling at the time of furnishing or sale of nonprescription hypodermic needles or syringes, as specified. By changing the definition of an existing crime, this bill would impose a state-mandated local program.

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. It is the intent of the Legislature to improve access to syringes and hypodermic needles so as to remove significant barriers for persons seeking to protect their health and the health of other persons, and to remove barriers for programs or businesses to provide sterile injection equipment and education to adults, thereby reducing the spread of communicable diseases and protecting the public health.

SEC. 2. Section 4140 of the Business and Professions Code is repealed.

~~4140. No person shall possess or have under his or her control any hypodermic needle or syringe except when acquired in accordance with this article.~~

SEC. 3. Section 4145 of the Business and Professions Code is amended to read:

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if ~~one~~ *the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof* of ~~the following requirements is met:~~ *a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.*

~~(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.~~

~~(2) Pursuant to authorization by a county, with respect to all of~~

(b) Notwithstanding any other provision of ~~the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2018,~~ *law, as* a *public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or* pharmacist ~~may furnish~~ *may, without a prescription* or ~~sell 10~~ *a permit, furnish 30* or fewer hypodermic needles ~~or~~ *and* syringes ~~at any one time~~ *for human use* to a person 18 years of age or older ~~if the pharmacist works for a pharmacy that is registered with the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter~~*, and a person 18 years of age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist*.

~~(b)~~

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy that furnishes nonprescription

hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program.

(2) It shall furnish, or make available, mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a personal medical sharps disposal container that meets applicable state and federal standards for disposal of medical sharps waste.

(f) A pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

SEC. 4. Section 4148 of the Business and Professions Code is amended to read:

4148. All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144, or 4145*, or under Section 11364, 121349, or 121349.1 of the Health and Safety Code*.

SEC. 5. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a

container that meets state and federal standards for disposal of sharps waste.

(c) ~~Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, for the period commencing January 1, 2005, and ending December 31, 2018, subdivision (a)~~ *As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section* shall not apply to the possession solely for personal use of ~~10~~ *30* or fewer hypodermic needles or syringes if acquired from ~~an~~ *a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is* authorized ~~source~~ *by law to provide sterile syringes or hypodermic needles without a prescription*.

SEC. 6. Section 121281 is added to the Health and Safety Code, to read:

121281. In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting their health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

SEC. 7. Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code is repealed.

SEC. 8. 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.

O

SB 41 – Yee

HIV & hepatitis prevention: Sterile syringe access

Problem

California is 1 of only 3 states in the US that prohibit a pharmacist from furnishing a syringe to an adult without a prescription. Most states never required a prescription to purchase a sterile syringe, and of those that did, most amended their laws in light of the AIDS epidemic and the clear evidence that shows that allowing adults to access sterile syringes prevents the transmission of HIV, hepatitis C, and other blood-borne diseases, without contributing to increased drug use, drug injection, crime or unsafe discard of syringes.

Sharing of used syringes is the most common cause of new hepatitis C infections in the state (approximately 3,000 per year) and the second most common cause of HIV infection (approximately 750 per year). By the end of 2008, 18 percent of cumulative cases of AIDS among men in the state were attributed to syringe sharing, or among men who have sex with men and also share syringes. Thirty-four percent of cases among women were attributable to sharing syringes. A very high proportion of other cases among women were caused by sexual contact with a man who had shared a used syringe.

These diseases are costly and potentially deadly. Hospitalizations for hepatitis B & C cost the state $2 billion in 2007, according to a 2009 report of California Research Bureau.

The California Department of Public Health (CDPH), the Federal Centers for Disease Control & Prevention, the World Health Organization, and all leading health policy research organizations agree – safe and legal syringe access through pharmacy outlets is a key component to the prevention and control of HIV/AIDS, hepatitis C and hepatitis B.

Existing Law

In 2004, Governor Schwarzenegger signed legislation to create a 5-year pilot project to assess the safety and efficacy of allowing adults to purchase and possess up to 10 syringes without prescription. The law mandates an evaluation be completed by the State Department of Health Services (now CDPH). The pilot projects were only in jurisdictions that authorized participation, and required each county to register pharmacies and to provide them with information on HIV, hepatitis and drug treatment. The mandated evaluation was to be published by January 15, 2010. Though delayed, it is likely to be published before the first policy committee.

Last year, Governor Schwarzenegger singed a bill to extend the sunset until December 31, 2018.

This Bill

SB 41 would lift the sunset and allow physicians and pharmacists statewide the discretion to furnish up to 30 syringes to an adult without a prescription, and to allow an adult to possess up to 30 syringes solely for personal use.

As a cost saving measure, the bill repeals the duties on the county health departments that were part of the pilot, and repeals many CDPH duties. The bill requires CDPH to work with Board of Pharmacy to provide information to pharmacists including information on how to access drug treatment, HIV and hepatitis screening, and on how to dispose of sharps safely.

The legislation makes conforming changes to encourage individuals to possess syringes until such time as they can dispose of syringes safely, without undue fear of arrest or confiscation of their syringes.

Support from previous legislation, SB 1029 (Yee, 2010)

San Francisco AIDS Foundation (Co-Sponsor)
Drug Policy Alliance Network (Co-Sponsor)
AIDS Project Los Angeles
American Civil Liberties Union
Board of Supervisors County of Santa Clara
California Association of Alcohol and Drug Program Executives, Inc.
California Communities United Institute
California Hepatitis Alliance (CalHEP)
California Medical Association
California Nurses Association

Contact: Nicolina Hernandez (916) 651-4008

California Opioid Maintenance Providers
California Pharmacists Association
California Psychiatric Association
California Retailers Association
California Society of Addiction Medicine
City and County of San Francisco
City of West Hollywood
County Alcohol & Drug Program Administrators Association of California
County of Alameda
Equality California
Friends Committee on Legislation of California
Health Officers Association of California
Osteopathic Physicians and Surgeons of California
Planned Parenthood Affiliates of California, Inc.
Planned Parenthood Affiliates of California, Action Fund of San Diego & Riverside Counties
Planned Parenthood Advocacy Project of Los Angeles County
Rite Aid
Republican Liberty Caucus
San Francisco Mayor's Hepatitis C Task Force
Walgreen's
C. Edward Dilkes, attorney
Editorial – AlterNet (5/19/2010)

Support for Safe, Legal Syringe Access

American Academy of Family Physicians
American Academy of Pediatrics
American Academy of Physician Assistants
American Bar Association
American College of Preventive Medicine
American Foundation for AIDS Research
American Medical Association
American Medical Students Association
American Nurses Association
American Pharmaceutical Association
American Psychiatric Association
American Psychological Association
American Public Health Association
American Society of Addiction Medicine
Association of State and Territorial Health Officials
Council of State and Territorial Epidemiologists
Infectious Disease Society of America
International Federation of Red Cross and Red Crescent Societies
Kaiser Foundation
National Alliance of State and Territorial AIDS Directors
National Association for the Advancement of Colored People
National Association of Boards of Pharmacy
National Association of Social Workers
National Association of State Alcohol and Drug Abuse Directors
National Black Caucus of State Legislators
National Black Police Association
United Nations: General Assembly, Office of Drugs and Crime
United Church of Christ
U.S. Conference of Mayors
U.S. Federal Government: Government Accounting Office, Health and Human Services, National Institute on Drug Abuse, National Institutes on Health
World Bank
World Health Organization

Contact: Nicolina Hernandez (916) 651-4008

ASSEMBLY BILL No. 36

Introduced by Assembly Member Hill

December 6, 2010

An act to amend, repeal, and add Section 11100 of, and to add and repeal Section 11100.02 of, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 36, as introduced, Hill. Ephedrine: retail sale.

(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, norpseudoephedrine, or phenylpropanolamine 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. Existing law prohibits the sale of more than 3 packages or 9 grams of a nonprescription product containing ephedrine or the other drugs, as specified.

This bill would instead provide that it is a misdemeanor, punishable as specified, for any retail distributor, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority, to

sell or distribute to a person specified amounts of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within specified time limits, to sell or distribute any of those substances to a person whose information has generated an alert, or, except under specified conditions, to sell or distribute to any purchaser a nonprescription product containing any amount of those substances. The bill would contain provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified. The bill would require retail distributors to transmit sale information to the National Precursor Log Exchange (NPLEx) for purposes of determining whether the sale would violate these provisions. The bill would require the Department of Justice to enter into a memorandum of understanding with the National Association of Drug Diversion Investigators regarding the transaction records in NPLEx, as specified. The bill would provide that the information in the system may not be used for any purpose other than to meet the requirements of, or comply with, this act or a certain federal act, as specified. The bill would specify legislative findings and intent. The bill's provisions would remain in effect only until January 1, 2018. By creating a new crime, 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:

1 SECTION 1. Section 11100 of the Health and Safety Code is
2 amended to read:
3 11100. (a) Any manufacturer, wholesaler, retailer, or other
4 person or entity in this state that sells, transfers, or otherwise
5 furnishes any of the following substances to any person or entity
6 in this state or any other state shall submit a report to the
7 Department of Justice of all of those transactions:
8 (1) Phenyl-2-propanone.
9 (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)~~ *(i)* 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)~~ *(ii)* 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~~ *State* Department of ~~Health Services;~~ *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~~ *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) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to

~~subdivision~~ *subsection* (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 is unlawful for any manufacturer, wholesaler, retailer, or other person 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 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 noncapsulated 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 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 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, 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.~~

(h) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 2. Section 11100 is added to the Health and Safety Code, 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 (i) 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 (ii) 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 State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the 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) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subsection (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 is unlawful for any manufacturer, wholesaler, retailer, or other person 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 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 (A) 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 (B) 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 (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (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 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 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, 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.

(j) This section shall become operative on January 1, 2018.

SEC. 3. Section 11100.02 is added to the Health and Safety Code, to read:

11100.02. (a) Notwithstanding any other law, it is unlawful for any retail distributor to knowingly do the following, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority:

(1) To sell or distribute to the same purchaser within any 30-day period more than nine grams, or within any day more than 3.6 grams, of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in 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 (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(2) To sell or distribute any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to a person whose information has generated an alert as described in paragraph (3) of subdivision (d) regarding that sale.

(3) To sell or distribute to any purchaser a nonprescription product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, except under the following conditions:

(A) The purchaser shall produce valid government-issued photo identification.

(B) The purchaser shall sign a written or electronic log showing the following:

(i) The date and time of the transaction.

(ii) The identification number presented.

(iii) The agency issuing the identification and the type of identification issued.

(iv) The name, date of birth, and address of the purchaser.

(v) The amount of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in the material, compound, mixture, or preparation sold.

(b) The retail distributor shall store any product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine either behind the counter or in a locked cabinet so that the customer does not have access to the product.

(c) (1) To facilitate the monitoring of the sales of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, the retail distributor shall record all of the following information at the point of sale regarding the proposed transaction for the purpose of complying with this section or the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act, and for no other purpose:

(A) The date and time of the transaction.

(B) The identification number of the purchaser, issuing agency of the identification, and the type of identification used.

(C) The name, date of birth, and address of the purchaser verified through a photo identification of the purchaser.

(D) The name, quantity of packages, and total gram weight of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in a product or products purchased, received, or otherwise acquired.

(E) The name or initials of the person making the sale.

(2) Beginning January 1, 2013, the retail distributor shall transmit the information immediately to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI) for purposes of determining whether the proposed sale would violate this section and therefore may not proceed, provided that the NPLEx system is available to retailers in the state without a charge for accessing the system. The transaction information shall not be accessed, stored, or used by the retail distributor for any purpose other than to meet the requirements set forth in this section or to comply with the provisions of the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. The retail distributor shall not maintain a separate copy of the transaction information except as required by the federal Combat Methamphetamine Epidemic Act of 2005.

(3) (A) A retail distributor shall provide notice electronically, in writing, or by signage to purchasers that the information collected pursuant to the federal Combat Methamphetamine

Epidemic Act of 2005 and this section shall be provided to law enforcement for purposes of determining the legality of a proposed sale.

(B) The Legislature finds that it is necessary for probable cause to be demonstrated to trigger an investigation in connection with an individual whose requested purchase is denied by the system a single time.

(4) This subdivision shall not be construed to require a retail distributor to maintain state-required records relating to the sale of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in a separate location or log from records required by federal law to be kept with respect to those products.

(5) The recording requirements specified in this subdivision shall not apply to the sale of a single package containing not more than 60 milligrams of pseudoephedrine, consistent with the federal Combat Methamphetamine Epidemic Act of 2005.

(6) If a retail distributor experiences mechanical or electronic failure of the system and is unable to comply with the recording requirements of this subdivision, the retail distributor shall maintain the required records in a written log or an alternative electronic recordkeeping mechanism until the retail distributor is able to comply with the recording requirements of this subdivision.

(d) (1) Provided that the department executes a memorandum of understanding (MOU) with NADDI governing access, pursuant to this subdivision, NADDI shall forward California transaction records in NPLEx to the Department of Justice weekly and provide real-time access to NPLEx information through the NPLEx online portal to law enforcement in the state as authorized by the department.

(2) The system shall allow retail distributors of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to enter into the database the information specified in subdivision (d) regarding the proposed sale of those products.

(3) The system shall be capable of providing the retail distributor with an immediate real-time alert any time any provision of this section is being violated by a proposed sale.

(4) The MOU shall state that no party to the MOU nor any entity under contract to provide the electronic authorization and

monitoring system shall be authorized to use the information contained in the system for any purpose other than those set forth in this section, the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. However, the system operator shall be authorized to analyze the information for the sole purpose of assessing and improving the performance and efficacy of the system. In addition, the MOU shall require that any retail distributor's access to the electronic authorization and monitoring system's database is limited solely to records of sales transactions made by that retail distributor, which access shall be solely for purposes of complying with the federal Combat Methamphetamine Epidemic Act of 2005 or this section, or to respond to a duly authorized law enforcement request or court order for information collected under that act or this section.

(5) The system's security program shall comply with the security standards for the Criminal Justice Information System of the Federal Bureau of Investigation and may be audited once a year by the department.

(6) A retail distributor's use of the system shall be subject to Section 56.101 of the Civil Code. A retail distributor shall not maintain any records collected under this system for longer than two years, or as otherwise required by the federal Combat Methamphetamine Epidemic Act of 2005.

(7) Law enforcement access to the system shall be recorded by means of a unique access code for each individual accessing the system. Each user's history shall be maintained and may be audited by the department.

(8) The department may submit recommendations to NADDI regarding system changes to assist in identifying false identification cards.

(e) The State Board of Equalization shall notify all retailers about the requirement to submit transactions to NPLEx no later than September 1, 2012.

(f) This section shall not apply to a health care practitioner with prescriptive authority who is currently licensed in this state.

(g) (1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section 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 section, the following terms have the following meanings:

(1) "Department" means the Department of Justice.

(2) "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.

(3) "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.

(4) "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.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as 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, 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 amounts at or below that specified in subdivision (a). "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.

(j) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

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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