



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 23, 2011

To: Legislation and Regulation Committee

Subject: Agenda Item A1 – Board Sponsored Legislation

FOR INFORMATION:

a. Board Sponsored Legislation

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

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. This modification will be inserted into the omnibus bill, which has not yet been introduced.

§ 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.

2. Senate Bill 431 (Emmerson)

Senator Emmerson has authored a bill that contains the following board-sponsored provisions. A copy of the bill follows this memorandum.

The following provisions were created to help secure elements of the Consumer Protection Enforcement Initiative and are currently in SB 431:

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

This provision will specify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. It will also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a copy of the audit results within another 30 days.

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

This provision will 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

This provision would provide that that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

Provisions to be amended into SB 431: Sections 4040.5, 4081, and 4126.5 – Regarding the Return of Medication via Reverse Distributors

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 that includes the provisions below. These but they were not advanced in the prior session. The text for these sections follows the copy of SB 431.

a. Add section 4126.7 – 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.

- 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 hazardous waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines “hazardous waste hauler” for purposes of this section only. .

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

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

Introduced by Senator EmmersonFebruary 16, 2011

An act to amend Sections 4104, 4105, and 4112 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 431, as introduced, Emmerson. Pharmacies: regulation.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for administering and enforcing the provisions of that law, including the licensure of pharmacies, as defined, and nonresident pharmacies that ship, mail, or deliver controlled substances or dangerous drugs or devices, as defined, into this state. The law requires that each pharmacy establish procedures for addressing the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy, and that an entity licensed by the board retain records of the acquisition and disposition of dangerous drugs and devices in a specified manner. The law makes a knowing violation of its provisions a misdemeanor.

This bill would require a pharmacy to conduct an audit of the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy and provide, as specified, the board with a certified copy of the audit and its results. The bill would also require an entity licensed by the board to provide records to designated persons within 72 hours of the time of the request, unless that timeframe is extended by the board. The bill would prohibit a pharmacist whose license was revoked by the board to perform pharmacy duties, as specified, for a nonresident pharmacy.

Because this bill would specify additional requirements under the Pharmacy Law, a violation of which is a crime, it would impose a state-mandated local program by creating additional crimes.

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 4104 of the Business and Professions
- 2 Code is amended to read:
- 3 4104. (a) Every pharmacy shall have in place procedures for
- 4 taking action to protect the public when a licensed individual
- 5 employed by or with the pharmacy is discovered or known to be
- 6 chemically, mentally, or physically impaired to the extent it affects
- 7 his or her ability to practice the profession or occupation authorized
- 8 by his or her license, or is discovered or known to have engaged
- 9 in the theft, diversion, or self-use of dangerous drugs.
- 10 (b) Every pharmacy shall have written policies and procedures
- 11 for addressing chemical, mental, or physical impairment, as well
- 12 as theft, diversion, or self-use of dangerous drugs, among licensed
- 13 individuals employed by or with the pharmacy.
- 14 (c) Every pharmacy shall report *and provide* to the board, within
- 15 30 days of the receipt or development of the following information
- 16 with regard to any licensed individual employed by or with the
- 17 pharmacy:
- 18 (1) Any admission by a licensed individual of chemical, mental,
- 19 or physical impairment affecting his or her ability to practice.
- 20 (2) Any admission by a licensed individual of theft, diversion,
- 21 or self-use of dangerous drugs.
- 22 (3) Any video or documentary evidence demonstrating chemical,
- 23 mental, or physical impairment of a licensed individual to the
- 24 extent it affects his or her ability to practice.
- 25 (4) Any video or documentary evidence demonstrating theft,
- 26 diversion, or self-use of dangerous drugs by a licensed individual.

1 (5) Any termination based on chemical, mental, or physical
2 impairment of a licensed individual to the extent it affects his or
3 her ability to practice.

4 (6) Any termination of a licensed individual based on theft,
5 diversion, or self-use of dangerous drugs.

6 *(d) The pharmacy shall conduct an audit to determine the*
7 *quantity and type of dangerous drugs stolen, diverted, or used by*
8 *a licensed individual employed by or with the pharmacy. The*
9 *pharmacy shall submit to the board a certified copy of the audit*
10 *within 30 days of the receipt or development of information*
11 *described in paragraph (4) of subdivision (c).*

12 ~~(e)~~

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

19 SEC. 2. Section 4105 of the Business and Professions Code is
20 amended to read:

21 4105. (a) All records or other documentation of the acquisition
22 and disposition of dangerous drugs and dangerous devices by any
23 entity licensed by the board shall be retained on the licensed
24 premises in a readily retrievable form.

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

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

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

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

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

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

9 *(f) When requested by an authorized officer of the law or by an*
10 *authorized representative of the board, the owner, corporate*
11 *officer, or manager of an entity licensed by the board shall provide*
12 *the board with the requested records within 72 hours of the time*
13 *the request was made. The entity may request in writing an*
14 *extension of this timeframe for a period not to exceed 14 days from*
15 *the date the records were requested. A request for an extension of*
16 *time is subject to the approval of the board.*

17 SEC. 3. Section 4112 of the Business and Professions Code is
18 amended to read:

19 4112. (a) Any pharmacy located outside this state that ships,
20 mails, or delivers, in any manner, controlled substances, dangerous
21 drugs, or dangerous devices into this state shall be considered a
22 nonresident pharmacy.

23 (b) A person may not act as a nonresident pharmacy unless he
24 or she has obtained a license from the board. The board may
25 register a nonresident pharmacy that is organized as a limited
26 liability company in the state in which it is licensed.

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

35 (d) All nonresident pharmacies shall comply with all lawful
36 directions and requests for information from the regulatory or
37 licensing agency of the state in which it is licensed as well as with
38 all requests for information made by the board pursuant to this
39 section. The nonresident pharmacy shall maintain, at all times, a
40 valid unexpired license, permit, or registration to conduct the

1 pharmacy in compliance with the laws of the state in which it is a
2 resident. As a prerequisite to registering with the board, the
3 nonresident pharmacy shall submit a copy of the most recent
4 inspection report resulting from an inspection conducted by the
5 regulatory or licensing agency of the state in which it is located.

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

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

18 (g) *A nonresident pharmacy shall not permit a pharmacist whose*
19 *license has been revoked by the board to manufacture, compound,*
20 *furnish, sell, dispense, or initiate the prescription of a dangerous*
21 *drug or dangerous device, or to provide any pharmacy-related*
22 *service, to a person residing in California.*

23 ~~(g)~~

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

37 ~~(h)~~

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

40 ~~(i)~~

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

5 (j)

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

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

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An act to amend Sections 4081 and 4126.5 of, and to add Section 4126.7
to, the Business and Professions Code, relating to pharmacies.



110537407470BILL

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4081 of the Business and Professions Code is amended to read:

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) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.



(d) Any record pertaining to the return of dangerous drugs 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 name of the reverse distributor or wholesaler to whom the drugs were provided.

(e) Any record pertaining to the return of dangerous drugs to a hazardous waste hauler, as described in Section 117660 of the Health and Safety Code, shall list the volume in weight or measurement of the pharmaceutical waste returned, the date the waste was returned, and the name of the hazardous waste hauler to whom the waste was provided.

SEC. 2. Section 4126.5 of the Business and Professions Code is amended to read:

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 hazardous waste hauler, as described in Section 117660 of the Health and Safety Code, for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy by a patient or patient's agent.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

SEC. 3. Section 4126.7 is added to the Business and Professions Code, to read:

4126.7. (a) A reverse distributor shall not accept the return of dangerous drugs that have been dispensed to a patient that are later returned by the patient or the patient's agent to the pharmacy or another licensed entity.



(b) Dangerous drugs returned by a patient or a patient's agent to a pharmacy, if accepted by the pharmacy, may be picked up or handled only by a hazardous waste hauler, as described in Section 117660 of the Health and Safety Code.

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

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.



110537407470BILL

Agenda Item 2a



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 24, 2011
To: Legislation and Regulation Committee
Subject: Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Agenda Item 2.a: Board of Pharmacy/Licensing

Below are summaries of bills that impact the board's operations directly or the licensing by the board. A bill analysis and a copy of the most recent version of the bill are provided in unless otherwise noted.

AB 377 (Solorio) Pharmacy: Centralized hospital packaging

Summary: This bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified.

Recent Action: Hearing Scheduled for April 12, 2011 in the Assembly Health Committee.

AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies

Summary: This bill would require the Department of Corrections and Rehabilitation to license all distributions centers and facilities with the board as part of its comprehensive pharmacy services program.

Recent Action: With the Rules Committee awaiting referral.

AB 847 (Lowenthal, Bonnie) Pharmacy: clinics

Summary: Would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a clinic operating under these provisions be licensed by the California State Board of Pharmacy and would make that licensure optional.

Recent Action: Referred to Assembly Health Committee.

SB 100 (Price) Healing Arts

Summary: This bill would authorize the board to issue a clinic license to a clinic that is owned in whole, or in part by a physician.

Recent Action: Referred to Health Committee and Business, Professions and Economic Development Committee.

SB 632 (Emmerson) Pharmacy

Summary: This is currently a spot bill.

Recent Action: Referred to Rules Committee

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 377

VERSION: As Introduced February 14, 2011

AUTHOR: Solorio

SPONSOR: California Hospital Association

BOARD POSITION: None

SUBJECT: Pharmacies: Centralized Hospital Packaging

AFFECTED SECTIONS: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Referred to Assembly Health

EXISTING LAW:

1. Defines a hospital pharmacy as a pharmacy licensed by the board that is located inside a hospital as specified.
2. Allows a hospital pharmacy to be located outside of the hospital building if the hospital pharmacy is on the California Department of Public Health's consolidated license and if the pharmacy is only providing pharmacy services to inpatients of the hospital.
3. Defines "manufacturer" and exempts compounding, as specified from the definition.

THIS BILL WOULD:

1. Specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius, which is regulated under a hospital's license.
2. Specify that unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership must be barcoded to be readable at the patient's bedside.
3. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
4. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for purposes of administering medication pursuant to a prescription order.

5. Require a pharmacy performing such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:

According to the author, "technology is now capable of providing hospitals with a method to deliver barcoded unit-doses to in-patients' bedsides. However, the cost of this technology renders it virtually impossible for hospitals to do within the structures of the current hospital pharmacy. In addition, because the new central pharmacy would serve multiple hospitals (though the hospitals are under common ownership), currently lawful hospital pharmacy activities might run afoul of the manufacturing law." The author notes that the potential to finally and effectively address in-patient medication errors is greatly expanded by this proposal.

FISCAL IMPACT:

Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

During the October 2009 Board Meeting, the board heard presentations by technology vendors as well as hospital systems representatives regarding the technology available to centralize some pharmacy related functions, including the packaging of items into unit-dose as well as preparation of compounded medicine.

PREVIOUS LEGISLATION:

The board previously supported AB 1370 (Solorio, 2009) which contained provisions similar to this bill.

The board previously supported AB 2077 (Solorio, 2010) which contained provisions similar to this bill. This bill was vetoed by the governor.

"This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date Action

Mar. 7 Referred to Coms. on HEALTH and B., P. & C.P.
Feb. 15 From printer. May be heard in committee March 17.
Feb. 14 Read first time. To print.

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as introduced, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the 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:

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets

1 all of the requirements of this chapter and the rules and regulations
2 of the board.

3 (b) A hospital pharmacy also includes a pharmacy, *licensed by*
4 *the board*, that may be located outside of the hospital, in *either*
5 another physical plant ~~that is regulated under a hospital's~~
6 ~~consolidated license issued pursuant to Section 1250.8 of the Health~~
7 ~~and Safety Code. As a condition of licensure by the board, the~~
8 ~~pharmacy in another physical plant shall provide pharmaceutical~~
9 ~~services only to registered hospital patients who are on the premises~~
10 ~~of the same physical plant in which the pharmacy is located. The~~
11 ~~pharmacy services provided shall be directly related to the services~~
12 ~~or treatment plan administered in the physical plant on the same~~
13 ~~premises or on a separate premises, located within a 100 mile~~
14 ~~radius of the hospital, that is regulated under a hospital's license.~~
15 Nothing in this ~~paragraph~~ *subdivision* shall be construed to restrict
16 or expand the services that a hospital pharmacy may provide.

17 (c) *Any unit-dose medication produced by a hospital pharmacy*
18 *under common ownership, as described in Section 4033, shall be*
19 *barcoded to be readable at the patient's bedside.*

20 (d) *A hospital pharmacy may prepare and store a limited*
21 *quantity of unit-dose medications in advance of receipt of a*
22 *patient-specific prescription in a quantity as is necessary to ensure*
23 *continuity of care for an identified population of patients of the*
24 *hospital based on a documented history of prescriptions for that*
25 *patient population.*

26 (e) *Nothing in this section shall limit the obligation of a hospital*
27 *pharmacy, hospital, or pharmacist to comply with all applicable*
28 *federal and state laws.*

29 SEC. 2. Section 4033 of the Business and Professions Code is
30 amended to read:

31 4033. (a) (1) "Manufacturer" means and includes every person
32 who prepares, derives, produces, compounds, or repackages any
33 drug or device except a pharmacy that manufactures on the
34 immediate premises where the drug or device is sold to the ultimate
35 consumer.

36 (2) Notwithstanding paragraph (1), "manufacturer" shall not
37 mean a pharmacy compounding *or repackaging* a drug for
38 parenteral therapy, ~~pursuant to or oral therapy in a prescription,~~
39 *hospital* for delivery to another pharmacy *or hospital under*
40 *common ownership* for the purpose of ~~delivering~~ *dispensing* or

1 administering the drug, *pursuant to a prescription or order*, to the
2 patient or patients named in the prescription, ~~provided that neither~~
3 ~~or order. A pharmacy compounding or repackaging a drug as~~
4 ~~described in this paragraph shall notify the components for board~~
5 ~~in writing of the drug nor location where the drug are compounded,~~
6 ~~fabricated, packaged, compounding or otherwise prepared prior~~
7 ~~repackaging is being performed within 30 days of initiating the~~
8 ~~compounding or repackaging. The pharmacy shall report any~~
9 ~~change in that information to receipt the board in writing within~~
10 ~~30 days of the prescription change.~~

11 (3) Notwithstanding paragraph (1), “manufacturer” shall not
12 mean a pharmacy that, at a patient’s request, repackages a drug
13 previously dispensed to the patient, or to the patient’s agent,
14 pursuant to a prescription.

15 (b) Notwithstanding subdivision (a), as used in Sections 4034,
16 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
17 means a person who prepares, derives, manufactures, produces,
18 or repackages a dangerous drug, as defined in Section 4022, device,
19 or cosmetic. Manufacturer also means the holder or holders of a
20 New Drug Application (NDA), an Abbreviated New Drug
21 Application (ANDA), or a Biologics License Application (BLA),
22 provided that such application has been approved; a manufacturer’s
23 ~~third party~~ *third-party* logistics provider; a private label distributor
24 (including colicensed partners) for whom the private label
25 distributor’s prescription drugs are originally manufactured and
26 labeled for the distributor and have not been repackaged; or the
27 distributor agent for the manufacturer, contract manufacturer, or
28 private label distributor, whether the establishment is a member
29 of the manufacturer’s affiliated group (regardless of whether the
30 member takes title to the drug) or is a contract distributor site.

31 SEC. 3. No reimbursement is required by this act pursuant to
32 Section 6 of Article XIII B of the California Constitution because
33 the only costs that may be incurred by a local agency or school
34 district will be incurred because this act creates a new crime or
35 infraction, eliminates a crime or infraction, or changes the penalty
36 for a crime or infraction, within the meaning of Section 17556 of
37 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 399

VERSION: As Introduced February 14, 2011

AUTHOR: Lowenthal

SPONSOR: Author

BOARD POSITION: None

SUBJECT: Corrections: offender pharmacies

Affected Sections: Amend Section 5024.2 of the Penal Code

CURRENT STATUS: May be heard committee March 17, 2011.

EXISTING LAW:

1. Specifies that the Department of Corrections and rehabilitation is authorized to maintain and operate a comprehensive pharmacy services program for facilities under its jurisdiction.
2. Specifies that the program shall incorporate all of the following:
 - Statewide pharmacy administration system with direct authority and responsibility for program administration and oversight.
 - Use qualified pharmacists, consistent with the size and scope of the medical services provided.
 - Have written procedures and practices pertaining to the delivery of pharmaceutical services.
 - Have a statewide Pharmacy and Therapeutics Committee responsible for:
 - Developing and managing a department formulary
 - Standardizing the strengths and dosage forms used
 - Maintaining and monitoring the review and corrective actions relating to errors
 - Conducting regular review of department formulary
 - Use of generic medications, unless an exception is reviewed and approved.
 - Use of an enterprise-based pharmacy operating system that provides management with prescription workloads, medication utilization, prescribing date and other information.
3. Allows the department to operate and maintain a centralized pharmacy distribution center and states the intention of the legislation that the pharmacy be licensed by the board.

4. Established the requirements of the centralized pharmacy distribution center to include the following:
 - Order and package bulk pharmaceuticals and prescription and stock orders for all department correctional facilities
 - Label medications as required by law.
 - Provide barcode validation matching the drug to the prescription or floor stock order.
 - Sort completed orders for shipping and delivery.
5. Allows for the reissue of unused and unexpired medications.
6. Specifies that the centralized pharmacy distribution center should maintain a quality control check.
7. Requires the department to investigate and initiate potential systematic improvements.
8. Establishes reporting requirements as specified and sunsets this requirement on March 1, 2016.

THIS BILL WOULD:

Maintain all of the same provisions above, however would make certain portions mandatory and removes intent language. Specifically,

1. The centralized pharmacy distribution center and institutional pharmacies shall be licensed as pharmacies by the board and shall meet all applicable regulations.
2. The center shall maintain a system of quality control checks on each process used,
3. The department shall ensure that there is a program providing for regular inspection of all department pharmacies in the state to verify compliance.

AUTHOR'S INTENT:

To strengthen the protocols in existing law and require California Department of Corrections and Rehabilitation to fully implement a comprehensive pharmacy services program.

FISCAL IMPACT:

We anticipate a portion of an inspector personnel year (PY) will be necessary to ensure compliance with these provisions. This workload can be absorbed if the board is able to fill all authorized inspector positions.

PREVIOUS LEGISLATION:

AB 2747 (B. Lowenthal, 2010) was introduced to codify the overhaul of the pharmacy system for the California Department of Corrections and Rehabilitation and required the department to operate a comprehensive pharmacy services program, including a centralized pharmacy distribution center. This bill was vetoed. However, the 2010-11 Budget trailer bill incorporated many of the provisions of AB 2747.

SUPPORT/OPPOSITION

Unknown

HISTORY:

Date Action

Feb. 15 From printer. May be heard in committee March 17.

Feb. 14 Read first time. To print.

ASSEMBLY BILL

No. 399

Introduced by Assembly Member Bonnie Lowenthal

February 14, 2011

An act to amend Section 5024.2 of the Penal Code, relating to corrections.

LEGISLATIVE COUNSEL'S DIGEST

AB 399, as introduced, Bonnie Lowenthal. Corrections: offender pharmacies.

Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that may incorporate specified features, including a statewide pharmacy administration system with direct authority and responsibility for program administration and oversight, and a multidisciplinary, statewide Pharmacy and Therapeutics Committee with specified responsibilities.

This bill would, instead, require a comprehensive pharmacy services program to incorporate those specified features.

Existing law authorizes the department to operate and maintain a centralized pharmacy distribution center and states that the centralized pharmacy distribution center and institutional pharmacies should be licensed as pharmacies by the California State Board of Pharmacy and should meet all applicable regulations applying to a pharmacy.

This bill would, instead, require that the centralized pharmacy distribution center and institutional pharmacies be licensed as pharmacies by the California State Board of Pharmacy and meet all applicable regulations applying to a pharmacy.

Existing law states that the centralized pharmacy distribution center should maintain a system of quality control checks on each process used to package, label, and distribute medications, and that the department should ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable laws, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department’s inmate patients.

This bill would, instead, require the centralized pharmacy distribution center to maintain a system of quality control checks on each process used to package, label, and distribute medications, and would require the department to ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable laws, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department’s inmate patients.

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

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

- 1 SECTION 1. Section 5024.2 of the Penal Code is amended to
- 2 read:
- 3 5024.2. (a) The Department of Corrections and Rehabilitation
- 4 is authorized to maintain and operate a comprehensive pharmacy
- 5 services program for those facilities under the jurisdiction of the
- 6 department that is both cost effective and efficient, ~~and may that~~
- 7 *program shall* incorporate *all of* the following:
- 8 (1) A statewide pharmacy administration system with direct
- 9 authority and responsibility for program administration and
- 10 oversight.
- 11 (2) Medically necessary pharmacy services using professionally
- 12 and legally qualified pharmacists, consistent with the size and the
- 13 scope of medical services provided.
- 14 (3) Written procedures and operational practices pertaining to
- 15 the delivery of pharmaceutical services.
- 16 (4) A multidisciplinary, statewide Pharmacy and Therapeutics
- 17 Committee responsible for all of the following:
- 18 (A) Developing and managing a department formulary.

1 (B) Standardizing the strengths and dosage forms for
2 medications used in department facilities.

3 (C) Maintaining and monitoring a system for the review and
4 evaluation of corrective actions related to errors in prescribing,
5 dispensing, and administering medications.

6 (D) Conducting regular therapeutic category reviews for
7 medications listed in the department formulary.

8 (E) Evaluating medication therapies and providing input to the
9 development of disease management guidelines used in the
10 department.

11 (5) A requirement for the use of generic medications, when
12 available, unless an exception is reviewed and approved in
13 accordance with an established nonformulary approval process.

14 (6) Use of an enterprise-based pharmacy operating system that
15 provides management with information on prescription workloads,
16 medication utilization, prescribing data, and other key pharmacy
17 information.

18 (b) The department is authorized to operate and maintain a
19 centralized pharmacy distribution center to provide advantages of
20 scale and efficiencies related to medication purchasing, inventory
21 control, volume production, drug distribution, workforce utilization,
22 and increased patient safety. ~~It is the intent of the Legislature that~~
23 ~~the~~ *The* centralized pharmacy distribution center and institutional
24 pharmacies *shall* be licensed as pharmacies by the California State
25 Board of Pharmacy—~~meeting and shall meet~~ all applicable
26 regulations applying to a pharmacy.

27 (1) To the extent it is cost effective and efficient, the centralized
28 pharmacy distribution center should include systems to do the
29 following:

30 (A) Order and package bulk pharmaceuticals and prescription
31 and stock orders for all department correctional facilities.

32 (B) Label medications as required to meet state and federal
33 prescription requirements.

34 (C) Provide barcode validation matching the drug to the specific
35 prescription or floor stock order.

36 (D) Sort completed orders for shipping and delivery to
37 department facilities.

38 (2) Notwithstanding any other requirements, the department
39 centralized pharmacy distribution center is authorized to do the
40 following:

- 1 (A) Package bulk pharmaceuticals into both floor stock and
- 2 patient-specific packs.
- 3 (B) Reclaim, for reissue, unused and unexpired medications.
- 4 (C) Distribute the packaged products to department facilities
- 5 for use within the state corrections system.
- 6 (3) The centralized pharmacy distribution center ~~should~~ *shall*
- 7 maintain a system of quality control checks on each process used
- 8 to package, label, and distribute medications. The quality control
- 9 system may include a regular process of random checks by a
- 10 licensed pharmacist.
- 11 (c) The department may investigate and initiate potential
- 12 systematic improvements in order to provide for the safe and
- 13 efficient distribution and control of, and accountability for, drugs
- 14 within the department’s statewide pharmacy administration system,
- 15 taking into account factors unique to the correctional environment.
- 16 (d) The department ~~should~~ *shall* ensure that there is a program
- 17 providing for the regular inspection of all department pharmacies
- 18 in the state to verify compliance with applicable law, rules,
- 19 regulations, and other standards as may be appropriate to ensure
- 20 the health, safety, and welfare of the department’s inmate patients.
- 21 (e) On March 1, 2012, and each March 1 thereafter, the
- 22 department shall report all of the following to the Joint Legislative
- 23 Budget Committee, the Senate Committee on Appropriations, the
- 24 Senate Committee on Budget and Fiscal Review, the Senate
- 25 Committee on Health, the Senate Committee on Public Safety, the
- 26 Assembly Committee on Appropriations, the Assembly Committee
- 27 on Budget, the Assembly Committee on Health, and the Assembly
- 28 Committee on Public Safety:
- 29 (1) The extent to which the Pharmacy and Therapeutics
- 30 Committee has been established and achieved the objectives set
- 31 forth in this section, as well as the most significant reasons for
- 32 achieving or not achieving those objectives.
- 33 (2) The extent to which the department is achieving the objective
- 34 of operating a fully functioning and centralized pharmacy
- 35 distribution center, as set forth in this section, that distributes
- 36 pharmaceuticals to every adult prison under the jurisdiction of the
- 37 department, as well as the most significant reasons for achieving
- 38 or not achieving that objective.

1 (3) The extent to which the centralized pharmacy distribution
2 center is achieving cost savings through improved efficiency and
3 distribution of unit dose medications.

4 (4) A description of planned or implemented initiatives to
5 accomplish the next 12 months' objectives for achieving the goals
6 set forth in this section, including a fully functioning and
7 centralized pharmacy distribution center that distributes
8 pharmaceuticals to every adult facility under the jurisdiction of
9 the department.

10 (5) The costs for prescription pharmaceuticals for the previous
11 fiscal year, both statewide and at each adult prison under the
12 jurisdiction of the department, and a comparison of these costs
13 with those of the prior fiscal year.

14 (f) The requirement for submitting a report imposed under
15 subdivision (e) is inoperative on March 1, 2016, pursuant to Section
16 10231.5 of the Government Code.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 847

VERSION: As Introduced February 17, 2011

AUTHOR: Lowenthal

SPONSOR: Long Beach Endoscopy Center

BOARD POSITION: None

SUBJECT: Pharmacy: clinics

Affected Sections: Amend Sections 4190 and 4195 of the Business and Professions Code

CURRENT STATUS: Referred to Assembly Health

EXISTING LAW:

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale or maintain a commingled drug stock unless licensed by the California State Board of Pharmacy.
2. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:

1. Expand the definition of a surgical clinic Section 4190 to include:
 - licensure by the Department of Public Health (DPH) under H&SC Section 1204
 - an outpatient setting accredited by an approved agency as defined in 1248 of the Health and Safety Code
 - an ambulatory surgical center certified to participate in the Medicare Program
2. Authorize any of the clinics referenced above to purchase drugs at wholesale as specified.
3. Make licensure with the board optional.
4. Require notification to the board of any changes in ownership for any clinic licensed by the board.
5. Specify that nothing in the section will limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer or furnish drugs at a clinic.

6. Specify that the board has authority to inspect any clinic that is licensed by the board.

AUTHOR'S INTENT:

The author notes that most clinics and their surgeons cannot be expected to operate their own "individual" pharmacy and continue to provide the high quality, low cost care patients and the system rely on. As a result, patient access to these clinics will be compromised.

FISCAL IMPACT:

Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

Current law allows the board to issue a clinic license only to an entity licensed under H&S Code section 1204. The board's license allow a clinic to purchase drugs at wholesale as well as allows for a common drug supply from which prescribers may dispense. To ensure the appropriate regulation of this common drug supply, the clinic must provide the board with the name of the professional director and specifies that this person is responsible for the safe, orderly and lawful provisions of pharmacy law. In addition, the professional director is also required to retain a consulting pharmacist who is responsible for approving the policies and procedures in conjunction with the director.

This bill will expands these provisions to allow clinics that are able to purchase drugs at wholesale and dispense from a common drug stock. However because licensure with the board is optional, none of the oversight that currently exists would apply. This would be true even for surgical clinics that are currently licensed by the board. From a consumer protection standpoint, the change could result in a significant deficiency in that no person would be responsible for ensuring the safety of the drugs being used in such a clinic.

In response to a lawsuit that the California Department of Public Health was involved in regarding the regulation of a physician-owned ambulatory surgical clinic, several legislative remedies have been offered. Past remedies have generally expanded the conditions for licensure to allow the board to license surgical clinics that participate in the Medicare Program as well as those that were accredited by an approved agency. A summary of the lawsuit is provided below.

The California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to "...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this ruling means that ambulatory

surgical clinics owned and operated by physicians do not qualify as “surgical clinics” within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the “*Capen* decision,” the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the ruling, the California State Board of Pharmacy could no longer issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

PREVIOUS LEGISLATION

AB 2077 (Lowenthal) of 2010 contained provisions that would have expanded the conditions under which the board can issue a clinic license including surgical clinics licensed by the Department of Public Health, those certified to participate in the Medicare Program and those accredited by an approved agency. The board had a support position on this bill that was subsequently vetoed by Governor Schwarzenegger with the following veto message.

“This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California.”

AB 1574 (Plescia) of 2008 contained similar provisions to those proposed in AB 2077 and would have required the Board to inspect outpatient settings and ASCs within 120 days of issuing a clinic license and then at least annually thereafter. AB 1574 was vetoed by Governor Schwarzenegger who stated that the bill failed to address the larger issue concerning the Capen v. Shewry ruling. The board had a support position on this bill.

AB 2122 (Plescia) of 2008 would have required surgical clinics to meet prescribed licensing requirements and standards, including compliance with Medicare conditions of participation, and also contained provisions nearly identical to those proposed in AB 1574. AB 2122 died in Assembly Appropriations Committee. The board did not have a position on this bill.

AB 543 (Plescia) of 2007 also would have required surgical clinics to meet specified operating and staffing standards, to limit surgical procedures, as specified, and to develop and implement policies and procedures consistent with Medicare conditions of participation, including interpretive guidelines. AB 543 was vetoed by Governor Schwarzenegger who, stated that the bill did not establish appropriate time limits for performing surgery under general anesthesia, inappropriately restricted administrative flexibility, and created fiscal pressure during ongoing budget challenges. The board had a support position on this bill.

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. “While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner.” The board had no position on this bill.

SUPPORT/OPPOSITION

Unknown

HISTORY:

Date	Action
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Mar. 10	Referred to Coms. on HEALTH and B., P. & C.P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

ASSEMBLY BILL

No. 847

Introduced by Assembly Member Bonnie Lowenthal

February 17, 2011

An act to amend Sections 4190 and 4195 of, and to amend the heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 847, as introduced, Bonnie Lowenthal. Pharmacy: clinics.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a knowing violation of its provisions a crime. Existing law authorizes a surgical clinic, as defined, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the surgical clinic. Existing law requires these surgical clinics to obtain a license from the board and to comply with various regulatory requirements, and requires a surgical clinic to maintain specified records. Existing law authorizes the board to inspect a surgical clinic at any time in order to determine whether a surgical clinic is operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a clinic operating under these provisions be licensed by the California State Board of Pharmacy and would make that

licensure optional. The bill would specify that the board is authorized to inspect only a clinic that is licensed by the board.

Because a knowing violation of these requirements by outpatient settings and ambulatory surgical centers would be a crime, the 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:

1 SECTION 1. The heading of Article 14 (commencing with
2 Section 4190) of Chapter 9 of Division 2 of the Business and
3 Professions Code is amended to read:

4
5 Article 14. ~~Surgical~~ Clinics

6
7 SEC. 2. Section 4190 of the Business and Professions Code is
8 amended to read:

9 4190. (a) *For the purposes of this article, "clinic" means a*
10 *surgical clinic licensed pursuant to paragraph (1) of subdivision*
11 *(b) of Section 1204 of the Health and Safety Code, an outpatient*
12 *setting accredited by an accreditation agency, as defined in Section*
13 *1248 of the Health and Safety Code, or an ambulatory surgical*
14 *center certified to participate in the Medicare Program under Title*
15 *XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et*
16 *seq.).*

17 (a)
18 (b) Notwithstanding any provision of this chapter, a ~~surgical~~
19 ~~elinic, as defined in paragraph (1) of subdivision (b) of Section~~
20 ~~1204 of the Health and Safety Code~~ clinic may purchase drugs at
21 wholesale for administration or dispensing, under the direction of
22 a physician *and surgeon*, to patients registered for care at the clinic,
23 as provided in subdivision ~~(b)~~: (c). The clinic shall keep records
24 of the kind and amounts of drugs purchased, administered, and
25 dispensed, and the records shall be available and maintained for

1 a minimum of three years for inspection by all properly authorized
2 personnel.

3 ~~(b)~~

4 (c) The drug distribution service of a ~~surgical~~ clinic shall be
5 limited to the use of drugs for administration to the patients of the
6 ~~surgical~~ clinic and to the dispensing of drugs for the control of
7 pain and nausea for patients of the clinic. Drugs shall not be
8 dispensed in an amount greater than that required to meet the
9 patient's needs for 72 hours. Drugs for administration shall be
10 those drugs directly applied, whether by injection, inhalation,
11 ingestion, or any other means, to the body of a patient for his or
12 her immediate needs.

13 ~~(e) No surgical clinic shall operate without a license issued by~~
14 ~~the board nor shall it be entitled to the benefits of this section until~~
15 ~~it has obtained a license from the board. A~~

16 (d) A clinic may, at its option, apply for a license issued by the
17 board pursuant to this section.

18 (e) If a clinic elects to obtain a license pursuant to subdivision
19 (d), a separate license shall be required for each clinic location. A
20 clinic licensed by the board shall notify the board of any change
21 in the clinic's address on a form furnished by the board.

22 ~~(d) Any~~

23 (f) If a clinic is licensed by the board, any proposed change in
24 ownership or beneficial interest in the licensee shall be reported
25 to the board, on a form to be furnished by the board, at least 30
26 days prior to the execution of any agreement to purchase, sell,
27 exchange, gift or otherwise transfer any ownership or beneficial
28 interest or prior to any transfer of ownership or beneficial interest,
29 whichever occurs earlier.

30 (g) Nothing in this section shall limit the ability of a physician
31 and surgeon or a group medical practice to prescribe, dispense,
32 administer, or furnish drugs at a clinic or surgical clinic as
33 provided in Sections 2241.5, 2242, and 4170.

34 SEC. 3. Section 4195 of the Business and Professions Code is
35 amended to read:

36 4195. The board shall have the authority to inspect a clinic *that*
37 *is licensed pursuant to this article* at any time in order to determine
38 whether ~~a~~ the clinic is, or is not, operating in compliance with this
39 article and all other provisions of the law.

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

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 100

VERSION: As Introduced January 11, 2011

AUTHOR: Price

SPONSOR: Author

BOARD POSITION:

SUBJECT: Pharmacy: Clinics

AFFECTED SECTIONS: Amend Sections 651 and 2023.5 of, and to add Section 2027.5 to, the Business and Professions Code, and to amend Sections 1204, 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.55, and 1279 of, and to add Sections 1204.6, 1204.7, and 1204.8 to, the Health and Safety Code, relating to healing arts.

CURRENT STATUS: Referred to Health Committee and Business Professions and Economic Development Committee

EXISTING LAW:

1. Health and Safety Code section 1204 (b)(1) defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Business and Professions Code Section 4190 authorizes a surgical clinic as defined in H&SC 1204(b)(1) to purchase drugs at wholesaler.
3. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:

Specify that a surgical clinic includes a surgical clinic that is owned in whole or in part by a physician.

AUTHOR'S INTENT:

This bill will clarify Capen v. Shewry (2007) 147 Cal.App.4th 680 and give surgical clinics that are owned in whole or in part by physicians the option to be licensed by the State Department of Public Health. The author's office indicates that several of the provisions contained in this bill will be removed, but the changes affecting the board will remain.

COMMENTS:

In response to a lawsuit that the California Department of Public Health was involved in regarding the regulation of a physician-owned ambulatory surgical clinic, several legislative remedies have been offered. Past remedies have generally expanded the conditions for licensure to allow the board to license surgical clinics that participate in the Medicare Program as well as those that were accredited by an approved agency. A summary of the lawsuit is provided below.

The California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to “...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board.” (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as “surgical clinics” within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the “*Capen* decision,” the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the ruling, the California State Board of Pharmacy could no longer issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

PRIOR HISTORY/RELATED BILLS:

AB 847 (Lowenthal, 2011) would expand upon clinics that are able to purchase drugs at wholesale and dispense from a common drug stock and would make licensure with the board optional.

AB 2077 (Lowenthal, 2010) contained provisions that would have expanded the conditions under which the board can issue a clinic license including surgical clinics licensed by the Department of Public Health, those certified to participate in the Medicare Program and those accredited by an approved agency. The board had a support position on this bill that was subsequently vetoed by Governor Schwarzenegger with the following veto message.

“This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate

control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California.”

AB 1574 (Plescia, 2008) contained similar provisions to those proposed in AB 2077 and would have required the Board to inspect outpatient settings and ASCs within 120 days of issuing a clinic license and then at least annually thereafter. AB 1574 was vetoed by Governor Schwarzenegger who stated that the bill failed to address the larger issue concerning the Capen v. Shewry ruling. The board had a support position on this bill.

AB 2122 (Plescia, 2008) would have required surgical clinics to meet prescribed licensing requirements and standards, including compliance with Medicare conditions of participation, and also contained provisions nearly identical to those proposed in AB 1574. AB 2122 died in Assembly Appropriations Committee. The board did not have a position on this bill.

AB 543 (Plescia, 2007) also would have required surgical clinics to meet specified operating and staffing standards, to limit surgical procedures, as specified, and to develop and implement policies and procedures consistent with Medicare conditions of participation, including interpretive guidelines. AB 543 was vetoed by Governor Schwarzenegger who, stated that the bill did not establish appropriate time limits for performing surgery under general anesthesia, inappropriately restricted administrative flexibility, and created fiscal pressure during ongoing budget challenges. The board had a support position on this bill.

AB 2308 (Plescia, 2006) This bill was vetoed by the governor. The veto message stated. “While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner.” The board had no position on this bill.

FISCAL IMPACT:

The board does not anticipate any significant fiscal impact. Any minor impact could be absorbed with existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Jan. 20 Referred to Coms. on B., P. & E.D. and HEALTH.

Jan. 12 From printer. May be acted upon on or after February 11.

Jan. 11 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator PriceJanuary 11, 2011

An act to amend Sections 651 and 2023.5 of, and to add Section 2027.5 to, the Business and Professions Code, and to amend Sections 1204, 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.55, and 1279 of, and to add Sections 1204.6, 1204.7, and 1204.8 to, the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 100, as introduced, Price. Healing arts.

(1) Existing law provides for the licensure and regulation of various healing arts practitioners and requires certain of those practitioners to use particular designations following their names in specified instances. Existing law provides that it is unlawful for healing arts licensees to disseminate or cause to be disseminated any form of public communication, as defined, containing a false, fraudulent, misleading, or deceptive statement, claim, or image to induce the rendering of services or the furnishing of products relating to a professional practice or business for which they are licensed. Existing law authorizes advertising by these healing arts licensees to include certain general information. A violation of these provisions is a misdemeanor.

This bill would require certain healing arts licensees to include in advertisements, as defined, certain words or designations following their names indicating the particular educational degree they hold or healing art they practice, as specified. By changing the definition of a crime, this bill would impose a state-mandated local program.

(2) Existing law requires the Medical Board of California, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field,

to review issues and problems relating to the use of laser or intense light pulse devices for elective cosmetic procedures by their respective licensees.

This bill would require the board to adopt regulations by January 1, 2013, regarding the appropriate level of physician availability needed within clinics or other settings using certain laser or intense pulse light devices for elective cosmetic procedures.

(3) Existing law requires the Medical Board of California to post on the Internet specified information regarding licensed physicians and surgeons.

This bill would require the board to post on its Internet Web site an easy-to-understand factsheet to educate the public about cosmetic surgery and procedures, as specified.

(4) Under existing law, the State Department of Public Health licenses and regulates clinics, including surgical clinics, as defined.

This bill would expand the definition of surgical clinics to include a surgical clinic owned in whole or in part by a physician and would require, until the department promulgates regulations for the licensing of surgical clinics, the department to use specified federal conditions of coverage.

(5) Existing law requires the Medical Board of California, as successor to the Division of Licensing of the Medical Board of California, to adopt standards for accreditation of outpatient settings, as defined, and, in approving accreditation agencies to perform this accreditation, to ensure that the certification program shall, at a minimum, include standards for specified aspects of the settings' operations. Existing law makes a willful violation of these and other provisions relating to outpatient settings a crime.

This bill would include, among those specified aspects, the submission for approval by an accreditation agency at the time of accreditation, a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery. The bill would also modify the definition of "outpatient setting" to include facilities that offer in vitro fertilization, as defined. By changing the definition of a crime, this bill would impose a state-mandated local program.

Existing law also requires the Medical Board of California to obtain and maintain a list of all accredited, certified, and licensed outpatient settings, and to notify the public, upon inquiry, whether a setting is

accredited, certified, or licensed, or whether the setting's accreditation, certification, or license has been revoked.

This bill would require the board, absent inquiry, to notify the public whether a setting is accredited, certified, or licensed, or the setting's accreditation, certification, or license has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency. The bill would also require the board to give the department notice of all accredited, certified, and licensed outpatient settings and to notify the department of accreditation standards, changes in the accreditation of an outpatient setting, or any disciplinary actions and corrective actions.

Existing law requires accreditation of an outpatient setting to be denied if the setting does not meet specified standards. Existing law authorizes an outpatient setting to reapply for accreditation at any time after receiving notification of the denial.

This bill would require the accreditation agency to immediately report to the Medical Board of California if the outpatient setting's certificate for accreditation has been denied. Because a willful violation of this requirement would be a crime, the bill would impose a state-mandated local program. The bill would also apply the denial of accreditation, or the revocation or suspension of accreditation by one accrediting agency to all other accrediting agencies.

Existing law authorizes the Medical Board of California, as successor to the Division of Medical Quality of the Medical Board of California, or an accreditation agency to, upon reasonable prior notice and presentation of proper identification, enter and inspect any accredited outpatient setting to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of the specified law.

This bill would delete the notice and identification requirements. The bill would require that every outpatient setting that is accredited be inspected by the accreditation agency, as specified, and would specify that it may also be inspected by the board and the department, as specified. The bill would require the board to ensure that accreditation agencies inspect outpatient settings.

Existing law authorizes the Medical Board of California to terminate approval of an accreditation agency if the agency is not meeting the criteria set by the board.

This bill would also authorize the board to issue a citation to the agency, including an administrative fine, in accordance with a specified system established by the board.

Existing law authorizes the Medical Board of California to evaluate the performance of an approved accreditation agency no less than every 3 years, or in response to complaints against an agency, or complaints against one or more outpatient settings accreditation by an agency that indicates noncompliance by the agency with the standards approved by the board.

This bill would make that evaluation mandatory.

(5) Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health and requires the department to periodically inspect those facilities, as specified.

This bill would state the intent of the Legislature that the department, as part of its periodic inspections of acute care hospitals, inspect the peer review process utilized by those hospitals.

(6) 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. (a) It is the intent of the Legislature to clarify
 2 Capen v. Shewry (2007) 147 Cal.App.4th 680 and give surgical
 3 clinics that are owned in whole or in part by physicians the option
 4 to be licensed by the State Department of Public Health. It is further
 5 the intent of the Legislature that this clarification shall not be
 6 construed to permit the practice of medicine in prohibition of the
 7 corporate practice of medicine pursuant to Section 2400 of the
 8 Business and Professions Code.

9 (b) It is the further intent of the Legislature to continue to give
 10 physicians and surgeons the option to obtain licensure from the
 11 State Department of Public Health if they are operating surgical
 12 clinics, or an accreditation through an accrediting agency approved
 13 by the Medical Board of California pursuant to Chapter 1.3

1 (commencing with Section 1248) of Division 2 of the Health and
2 Safety Code.

3 (c) It is the further intent of the Legislature, in order to ensure
4 patient protection, to provide appropriate oversight by the State
5 Department of Public Health, and to allow corrective action to be
6 taken against an outpatient setting if there is reason to believe that
7 there may be risk to patient safety, health, or welfare, that an
8 outpatient setting shall be deemed licensed by the State Department
9 of Public Health.

10 SEC. 2. Section 651 of the Business and Professions Code is
11 amended to read:

12 651. (a) It is unlawful for any person licensed under this
13 division or under any initiative act referred to in this division to
14 disseminate or cause to be disseminated any form of public
15 communication containing a false, fraudulent, misleading, or
16 deceptive statement, claim, or image for the purpose of or likely
17 to induce, directly or indirectly, the rendering of professional
18 services or furnishing of products in connection with the
19 professional practice or business for which he or she is licensed.
20 A “public communication” as used in this section includes, but is
21 not limited to, communication by means of mail, television, radio,
22 motion picture, newspaper, book, list or directory of healing arts
23 practitioners, Internet, or other electronic communication.

24 (b) A false, fraudulent, misleading, or deceptive statement,
25 claim, or image includes a statement or claim that does any of the
26 following:

27 (1) Contains a misrepresentation of fact.

28 (2) Is likely to mislead or deceive because of a failure to disclose
29 material facts.

30 (3) (A) Is intended or is likely to create false or unjustified
31 expectations of favorable results, including the use of any
32 photograph or other image that does not accurately depict the
33 results of the procedure being advertised or that has been altered
34 in any manner from the image of the actual subject depicted in the
35 photograph or image.

36 (B) Use of any photograph or other image of a model without
37 clearly stating in a prominent location in easily readable type the
38 fact that the photograph or image is of a model is a violation of
39 subdivision (a). For purposes of this paragraph, a model is anyone
40 other than an actual patient, who has undergone the procedure

1 being advertised, of the licensee who is advertising for his or her
2 services.

3 (C) Use of any photograph or other image of an actual patient
4 that depicts or purports to depict the results of any procedure, or
5 presents “before” and “after” views of a patient, without specifying
6 in a prominent location in easily readable type size what procedures
7 were performed on that patient is a violation of subdivision (a).
8 Any “before” and “after” views (i) shall be comparable in
9 presentation so that the results are not distorted by favorable poses,
10 lighting, or other features of presentation, and (ii) shall contain a
11 statement that the same “before” and “after” results may not occur
12 for all patients.

13 (4) Relates to fees, other than a standard consultation fee or a
14 range of fees for specific types of services, without fully and
15 specifically disclosing all variables and other material factors.

16 (5) Contains other representations or implications that in
17 reasonable probability will cause an ordinarily prudent person to
18 misunderstand or be deceived.

19 (6) Makes a claim either of professional superiority or of
20 performing services in a superior manner, unless that claim is
21 relevant to the service being performed and can be substantiated
22 with objective scientific evidence.

23 (7) Makes a scientific claim that cannot be substantiated by
24 reliable, peer reviewed, published scientific studies.

25 (8) Includes any statement, endorsement, or testimonial that is
26 likely to mislead or deceive because of a failure to disclose material
27 facts.

28 (c) Any price advertisement shall be exact, without the use of
29 phrases, including, but not limited to, “as low as,” “and up,”
30 “lowest prices,” or words or phrases of similar import. Any
31 advertisement that refers to services, or costs for services, and that
32 uses words of comparison shall be based on verifiable data
33 substantiating the comparison. Any person so advertising shall be
34 prepared to provide information sufficient to establish the accuracy
35 of that comparison. Price advertising shall not be fraudulent,
36 deceitful, or misleading, including statements or advertisements
37 of bait, discount, premiums, gifts, or any statements of a similar
38 nature. In connection with price advertising, the price for each
39 product or service shall be clearly identifiable. The price advertised
40 for products shall include charges for any related professional

1 services, including dispensing and fitting services, unless the
2 advertisement specifically and clearly indicates otherwise.

3 (d) Any person so licensed shall not compensate or give anything
4 of value to a representative of the press, radio, television, or other
5 communication medium in anticipation of, or in return for,
6 professional publicity unless the fact of compensation is made
7 known in that publicity.

8 (e) Any person so licensed may not use any professional card,
9 professional announcement card, office sign, letterhead, telephone
10 directory listing, medical list, medical directory listing, or a similar
11 professional notice or device if it includes a statement or claim
12 that is false, fraudulent, misleading, or deceptive within the
13 meaning of subdivision (b).

14 (f) Any person so licensed who violates this section is guilty of
15 a misdemeanor. A bona fide mistake of fact shall be a defense to
16 this subdivision, but only to this subdivision.

17 (g) Any violation of this section by a person so licensed shall
18 constitute good cause for revocation or suspension of his or her
19 license or other disciplinary action.

20 (h) Advertising by any person so licensed may include the
21 following:

22 (1) A statement of the name of the practitioner.

23 (2) A statement of addresses and telephone numbers of the
24 offices maintained by the practitioner.

25 (3) A statement of office hours regularly maintained by the
26 practitioner.

27 (4) A statement of languages, other than English, fluently spoken
28 by the practitioner or a person in the practitioner's office.

29 (5) (A) A statement that the practitioner is certified by a private
30 or public board or agency or a statement that the practitioner limits
31 his or her practice to specific fields.

32 (i) For the purposes of this section, a dentist licensed under
33 Chapter 4 (commencing with Section 1600) may not hold himself
34 or herself out as a specialist, or advertise membership in or
35 specialty recognition by an accrediting organization, unless the
36 practitioner has completed a specialty education program approved
37 by the American Dental Association and the Commission on Dental
38 Accreditation, is eligible for examination by a national specialty
39 board recognized by the American Dental Association, or is a

1 diplomate of a national specialty board recognized by the American
2 Dental Association.

3 (ii) A dentist licensed under Chapter 4 (commencing with
4 Section 1600) shall not represent to the public or advertise
5 accreditation either in a specialty area of practice or by a board
6 not meeting the requirements of clause (i) unless the dentist has
7 attained membership in or otherwise been credentialed by an
8 accrediting organization that is recognized by the board as a bona
9 fide organization for that area of dental practice. In order to be
10 recognized by the board as a bona fide accrediting organization
11 for a specific area of dental practice other than a specialty area of
12 dentistry authorized under clause (i), the organization shall
13 condition membership or credentialing of its members upon all of
14 the following:

15 (I) Successful completion of a formal, full-time advanced
16 education program that is affiliated with or sponsored by a
17 university based dental school and is beyond the dental degree at
18 a graduate or postgraduate level.

19 (II) Prior didactic training and clinical experience in the specific
20 area of dentistry that is greater than that of other dentists.

21 (III) Successful completion of oral and written examinations
22 based on psychometric principles.

23 (iii) Notwithstanding the requirements of clauses (i) and (ii), a
24 dentist who lacks membership in or certification, diplomate status,
25 other similar credentials, or completed advanced training approved
26 as bona fide either by an American Dental Association recognized
27 accrediting organization or by the board, may announce a practice
28 emphasis in any other area of dental practice only if the dentist
29 incorporates in capital letters or some other manner clearly
30 distinguishable from the rest of the announcement, solicitation, or
31 advertisement that he or she is a general dentist.

32 (iv) A statement of certification by a practitioner licensed under
33 Chapter 7 (commencing with Section 3000) shall only include a
34 statement that he or she is certified or eligible for certification by
35 a private or public board or parent association recognized by that
36 practitioner's licensing board.

37 (B) A physician and surgeon licensed under Chapter 5
38 (commencing with Section 2000) by the Medical Board of
39 California may include a statement that he or she limits his or her
40 practice to specific fields, but shall not include a statement that he

1 or she is certified or eligible for certification by a private or public
2 board or parent association, including, but not limited to, a
3 multidisciplinary board or association, unless that board or
4 association is (i) an American Board of Medical Specialties
5 member board, (ii) a board or association with equivalent
6 requirements approved by that physician and surgeon’s licensing
7 board, or (iii) a board or association with an Accreditation Council
8 for Graduate Medical Education approved postgraduate training
9 program that provides complete training in that specialty or
10 subspecialty. A physician and surgeon licensed under Chapter 5
11 (commencing with Section 2000) by the Medical Board of
12 California who is certified by an organization other than a board
13 or association referred to in clause (i), (ii), or (iii) shall not use the
14 term “board certified” in reference to that certification, unless the
15 physician and surgeon is also licensed under Chapter 4
16 (commencing with Section 1600) and the use of the term “board
17 certified” in reference to that certification is in accordance with
18 subparagraph (A). A physician and surgeon licensed under Chapter
19 5 (commencing with Section 2000) by the Medical Board of
20 California who is certified by a board or association referred to in
21 clause (i), (ii), or (iii) shall not use the term “board certified” unless
22 the full name of the certifying board is also used and given
23 comparable prominence with the term “board certified” in the
24 statement.

25 For purposes of this subparagraph, a “multidisciplinary board
26 or association” means an educational certifying body that has a
27 psychometrically valid testing process, as determined by the
28 Medical Board of California, for certifying medical doctors and
29 other health care professionals that is based on the applicant’s
30 education, training, and experience.

31 For purposes of the term “board certified,” as used in this
32 subparagraph, the terms “board” and “association” mean an
33 organization that is an American Board of Medical Specialties
34 member board, an organization with equivalent requirements
35 approved by a physician and surgeon’s licensing board, or an
36 organization with an Accreditation Council for Graduate Medical
37 Education approved postgraduate training program that provides
38 complete training in a specialty or subspecialty.

39 The Medical Board of California shall adopt regulations to
40 establish and collect a reasonable fee from each board or

1 association applying for recognition pursuant to this subparagraph.
2 The fee shall not exceed the cost of administering this
3 subparagraph. Notwithstanding Section 2 of Chapter 1660 of the
4 Statutes of 1990, this subparagraph shall become operative July
5 1, 1993. However, an administrative agency or accrediting
6 organization may take any action contemplated by this
7 subparagraph relating to the establishment or approval of specialist
8 requirements on and after January 1, 1991.

9 (C) A doctor of podiatric medicine licensed under Chapter 5
10 (commencing with Section 2000) by the Medical Board of
11 California may include a statement that he or she is certified or
12 eligible or qualified for certification by a private or public board
13 or parent association, including, but not limited to, a
14 multidisciplinary board or association, if that board or association
15 meets one of the following requirements: (i) is approved by the
16 Council on Podiatric Medical Education, (ii) is a board or
17 association with equivalent requirements approved by the
18 California Board of Podiatric Medicine, or (iii) is a board or
19 association with the Council on Podiatric Medical Education
20 approved postgraduate training programs that provide training in
21 podiatric medicine and podiatric surgery. A doctor of podiatric
22 medicine licensed under Chapter 5 (commencing with Section
23 2000) by the Medical Board of California who is certified by a
24 board or association referred to in clause (i), (ii), or (iii) shall not
25 use the term “board certified” unless the full name of the certifying
26 board is also used and given comparable prominence with the term
27 “board certified” in the statement. A doctor of podiatric medicine
28 licensed under Chapter 5 (commencing with Section 2000) by the
29 Medical Board of California who is certified by an organization
30 other than a board or association referred to in clause (i), (ii), or
31 (iii) shall not use the term “board certified” in reference to that
32 certification.

33 For purposes of this subparagraph, a “multidisciplinary board
34 or association” means an educational certifying body that has a
35 psychometrically valid testing process, as determined by the
36 California Board of Podiatric Medicine, for certifying doctors of
37 podiatric medicine that is based on the applicant’s education,
38 training, and experience. For purposes of the term “board certified,”
39 as used in this subparagraph, the terms “board” and “association”
40 mean an organization that is a Council on Podiatric Medical

1 Education approved board, an organization with equivalent
2 requirements approved by the California Board of Podiatric
3 Medicine, or an organization with a Council on Podiatric Medical
4 Education approved postgraduate training program that provides
5 training in podiatric medicine and podiatric surgery.

6 The California Board of Podiatric Medicine shall adopt
7 regulations to establish and collect a reasonable fee from each
8 board or association applying for recognition pursuant to this
9 subparagraph, to be deposited in the State Treasury in the Podiatry
10 Fund, pursuant to Section 2499. The fee shall not exceed the cost
11 of administering this subparagraph.

12 (6) A statement that the practitioner provides services under a
13 specified private or public insurance plan or health care plan.

14 (7) A statement of names of schools and postgraduate clinical
15 training programs from which the practitioner has graduated,
16 together with the degrees received.

17 (8) A statement of publications authored by the practitioner.

18 (9) A statement of teaching positions currently or formerly held
19 by the practitioner, together with pertinent dates.

20 (10) A statement of his or her affiliations with hospitals or
21 clinics.

22 (11) A statement of the charges or fees for services or
23 commodities offered by the practitioner.

24 (12) A statement that the practitioner regularly accepts
25 installment payments of fees.

26 (13) Otherwise lawful images of a practitioner, his or her
27 physical facilities, or of a commodity to be advertised.

28 (14) A statement of the manufacturer, designer, style, make,
29 trade name, brand name, color, size, or type of commodities
30 advertised.

31 (15) An advertisement of a registered dispensing optician may
32 include statements in addition to those specified in paragraphs (1)
33 to (14), inclusive, provided that any statement shall not violate
34 subdivision (a), (b), (c), or (e) or any other section of this code.

35 (16) A statement, or statements, providing public health
36 information encouraging preventative or corrective care.

37 (17) Any other item of factual information that is not false,
38 fraudulent, misleading, or likely to deceive.

39 (i) (1) *Advertising by the following licensees shall include the*
40 *designations as follows:*

- 1 (A) Advertising by a chiropractor licensed under Chapter 2
2 (commencing with Section 1000) shall include the designation
3 “DC” or the word “chiropractor” immediately following the
4 chiropractor’s name.
- 5 (B) Advertising by a dentist licensed under Chapter 4
6 (commencing with Section 1600) shall include the designation
7 “DDS” or “DMD” immediately following the dentist’s name.
- 8 (C) Advertising by a physician and surgeon licensed under
9 Chapter 5 (commencing with Section 2000) shall include the
10 designation “MD” immediately following the physician and
11 surgeon’s name.
- 12 (D) Advertising by an osteopathic physician and surgeon
13 certified under Article 21 (commencing with Section 2450) shall
14 include the designation “DO” immediately following the
15 osteopathic physician and surgeon’s name.
- 16 (E) Advertising by a podiatrist certified under Article 22
17 (commencing with Section 2460) of Chapter 5 shall include the
18 designation “DPM” immediately following the podiatrist’s name.
- 19 (F) Advertising by a registered nurse licensed under Chapter
20 6 (commencing with Section 2700) shall include the designation
21 “RN” immediately following the registered nurse’s name.
- 22 (G) Advertising by a licensed vocational nurse under Chapter
23 6.5 (commencing with Section 2840) shall include the designation
24 “LVN” immediately following the licensed vocational nurse’s
25 name.
- 26 (H) Advertising by a psychologist licensed under Chapter 6.6
27 (commencing with Section 2900) shall include the designation
28 “Ph.D.” immediately following the psychologist’s name.
- 29 (I) Advertising by an optometrist licensed under Chapter 7
30 (commencing with Section 3000) shall include the applicable
31 designation or word described in Section 3098 immediately
32 following the optometrist’s name.
- 33 (J) Advertising by a physician assistant licensed under Chapter
34 7.7 (commencing with Section 3500) shall include the designation
35 “PA” immediately following the physician assistant’s name.
- 36 (K) Advertising by a naturopathic doctor licensed under Chapter
37 8.2 (commencing with Section 3610) shall include the designation
38 “ND” immediately following the naturopathic doctor’s name.
39 However, if the naturopathic doctor uses the term or designation

1 “Dr.” in an advertisement, he or she shall further identify himself
2 by any of the terms listed in Section 3661.

3 (2) For purposes of this subdivision, “advertisement” includes
4 communication by means of mail, television, radio, motion picture,
5 newspaper, book, directory, Internet, or other electronic
6 communication.

7 (3) Advertisements do not include any of the following:

8 (A) A medical directory released by a health care service plan
9 or a health insurer.

10 (B) A billing statement from a health care practitioner to a
11 patient.

12 (C) An appointment reminder from a health care practitioner
13 to a patient.

14 (4) This subdivision shall not apply until January 1, 2013, to
15 any advertisement that is published annually and prior to July 1,
16 2012.

17 (5) This subdivision shall not apply to any advertisement or
18 business card disseminated by a health care service plan that is
19 subject to the requirements of Section 1367.26 of the Health and
20 Safety Code.

21 (i)

22 (j) Each of the healing arts boards and examining committees
23 within Division 2 shall adopt appropriate regulations to enforce
24 this section in accordance with Chapter 3.5 (commencing with
25 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
26 Code.

27 Each of the healing arts boards and committees and examining
28 committees within Division 2 shall, by regulation, define those
29 efficacious services to be advertised by businesses or professions
30 under their jurisdiction for the purpose of determining whether
31 advertisements are false or misleading. Until a definition for that
32 service has been issued, no advertisement for that service shall be
33 disseminated. However, if a definition of a service has not been
34 issued by a board or committee within 120 days of receipt of a
35 request from a licensee, all those holding the license may advertise
36 the service. Those boards and committees shall adopt or modify
37 regulations defining what services may be advertised, the manner
38 in which defined services may be advertised, and restricting
39 advertising that would promote the inappropriate or excessive use
40 of health services or commodities. A board or committee shall not,

1 by regulation, unreasonably prevent truthful, nondeceptive price
2 or otherwise lawful forms of advertising of services or
3 commodities, by either outright prohibition or imposition of
4 onerous disclosure requirements. However, any member of a board
5 or committee acting in good faith in the adoption or enforcement
6 of any regulation shall be deemed to be acting as an agent of the
7 state.

8 ~~(j)~~

9 (k) The Attorney General shall commence legal proceedings in
10 the appropriate forum to enjoin advertisements disseminated or
11 about to be disseminated in violation of this section and seek other
12 appropriate relief to enforce this section. Notwithstanding any
13 other provision of law, the costs of enforcing this section to the
14 respective licensing boards or committees may be awarded against
15 any licensee found to be in violation of any provision of this
16 section. This shall not diminish the power of district attorneys,
17 county counsels, or city attorneys pursuant to existing law to seek
18 appropriate relief.

19 ~~(k)~~

20 (l) A physician and surgeon or doctor of podiatric medicine
21 licensed pursuant to Chapter 5 (commencing with Section 2000)
22 by the Medical Board of California who knowingly and
23 intentionally violates this section may be cited and assessed an
24 administrative fine not to exceed ten thousand dollars (\$10,000)
25 per event. Section 125.9 shall govern the issuance of this citation
26 and fine except that the fine limitations prescribed in paragraph
27 (3) of subdivision (b) of Section 125.9 shall not apply to a fine
28 under this subdivision.

29 SEC. 3. Section 2023.5 of the Business and Professions Code
30 is amended to read:

31 2023.5. (a) The board, in conjunction with the Board of
32 Registered Nursing, and in consultation with the Physician
33 Assistant Committee and professionals in the field, shall review
34 issues and problems surrounding the use of laser or intense light
35 pulse devices for elective cosmetic procedures by physicians and
36 surgeons, nurses, and physician assistants. The review shall include,
37 but need not be limited to, all of the following:

- 38 (1) The appropriate level of physician supervision needed.
- 39 (2) The appropriate level of training to ensure competency.

1 (3) Guidelines for standardized procedures and protocols that
2 address, at a minimum, all of the following:

3 (A) Patient selection.

4 (B) Patient education, instruction, and informed consent.

5 (C) Use of topical agents.

6 (D) Procedures to be followed in the event of complications or
7 side effects from the treatment.

8 (E) Procedures governing emergency and urgent care situations.

9 (b) On or before January 1, 2009, the board and the Board of
10 Registered Nursing shall promulgate regulations to implement
11 changes determined to be necessary with regard to the use of laser
12 or intense pulse light devices for elective cosmetic procedures by
13 physicians and surgeons, nurses, and physician assistants.

14 *(c) On or before January 1, 2013, the board shall adopt*
15 *regulations regarding the appropriate level of physician*
16 *availability needed within clinics or other settings using laser or*
17 *intense pulse light devices for elective cosmetic procedures.*
18 *However, these regulations shall not apply to laser or intense pulse*
19 *light devices approved by the federal Food and Drug*
20 *Administration for over-the-counter use by a health care*
21 *practitioner or by an unlicensed person on himself or herself.*

22 *(d) Nothing in this section shall be construed to modify the*
23 *prohibition against the unlicensed practice of medicine.*

24 SEC. 4. Section 2027.5 is added to the Business and Professions
25 Code, to read:

26 2027.5. The board shall post on its Internet Web site an
27 easy-to-understand factsheet to educate the public about cosmetic
28 surgery and procedures, including their risks. Included with the
29 factsheet shall be a comprehensive list of questions for patients to
30 ask their physician and surgeon regarding cosmetic surgery.

31 SEC. 5. Section 1204 of the Health and Safety Code is amended
32 to read:

33 1204. Clinics eligible for licensure pursuant to this chapter are
34 primary care clinics and specialty clinics.

35 (a) (1) Only the following defined classes of primary care
36 clinics shall be eligible for licensure:

37 (A) A “community clinic” means a clinic operated by a
38 tax-exempt nonprofit corporation that is supported and maintained
39 in whole or in part by donations, bequests, gifts, grants, government
40 funds or contributions, that may be in the form of money, goods,

1 or services. In a community clinic, any charges to the patient shall
2 be based on the patient's ability to pay, utilizing a sliding fee scale.
3 No corporation other than a nonprofit corporation, exempt from
4 federal income taxation under paragraph (3) of subsection (c) of
5 Section 501 of the Internal Revenue Code of 1954 as amended, or
6 a statutory successor thereof, shall operate a community clinic;
7 provided, that the licensee of any community clinic so licensed on
8 the effective date of this section shall not be required to obtain
9 tax-exempt status under either federal or state law in order to be
10 eligible for, or as a condition of, renewal of its license. No natural
11 person or persons shall operate a community clinic.

12 (B) A "free clinic" means a clinic operated by a tax-exempt,
13 nonprofit corporation supported in whole or in part by voluntary
14 donations, bequests, gifts, grants, government funds or
15 contributions, that may be in the form of money, goods, or services.
16 In a free clinic there shall be no charges directly to the patient for
17 services rendered or for drugs, medicines, appliances, or
18 apparatuses furnished. No corporation other than a nonprofit
19 corporation exempt from federal income taxation under paragraph
20 (3) of subsection (c) of Section 501 of the Internal Revenue Code
21 of 1954 as amended, or a statutory successor thereof, shall operate
22 a free clinic; provided, that the licensee of any free clinic so
23 licensed on the effective date of this section shall not be required
24 to obtain tax-exempt status under either federal or state law in
25 order to be eligible for, or as a condition of, renewal of its license.
26 No natural person or persons shall operate a free clinic.

27 (2) Nothing in this subdivision shall prohibit a community clinic
28 or a free clinic from providing services to patients whose services
29 are reimbursed by third-party payers, or from entering into
30 managed care contracts for services provided to private or public
31 health plan subscribers, as long as the clinic meets the requirements
32 identified in subparagraphs (A) and (B). For purposes of this
33 subdivision, any payments made to a community clinic by a
34 third-party payer, including, but not limited to, a health care service
35 plan, shall not constitute a charge to the patient. This paragraph is
36 a clarification of existing law.

37 (b) The following types of specialty clinics shall be eligible for
38 licensure as specialty clinics pursuant to this chapter:

39 (1) A "surgical clinic" means a clinic that is not part of a hospital
40 and that provides ambulatory surgical care for patients who remain

1 less than 24 hours, *including a surgical clinic that is owned in*
2 *whole or in part by a physician.* A surgical clinic does not include
3 any place or establishment owned or leased and operated as a clinic
4 or office by one or more physicians or dentists in individual or
5 group practice, regardless of the name used publicly to identify
6 the place or establishment, provided, however, that physicians or
7 dentists may, at their option, apply for licensure.

8 (2) A “chronic dialysis clinic” means a clinic that provides less
9 than 24-hour care for the treatment of patients with end-stage renal
10 disease, including renal dialysis services.

11 (3) A “rehabilitation clinic” means a clinic that, in addition to
12 providing medical services directly, also provides physical
13 rehabilitation services for patients who remain less than 24 hours.
14 Rehabilitation clinics shall provide at least two of the following
15 rehabilitation services: physical therapy, occupational therapy,
16 social, speech pathology, and audiology services. A rehabilitation
17 clinic does not include the offices of a private physician in
18 individual or group practice.

19 (4) An “alternative birth center” means a clinic that is not part
20 of a hospital and that provides comprehensive perinatal services
21 and delivery care to pregnant women who remain less than 24
22 hours at the facility.

23 SEC. 6. Section 1204.6 is added to the Health and Safety Code,
24 to read:

25 1204.6. Until the department promulgates regulations for the
26 licensing of surgical clinics, the department shall use the federal
27 conditions of coverage, as set forth in Subpart C of Part 416 of
28 Title 42 of the Code of Federal Regulations, as those conditions
29 existed on May 18, 2009, as the basis for licensure for facilities
30 licensed pursuant to paragraph (1) of subdivision (b) of Section
31 1204.

32 SEC. 7. Section 1204.7 is added to the Health and Safety Code,
33 to read:

34 1204.7. (a) An outpatient setting, as defined in subdivision (a)
35 of Section 1248, that is accredited by an accrediting agency
36 approved by the Medical Board of California, shall be deemed
37 licensed by the department and shall be required to pay an annual
38 licensing fee as established pursuant to Section 1266.

39 (b) The department shall have only that authority over outpatient
40 settings specified in Chapter 3.1 (commencing with Section 1248).

1 (c) The department shall notify the Medical Board of California
2 of any action taken against an outpatient setting and, if licensure
3 of an outpatient setting is revoked or suspended by the department
4 for any reason, then accreditation shall be void by operation of
5 law. Notwithstanding Sections 1241 and 131071, proceedings shall
6 not be required to void the accreditation of an outpatient setting
7 under these circumstances.

8 SEC. 8. Section 1204.8 is added to the Health and Safety Code,
9 to read:

10 1204.8. A clinic licensed pursuant to paragraph (1) of
11 subdivision (b) of Section 1204 or an outpatient setting, as defined
12 in Section 1248, shall be subject to the reporting requirements in
13 Section 1279.1 and the penalties for failure to report specified in
14 Section 1280.4.

15 SEC. 9. Section 1248 of the Health and Safety Code is amended
16 to read:

17 1248. For purposes of this chapter, the following definitions
18 shall apply:

19 (a) “Division” means the *Medical Board of California*. All
20 references in this chapter to the division, the Division of Licensing
21 of the Medical Board of ~~California~~, *California*, or the Division of
22 *Medical Quality shall be deemed to refer to the Medical Board of*
23 *California pursuant to Section 2002 of the Business and*
24 *Professions Code.*

25 ~~(b) “Division of Medical Quality” means the Division of~~
26 ~~Medical Quality of the Medical Board of California.~~

27 (e)

28 (b) (1) “Outpatient setting” means any facility, clinic,
29 unlicensed clinic, center, office, or other setting that is not part of
30 a general acute care facility, as defined in Section 1250, and where
31 anesthesia, except local anesthesia or peripheral nerve blocks, or
32 both, is used in compliance with the community standard of
33 practice, in doses that, when administered have the probability of
34 placing a patient at risk for loss of the patient’s life-preserving
35 protective reflexes.

36 (2) “Outpatient setting” also means facilities that offer *in vitro*
37 *fertilization, as defined in subdivision (b) of Section 1374.55.*

38 (3) “Outpatient setting” does not include, among other settings,
39 any setting where anxiolytics and analgesics are administered,
40 when done so in compliance with the community standard of

1 practice, in doses that do not have the probability of placing the
2 patient at risk for loss of the patient’s life-preserving protective
3 reflexes.

4 ~~(d)~~

5 (c) “Accreditation agency” means a public or private
6 organization that is approved to issue certificates of accreditation
7 to outpatient settings by the ~~division~~ board pursuant to Sections
8 1248.15 and 1248.4.

9 SEC. 10. Section 1248.15 of the Health and Safety Code is
10 amended to read:

11 1248.15. (a) The ~~division~~ board shall adopt standards for
12 accreditation and, in approving accreditation agencies to perform
13 accreditation of outpatient settings, shall ensure that the
14 certification program shall, at a minimum, include standards for
15 the following aspects of the settings’ operations:

16 (1) Outpatient setting allied health staff shall be licensed or
17 certified to the extent required by state or federal law.

18 (2) (A) Outpatient settings shall have a system for facility safety
19 and emergency training requirements.

20 (B) There shall be onsite equipment, medication, and trained
21 personnel to facilitate handling of services sought or provided and
22 to facilitate handling of any medical emergency that may arise in
23 connection with services sought or provided.

24 (C) In order for procedures to be performed in an outpatient
25 setting as defined in Section 1248, the outpatient setting shall do
26 one of the following:

27 (i) Have a written transfer agreement with a local accredited or
28 licensed acute care hospital, approved by the facility’s medical
29 staff.

30 (ii) Permit surgery only by a licensee who has admitting
31 privileges at a local accredited or licensed acute care hospital, with
32 the exception that licensees who may be precluded from having
33 admitting privileges by their professional classification or other
34 administrative limitations, shall have a written transfer agreement
35 with licensees who have admitting privileges at local accredited
36 or licensed acute care hospitals.

37 ~~(iii) Submit~~

38 (D) The outpatient setting shall submit for approval by an
39 accrediting agency a detailed procedural plan for handling medical

1 emergencies that shall be reviewed at the time of accreditation.

2 No reasonable plan shall be disapproved by the accrediting agency.

3 (E) *The outpatient setting shall submit for approval by an*
4 *accreditation agency at the time accreditation of a detailed plan,*
5 *standardized procedures, and protocols to be followed in the event*
6 *of serious complications or side effects from surgery that would*
7 *place a patient at high risk for injury or harm or to govern*
8 *emergency and urgent care situations.*

9 (D)

10 (F) All physicians and surgeons transferring patients from an
11 outpatient setting shall agree to cooperate with the medical staff
12 peer review process on the transferred case, the results of which
13 shall be referred back to the outpatient setting, if deemed
14 appropriate by the medical staff peer review committee. If the
15 medical staff of the acute care facility determines that inappropriate
16 care was delivered at the outpatient setting, the acute care facility's
17 peer review outcome shall be reported, as appropriate, to the
18 accrediting body, the Health Care Financing Administration, the
19 State Department of ~~Health Services~~, *Public Health*, and the
20 appropriate licensing authority.

21 (3) The outpatient setting shall permit surgery by a dentist acting
22 within his or her scope of practice under Chapter 4 (commencing
23 with Section 1600) of *Division 2 of the Business and Professions*
24 *Code* or physician and surgeon, osteopathic physician and surgeon,
25 or podiatrist acting within his or her scope of practice under
26 Chapter 5 (commencing with Section 2000) of *Division 2 of the*
27 *Business and Professions Code* or the Osteopathic Initiative Act.
28 The outpatient setting may, in its discretion, permit anesthesia
29 service by a certified registered nurse anesthetist acting within his
30 or her scope of practice under Article 7 (commencing with Section
31 2825) of Chapter 6 of *Division 2 of the Business and Professions*
32 *Code*.

33 (4) Outpatient settings shall have a system for maintaining
34 clinical records.

35 (5) Outpatient settings shall have a system for patient care and
36 monitoring procedures.

37 (6) (A) Outpatient settings shall have a system for quality
38 assessment and improvement.

39 (B) Members of the medical staff and other practitioners who
40 are granted clinical privileges shall be professionally qualified and

1 appropriately credentialed for the performance of privileges
2 granted. The outpatient setting shall grant privileges in accordance
3 with recommendations from qualified health professionals, and
4 credentialing standards established by the outpatient setting.

5 (C) Clinical privileges shall be periodically reappraised by the
6 outpatient setting. The scope of procedures performed in the
7 outpatient setting shall be periodically reviewed and amended as
8 appropriate.

9 (7) Outpatient settings regulated by this chapter that have
10 multiple service locations governed by the same standards may
11 elect to have all service sites surveyed on any accreditation survey.
12 Organizations that do not elect to have all sites surveyed shall have
13 a sample, not to exceed 20 percent of all service sites, surveyed.
14 The actual sample size shall be determined by the ~~division~~ board.
15 The accreditation agency shall determine the location of the sites
16 to be surveyed. Outpatient settings that have five or fewer sites
17 shall have at least one site surveyed. When an organization that
18 elects to have a sample of sites surveyed is approved for
19 accreditation, all of the organizations' sites shall be automatically
20 accredited.

21 (8) Outpatient settings shall post the certificate of accreditation
22 in a location readily visible to patients and staff.

23 (9) Outpatient settings shall post the name and telephone number
24 of the accrediting agency with instructions on the submission of
25 complaints in a location readily visible to patients and staff.

26 (10) Outpatient settings shall have a written discharge criteria.

27 (b) Outpatient settings shall have a minimum of two staff
28 persons on the premises, one of whom shall either be a licensed
29 physician and surgeon or a licensed health care professional with
30 current certification in advanced cardiac life support (ACLS), as
31 long as a patient is present who has not been discharged from
32 supervised care. Transfer to an unlicensed setting of a patient who
33 does not meet the discharge criteria adopted pursuant to paragraph
34 (10) of subdivision (a) shall constitute unprofessional conduct.

35 (c) An accreditation agency may include additional standards
36 in its determination to accredit outpatient settings if these are
37 approved by the ~~division~~ board to protect the public health and
38 safety.

39 (d) No accreditation standard adopted or approved by the
40 ~~division~~, board, and no standard included in any certification

1 program of any accreditation agency approved by the ~~division,~~
 2 *board*, shall serve to limit the ability of any allied health care
 3 practitioner to provide services within his or her full scope of
 4 practice. Notwithstanding this or any other provision of law, each
 5 outpatient setting may limit the privileges, or determine the
 6 privileges, within the appropriate scope of practice, that will be
 7 afforded to physicians and allied health care practitioners who
 8 practice at the facility, in accordance with credentialing standards
 9 established by the outpatient setting in compliance with this
 10 chapter. Privileges may not be arbitrarily restricted based on
 11 category of licensure.

12 *(e) The board shall adopt standards that it deems necessary for*
 13 *outpatient settings that offer in vitro fertilization.*

14 SEC. 11. Section 1248.2 of the Health and Safety Code is
 15 amended to read:

16 1248.2. (a) Any outpatient setting may apply to an
 17 accreditation agency for a certificate of accreditation. Accreditation
 18 shall be issued by the accreditation agency solely on the basis of
 19 compliance with its standards as approved by the ~~division~~ *board*
 20 under this chapter.

21 *(b) The board shall submit to the State Department of Public*
 22 *Health the information required pursuant to paragraph (3) of*
 23 *subdivision (d) within 10 days of the accreditation of an outpatient*
 24 *setting.*

25 ~~(b)~~

26 *(c) The ~~division~~ board shall obtain and maintain a list of all*
 27 *accredited, certified, and licensed outpatient settings from the*
 28 *information provided by the accreditation, certification, and*
 29 *licensing agencies approved by the ~~division,~~ board, and shall notify*
 30 *the ~~public, upon inquiry,~~ public whether a setting is accredited,*
 31 *certified, or licensed, or ~~whether~~ the setting's accreditation,*
 32 *certification, or license has been ~~revoked.~~ revoked, suspended, or*
 33 *placed on probation, or the setting has received a reprimand by*
 34 *the accreditation agency. The board shall provide notice to the*
 35 *department within 10 days when an outpatient setting's*
 36 *accreditation has been revoked, suspended, or placed on probation.*
 37 *The department shall notify the board within 10 days if the license*
 38 *of a surgical clinic, as defined in paragraph (1) of subdivision (b)*
 39 *of Section 1204, has been revoked.*

1 (d) (1) *The board shall, on or before February 1, 2012, provide*
2 *the department with a list of all outpatient settings that are*
3 *accredited as of January 1, 2012.*

4 (2) *Beginning April 1, 2012, the board shall provide the*
5 *department with an updated list of outpatient settings every three*
6 *months.*

7 (3) *The list of outpatient settings shall include all of the*
8 *following:*

9 (A) *Name, address, and telephone number of the owner.*

10 (B) *Name and address of the facility.*

11 (C) *The name and telephone number of the accreditation agency.*

12 (D) *The effective and expiration dates of the accreditation.*

13 (e) *The board shall provide the department with all accreditation*
14 *standards approved by the board, free of charge. Accreditation*
15 *standards provided to the department by the board shall not be*
16 *subject to public disclosure provisions of the California Public*
17 *Records Act (Chapter 3.5 commencing with Section 6250) of*
18 *Division 7 of Title 1 of the Government Code).*

19 SEC. 12. Section 1248.25 of the Health and Safety Code is
20 amended to read:

21 1248.25. If an outpatient setting does not meet the standards
22 approved by the ~~division, board~~, accreditation shall be denied by
23 the accreditation agency, which shall provide the outpatient setting
24 notification of the reasons for the denial. An outpatient setting may
25 reapply for accreditation at any time after receiving notification
26 of the denial. *The accreditation agency shall immediately report*
27 *to the board if the outpatient setting's certificate for accreditation*
28 *has been denied.*

29 SEC. 13. Section 1248.35 of the Health and Safety Code is
30 amended to read:

31 1248.35. (a) *Every outpatient setting which is accredited shall*
32 *be inspected by the accreditation agency and may also be inspected*
33 *by the Medical Board of California. The Medical Board of*
34 *California shall ensure that accreditation agencies inspect*
35 *outpatient settings.*

36 (b) *Unless otherwise specified, the following requirements apply*
37 *to inspections described in subdivision (a).*

38 (1) *The frequency of inspection shall depend upon the type and*
39 *complexity of the outpatient setting to be inspected.*

1 (2) *Inspections shall be conducted no less often than once every*
2 *three years by the accreditation agency and as often as necessary*
3 *by the Medical Board of California to ensure the quality of care*
4 *provided.*

5 (a)

6 (3) ~~The Division of Medical Quality Board of California or an~~
7 ~~the accreditation agency may, upon reasonable prior notice and~~
8 ~~presentation of proper identification, may enter and inspect any~~
9 ~~outpatient setting that is accredited by an accreditation agency at~~
10 ~~any reasonable time to ensure compliance with, or investigate an~~
11 ~~alleged violation of, any standard of the accreditation agency or~~
12 ~~any provision of this chapter.~~

13 (b)

14 (c) If an accreditation agency determines, as a result of its
15 inspection, that an outpatient setting is not in compliance with the
16 standards under which it was approved, the accreditation agency
17 may do any of the following:

18 (1) Issue a reprimand.

19 (2) Place the outpatient setting on probation, during which time
20 the setting shall successfully institute and complete a plan of
21 correction, approved by the ~~division board~~ or the accreditation
22 agency, to correct the deficiencies.

23 (3) Suspend or revoke the outpatient setting's certification of
24 accreditation.

25 (e)

26 (d) Except as is otherwise provided in this subdivision, before
27 suspending or revoking a certificate of accreditation under this
28 chapter, the accreditation agency shall provide the outpatient setting
29 with notice of any deficiencies and *the outpatient setting shall*
30 *agree with the accreditation agency on a plan of correction that*
31 *shall give the outpatient setting reasonable time to supply*
32 *information demonstrating compliance with the standards of the*
33 *accreditation agency in compliance with this chapter, as well as*
34 *the opportunity for a hearing on the matter upon the request of the*
35 *outpatient center. During that allotted time, a list of deficiencies*
36 *and the plan of correction shall be conspicuously posted in a clinic*
37 *location accessible to public view. Within 10 days after the*
38 *adoption of the plan of correction, the accrediting agency shall*
39 *send a list of deficiencies and the corrective action to be taken to*
40 *both the board and the department.* The accreditation agency may

1 immediately suspend the certificate of accreditation before
2 providing notice and an opportunity to be heard, but only when
3 failure to take the action may result in imminent danger to the
4 health of an individual. In such cases, the accreditation agency
5 shall provide subsequent notice and an opportunity to be heard.

6 ~~(d) If the division determines that deficiencies found during an~~
7 ~~inspection suggests that the accreditation agency does not comply~~
8 ~~with the standards approved by the division, the division may~~
9 ~~conduct inspections, as described in this section, of other settings~~
10 ~~accredited by the accreditation agency to determine if the agency~~
11 ~~is accrediting settings in accordance with Section 1248.15.~~

12 *(e) The department may enter and inspect an outpatient setting*
13 *upon receipt of a notice of corrective action or if it has reason to*
14 *believe that there may be risk to patient safety, health, or welfare.*

15 *(f) An outpatient setting that does not comply with a corrective*
16 *action may be required by the department to pay similar penalties*
17 *assessed against a surgical clinic licensed pursuant to paragraph*
18 *(1) of subdivision (b) of Section 1204, and may have its license*
19 *suspended or revoked pursuant to Article 5 (commencing with*
20 *Section 1240) of Chapter 1.*

21 *(g) If the licensee disputes a determination by the department*
22 *regarding the alleged deficiency, the alleged failure to correct a*
23 *deficiency, the reasonableness of the proposed deadline for*
24 *correction, or the amount of the penalty, the licensee may, within*
25 *10 days, request a hearing pursuant to Section 130171. Penalties*
26 *shall be paid when appeals have been exhausted and the*
27 *department's position has been upheld.*

28 *(h) Moneys collected by the department as a result of*
29 *administrative penalties imposed under this section shall be*
30 *deposited into the Internal Departmental Quality Improvement*
31 *Account established pursuant to Section 1280.15. These moneys*
32 *shall be tracked and available for expenditure, upon appropriation*
33 *by the Legislature, to support internal departmental quality*
34 *improvement activities.*

35 *(i) If, after an inspection authorized pursuant to this section,*
36 *the department finds a violation of a standard of the facility's*
37 *accrediting agency or any provision of this chapter or the*
38 *regulations promulgated thereunder, or if the facility fails to pay*
39 *a licensing fee or an administrative penalty assessed under this*
40 *chapter, the department may take any action pursuant to Article*

1 5 (commencing with Section 1240) of Chapter 1 and shall report
 2 the violation to the board and may recommend that accreditation
 3 be revoked, canceled, or not renewed.

4 (j) Reports on the results of any inspection conducted pursuant
 5 to subdivision (a) shall be kept on file with the board or the
 6 accreditation agency along with the plan of correction and the
 7 outpatient setting comments. The inspection report may include a
 8 recommendation for reinspection. All inspection reports, lists of
 9 deficiencies, and plans of correction shall be public records open
 10 to public inspection.

11 (k) The accreditation agency shall, within 24 hours, report to
 12 the board if the outpatient setting has been issued a reprimand or
 13 if the outpatient setting's certification of accreditation has been
 14 suspended or revoked or if the outpatient setting has been placed
 15 on probation.

16 (l) If one accrediting agency denies accreditation, or revokes
 17 or suspends the accreditation of an outpatient setting, this action
 18 shall apply to all other accrediting agencies.

19 SEC. 14. Section 1248.5 of the Health and Safety Code is
 20 amended to read:

21 1248.5. ~~The division may board shall~~ evaluate the performance
 22 of an approved accreditation agency no less than every three years,
 23 or in response to complaints against an agency, or complaints
 24 against one or more outpatient settings accreditation by an agency
 25 that indicates noncompliance by the agency with the standards
 26 approved by the ~~division~~ board.

27 SEC. 15. Section 1248.55 of the Health and Safety Code is
 28 amended to read:

29 1248.55. (a) If the accreditation agency is not meeting the
 30 criteria set by the ~~division~~ board, the ~~division~~ board may terminate
 31 approval of the ~~agency~~ agency or may issue a citation to the
 32 agency in accordance with the system established under subdivision
 33 (b).

34 (b) The board may establish, by regulation, a system for the
 35 issuance of a citation to an accreditation agency that is not meeting
 36 the criteria set by the board. This system shall meet the
 37 requirements of Section 125.9 of the Business and Professions
 38 Code, as applicable, except that both of the following shall apply:

39 (1) Failure of an agency to pay an administrative fine assessed
 40 pursuant to a citation within 30 days of the date of the assessment,

1 *unless the citation is being appealed, may result in the board's*
2 *termination of approval of the agency. Where a citation is not*
3 *contested and a fine is not paid, the full amount of the assessed*
4 *fine shall be added to the renewal fee established under Section*
5 *1248.6. Approval of an agency shall not be renewed without*
6 *payment of the renewal fee and fine.*

7 (2) *Administrative fines collected pursuant to the system shall*
8 *be deposited in the Outpatient Setting Fund of the Medical Board*
9 *of California established under Section 1248.6.*

10 ~~(b)~~

11 (c) *Before terminating approval of an accreditation agency, the*
12 ~~division board~~ *shall provide the accreditation agency with notice*
13 *of any deficiencies and reasonable time to supply information*
14 *demonstrating compliance with the requirements of this chapter,*
15 *as well as the opportunity for a hearing on the matter in compliance*
16 *with Chapter 5 (commencing with Section 11500) of Part 1 of*
17 *Division 3 of Title 2 of the Government Code.*

18 ~~(e)~~

19 (d) (1) *If approval of the accreditation agency is terminated by*
20 ~~the division board,~~ *outpatient settings accredited by that agency*
21 *shall be notified by the ~~division board~~ and, except as provided in*
22 *paragraph (2), shall be authorized to continue to operate for a*
23 *period of 12 months in order to seek accreditation through an*
24 *approved accreditation agency, unless the time is extended by the*
25 ~~division board~~ *for good cause.*

26 (2) ~~The division board~~ *may require that an outpatient setting,*
27 *that has been accredited by an accreditation agency whose approval*
28 *has been terminated by the ~~division board,~~ cease operations*
29 *immediately in if the event that the ~~division board~~ is in possession*
30 *of information indicating that continued operation poses an*
31 *imminent risk of harm to the health of an individual. In such cases,*
32 ~~the division board~~ *shall provide the outpatient setting with notice*
33 *of its action, the reason underlying it, and a subsequent opportunity*
34 *for a hearing on the matter. An outpatient setting that is ordered*
35 *to cease operations under this paragraph may reapply for a*
36 *certificate of accreditation after six months and shall notify the*
37 ~~division board~~ *promptly of its reapplication. The board shall notify*
38 *the department of any action taken pursuant to this section for an*
39 *outpatient setting. Upon cancellation, revocation, nonrenewal, or*
40 *any other loss of accreditation, an outpatient setting's license shall*

1 *be void by operation of law. Notwithstanding Sections 1241 and*
2 *131071, no proceedings shall be required to void the license of an*
3 *outpatient setting.*

4 SEC. 16. Section 1279 of the Health and Safety Code is
5 amended to read:

6 1279. (a) Every health facility for which a license or special
7 permit has been issued shall be periodically inspected by the
8 department, or by another governmental entity under contract with
9 the department. The frequency of inspections shall vary, depending
10 upon the type and complexity of the health facility or special
11 service to be inspected, unless otherwise specified by state or
12 federal law or regulation. The inspection shall include participation
13 by the California Medical Association consistent with the manner
14 in which it participated in inspections, as provided in Section 1282
15 prior to September 15, 1992.

16 (b) Except as provided in subdivision (c), inspections shall be
17 conducted no less than once every two years and as often as
18 necessary to ensure the quality of care being provided.

19 (c) For a health facility specified in subdivision (a), (b), or (f)
20 of Section 1250, inspections shall be conducted no less than once
21 every three years, and as often as necessary to ensure the quality
22 of care being provided.

23 (d) During the inspection, the representative or representatives
24 shall offer such advice and assistance to the health facility as they
25 deem appropriate.

26 (e) For acute care hospitals of 100 beds or more, the inspection
27 team shall include at least a physician, registered nurse, and persons
28 experienced in hospital administration and sanitary inspections.
29 During the inspection, the team shall offer advice and assistance
30 to the hospital as it deems appropriate.

31 (f) The department shall ensure that a periodic inspection
32 conducted pursuant to this section is not announced in advance of
33 the date of inspection. An inspection may be conducted jointly
34 with inspections by entities specified in Section 1282. However,
35 if the department conducts an inspection jointly with an entity
36 specified in Section 1282 that provides notice in advance of the
37 periodic inspection, the department shall conduct an additional
38 periodic inspection that is not announced or noticed to the health
39 facility.

1 (g) Notwithstanding any other provision of law, the department
2 shall inspect for compliance with provisions of state law and
3 regulations during a state periodic inspection or at the same time
4 as a federal periodic inspection, including, but not limited to, an
5 inspection required under this section. If the department inspects
6 for compliance with state law and regulations at the same time as
7 a federal periodic inspection, the inspection shall be done consistent
8 with the guidance of the federal Centers for Medicare and Medicaid
9 Services for the federal portion of the inspection.

10 (h) The department shall emphasize consistency across the state
11 and *in* its district offices when conducting licensing and
12 certification surveys and complaint investigations, including the
13 selection of state or federal enforcement remedies in accordance
14 with Section 1423. The department may issue federal deficiencies
15 and recommend federal enforcement actions in those circumstances
16 where they provide more rigorous enforcement action.

17 (i) *It is the intent of the Legislature that the department, pursuant*
18 *to its existing regulations, inspect the peer review process utilized*
19 *by acute care hospitals as part of its periodic inspection of those*
20 *hospitals pursuant to this section.*

21 SEC. 17. No reimbursement is required by this act pursuant
22 to Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the penalty
26 for a crime or infraction, within the meaning of Section 17556 of
27 the Government Code, or changes the definition of a crime within
28 the meaning of Section 6 of Article XIII B of the California
29 Constitution.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 632

VERSION: As Introduced February 18, 2011

AUTHOR: Emmerson

SPONSOR:

BOARD POSITION: None

SUBJECT: Pharmacy

Affected Sections: Amend Section 4037 of the Business and Professions Code.

CURRENT STATUS: Rules Committee

EXISTING LAW:

Defines pharmacy as an area, place or premises licensed by the board in which the practice of pharmacy is practiced and where prescriptions are compounded.

THIS BILL WOULD:

Make technical, nonsubstantive changes to that provision.

AUTHOR'S INTENT:

This is currently a spot bill.

COMMENTS:

Staff will continue to watch this bill for amendments and will bring the legislation back to the board to consideration.

PRIOR HISTORY/RELATED BILLS:

Unknown

FISCAL IMPACT:

Unknown

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Mar. 3 Referred to Com. on RLS.

Feb. 20 From printer. May be acted upon on or after March 22.

Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Emmerson

February 18, 2011

An act to amend Section 4037 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 632, as introduced, Emmerson. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. Existing law defines the term "pharmacy" for the purposes of these provisions.

This bill would make a technical, nonsubstantive change to that provision.

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

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

1 SECTION 1. Section 4037 of the Business and Professions
2 Code is amended to read:
3 4037. (a) "Pharmacy" ~~means~~ *shall mean* an area, place, or
4 premises licensed by the board in which the profession of pharmacy
5 is practiced and where prescriptions are compounded. "Pharmacy"
6 includes, but is not limited to, any area, place, or premises
7 described in a license issued by the board wherein controlled
8 substances, dangerous drugs, or dangerous devices are stored,
9 possessed, prepared, manufactured, derived, compounded, or
10 repackaged, and from which the controlled substances, dangerous

1 drugs, or dangerous devices are furnished, sold, or dispensed at
2 retail.

3 (b) “Pharmacy” shall not include any area in a facility licensed
4 by the State Department of Public Health where floor supplies,
5 ward supplies, operating room supplies, or emergency room
6 supplies of dangerous drugs or dangerous devices are stored or
7 possessed solely for treatment of patients registered for treatment
8 in the facility or for treatment of patients receiving emergency care
9 in the facility.

Agenda Item 2b



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 24, 2011
To: Legislation and Regulation Committee
Subject: Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Agenda Item 2.b: Controlled substances/marijuana

Below are summaries of bills relating to controlled substances and marijuana. A bill analysis and a copy of the most recent version of the bill are provided in unless otherwise noted.

AB 507 (Hayashi) Pain Management

Summary: Would exempt from the unprofessional conduct provisions, any holder of a license who has a medical basis for furnishing dangerous drugs or prescription controlled substances, including for pain or a condition causing pain.

Recent Action: Assembly Health Committee hearing scheduled for April 5, 2011.

SB 847 (Correa) Medical Cannabis Licensing Act

Summary: This bill would require the Department of Corrections and Rehabilitation to license all distributions centers and facilities with the board as part of its comprehensive pharmacy services program.

Recent Action: Senate Governance and Finance Committee Hearing April 27, 2011

SB 786 (Dutton) Pharmacy: clinics

Summary: This is a spot bill.

Recent Action: Referred to Rules Committee.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 507

VERSION: As Amended March 21, 2011

AUTHOR: Hayashi

SPONSOR: American Cancer Society

BOARD POSITION: None

SUBJECT: Pain Management

Affected Sections: Amend Section 4301 of the Business and Professions Code, and to amend Sections 124960 and 124961 of the Health and Safety Code and repeal Section 11453 of the Health and Safety Code.

CURRENT STATUS: Assembly Health Committee hearing scheduled for April 5, 2011.

EXISTING LAW:

1. Business and Professions Code Section 4301 authorizes the board to take action against any holder of a license that is guilty of unprofessional conduct as specified. Unprofessional conduct includes several elements including the clearly excessive furnishing of controlled substances in violation of Health and Safety Code section 11153(a).
2. Health and Safety Code Section 11453 authorizes the Department of Justice to employ of physician to interview and examine any patient for whom any Scheduled I – III controlled substance has been furnished as specified.
3. Health and Safety Code Section 124960 sets forth legislative findings and declarations including the state's right and duty to control the illegal use of opiates, inadequate treatment of acute and chronic pain is a significant health program, patients that suffer from severe chronic intractable pain should have access to proper treatment of his or her pain, many patients suffering require referral to a physician with expertise, opiates can be an accepted treatment for patients in severe chronic intractable pain and provides that a patient's physician may refuse to prescribe opiate medication however the physician shall inform that patient about physicians that special in such treatment.
4. Establishes the Pain Patient's Bill of Rights that includes:
 - a. A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.
 - b. A patient has the option to choose opiate medications to relieve the pain as specified.

- c. A physician's right to refuse to prescribe opiate medication, however requires the physician to inform the patient about physicians that specialize in such treatment.
- d. A physician who uses opiate therapy may prescribe dosage deemed medically necessary consistent with Section 2241.5 of the Business and Professions Code
- e. A patient may request that the physician provide an identifying notice of the prescription for purposes of emergency treatment or law information.
- f. Nothing in the section limits any reporting or disciplinary provisions against those who violate prescribing practices or applicability of federal and state laws that regulate dangerous drugs or controlled substances.

AS AMENDED THIS BILL WOULD:

1. Amend B&PC 4301(d) to include any holder of a license who has a medical basis for furnishing dangerous drugs or prescription controlled substances, including for pain or a condition causing pain, shall not be subject to disciplinary action.
2. Repeals the provisions authorizing the DOJ to employ a physician to interview and examine any patient for whom any Scheduled I – III controlled substance has been furnished as specified.
3. Replaces the clause “severe chronic intractable pain” with “pain or a condition causing pain, including, but not limited to, intractable pain”.
4. Requires a physician that refuses to prescribe opiate medication to refer a patient to a physician who treats pain with methods that include the use of opiates.

AUTHOR'S INTENT:

According to the author's office, this bill eliminates ambiguities and inconsistencies in the Intractable Pain Treatment Act that negatively affect appropriate clinical interpretation. The author also indicated that the bill clarifies when a pharmacist is subject to unprofessional conduct standards for dispensing controlled substances and make conforming changes in existing law.

COMMENTS:

Board staff was recently advised by the author's office that the proposed amendments to B&PC 4301(d) may be removed. If the amendment is not removed, the board will need to consider the important role a pharmacist plays in not only dispensing a medicine, but serving as the last important check in a health care team. The proposed amendment could limit the board's ability to discipline a pharmacist's license when they fail to exercise their professional judgment.

In the past three calendar years, the board has initiated 36 investigations alleging violations of Health and Safety Code Section 11153. This code establishes the corresponding responsibility that rests with a pharmacist who fills a prescription for a

controlled substance and the board relies upon B&PC 4301(d) to establish such action as unprofessional conduct for purposes of discipline. Further, the proposed amendment to this section creates some additional challenges in that the board will need to establish that the prescriptions were not provided for legitimate medical purposes, requiring the use of medical experts. The use of such experts will be both costly to the board as well as increase the overall case closure time, which runs afoul of the Consumer Protection Enforcement Initiative.

FISCAL IMPACT:

The board estimates an additional \$5,000 for each investigation to cover the costs associated with the expert review and testimony required for each case referred to the Office of the Attorney General.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

- Mar. 22 Re-referred to Com. on HEALTH.
- Mar. 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 3 Referred to Coms. on HEALTH and B., P. & C.P.
- Feb. 16 From printer. May be heard in committee March 18.
- Feb. 15 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 21, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 507

Introduced by Assembly Member Hayashi

February 15, 2011

An act to amend Section 4301 of the Business and Professions Code, and to amend Sections 124960 and 124961 of, and to repeal Section 11453 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 507, as amended, Hayashi. Pain management.

(1) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy technicians by the California State Board of Pharmacy.

Existing law requires the board to take action against any holder of a license who is guilty of unprofessional conduct, as defined, including, but not limited to, the clearly excessive furnishing of controlled substances in violation of prescribed statutory provisions relating to the prescription of a controlled substance.

This bill would exempt from this provision any holder of a license who has a medical basis for furnishing dangerous drugs or prescription controlled substances, including for pain or a condition causing pain.

(2) Existing law authorizes the Department of Justice to employ a physician to interview and examine any patient in connection with the prescription possession or use of a controlled substance, requires the patient to submit to the interview and examination, and authorizes the physician to testify in prescribed administrative proceedings.

This bill would repeal that provision.

(3) Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California, and the violation of specified provisions of the act is a crime. Existing law authorizes a physician and surgeon to prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition, drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

This bill would conform findings and declarations and other references to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

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

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

1 SECTION 1. Section 4301 of the Business and Professions
 2 Code is amended to read:
 3 4301. The board shall take action against any holder of a license
 4 who is guilty of unprofessional conduct or whose license has been
 5 procured by fraud or misrepresentation or issued by mistake.
 6 Unprofessional conduct shall include, but is not limited to, any of
 7 the following:
 8 (a) Gross immorality.
 9 (b) Incompetence.
 10 (c) Gross negligence.
 11 (d) The clearly excessive furnishing of controlled substances
 12 in violation of subdivision (a) of Section 11153 of the Health and
 13 Safety Code. Any holder of a license who has a medical basis for
 14 furnishing dangerous drugs or prescription controlled substances,
 15 including for pain or a condition causing pain, shall not be subject
 16 to disciplinary action pursuant to this section.
 17 (e) The clearly excessive furnishing of controlled substances in
 18 violation of subdivision (a) of Section 11153.5 of the Health and
 19 Safety Code. Factors to be considered in determining whether the
 20 furnishing of controlled substances is clearly excessive shall
 21 include, but not be limited to, the amount of controlled substances
 22 furnished, the previous ordering pattern of the customer (including
 23 size and frequency of orders), the type and size of the customer,
 24 and where and to whom the customer distributes its product.

1 (f) The commission of any act involving moral turpitude,
2 dishonesty, fraud, deceit, or corruption, whether the act is
3 committed in the course of relations as a licensee or otherwise,
4 and whether the act is a felony or misdemeanor or not.

5 (g) Knowingly making or signing any certificate or other
6 document that falsely represents the existence or nonexistence of
7 a state of facts.

8 (h) The administering to oneself, of any controlled substance,
9 or the use of any dangerous drug or of alcoholic beverages to the
10 extent or in a manner as to be dangerous or injurious to oneself,
11 to a person holding a license under this chapter, or to any other
12 person or to the public, or to the extent that the use impairs the
13 ability of the person to conduct with safety to the public the practice
14 authorized by the license.

15 (i) Except as otherwise authorized by law, knowingly selling,
16 furnishing, giving away, or administering, or offering to sell,
17 furnish, give away, or administer, any controlled substance to an
18 addict.

19 (j) The violation of any of the statutes of this state, of any other
20 state, or of the United States regulating controlled substances and
21 dangerous drugs.

22 (k) The conviction of more than one misdemeanor or any felony
23 involving the use, consumption, or self-administration of any
24 dangerous drug or alcoholic beverage, or any combination of those
25 substances.

26 (l) The conviction of a crime substantially related to the
27 qualifications, functions, and duties of a licensee under this chapter.
28 The record of conviction of a violation of Chapter 13 (commencing
29 with Section 801) of Title 21 of the United States Code regulating
30 controlled substances or of a violation of the statutes of this state
31 regulating controlled substances or dangerous drugs shall be
32 conclusive evidence of unprofessional conduct. In all other cases,
33 the record of conviction shall be conclusive evidence only of the
34 fact that the conviction occurred. The board may inquire into the
35 circumstances surrounding the commission of the crime, in order
36 to fix the degree of discipline or, in the case of a conviction not
37 involving controlled substances or dangerous drugs, to determine
38 if the conviction is of an offense substantially related to the
39 qualifications, functions, and duties of a licensee under this chapter.
40 A plea or verdict of guilty or a conviction following a plea of nolo

1 contendere is deemed to be a conviction within the meaning of
2 this provision. The board may take action when the time for appeal
3 has elapsed, or the judgment of conviction has been affirmed on
4 appeal or when an order granting probation is made suspending
5 the imposition of sentence, irrespective of a subsequent order under
6 Section 1203.4 of the Penal Code allowing the person to withdraw
7 his or her plea of guilty and to enter a plea of not guilty, or setting
8 aside the verdict of guilty, or dismissing the accusation,
9 information, or indictment.

10 (m) The cash compromise of a charge of violation of Chapter
11 13 (commencing with Section 801) of Title 21 of the United States
12 Code regulating controlled substances or of Chapter 7
13 (commencing with Section 14000) of Part 3 of Division 9 of the
14 Welfare and Institutions Code relating to the Medi-Cal program.
15 The record of the compromise is conclusive evidence of
16 unprofessional conduct.

17 (n) The revocation, suspension, or other discipline by another
18 state of a license to practice pharmacy, operate a pharmacy, or do
19 any other act for which a license is required by this chapter.

20 (o) Violating or attempting to violate, directly or indirectly, or
21 assisting in or abetting the violation of or conspiring to violate any
22 provision or term of this chapter or of the applicable federal and
23 state laws and regulations governing pharmacy, including
24 regulations established by the board or by any other state or federal
25 regulatory agency.

26 (p) Actions or conduct that would have warranted denial of a
27 license.

28 (q) Engaging in any conduct that subverts or attempts to subvert
29 an investigation of the board.

30 (r) The selling, trading, transferring, or furnishing of drugs
31 obtained pursuant to Section 256b of Title 42 of the United States
32 Code to any person a licensee knows or reasonably should have
33 known, not to be a patient of a covered entity, as defined in
34 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
35 United States Code.

36 (s) The clearly excessive furnishing of dangerous drugs by a
37 wholesaler to a pharmacy that primarily or solely dispenses
38 prescription drugs to patients of long-term care facilities. Factors
39 to be considered in determining whether the furnishing of
40 dangerous drugs is clearly excessive shall include, but not be

1 limited to, the amount of dangerous drugs furnished to a pharmacy
2 that primarily or solely dispenses prescription drugs to patients of
3 long-term care facilities, the previous ordering pattern of the
4 pharmacy, and the general patient population to whom the
5 pharmacy distributes the dangerous drugs. That a wholesaler has
6 established, and employs, a tracking system that complies with
7 the requirements of subdivision (b) of Section 4164 shall be
8 considered in determining whether there has been a violation of
9 this subdivision. This provision shall not be interpreted to require
10 a wholesaler to obtain personal medical information or be
11 authorized to permit a wholesaler to have access to personal
12 medical information except as otherwise authorized by Section 56
13 and following of the Civil Code. For purposes of this section,
14 “long-term care facility” shall have the same meaning given the
15 term in Section 1418 of the Health and Safety Code.

16 SEC. 2. Section 11453 of the Health and Safety Code is
17 repealed.

18 SEC. 3. Section 124960 of the Health and Safety Code is
19 amended to read:

20 124960. The Legislature finds and declares all of the following:

21 (a) The state has a right and duty to control the illegal use of
22 opiate drugs.

23 (b) Inadequate treatment of acute and chronic pain originating
24 from cancer or noncancerous conditions is a significant health
25 problem.

26 (c) For some patients, pain management is the single most
27 important treatment a physician can provide.

28 (d) A patient suffering from pain or a condition causing pain,
29 including, but not limited to, intractable pain should have access
30 to proper treatment of his or her pain.

31 (e) Due to the complexity of their problems, many patients
32 suffering from pain or a condition causing pain, including, but not
33 limited to, intractable pain may require referral to a physician with
34 expertise in the treatment of pain or a condition causing pain,
35 including, but not limited to, intractable pain. In some cases, pain
36 or a condition causing pain, including, but not limited to, intractable
37 pain is best treated by a team of clinicians in order to address the
38 associated physical, psychological, social, and vocational issues.

39 (f) In the hands of knowledgeable, ethical, and experienced pain
40 management practitioners, opiates administered for ~~severe acute~~

1 ~~and~~ pain or a condition causing pain, including, but not limited to,
2 intractable pain can be safe.

3 (g) Opiates can be an accepted treatment for patients in pain or
4 a condition causing pain, including, but not limited to, intractable
5 pain who have not obtained relief from any other means of
6 treatment.

7 (h) A patient suffering from pain or a condition causing pain,
8 including, but not limited to, intractable pain has the option to
9 request or reject the use of any or all modalities to relieve his or
10 her pain.

11 (i) A physician treating a patient who suffers from pain or a
12 condition causing pain, including, but not limited to, intractable
13 pain may prescribe a dosage deemed medically necessary to relieve
14 pain as long as the prescribing is in conformance with ~~the~~
15 ~~provisions of the California Intractable Pain Treatment Act, Section~~
16 2241.5 of the Business and Professions Code.

17 (j) A patient who suffers from ~~severe chronic intractable pain~~
18 *pain or a condition causing pain, including, but not limited to,*
19 *intractable pain,* has the option to choose opiate medication for
20 the treatment of the severe chronic intractable pain as long as the
21 prescribing is in conformance with the provisions of Section 2241.5
22 of the Business and Professions Code.

23 (k) The patient's physician may refuse to prescribe opiate
24 medication for a patient who requests the treatment for pain or a
25 condition causing pain, including, but not limited to, intractable
26 pain. However, that physician shall ~~inform~~ *refer* the patient ~~that~~
27 ~~there are~~ *to* physicians who ~~specialize in the treatment of pain~~ *treat*
28 *pain* or a condition causing pain, including, but not limited to,
29 intractable pain with methods that include the use of opiates.

30 SEC. 4. Section 124961 of the Health and Safety Code is
31 amended to read:

32 124961. Nothing in this section shall be construed to alter any
33 of the provisions set forth in Section 2241.5 of the Business and
34 Professions Code. This section shall be known as the Pain Patient's
35 Bill of Rights.

36 (a) A patient suffering from pain or a condition causing pain,
37 including, but not limited to, intractable pain has the option to
38 request or reject the use of any or all modalities in order to relieve
39 his or her pain.

1 (b) A patient who suffers from pain or a condition causing pain,
2 including, but not limited to, intractable pain has the option to
3 choose opiate medications to relieve that pain without first having
4 to submit to an invasive medical procedure, which is defined as
5 surgery, destruction of a nerve or other body tissue by
6 manipulation, or the implantation of a drug delivery system or
7 device, as long as the prescribing physician acts in conformance
8 with the provisions of the California Intractable Pain Treatment
9 Act, Section 2241.5 of the Business and Professions Code.

10 (c) The patient's physician may refuse to prescribe opiate
11 medication for the patient who requests a treatment for pain or a
12 condition causing pain, including, but not limited to, intractable
13 pain. However, that physician shall refer the patient to physicians
14 who treat pain and whose methods include the use of opiates.

15 (d) A physician who uses opiate therapy to relieve pain or a
16 condition causing pain, including, but not limited to, intractable
17 pain may prescribe a dosage deemed medically necessary to relieve
18 the patient's pain, as long as that prescribing is in conformance
19 with Section 2241.5 of the Business and Professions Code.

20 (e) A patient may voluntarily request that his or her physician
21 provide an identifying notice of the prescription for purposes of
22 emergency treatment or law enforcement identification.

23 (f) Nothing in this section shall do either of the following:

24 (1) Limit any reporting or disciplinary provisions applicable to
25 licensed physicians and surgeons who violate prescribing practices
26 or other provisions set forth in the Medical Practice Act, Chapter
27 5 (commencing with Section 2000) of Division 2 of the Business
28 and Professions Code, or the regulations adopted thereunder.

29 (2) Limit the applicability of any federal statute or federal
30 regulation or any of the other statutes or regulations of this state
31 that regulate dangerous drugs or controlled substances.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 847

VERSION: As Introduced February 18, 2011

AUTHOR: Correa

SPONSOR:

BOARD POSITION: None

SUBJECT: Medical Cannabis Licensing Act

Affected Sections: Add Division 8.9 (beginning with Section 22992.10) to the Business and Professions Code

CURRENT STATUS: Senate Governance and Finance Committee Hearing April 27, 2011

EXISTING LAW:

The Compassionate Use Act of 1996 prohibits prosecution, pursuant to the laws relating to the cultivation and possession of marijuana.

THIS BILL WOULD:

1. Create the Medical Cannabis Licensing Act.
2. Set for legislative findings and declarations including the need for the Compassionate Act of 1996, the lack of regulatory structure and the problems associated with this lack of structure, the Medical Marijuana Act that allowed for the issuance of identification cards as a means to facilitate implementation, and state that the intent of this legislation is to provide a functional licensing scheme to meet the needs of eligible patients.
3. Define various terms used throughout the article, including "Department" as the Department of Public Health and "Board" as the State Board of Equalization.
4. Authorize the Department of Public Health to administer this program and exempt individuals that cultivate and use medical marijuana exclusively for self use.
5. Establish the general parameters for application for a license issues pursuant to this article, establish the department's authority to deny an application and the department's ability to collect fees.
6. Require the department to work with the board to develop the indicia and to develop the regulations to determine the design and size of the standard indicia and allow for the board to collect the fees for the administration of the indicia.

7. Require the department to ensure product safety by testing samples as specified.
8. Require the department, in consultation with the Board of Pharmacy, to establish an inspection program and allow for the collection of fees to offset the costs.
9. Require the department, in consultation with the Attorney General's Office, to establish a medical cannabis facilities security program as specified, require the department to inspect for compliance and establish reporting requirements for employees of licensed facilities.
10. Require the department to create an advisory committee comprised of local health officers, land use officials and law enforcement, and to assist the committee in resolving security and related land use problems.
11. Establish the Medical Cannabis Licensing Fund
12. Specify that the department and the board are the sole agencies for enforcement of this division, and grants immunities as well as the consequences for violations.

AUTHOR'S INTENT:

Board staff was unable to speak with the author's office. Updated information will be provided during the next committee meeting or during the board meeting.

COMMENTS:

Although California law has established provisions to allow for the cultivation and use of medical marijuana, the federal government does not have similar provisions. Board staff receives questions from pharmacists and pharmacy owners on this topic with some regularity. Board staff responds to such inquiries about a pharmacist's role in the dispensing of medical marijuana by advising individuals that dispensing medical marijuana would be in conflict with federal law and that the individual or business would be at risk of losing their DEA permit.

FISCAL IMPACT:

The board estimates a minor fiscal impact, about \$8,000 to assist in the development of the inspection program that will be used by the California Department of Public Health.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

- Mar. 22 Set for hearing April 27.
- Mar. 17 Withdrawn from committee. Re-referred to Coms. on Gov. & F. and HEALTH.
- Mar. 10 Referred to Coms. on HEALTH and Gov. & F.
- Feb. 19 From printer. May be acted upon on or after March 21.
- Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator CorreaFebruary 18, 2011

An act to add Division 8.9 (commencing with Section 22992.10) to the Business and Professions Code, relating to cannabis, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 847, as introduced, Correa. Medical Cannabis Licensing Act.

Existing law, the Compassionate Use Act of 1996, an initiative measure, prohibits prosecution, pursuant to provisions of law relating to the possession or cultivation of marijuana, of a patient or a patient's primary caregiver who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

This bill would establish the Medical Cannabis Licensing Act, to require a producer, distributor, or seller to be licensed by the State Department of Public Health to engage in the production, distribution, or sale of medical marijuana, and would require the license to be renewed every 12 months. This bill would require an applicant for a license to provide specified information. This bill would require establishment of an indicia program, to be administered by the State Board of Equalization, to require traceable, secure indicia of licensure to be placed on medical marijuana, would require establishment of a product testing program and a facilities inspection program administered by the department, and would authorize assessment of related fees.

This bill would require all moneys collected to be deposited in the Medical Cannabis Licensing Fund, which would be created in the State Treasury, and would, except for moneys derived from penalties,

continuously appropriate moneys in the fund solely for the purpose of implementing, enforcing, and administering the licensing program.

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

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

1 SECTION 1. Division 8.9 (commencing with Section 22992.10)
2 is added to the Business and Professions Code, to read:

3
4 DIVISION 8.9. MEDICAL CANNABIS LICENSING ACT

5
6 CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS

7
8 22992.10. (a) This division shall be known, and may be cited,
9 as the Medical Cannabis Licensing Act.

10 (b) The Legislature finds and declares all of the following:

11 (1) The people enacted the Compassionate Use Act to, in part,
12 ensure that seriously ill Californians have the right to obtain and
13 use marijuana for medical purposes where that medical use is
14 deemed appropriate and has been recommended by a physician,
15 and to provide related immunities from prosecution for patients,
16 primary caregivers, and physicians.

17 (2) However, the lack of an adequate regulatory structure for
18 the production, distribution, and sale of medical marijuana presents
19 California with many serious problems, including, but not limited
20 to, all of the following:

21 (A) Problems relating to the inability to ensure that the product
22 is not contaminated with pesticides or other dangerous chemicals.

23 (B) Problems relating to the security of the cultivation,
24 packaging, and retail facilities.

25 (C) Problems relating to the inability to ensure that medical
26 marijuana product is not diverted for nonmedical uses.

27 (D) Problems relating to the inability to prevent the introduction
28 of unauthorized product.

29 (3) Subsequent legislation, the Medical Marijuana Program,
30 provided some solutions by establishing a voluntary program for
31 the issuance of identification cards for persons authorized under
32 the Compassionate Use Act to protect them from arrest for

1 cultivation or possession of medical marijuana. However, the
2 program was only a partial solution.

3 (4) In enacting the Compassionate Use Act, the people
4 encouraged state government “to implement a plan to provide for
5 the safe and affordable distribution of marijuana to all patients in
6 medical need of marijuana.”

7 (5) By enacting this division the Legislature accepts that
8 invitation and challenge, and seeks to provide a complete,
9 functional, licensing scheme that would permit the secure
10 production, distribution, and sale of uncontaminated and affordable
11 medical marijuana to meet the needs of eligible patients under the
12 Compassionate Use Act and the Medical Marijuana Program.

13 22992.15. For purposes of this division, the following terms
14 have the following meanings:

15 (a) “Department” means the State Department of Public Health.

16 (b) “Board” means the State Board of Equalization.

17 (c) “Cannabis” or “marijuana” means all parts of the plant
18 *Cannabis sativa* L., whether growing or not; the seeds thereof; the
19 resin extracted from any part of the plant; and every compound,
20 manufacture, salt, derivative, mixture, or preparation of the plant,
21 its seeds, or resin. “Cannabis” or “marijuana” does not include the
22 mature stalks of the plant, fiber produced from the stalks, oil or
23 cake made from the seeds of the plant, any other compound,
24 manufacture, salt, derivative, mixture, or preparation of the mature
25 stalks (except the resin extracted therefrom), fiber, oil, or cake, or
26 the sterilized seed of the plant which is incapable of germination.

27 (d) “Fund” means the Medical Cannabis Licensing Fund
28 established in subdivision (a) of Section 22993.10.

29 (e) “Account” means the Medical Cannabis Enforcement
30 Penalties Account established in subdivision (b) of Section
31 22993.10.

32 (f) “License” means a license issued by the department pursuant
33 to this division.

34 (g) “Licensee” means any person holding a license issued by
35 the department pursuant to this division.

36 (h) “Medical marijuana” or “medical cannabis” means marijuana
37 that is authorized under Section 11362.5 of the Health and Safety
38 Code or regulated under the Medical Marijuana Program.

- 1 (i) “Medical Marijuana Program” means Article 2.5
2 (commencing with Section 11362.7) of Chapter 6 of Division 10
3 of the Health and Safety Code.
- 4 (j) “Person” means a person as defined in Section 30010 of the
5 Revenue and Taxation Code.
- 6 (k) “Compassionate Use Act” means the Compassionate Use
7 Act of 1996 (Section 11362.5 of the Health and Safety Code)
8 enacted by initiative measure (Proposition 215) approved by the
9 voters at the November 5, 1996, general election.
- 10 (l) “Primary caregiver” means a person designated by a medical
11 marijuana patient as his or her primary caregiver under the
12 Compassionate Use Act.
- 13 (m) “Sale,” “sell,” or “sold” includes any transfer of title or
14 possession for consideration, barter, or exchange, by any manner
15 or by any means.
- 16 (n) “Seller” means any person making a sale of medical
17 marijuana in this state.
- 18 (o) “Cultivator” means any person cultivating medical marijuana
19 for sale in this state.
- 20 (p) “Distributor” means any person distributing medical
21 marijuana for sale in this state.
- 22 (q) “Producer” means a person cultivating medical marijuana
23 or packaging it, or both, for sale in this state.
- 24 (r) “Indicia” means a mark, sign, stamp, or other evidence of
25 issuance of a license and payment of applicable fees, as required
26 by this division.
- 27 22992.20. (a) The State Department of Public Health shall
28 administer this division to establish a statewide program to license
29 producers, distributors, and sellers of medical cannabis. The
30 department may adopt and enforce regulations relating to the
31 administration and enforcement of this division.
- 32 (b) No person is subject to the requirements of this division if
33 that person is exempt from regulation under the United States
34 Constitution, the laws of the United States, or the California
35 Constitution.
- 36 (c) This division does not apply to activities of a patient under
37 the Compassionate Use Act who cultivates and uses medical
38 marijuana exclusively for his or her own personal medical use, as
39 provided for in the Compassionate Use Act.

1 CHAPTER 2. LICENSE FOR PRODUCERS, DISTRIBUTORS, AND
2 SELLERS OF MEDICAL CANNABIS

3
4 22992.25. (a) Commencing on the effective date of licensing
5 regulations adopted by the department relating to the production,
6 distribution, and sale of medical cannabis pursuant to this division,
7 a person that produces, distributes, or sells medical marijuana shall
8 have in place and maintain a license to engage in the production,
9 distribution, or sale, as appropriate, of medical cannabis pursuant
10 to this division.

11 (b) A license is not assignable or transferable. A person that
12 obtains a license, that ceases to produce, distribute, or sell as
13 specified in the license, or that never commenced those activities
14 and decides not to do so, or whose license is suspended or revoked,
15 shall immediately surrender the license to the department.

16 (c) A license shall be valid for a 12-month period, and shall be
17 renewed annually.

18 22992.30. (a) An application for a license shall be filed on a
19 form prescribed by the department and shall include all of the
20 following:

21 (1) The name, address, and telephone number of the applicant.

22 (2) The signature of the applicant.

23 (3) A description of the manner in which the person is authorized
24 to possess, cultivate, or provide medical marijuana pursuant to the
25 Compassionate Use Act or the Medical Marijuana Program, or
26 both. This may include a requirement that the applicant provide
27 copies of written designations, designating the applicant as primary
28 caregiver, executed by medical marijuana patients under the
29 Compassionate Use Act.

30 (4) A list of all prospective employees, their identifying
31 information, and a description of their duties.

32 (5) Any other information the department may require.

33 (b) The department shall investigate to determine the truthfulness
34 and completeness of the information provided in the application,
35 and shall include these costs within the application fee. The
36 department may deny an application if the applicant knowingly
37 made a false statement of fact required to be revealed in the license
38 application.

39 (c) The applicant and each prospective employee shall submit
40 to a criminal background check conducted by the Department of

1 Justice. The cost of this background check shall be paid by the
2 applicant.

3 (d) The department shall provide electronic means for applicants
4 to download and submit applications.

5 22992.35. The department may deny the application for
6 licensure if the application is incomplete or if the department finds
7 that the applicant has not demonstrated, to the satisfaction of the
8 department, that the applicant will comply with the requirements
9 of this division, including, but not limited to, the rules and
10 regulations of the department and the board.

11 22992.40. (a) An initial license fee, not to exceed ____ dollars
12 (\$____), shall be submitted with each application.

13 (b) A fee, not to exceed ____ dollars (\$____), shall be submitted
14 for each application for the annual renewal of a license.

15 (c) If a license is reinstated after its expiration, the licensee, as
16 a condition precedent to its reinstatement, shall pay a reinstatement
17 fee not to exceed ____ dollars (\$____).

18

19 CHAPTER 3. MEDICAL CANNABIS LICENSING INDICIA PROGRAM

20

21 22992.45. (a) The board shall administer the indicia program
22 pursuant to this chapter.

23 (b) The board, in consultation with the department, shall design
24 a system requiring the use of indicia upon all medical marijuana
25 using reasonably available technology to facilitate all of the
26 following related to the production, distribution, and sale of
27 medical marijuana pursuant to a license under this division:

28 (1) Secure production, distribution, and sale of uncontaminated
29 and affordable medical marijuana product.

30 (2) Effective enforcement of applicable state laws.

31 (3) Effective tracking and tracing of medical marijuana products.

32 (4) Field auditing and inspections.

33 (5) Elimination and apprehension of counterfeit marijuana
34 product and indicia.

35 (6) Collection of all applicable fees for the purposes of this
36 division.

37 (7) Prevention of marijuana sales that are not authorized under
38 this division, the Compassionate Use Act, or the Medical Marijuana
39 Program.

1 (c) The board shall design, develop, and produce, or may
2 procure, indicia meeting the requirements of this chapter of designs
3 and denominations, as determined by the board, that are suitable
4 to be affixed to product in bulk during production, and affixed to
5 standardized retail medical marijuana packages for distribution
6 and sale.

7 (d) The board, in consultation with the department, shall adopt
8 regulations to determine the standardized design and size of the
9 package, and location of the indicia.

10 22992.50. (a) Commencing on the effective date of the
11 regulations adopted by the board pursuant to this chapter, no
12 licensee shall engage in the production, distribution, or sale of
13 medical marijuana pursuant to this division without complying
14 with this chapter.

15 (b) The regulations shall provide for the distribution of the
16 indicia to licensees for placement on all medical marijuana
17 produced, distributed, and sold in this state, and shall establish the
18 indicia fee to be paid by the licensee, not to exceed ____ dollars
19 (\$____) per indicium for bulk product in production, and not to
20 exceed ____ dollars (\$____) per indicium for standardized retail
21 medical marijuana packages for distribution and sale.

22 (c) The fee imposed and levied pursuant to this section shall be
23 paid, and the indicia shall be used, in a manner determined by
24 regulations adopted by the board. The indicia fee shall not exceed
25 the cost of administering and enforcing the indicia component of
26 this division including, but not limited to, all administrative costs
27 of the board and the department.

28 22992.55. (a) The indicia shall have tracking and tracing
29 capabilities utilizing high-security encrypted coding, similar to
30 that in use on tobacco commercialized in California, to reasonably
31 ensure and monitor that all medical marijuana produced,
32 distributed, and sold in California is in compliance with applicable
33 law.

34 (b) The indicia shall be secure, counterfeit resistant, and
35 encrypted with certain information to identify, at a minimum, all
36 of the following:

37 (1) The name and address of the party affixing the indicia to
38 the final units of sale.

39 (2) The date the indicia are affixed to the final units of sale.

40 (3) The denominated value of the indicia.

1 (c) The indicia shall be readable and traceable from the point
2 of production to the point of sale and shall be readable by a scanner
3 or similar device that may be utilized by the department, the board,
4 or licensed medical marijuana product producers, distributors,
5 sellers, and others, as determined by regulations adopted by the
6 board.

7 (d) The indicia shall be produced in a secure facility certified
8 in accordance with accepted industry security assistance standards,
9 shall incorporate overt, semicovert, and covert data, and shall
10 capture encrypted data in real time. The encrypted data collected
11 shall be provided by producers, distributors, and sellers, and shall
12 be retained by the state in a secure data collection, management,
13 and decision support system.

14 (e) Only parties approved by the regulations of the board shall
15 affix and cancel the indicia. The regulations shall not authorize
16 any person to sell indicia except duly constituted agents and
17 assistants of the board or the department.

18 (f) Licensees shall maintain records in regard to medical
19 marijuana products and the associated indicia, as prescribed by
20 the board, in consultation with the department, and those records
21 shall be available to the department and the board for inspection
22 and audit.

23

24 CHAPTER 4. MEDICAL CANNABIS PRODUCT SAFETY INSPECTION

25

26 22992.60. (a) In order to ensure patient safety, the department
27 shall establish a program of medical marijuana testing with the
28 goal of ensuring that medical marijuana distributed under the
29 Compassionate Use Act is free from contamination and not
30 otherwise adulterated.

31 (b) The program shall take random, periodic, and focused
32 samples of product from producers, distributors, and sellers for
33 the purposes of conducting laboratory testing of the product to
34 ensure that the product is not contaminated by pesticides or other
35 dangerous chemicals, or otherwise adulterated.

36 (c) The department shall pay the producer, distributor, and seller
37 for samples taken pursuant to this chapter in a manner established
38 by regulations of the department. Moneys in the fund may be used
39 for this purpose.

1 22992.65. The department shall, in consultation with the
2 California State Board of Pharmacy, establish a facilities inspection
3 program to inspect licensee cultivation, packaging, distribution,
4 and retail facilities to ensure hygienic conditions and product
5 safety.

6 22992.70. (a) The department shall establish a product testing
7 and facilities inspection fee not to exceed ____ dollars (\$____) to
8 be assessed to producers, distributors, and sellers of medical
9 marijuana, and to be collected as a component of the annual
10 licensing fee. The fees shall be deposited into the fund. The total
11 fee pursuant to this chapter shall not exceed the costs of the
12 sampling, testing, and inspection program, including, but not
13 limited to, all costs of administration, including, but not limited
14 to, the costs of the California State Board of Pharmacy.

15 (b) The department may directly perform, or may contract with
16 a private or public entity for performance of, its product sampling,
17 laboratory testing, and facilities inspection duties pursuant to this
18 chapter.

19

20 CHAPTER 5. MEDICAL CANNABIS FACILITIES SECURITY

21

22 22992.75. (a) The department, in consultation with the
23 Attorney General, shall establish a medical cannabis facilities
24 security program.

25 (b) The program shall have as a primary goal to ensure that
26 licensee facilities meet all of the following requirements:

27 (1) They do not become magnets for increased violence or theft
28 because of the cannabis located therein.

29 (2) They adopt and follow stringent internal safeguards to ensure
30 security of the medical marijuana product and the facilities.

31 (3) They are not located in inappropriate community settings
32 where traffic safety, incompatible land use, proximity to schools,
33 and other safety issues are raised.

34 22992.80. (a) The department shall establish facility security
35 standards applicable to all licensed facilities, and shall conduct a
36 security inspection of all licensed facilities to ensure compliance.
37 The facilities security inspections may be combined with the
38 product safety inspections conducted under Chapter 4 (commencing
39 with Section 22992.60).

1 (b) If a licensed facility experiences extraordinary security
2 breaches, in number or severity, the department may order the
3 licensee to enhance the security for that facility, including, but not
4 limited to, upgrading electronic or other security systems or hiring
5 additional security personnel.

6 22992.85. (a) Within five business days, a licensee shall notify
7 the department and the board of any employee who no longer is
8 employed by the licensee, and any other personnel changes, as
9 determined by the regulations of the department or board.

10 (b) The names and other identifying information of all
11 prospective new employees shall be provided to the department
12 for a criminal background check and approval prior to commencing
13 their employment.

14 22992.90. (a) The department shall establish an advisory
15 committee comprised of local health officers, land use officials,
16 and law enforcement officers to discuss local facility security and
17 related land use issues, and to assist committee members in
18 resolving their local facility security and related land use problems.

19 (b) The department may provide annual grants to cities, counties,
20 or cities and counties for the establishment of increased local
21 security measures that are directly related to assisting the effort to
22 ensure the security of licensed facilities. The grants shall be made
23 from moneys in the fund, and shall not exceed an annual statewide
24 total of _____dollars (\$_____).

25 (c) The department shall assess an annual fee to each licensee
26 not to exceed the cost to the department, including, but not limited
27 to, the costs of the Attorney General and the committee, of
28 implementing this chapter. The fee shall be assessed as a
29 component of the license or renewal fee.

30

31 CHAPTER 6. FISCAL PROVISIONS: MEDICAL CANNABIS
32 LICENSING FUND

33

34 22993.10. (a) All moneys collected pursuant to this division
35 shall be deposited in the Medical Cannabis Licensing Fund, which
36 is hereby established within the State Treasury.

37 (b) There is hereby established the Medical Cannabis
38 Enforcement Penalties Account within the fund, to receive the
39 penalty amounts collected pursuant to 22993.40.

1 (c) Notwithstanding Section 16305.7 of the Government Code,
2 the fund shall also include any interest and dividends earned on
3 money in the fund.

4 (d) Notwithstanding Section 13340 of the Government Code,
5 all moneys in the fund, except for moneys in the Medical Cannabis
6 Enforcement Penalties Account, are hereby continuously
7 appropriated, without regard to fiscal year, to the department solely
8 for the purpose of fully funding all costs associated with
9 implementing, enforcing, and administering this division with
10 respect to the purpose for which those moneys were collected.

11 (e) Moneys in the Medical Cannabis Enforcement Penalties
12 Account shall be available, upon appropriation by the Legislature,
13 for the purposes of this division.

14 (f) The department and the board shall enter into an interagency
15 agreement relating to the allocation of moneys in the fund from
16 the department to the board for costs incurred in the performance
17 of the board's duties under this division.

18 22993.15. (a) The setting of fees pursuant to this division is
19 exempt from the rulemaking provisions of the Administrative
20 Procedure Act (Chapter 3.5 (commencing with Section 11340) of
21 Part 1 of Division 3 of Title 2 of the Government Code).

22 (b) All maximum fee levels pursuant to this division shall be
23 adjusted to reflect annual increases, if any, in the California
24 Consumer Price Index, as recorded by the California Department
25 of Industrial Relations for the most recent year available.

26 (c) The total fees collected pursuant to this division, exclusive
27 of any penalties, shall not exceed the total costs of implementing
28 this division.

29

30 CHAPTER 7. MEDICAL CANNABIS LICENSING ENFORCEMENT
31 AND IMMUNITIES

32

33 22993.20. (a) The department, the board, and their authorized
34 agents shall be the sole agencies for the enforcement of this
35 division and regulation of activity authorized pursuant to this
36 division.

37 (b) A licensee in good standing performing any activities related
38 to the cultivation, packaging, distribution, or sale of medical
39 marijuana within the scope of the license pursuant to this division
40 shall be subject only to the enforcement provisions of this division,

1 and shall be immune from arrest or prosecution for violation of
2 Section 11357, 11358, 11359, or 11360 of the Health and Safety
3 Code, or any other provision of law related to the possession,
4 cultivation, packaging, distribution, or sale of marijuana.

5 22993.25. (a) If a licensee fails to comply with this division
6 or any rule or regulation of the department or the board adopted
7 under this division, the department, in consultation with the board,
8 as appropriate, upon hearing, after giving the licensee at least 10
9 days' notice in writing specifying the time and place of hearing
10 and requiring the licensee to show cause why the license should
11 not be suspended or revoked, may suspend or revoke the license.

12 (b) The notice may be served personally or by United States
13 mail, postage prepaid, to the licensee at the licensee's last known
14 address or place of business in this state.

15 (c) The department shall not restore a suspended license, or
16 issue a new license to a person whose license has been revoked,
17 unless the department is satisfied that the person has made a
18 satisfactory good faith showing that the person will comply with
19 this division, including, but not limited to, the rules and regulations
20 of the department and the board.

21 22993.30. (a) Except as set forth in subdivision (c), the
22 immunities set forth in this chapter apply only to activities of a
23 licensee in good standing that are within the scope of the license.

24 (b) The immunities set forth in this chapter do not apply to
25 activities that are knowingly beyond the scope of the license, or
26 that occur while the license is suspended or revoked.

27 (c) (1) If a license is suspended, the order suspending the license
28 shall specify the conduct, including, but not limited to, possession
29 of the product in secure facilities, that remains subject to the
30 immunities set forth in this chapter, pending resolution of the issues
31 upon which the suspension is based.

32 (2) If the license is revoked, the order revoking the license shall
33 specify the manner in which the former licensee shall dispose of
34 the product and close down its operations.

35 (3) Activities authorized under an order suspending or revoking
36 a license are protected by the immunities set forth in this chapter.

37 22993. 35. (a) If, upon inspection of the licensee's facilities,
38 or after laboratory testing of the sample product, the department
39 determines that there is cause to believe that either conditions
40 relating to production, or conditions at the facilities, or adulteration

1 or contamination of the product, present a risk of harm to patients,
2 the department shall so notify the licensee.

3 (b) The department shall require that the licensee take immediate
4 steps to protect patients. The department shall also require the
5 licensee to develop and, after approval by the department,
6 implement an immediate plan of correction designed to resolve,
7 within 30 days, the problems that are the underlying cause of the
8 risk of harm.

9 (c) The department shall establish a focused inspection or
10 product testing schedule to ensure compliance with the plan.

11 (d) Pending full and satisfactory implementation of a plan of
12 correction, the department may temporarily suspend the license
13 pursuant to this section if any of the following apply:

14 (1) The nature of the public health risk warrants a suspension
15 until the problem is corrected.

16 (2) Implementing the plan of correction would require more
17 than 30 days.

18 (3) The correction plan proposed by the licensee is not approved
19 because it does not propose a satisfactory solution.

20 (4) The problem is a recurring problem with the licensee.

21 (e) The licensee shall reimburse the department for the costs of
22 implementing this section. These fees shall be collected at the time
23 of approval of the correction plan. All costs reimbursed pursuant
24 to this subdivision shall be deposited into the fund.

25 22993.40. (a) The department may assess a civil penalty in an
26 amount not to exceed ____ dollars (\$____) per violation against
27 any licensee for knowing or willful failure to comply with any
28 provision of this division, including, but not limited to, any
29 regulation adopted by the department or the board pursuant to this
30 division. The penalty shall be in addition to any other enforcement
31 provisions or remedies that may apply.

32 (b) The penalties received pursuant to this section shall be
33 deposited into the Medical Cannabis Enforcement Penalties
34 Account.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 786

VERSION: As Introduced February 18, 2011

AUTHOR: Dutton

SPONSOR:

BOARD POSITION: None

SUBJECT: **Controlled Substances**

Affected Sections: Amend Section 11379 of the Health and Safety Code

CURRENT STATUS: Referred to Rules Committee

EXISTING LAW:

Makes it a felony to transport, import into this state, sell, furnish, administer, or give away specified controlled substances, unless it is done pursuant to an authorized prescription by a practitioner licensed in this state.

THIS BILL WOULD:

Make a technical, nonsubstantive change to this provision.

AUTHOR'S INTENT:

The author's office indicated that this is a spot bill.

COMMENTS:

Staff will continue to watch this bill for amendments and will bring the legislation back to the board to consideration.

FISCAL IMPACT:

Unknown

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Mar. 10 Referred to Com. on RLS.

Feb. 20 From printer. May be acted upon on or after March 22.

Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Dutton

February 18, 2011

An act to amend Section 11379 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 786, as introduced, Dutton. Controlled substances.

Existing law makes it felony to transport, import into this state, sell, furnish, administer, or give away specified controlled substances, unless upon the prescription of a physician, dentist, podiatrist, or veterinarian licensed to practice in this state.

This bill would make a technical, nonsubstantive change to this provision.

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

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

1 SECTION 1. Section 11379 of the Health and Safety Code is
2 amended to read:
3 11379. (a) Except as otherwise provided in subdivision (b)
4 and in Article 7 (commencing with Section 4211) of Chapter 9 of
5 Division 2 of the Business and Professions Code, every person
6 who transports, imports into this state, sells, furnishes, administers,
7 or gives away, or offers to transport, import into this state, sell,
8 furnish, administer, or give away, or attempts to import into this
9 state or transport any controlled substance which is (1) classified
10 in Schedule III, IV, or V and which is not a narcotic drug, except
11 subdivision (g) of Section 11056, (2) specified in subdivision (d)

1 of Section 11054, except paragraphs (13), (14), (15), (20), (21),
2 (22), and (23) of subdivision (d), (3) specified in paragraph (11)
3 of subdivision (c) of Section 11056, (4) specified in paragraph (2)
4 or (3) of subdivision (f) of Section 11054, or (5) specified in
5 subdivision (d) or (e), except paragraph (3) of subdivision (e), or
6 specified in subparagraph (A) of paragraph (1) of subdivision (f),
7 of Section 11055, unless upon the prescription of a physician,
8 dentist, podiatrist, or veterinarian, licensed to practice in this state,
9 shall be punished by imprisonment in the state prison for a period
10 of two, three, or four years.

11 (b) Notwithstanding the penalty provisions of subdivision (a),
12 any person who transports for sale any controlled ~~substances~~
13 *substance* specified in subdivision (a) within this state from one
14 county to another noncontiguous county shall be punished by
15 imprisonment in the state prison for three, six, or nine years.

Agenda Item 2c



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 24, 2011
To: Legislation and Regulation Committee
Subject: Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Agenda Item 2.c: Reporting Requirements/Records

Below are summaries of bills relating to reporting requirements or records. A bill analysis and a copy of the most recent version of the bill are provided in unless otherwise noted.

SB 260 (Canella) Controlled substances

Summary: This bill was recently amended. As amended the measure would make it a felony punishable by imprisonment in the state prison for 2, 4, or 6 years to possess, without regard to intent, 1/2pound or more of ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine, or 1/2pound or more of a substance containing ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine. and now established penalties for people that possess one

A copy of the bill and a bill analysis are not provided in light of these amendments.

SB 315 (Wright) Ephedrine and pseudeophedrine

Summary: 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.

Recent Action: Senate Public Safety Committee hearing on April 5, 2011

SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System

Summary: Would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations containing chorionic gonadotropin, a hormone, and Schedule IV to add additional depressants and stimulants

Recent Action: Amended March 22, 2011 and referred to Rule Committee.

This bill was amended on March 22, 2011. A revised bill analysis will be provided during the committee meeting.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 315

VERSION: As Introduced February 14, 2011

AUTHOR: Wright

SPONSOR:

BOARD POSITION: None

SUBJECT: Controlled Substances

Affected Sections: Amend Sections 11100 and 11106 of, and add Section 11375.5 to the Health and Safety Code

CURRENT STATUS: Senate Public Safety Committee hearing on April 5, 2011

EXISTING LAW:

Health and Safety Code Section 11100:

1. Requires any manufacturer, wholesaler, retailer or other person or entity in this state that sells, transfers or otherwise furnishes specified substances, to report to the Department of Justice (DOJ). These substances are controlled substances and/or chemical precursors for manufacture of illicit drugs.
2. Specifies that such entities, prior to selling, transferring or otherwise furnishing any specified substance shall require a letter of authorization that includes the currently valid business license or DEA registration, and the address of the business and proper identification of the purchaser. Information collected must also include how the substance is to be used, and specifies that this information shall be maintained for three years.
3. Defines proper identification to include two of the following:
 - a. Federal tax identification number
 - b. Seller's permit identification number
 - c. City or county business license number
 - d. State Department of Public Health License
 - e. Registration issued by federal Drug Enforcement Administration
 - f. Precursor business permit number issued by the Bureau of Narcotic Enforcement
 - g. Driver's license
 - h. Other identification issued by a state.
4. Requires any entity that exports a substance, as provided in this section, to any person or business located in a foreign country to notify the DOJ of the transaction and specifies that the notification shall include the name and

- quantity of the substance, the name, address and business identification number (if assigned by the foreign country).
5. Specifies that the DOJ may require such reports on a monthly basis.
 6. Requires reporting not less than 21 days in advance of a transaction to any entity in the US or on a monthly basis as determined by the DOJ.
 7. Requires the seller to affix his or her signature or provide other identification to the purchaser and specifies requirement for the use of a common carrier.
 8. Specifies exemptions to these provisions for the following:
 - a. Pharmacist or other authorized person who sells or furnishes a substance pursuant to a prescription
 - b. Any physician, dentist, podiatrist or veterinarian who administers or furnishes a substance to his or her patients.
 - c. Manufacturers and board licensed wholesalers from these provisions as specified, but requires records of suspicious sales and transfers as determined by the DOJ.
 - d. Any analytical research facility that is registered with the federal DEA.
 - e. A state-licensed health care facility that administers or furnishes a substance to its patients.
 - f. Specified products that are sold over the counter without a prescription, unless the individual transaction involves more than three packages or nine grams of the substance.
 - g. Any transfer or a substance for lawful disposal as waste.
 9. Creates penalties for non-compliance, including jail time and fines as specified.
 10. Specifies the conditions under which it is unlawful to sell, transfer or otherwise furnish a substance to a person under 18 years of age.
 11. Defines several terms for purposes of this article.
 12. Specifies that these provisions preempt all local ordinances or regulations governing the sale of specified products.

Health and Safety Code Section 11106:

1. Requires any business that furnishes substances pursuant to H&SC 11100 to obtain a permit from the Department of Justice as specified and identifies the following exemptions:
 - a. Entities licensed by the board that are also registered by the DEA.
 - b. Pharmacists or other authorized persons furnishing the substance pursuant to a prescription
 - c. Any physician, dentist, podiatrist or veterinarian who administers or furnishes a substance to his or her patients
 - d. Any state-licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food-animal drug retailer licensed by the board.
 - e. Any analytical research facility that is registered with the federal DEA.
 - f. Sales, etc. or receipt of betadine or povidone solution as specified.

- g. Specified products that are sold over the counter without a prescription.
2. Defines the application process and required information and training necessary to qualify for a permit.
3. Authorizes the department to examine the records of licensees, identifies violations and sets forth the consequences for the violations.
4. Requires and defines the process to notice changes in ownership, management or employment.

THIS BILL WOULD:

Health and Safety Code Section 11100

1. Remove the provision allowing for the sale of products containing ephedrine, pseudoephedrine, norpseudoephedrine or phenylpropanolamine over the counter without a prescription.
2. Specify that it is unlawful for any entity to sell, transfer or otherwise furnish any of the substances provided in this section.
3. Specify that it is unlawful for any person under 18 to possess any of the substances provided in this section.
4. Remove the provision exempting specified products that are sold over the counter without a prescription, unless the individual transaction involves more than three packages or nine grams of the substance.
5. Modify the definition of "Pediatric liquid" and "retail distributor."
6. Remove the "sale for personal use" definition.

Health and Safety Code Section 11106

Specify that a permit will be required for the sale, transfer, furnishing or obtaining the preparations in solid or liquid form of products referenced in H&SC 11375.5 (generally products contain ephedrine).

Health and Safety Code Section 11375.5

Require a prescription to obtain any of the products listed in the section - - all products containing ephedrine.

AUTHOR'S INTENT:

"SB 315 will significantly reduce the production of methamphetamine in California by making pseudoephedrine, the main ingredient used to manufacture methamphetamine, available only to patients who obtain a doctor's prescription."

Information provided by the author's office states that retailers currently keep all ephedrine-containing products behind the counter and indicate that anyone who makes a purchase must show identification and the purchase is logged either by paper or electronically. The author's office also notes that this legislation is modeled after similar and very successful laws passed in Oregon and Mississippi which resulted in a huge drop in meth labs and meth production in those state.

PREVIOUS/RELATED LEGISLATION:

Prior to recent amendments, SB 260 (Solorio) contains similar provisions to the proposed changes in H&SC 11100.

FISCAL IMPACT:

The board could experience an increase in the number of investigations resulting from this change. However, if the board is able to fill all of its vacant inspector positions, it is anticipated that any minor increase in investigations could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Mar. 23 Set for hearing April 5.
Mar. 15 Withdrawn from committee. Re-referred to Coms. on PUB. S. and HEALTH.
Feb. 24 Referred to Coms. on HEALTH and PUB. S.
Feb. 15 From printer. May be acted upon on or after March 17.
Feb. 14 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator WrightFebruary 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:

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

- 1 (24) Thionylchloride.
- 2 (25) Benzyl cyanide.
- 3 (26) Ergonovine maleate.
- 4 (27) N-methylephedrine.
- 5 (28) N-ethylephedrine.
- 6 (29) N-methylpseudoephedrine.
- 7 (30) N-ethylpseudoephedrine.
- 8 (31) Chloroephedrine.
- 9 (32) Chloropseudoephedrine.
- 10 (33) Hydriodic acid.
- 11 (34) Gamma-butyrolactone, including butyrolactone;
12 butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro;
13 dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide;
14 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone;
15 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone
16 with Chemical Abstract Service number (96-48-0).
- 17 (35) 1,4-butanediol, including butanediol; butane-1,4-diol;
18 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane;
19 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene
20 1,4-diol with Chemical Abstract Service number (110-63-4).
- 21 (36) Red phosphorus, including white phosphorus,
22 hypophosphorous acid and its salts, ammonium hypophosphite,
23 calcium hypophosphite, iron hypophosphite, potassium
24 hypophosphite, manganese hypophosphite, magnesium
25 hypophosphite, sodium hypophosphite, and phosphorous acid and
26 its salts.
- 27 (37) Iodine or tincture of iodine.
- 28 (38) Any of the substances listed by the Department of Justice
29 in regulations promulgated pursuant to subdivision (b).
- 30 (b) The Department of Justice may adopt rules and regulations
31 in accordance with Chapter 3.5 (commencing with Section 11340)
32 of Part 1 of Division 3 of Title 2 of the Government Code that add
33 substances to subdivision (a) if the substance is a precursor to a
34 controlled substance and delete substances from subdivision (a).
35 However, no regulation adding or deleting a substance shall have
36 any effect beyond March 1 of the year following the calendar year
37 during which the regulation was adopted.
- 38 (c) (1) (A) Any manufacturer, wholesaler, retailer, or other
39 person or entity in this state, prior to selling, transferring, or
40 otherwise furnishing any substance specified in subdivision (a) to

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

13 (B) For the purposes of this paragraph, “proper identification”
14 for in-state or out-of-state purchasers includes two or more of the
15 following: federal tax identification number; seller’s permit
16 identification number; city or county business license number;
17 license issued by the ~~California Department of Health Services~~
18 *State Department of Public Health*; registration number issued by
19 the ~~Federal~~ *federal* Drug Enforcement Administration; precursor
20 business permit number issued by the Bureau of Narcotic
21 Enforcement of the ~~California~~ Department of Justice; driver’s
22 license; or other identification issued by a state.

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

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

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

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

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

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

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

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

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

- 1 (5) A state-licensed health care facility that administers or
- 2 furnishes a substance to its patients.
- 3 ~~(6) (A) Any sale, transfer, furnishing, or receipt of any product~~
- 4 ~~that contains ephedrine, pseudoephedrine, norpseudoephedrine,~~
- 5 ~~or phenylpropanolamine and which is lawfully sold, transferred,~~
- 6 ~~or furnished over the counter without a prescription pursuant to~~
- 7 ~~the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et~~
- 8 ~~seq.) or regulations adopted thereunder. However, this section~~
- 9 ~~shall apply to preparations in solid or liquid dosage form, except~~
- 10 ~~pediatric liquid forms, as defined, containing ephedrine,~~
- 11 ~~pseudoephedrine, norpseudoephedrine, or phenylpropanolamine~~
- 12 ~~where the individual transaction involves more than three packages~~
- 13 ~~or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine,~~
- 14 ~~or phenylpropanolamine.~~
- 15 ~~(B)~~
- 16 ~~(6) Any ephedrine, pseudoephedrine, norpseudoephedrine, or~~
- 17 ~~phenylpropanolamine product sale, transfer, furnishing, or receipt~~
- 18 ~~of a product specified in Section 11375.5 pursuant to prescription~~
- 19 ~~shall not be subject to the reporting or permitting requirements~~
- 20 ~~of this section, unless a product is subsequently removed from~~
- 21 ~~exemption pursuant to Section 814 of Title 21 of the United States~~
- 22 ~~Code Code, in which case the product shall similarly no longer be~~
- 23 ~~exempt from any state reporting or permitting requirement,~~
- 24 ~~requirement unless otherwise reinstated pursuant to subdivision~~
- 25 ~~(d) or (e) of Section 814 of Title 21 of the United States Code as~~
- 26 ~~an exempt product.~~
- 27 (7) The sale, transfer, furnishing, or receipt of any betadine or
- 28 povidone solution with an iodine content not exceeding 1 percent
- 29 in containers of eight ounces or less, or any tincture of iodine not
- 30 exceeding 2 percent in containers of one ounce or less, that is sold
- 31 over the counter.
- 32 (8) Any transfer of a substance specified in subdivision (a) for
- 33 purposes of lawful disposal as waste.
- 34 (f) (1) Any person specified in subdivision (a) or (d) who does
- 35 not submit a report as required by that subdivision or who
- 36 knowingly submits a report with false or fictitious information
- 37 shall be punished by imprisonment in a county jail not exceeding
- 38 six months, by a fine not exceeding five thousand dollars (\$5,000),
- 39 or by both the fine and imprisonment.

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

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

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

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

32 (4)

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

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

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

- 1 (1) “Drug store” is any entity described in Code 5912 of the
2 Standard Industrial Classification (SIC) Manual published by the
3 United States Office of Management and Budget, 1987 edition.
- 4 (2) “General merchandise store” is any entity described in Codes
5 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial
6 Classification (SIC) Manual published by the United States Office
7 of Management and Budget, 1987 edition.
- 8 (3) “Grocery store” is any entity described in Code 5411 of the
9 Standard Industrial Classification (SIC) Manual published by the
10 United States Office of Management and Budget, 1987 edition.
- 11 (4) “Pediatric liquid” means a nonencapsulated liquid whose
12 unit measure according to product labeling is stated in milligrams,
13 ounces, or other similar measure. In no instance shall the dosage
14 units exceed 15 milligrams of ~~phenylpropanolamine or~~
15 ~~pseudoephedrine~~ *any product specified in Section 11375.5* per five
16 milliliters of liquid product, except for liquid products primarily
17 intended for administration to children under two years of age for
18 which the recommended dosage unit does not exceed two milliliters
19 and the total package content does not exceed one fluid ounce.
- 20 (5) “Retail distributor” means a grocery store, general
21 merchandise store, drugstore, or other related entity, the activities
22 of ~~which, as~~ *which include being* a distributor of ~~ephedrine,~~
23 ~~pseudoephedrine, norpseudoephedrine, or phenylpropanolamine~~
24 ~~products, are limited exclusively to the sale of ephedrine,~~
25 ~~pseudoephedrine, norpseudoephedrine, or phenylpropanolamine~~
26 ~~products for personal use both in number of sales and volume of~~
27 ~~sales, any product specified in Section 11375.5 upon prescription~~
28 ~~only, except for pediatric liquids,~~ either directly to walk-in
29 customers or in face-to-face transactions by direct sales. “Retail
30 distributor” includes an entity that makes a direct sale, but does
31 not include the parent company of that entity if the company is
32 not involved in direct sales regulated by this article.
- 33 (6) ~~“Sale for personal use” means the sale in a single transaction~~
34 ~~to an individual customer for a legitimate medical use of a product~~
35 ~~containing ephedrine, pseudoephedrine, norpseudoephedrine, or~~
36 ~~phenylpropanolamine in dosages at or below that specified in~~
37 ~~paragraph (3) of subdivision (g).~~ “Sale for personal use” also
38 includes the sale of those products to employers to be dispensed
39 to employees from first-aid kits or medicine chests.

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

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

8 11106. (a) (1) (A) Any manufacturer, wholesaler, retailer, or
9 any other person or entity in this state that sells, transfers, or
10 otherwise furnishes any substance specified in subdivision (a) of
11 Section 11100 to a person or business entity in this state or any
12 other state or who obtains from a source outside of the state any
13 substance specified in subdivision (a) of Section 11100 shall submit
14 an application to, and obtain a permit for the conduct of that
15 business from, the Department of Justice. For any substance added
16 to the list set forth in subdivision (a) of Section 11100 on or after
17 January 1, 2002, the Department of Justice may postpone the
18 effective date of the requirement for a permit for a period not to
19 exceed six months from the listing date of the substance.

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

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

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

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

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

13 ~~(3)~~

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

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

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

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

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

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

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

14 (2) If any individual owner, manager, agent, representative, or
15 employee for the applicant who has direct access, management,
16 or control for any substance listed under subdivision (a) of Section
17 11100, is or has been convicted of a misdemeanor or felony relating
18 to any of the substances listed under subdivision (a) of Section
19 11100, any misdemeanor drug-related offense, or any felony under
20 the laws of this state or the United States.

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

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

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

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

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

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

1 or control for any substance listed under subdivision (a) of Section
2 11100, willfully violates or has been convicted of violating, any
3 federal, state, or local criminal statute, rule, or ordinance regulating
4 the manufacture, maintenance, disposal, sale, transfer, or furnishing
5 of any of those substances.

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

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

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

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

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

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

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

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

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

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

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

17 11375.5. (a) Any person who obtains any substance specified
18 in subdivision (b), unless upon the prescription of a physician,
19 dentist, podiatrist, or veterinarian, licensed to practice in this state,
20 shall be guilty of an infraction or a misdemeanor.

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

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

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

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AMENDED IN SENATE MARCH 22, 2011

SENATE BILL

No. 360

Introduced by Senator DeSaulnier

February 15, 2011

An act to amend ~~Section 11165~~ of *Section 6929 of the Family Code*, and to amend *Sections 11054, 11055, 11056, 11057, 11161.5, 11162.1, 11165, 11165.1, 11212, 11350, 11351, 11352, 11353, 11354, 11355, 11377, 11378, 11379, 11379.2, 11839.2, and 11875* of, and to add *Sections 11165.2 and 11165.3* to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 360, as amended, DeSaulnier. Controlled Substance Utilization Review and Evaluation System.

Existing law classifies certain controlled substances into designated schedules. Under existing law, unlawful possession of specified controlled substances is either a misdemeanor or a felony. Existing law requires the Department of Justice, contingent upon the availability of adequate funds from various funds related to health care, as specified, to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

~~This bill would make a technical, nonsubstantive change to that provision.~~

This bill would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations

containing chorionic gonadotropin, a hormone, and Schedule IV to add additional depressants and stimulants. By revising the definition of crimes, the bill would impose a state-mandated local program.

Existing law defines a security printer as a person approved to produce controlled substance prescription forms. Existing law requires that prescription forms for controlled substance prescriptions be obtained from security printers approved by the Department of Justice. These provisions authorize the department to approve a security printer who provides specified information to the department, including the location, names, and titles of the applicant's agent for service of process, all principal corporate officers, if any, and all managing general partners, if any. Existing law also requires those persons to provide a signed statement indicating whether they have ever been convicted of, or pled no contest to, a violation of any law or ordinance. Existing law authorizes the department to revoke its approval of a security printer for a violation of these provisions or action that would permit a denial.

This bill would expand those requirements imposed on an applicant for approval as a security printer to additionally require the applicant to provide the location, names, and titles of any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms and require those persons to submit the signed statement described above. The bill would also make conforming and related changes. In addition, the bill would require that controlled substance prescriptions provided in person be restricted to established customers. The bill would require security printers to obtain photo identification from the customer and maintain a log of the information, and to report any theft or loss of controlled substance prescriptions to the department via fax or e-mail within 24 hours of the incident. The bill would also require that controlled substance prescriptions be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California. The bill would authorize the department to impose restrictions, sanctions, or penalties against security printers who are not in compliance with provisions governing security printers, as specified.

Existing law governs the prescription forms for controlled substances. Among other things, the forms are required to include the preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

This bill would also require the forms to include the address of the prescribing practitioner. The bill would make an additional change relating to forms ordered for use by prescribers when treating patients in licensed health care facilities or certain clinics that are exempt from other requirements governing these forms. The bill would provide that prescription forms that are not in compliance with these provisions shall not be accepted after July 1, 2012.

The bill would establish a specified process by which a licensed health care practitioner or a pharmacist may obtain approval to access information stored on the Internet regarding the controlled substance history of a patient, as specified.

The bill would require that the theft or loss of prescription information be reported immediately to the department, as specified. The bill would also require the department to conduct audits of the Prescription Drug Monitoring System and authorize the department to establish a system for issuing citations, and for assessing and imposing administrative fines, not to exceed \$2,500 for each violation, that would be deposited in the CURES Program Special Fund, for violations of the program, as specified.

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: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

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

- 1 SECTION 1. Section 6929 of the Family Code is amended to
- 2 read:
- 3 6929. (a) As used in this section:
- 4 (1) "Counseling" means the provision of counseling services
- 5 by a provider under a contract with the state or a county to provide
- 6 alcohol or drug abuse counseling services pursuant to Part 2
- 7 (commencing with Section 5600) of Division 5 of the Welfare and
- 8 Institutions Code or pursuant to Division 10.5 (commencing with
- 9 Section 11750) of the Health and Safety Code.

- 1 (2) “Drug or alcohol” includes, but is not limited to, any
2 substance listed in any of the following:
- 3 (A) Section 380 or 381 of the Penal Code.
- 4 (B) Division 10 (commencing with Section 11000) of the Health
5 and Safety Code.
- 6 (C) Subdivision (f) of Section 647 of the Penal Code.
- 7 (3) “LAAM” means levoalphacetylmethadol as specified in
8 paragraph ~~(10)~~ (12) of subdivision (c) of Section 11055 of the
9 Health and Safety Code.
- 10 (4) “Professional person” means a physician and surgeon,
11 registered nurse, psychologist, clinical social worker, marriage
12 and family therapist, marriage and family therapist registered intern
13 when appropriately employed and supervised pursuant to Section
14 4980.43 of the Business and Professions Code, psychological
15 assistant when appropriately employed and supervised pursuant
16 to Section 2913 of the Business and Professions Code, or associate
17 clinical social worker when appropriately employed and supervised
18 pursuant to Section 4996.18 of the Business and Professions Code.
- 19 (b) A minor who is 12 years of age or older may consent to
20 medical care and counseling relating to the diagnosis and treatment
21 of a drug- or alcohol-related problem.
- 22 (c) The treatment plan of a minor authorized by this section
23 shall include the involvement of the minor’s parent or guardian,
24 if appropriate, as determined by the professional person or
25 treatment facility treating the minor. The professional person
26 providing medical care or counseling to a minor shall state in the
27 minor’s treatment record whether and when the professional person
28 attempted to contact the minor’s parent or guardian, and whether
29 the attempt to contact the parent or guardian was successful or
30 unsuccessful, or the reason why, in the opinion of the professional
31 person, it would not be appropriate to contact the minor’s parent
32 or guardian.
- 33 (d) The minor’s parent or guardian is not liable for payment for
34 any care provided to a minor pursuant to this section, except that
35 if the minor’s parent or guardian participates in a counseling
36 program pursuant to this section, the parent or guardian is liable
37 for the cost of the services provided to the minor and the parent
38 or guardian.
- 39 (e) This section does not authorize a minor to receive
40 replacement narcotic abuse treatment, in a program licensed

1 pursuant to Article 3 (commencing with Section 11875) of Chapter
2 1 of Part 3 of Division 10.5 of the Health and Safety Code, without
3 the consent of the minor's parent or guardian.

4 (f) It is the intent of the Legislature that the state shall respect
5 the right of a parent or legal guardian to seek medical care and
6 counseling for a drug- or alcohol-related problem of a minor child
7 when the child does not consent to the medical care and counseling,
8 and nothing in this section shall be construed to restrict or eliminate
9 this right.

10 (g) Notwithstanding any other provision of law, in cases where
11 a parent or legal guardian has sought the medical care and
12 counseling for a drug- or alcohol-related problem of a minor child,
13 the physician shall disclose medical information concerning the
14 care to the minor's parent or legal guardian upon his or her request,
15 even if the minor child does not consent to disclosure, without
16 liability for the disclosure.

17 *SEC. 2. Section 11054 of the Health and Safety Code is*
18 *amended to read:*

19 11054. (a) The controlled substances listed in this section are
20 included in Schedule I.

21 (b) Opiates. Unless specifically excepted or unless listed in
22 another schedule, any of the following opiates, including their
23 isomers, esters, ethers, salts, and salts of isomers, esters, and ethers
24 whenever the existence of those isomers, esters, ethers, and salts
25 is possible within the specific chemical designation:

- 26 (1) *1-(1-Phenylcyclohexyl)pyrrolidine.*
- 27 (2) *1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine.*
- 28 (3) *1-[1-(2-Thienyl)cyclohexyl]piperidine.*
- 29 (4) *1-[1-(2-Thienyl)cyclohexyl]pyrrolidine.*
- 30 (5) *1-Methyl-4-phenyl-4-propionoxypiperidine.*
- 31 (6) *2,5-Dimethoxy-4-(n)-propylthiophenethylamine.*
- 32 (7) *2,5-Dimethoxy-4-ethylamphetamine.*
- 33 (8) *2,5-Dimethoxyamphetamine.*
- 34 (9) *3,4,5-Trimethoxyamphetamine.*
- 35 (10) *3,4-Methylenedioxyamphetamine.*
- 36 (11) *3,4-Methylenedioxymethamphetamine.*
- 37 (12) *3,4-Methylenedioxy-N-ethylamphetamine.*
- 38 (13) *3-Methylfentanyl.*
- 39 (14) *3-Methylthiofentanyl.*
- 40 (15) *4-Bromo-2,5-dimethoxyamphetamine.*

- 1 (16) *4-Bromo-2,5-dimethoxyphenethylamine.*
- 2 (17) *4-Methoxyamphetamine.*
- 3 (18) *4-Methyl-2,5-dimethoxyamphetamine.*
- 4 (19) *4-Methylaminorex (cis isomer).*
- 5 (20) *5-Methoxy-3,4-methylenedioxyamphetamine.*
- 6 (21) *5-Methoxy-N,N-diisopropyltryptamine.*
- 7 ~~(1)~~
- 8 (22) Acetylmethadol.
- 9 ~~(2)~~
- 10 (23) Allylprodine.
- 11 ~~(3)~~
- 12 (24) Alphacetylmethadol (except levoalphacetylmethadol, also
- 13 known as ~~levo-alpha-acetylmethadol~~ *levo-alpha-acetylmethadol*,
- 14 levomethadyl acetate, or LAAM).
- 15 ~~(4)~~
- 16 (25) Alphameprodine.
- 17 ~~(5)~~
- 18 (26) Alphamethadol.
- 19 (27) *Alpha-methylfentanyl.*
- 20 (28) *Alpha-methylthiofentanyl.*
- 21 (29) *Alpha-methyltryptamine.*
- 22 (30) *Aminorex.*
- 23 ~~(6)~~
- 24 (31) Benzethidine.
- 25 ~~(7)~~
- 26 (32) Betacetylmethadol.
- 27 (33) *Beta-hydroxy-3-methylfentanyl.*
- 28 (34) *Beta-hydroxyfentanyl.*
- 29 ~~(8)~~
- 30 (35) Betameprodine.
- 31 ~~(9)~~
- 32 (36) Betamethadol.
- 33 ~~(10)~~
- 34 (37) Betaprodine.
- 35 (38) *Cathinone.*
- 36 ~~(11)~~
- 37 (39) Clonitazene.
- 38 (12)
- 39 (40) Dextromoramide.
- 40 ~~(13)~~

- 1 (41) Diampromide.
- 2 ~~(14)~~
- 3 (42) Diethylthiambutene.
- 4 ~~(15)~~
- 5 (43) Difenoxin.
- 6 ~~(16)~~
- 7 (44) Dimenoxadol.
- 8 ~~(17)~~
- 9 (45) Dimepheptanol.
- 10 ~~(18)~~
- 11 (46) Dimethylthiambutene.
- 12 ~~(19)~~
- 13 (47) Dioxaphetyl butyrate.
- 14 ~~(20)~~
- 15 (48) Dipipanone.
- 16 ~~(21)~~
- 17 (49) Ethylmethylthiambutene.
- 18 ~~(22)~~
- 19 (50) Etonitazene.
- 20 ~~(23)~~
- 21 (51) Etoxidine.
- 22 ~~(24)~~
- 23 (52) Furethidine.
- 24 ~~(25)~~
- 25 (53) Hydroxypethidine.
- 26 ~~(26)~~
- 27 (54) Ketobemidone.
- 28 ~~(27)~~
- 29 (55) Levomoramide.
- 30 ~~(28)~~
- 31 (56) Levophenacymorphan.
- 32 (57) *Methcathinone*.
- 33 ~~(29)~~
- 34 (58) Morpheridine.
- 35 (59) *N,N-Dimethylamphetamine*.
- 36 (60) *N-Benzylpiperazine*.
- 37 (61) *N-Ethyl-1-phenylcyclohexylamine*.
- 38 (62) *N-Hydroxy-3-4-methylenedioxyamphetamine*.
- 39 ~~(30)~~
- 40 (63) Noracymethadol.

- 1 ~~(31)~~
- 2 (64) Norlevorphanol.
- 3 ~~(32)~~
- 4 (65) Normethadone.
- 5 ~~(33)~~
- 6 (66) Norpipanone.
- 7 (67) *Para-Fluorofentanyl*.
- 8 (68) *Parahexyl*.
- 9 ~~(34)~~
- 10 (69) Phenadoxone.
- 11 ~~(35)~~
- 12 (70) Phenampromide.
- 13 ~~(36)~~
- 14 (71) Phenomorphan.
- 15 ~~(37)~~
- 16 (72) Phenoperidine.
- 17 ~~(38)~~
- 18 (73) Piritramide.
- 19 ~~(39)~~
- 20 (74) Proheptazine.
- 21 ~~(40)~~
- 22 (75) Properidine.
- 23 ~~(41)~~
- 24 (76) Propiram.
- 25 ~~(42)~~
- 26 (77) Racemoramide.
- 27 (78) *Thiofentanyl*.
- 28 ~~(43)~~
- 29 (79) Tilidine.
- 30 ~~(44)~~
- 31 (80) Trimeperidine.
- 32 ~~(45)~~
- 33 (81) Any substance which contains any quantity of
- 34 acetylfentanyl (N-[1-phenethyl-4-piperidinyl] acetanilide) or a
- 35 derivative thereof.
- 36 ~~(46)~~
- 37 (82) Any substance which contains any quantity of the thiophene
- 38 analog of acetylfentanyl (N-[1-[2-(2-thienyl)ethyl]-4-piperidinyl]
- 39 acetanilide) or a derivative thereof.
- 40 ~~(47)~~

1 (83) 1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

2 ~~(48)~~

3 (84) 1-(2-Phenethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

4 (c) Opium derivatives. Unless specifically excepted or unless
5 listed in another schedule, any of the following opium derivatives,
6 its salts, isomers, and salts of isomers whenever the existence of
7 those salts, isomers, and salts of isomers is possible within the
8 specific chemical designation:

9 (1) Acetorphine.

10 (2) Acetyldihydrocodeine.

11 (3) Benzylmorphine.

12 (4) Codeine methylbromide.

13 (5) Codeine-N-Oxide.

14 (6) Cyprenorphine.

15 (7) Desomorphine.

16 (8) Dihydromorphine.

17 (9) Drotebanol.

18 (10) Etorphine (except hydrochloride salt).

19 (11) Heroin.

20 (12) Hydromorphanol.

21 (13) Methyldesorphine.

22 (14) Methyldihydromorphine.

23 (15) Morphine methylbromide.

24 (16) Morphine methylsulfonate.

25 (17) Morphine-N-Oxide.

26 (18) Myrophine.

27 (19) Nicocodeine.

28 (20) Nicomorphine.

29 (21) Normorphine.

30 (22) Pholcodine.

31 (23) Thebacon.

32 (d) Hallucinogenic substances. Unless specifically excepted or
33 unless listed in another schedule, any material, compound, mixture,
34 or preparation, which contains any quantity of the following
35 hallucinogenic substances, or which contains any of its salts,
36 isomers, and salts of isomers whenever the existence of those salts,
37 isomers, and salts of isomers is possible within the specific
38 chemical designation (for purposes of this subdivision only, the
39 term “isomer” includes the optical, position, and geometric
40 isomers):

- 1 (1) 4-bromo-2,5-dimethoxy-amphetamine—Some trade or other
2 names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine;
3 4-bromo-2,5-DMA.
- 4 (2) 2,5-dimethoxyamphetamine—Some trade or other names:
5 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.
- 6 (3) 4-methoxyamphetamine—Some trade or other names:
7 4 - m e t h o x y - a l p h a - m e t h y l p h e n e t h y l a m i n e ,
8 paramethoxyamphetamine, PMA.
- 9 (4) 5-methoxy-3,4-methylenedioxy-amphetamine.
- 10 (5) 4-methyl-2,5-dimethoxy-amphetamine—Some trade or other
11 names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine;
12 “DOM”; and “STP.”
- 13 (6) 3,4-methylenedioxy amphetamine.
- 14 (7) 3,4,5-trimethoxy amphetamine.
- 15 (8) Bufotenine—Some trade or other names:
16 3 - (b e t a - d i m e t h y l a m i n o e t h y l) - 5 - h y d r o x y i n d o l e ;
17 3-(2-dimethylaminoethyl)-5 indolol; N,N-dimethylserolonin,
18 5-hydroxy-N,N-dimethyltryptamine; mappine.
- 19 (9) Diethyltryptamine—Some trade or other names:
20 N,N-Diethyltryptamine; DET.
- 21 (10) Dimethyltryptamine—Some trade or other names: DMT.
- 22 (11) Ibogaine—Some trade or other names: 7-Ethyl-6,6beta,
23 7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido
24 [1',2':1,2] azepino [5,4-b] indole; Tabernantheiboga.
- 25 (12) Lysergic acid diethylamide.
- 26 (13) Marijuana.
- 27 (14) Mescaline.
- 28 (15) Peyote—Meaning all parts of the plant presently classified
29 botanically as *Lophophora williamsii* Lemaire, whether growing
30 or not, the seeds thereof, any extract from any part of the plant,
31 and every compound, manufacture, salts, derivative, mixture, or
32 preparation of the plant, its seeds or extracts (interprets 21 U.S.C.
33 Sec. 812(c), Schedule 1(c)(12)).
- 34 (16) N-ethyl-3-piperidyl benzilate.
- 35 (17) N-methyl-3-piperidyl benzilate.
- 36 (18) Psilocybin.
- 37 (19) Psilocyn.
- 38 (20) Tetrahydrocannabinols. Synthetic equivalents of the
39 substances contained in the plant, or in the resinous extractives of
40 Cannabis, sp. and/or synthetic substances, derivatives, and their

1 isomers with similar chemical structure and pharmacological
2 activity such as the following: delta 1 cis or trans
3 tetrahydrocannabinol, and their optical isomers; delta 6 cis or trans
4 tetrahydrocannabinol, and their optical isomers; delta 3,4 cis or
5 trans tetrahydrocannabinol, and its optical isomers.

6 (Since nomenclature of these substances is not internationally
7 standardized, compounds of these structures, regardless of
8 numerical designation of atomic positions covered).

9 (21) Ethylamine analog of phencyclidine—Some trade or other
10 names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)
11 ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine,
12 PCE.

13 (22) Pyrrolidine analog of phencyclidine—Some trade or other
14 names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCP, PHP.

15 (23) Thiophene analog of phencyclidine—Some trade or other
16 names: 1-[1-(2 thienyl)-cyclohexyl]-piperidine, 2-thienyl analog
17 of phencyclidine, TPCP, TCP.

18 (e) Depressants. Unless specifically excepted or unless listed
19 in another schedule, any material, compound, mixture, or
20 preparation which contains any quantity of the following substances
21 having a depressant effect on the central nervous system, including
22 its salts, isomers, and salts of isomers whenever the existence of
23 those salts, isomers, and salts of isomers is possible within the
24 specific chemical designation:

25 (1) Mecloqualone.

26 (2) Methaqualone.

27 (3) Gamma hydroxybutyric acid (also known by other names
28 such as GHB; gamma hydroxy butyrate; 4-hydroxybutyrate;
29 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate),
30 including its immediate precursors, isomers, esters, ethers, salts,
31 and salts of isomers, esters, and ethers, including, but not limited
32 to, gammabutyrolactone, for which an application has not been
33 approved under Section 505 of the Federal Food, Drug, and
34 Cosmetic Act (21 U.S.C. Sec. 355).

35 (f) Unless specifically excepted or unless listed in another
36 schedule, any material, compound, mixture, or preparation which
37 contains any quantity of the following substances having a
38 stimulant effect on the central nervous system, including its
39 isomers:

40 (1) Cocaine base.

1 (2) Fenethylamine, including its salts.

2 (3) N-Ethylamphetamine, including its salts.

3 *SEC. 3. Section 11055 of the Health and Safety Code is*
4 *amended to read:*

5 11055. (a) The controlled substances listed in this section are
6 included in Schedule II.

7 (b) Any of the following substances, except those narcotic drugs
8 listed in other schedules, whether produced directly or indirectly
9 by extraction from substances of vegetable origin, or independently
10 by means of chemical synthesis, or by combination of extraction
11 and chemical synthesis:

12 (1) Opium, opiate, and any salt, compound, derivative, or
13 preparation of opium or opiate, with the exception of naloxone
14 hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone
15 hydrochloride), but including the following:

16 (A) Raw opium.

17 (B) Opium extracts.

18 (C) Opium fluid extracts.

19 (D) Powdered opium.

20 (E) Granulated opium.

21 (F) Tincture of opium.

22 (G) Codeine.

23 (H) Ethylmorphine.

24 (I) Hydrocodone.

25 (J) Hydromorphone.

26 (K) Metopon.

27 (L) Morphine.

28 (M) Oxycodone.

29 (N) Oxymorphone.

30 (O) Thebaine.

31 (2) Any salt, compound, isomer, or derivative, whether natural
32 or synthetic, of the substances referred to in paragraph (1), but not
33 including the isoquinoline alkaloids of opium.

34 (3) Opium poppy and poppy straw.

35 (4) Coca leaves and any salt, compound, derivative, or
36 preparation of coca leaves, but not including decocainized coca
37 leaves or extractions which do not contain cocaine or ecgonine.

38 (5) Concentrate of poppy straw (the crude extract of poppy straw
39 in either liquid, solid, or powder form which contains the
40 phenanthrene alkaloids of the opium poppy).

- 1 (6) Cocaine, except as specified in Section 11054.
- 2 (7) Ecgonine, whether natural or synthetic, or any salt, isomer,
- 3 derivative, or preparation thereof.
- 4 (c) Opiates. Unless specifically excepted or unless in another
- 5 schedule, any of the following opiates, including its isomers, esters,
- 6 ethers, salts, and salts of isomers, esters, and ethers whenever the
- 7 existence of those isomers, esters, ethers, and salts is possible
- 8 within the specific chemical designation, dextrorphan and
- 9 levopropoxyphene excepted:
 - 10 (1) Alfentanyl.
 - 11 (2) Alphaprodine.
 - 12 (3) Anileridine.
 - 13 (4) Bezitramide.
 - 14 (5) Bulk dextropropoxyphene (nondosage forms).
 - 15 (6) *Carfentanil*.
 - 16 ~~(6)~~
 - 17 (7) Dihydrocodeine.
 - 18 ~~(7)~~
 - 19 (8) Diphenoxylate.
 - 20 (9) *Etorphine HCl*.
 - 21 ~~(8)~~
 - 22 (10) Fentanyl.
 - 23 ~~(9)~~
 - 24 (11) Isomethadone.
 - 25 ~~(10)~~
 - 26 (12) Levoalphacetylmethadol, also known as
 - 27 levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This
 - 28 substance is authorized for the treatment of narcotic addicts under
 - 29 federal law (see Part 291 (commencing with Section 291.501) and
 - 30 Part 1308 (commencing with Section 1308.01) of Title 21 of the
 - 31 Code of Federal Regulations).
 - 32 ~~(11)~~
 - 33 (13) Levomethorphan.
 - 34 ~~(12)~~
 - 35 (14) Levorphanol.
 - 36 (15) *Lisdexamfetamine*.
 - 37 ~~(13)~~
 - 38 (16) Metazocine.
 - 39 ~~(14)~~
 - 40 (17) Methadone.

- 1 ~~(15)~~
2 (18) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,
3 4-diphenyl butane.
4 ~~(16)~~
5 (19) Moramide-Intermediate, 2-methyl-3-morpholino-1,
6 1-diphenylpropane-carboxylic acid.
7 (20) *Oripavine*.
8 ~~(17)~~
9 (21) Pethidine (meperidine).
10 ~~(18)~~
11 (2 2) P e t h i d i n e - I n t e r m e d i a t e - A ,
12 4-cyano-1-methyl-4-phenylpiperidine.
13 ~~(19)~~
14 (2 3) P e t h i d i n e - I n t e r m e d i a t e - B ,
15 ethyl-4-phenylpiperidine-4-carboxylate.
16 ~~(20)~~
17 (2 4) P e t h i d i n e - I n t e r m e d i a t e - C ,
18 1-methyl-4-phenylpiperidine-4-carboxylic acid.
19 ~~(21)~~
20 (25) Phenazocine.
21 ~~(22)~~
22 (26) Piminodine.
23 ~~(23)~~
24 (27) Racemethorphan.
25 ~~(24)~~
26 (28) Racemorphan.
27 (29) *Remifentanyl*.
28 ~~(25)~~
29 (30) Sufentanyl.
30 (31) *Tapentadol*.
31 (d) Stimulants. Unless specifically excepted or unless listed in
32 another schedule, any material, compound, mixture, or preparation
33 which contains any quantity of the following substances having a
34 stimulant effect on the central nervous system:
35 (1) Amphetamine, its salts, optical isomers, and salts of its
36 optical isomers.
37 (2) Methamphetamine, its salts, isomers, and salts of its isomers.
38 (3) Dimethylamphetamine (N,N-dimethylamphetamine), its
39 salts, isomers, and salts of its isomers.

1 (4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine),
2 its salts, isomers, and salts of its isomers.

3 (5) Phenmetrazine and its salts.

4 (6) Methylphenidate.

5 (7) Khat, which includes all parts of the plant classified
6 botanically as *Catha Edulis*, whether growing or not, the seeds
7 thereof, any extract from any part of the plant, and every
8 compound, manufacture, salt, derivative, mixture, or preparation
9 of the plant, its seeds, or extracts.

10 (8) Cathinone (also known as alpha-aminopropiophenone,
11 2-aminopropiophenone, and norephedrone).

12 (e) Depressants. Unless specifically excepted or unless listed
13 in another schedule, any material, compound, mixture, or
14 preparation which contains any quantity of the following substances
15 having a depressant effect on the central nervous system, including
16 its salts, isomers, and salts of isomers whenever the existence of
17 those salts, isomers, and salts of isomers is possible within the
18 specific chemical designation:

19 (1) Amobarbital.

20 (2) Pentobarbital.

21 (3) Phencyclidines, including the following:

22 (A) 1-(1-phenylcyclohexyl) piperidine (PCP).

23 (B) 1-(1-phenylcyclohexyl) morpholine (PCM).

24 (C) Any analog of phencyclidine which is added by the Attorney
25 General by regulation pursuant to this paragraph.

26 The Attorney General, or his or her designee, may, by rule or
27 regulation, add additional analogs of phencyclidine to those
28 enumerated in this paragraph after notice, posting, and hearing
29 pursuant to Chapter 3.5 (commencing with Section 11340) of Part
30 1 of Division 3 of Title 2 of the Government Code. The Attorney
31 General shall, in the calendar year of the regular session of the
32 Legislature in which the rule or regulation is adopted, submit a
33 draft of a proposed bill to each house of the Legislature which
34 would incorporate the analogs into this code. No rule or regulation
35 shall remain in effect beyond January 1 after the calendar year of
36 the regular session in which the draft of the proposed bill is
37 submitted to each house. However, if the draft of the proposed bill
38 is submitted during a recess of the Legislature exceeding 45
39 calendar days, the rule or regulation shall be effective until January
40 1 after the next calendar year.

1 (4) Secobarbital.

2 (5) Glutethimide.

3 (f) Immediate precursors. Unless specifically excepted or unless
4 listed in another schedule, any material, compound, mixture, or
5 preparation which contains any quantity of the following
6 substances:

7 (1) Immediate precursor to amphetamine and methamphetamine:

8 (A) Phenylacetone. Some trade or other names: phenyl-2
9 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

10 (2) Immediate precursors to phencyclidine (PCP):

11 (A) 1-phenylcyclohexylamine.

12 (B) 1-piperidinocyclohexane carbonitrile (PCC).

13 *SEC. 4. Section 11056 of the Health and Safety Code is*
14 *amended to read:*

15 11056. (a) The controlled substances listed in this section are
16 included in Schedule III.

17 (b) Stimulants. Unless specifically excepted or unless listed in
18 another schedule, any material, compound, mixture, or preparation
19 which contains any quantity of the following substances having a
20 stimulant effect on the central nervous system, including its salts,
21 isomers (whether optical, position, or geometric), and salts of those
22 isomers whenever the existence of those salts, isomers, and salts
23 of isomers is possible within the specific chemical designation:

24 (1) Those compounds, mixtures, or preparations in dosage unit
25 form containing any stimulant substances listed in Schedule II
26 which compounds, mixtures, or preparations were listed on August
27 25, 1971, as excepted compounds under Section 1308.32 of Title
28 21 of the Code of Federal Regulations, and any other drug of the
29 quantitative composition shown in that list for those drugs or which
30 is the same except that it contains a lesser quantity of controlled
31 substances.

32 (2) Benzphetamine.

33 (3) Chlorphentermine.

34 (4) Clortermine.

35 (5) Mazindol.

36 (6) Phendimetrazine.

37 (c) Depressants. Unless specifically excepted or unless listed
38 in another schedule, any material, compound, mixture, or
39 preparation which contains any quantity of the following substances
40 having a depressant effect on the central nervous system:

1 (1) Any compound, mixture, or preparation containing any of
2 the following:

- 3 (A) Amobarbital
- 4 ~~(B) Secobarbital~~
- 5 ~~(C) Pentobarbital~~
- 6 ~~or any salt thereof and one or more other active medicinal~~
- 7 ~~ingredients which are not listed in any schedule.~~

- 8 (B) Aprobarbital
- 9 (C) Butalbital
- 10 (D) Embutramide
- 11 (E) Nalorphine
- 12 (F) Pentobarbital
- 13 (G) Secobarbital
- 14 (H) Talbutal
- 15 (I) Thiamylal
- 16 (J) Thiopental
- 17 (K) Tiletamine & Zolazepam
- 18 (L) Vinbarbital

19 *or any salt thereof and one or more other active medicinal*
20 *ingredients which are not listed in any schedule.*

21 (2) Any suppository dosage form containing any of the
22 following:

- 23 (A) Amobarbital
- 24 ~~(B) Secobarbital~~
- 25 ~~(C) Pentobarbital~~
- 26 ~~or any salt of any of these drugs and approved by the federal Food~~
- 27 ~~and Drug Administration for marketing only as a suppository.~~

- 28 (B) Aprobarbital
- 29 (C) Butalbital
- 30 (D) Embutramide
- 31 (E) Nalorphine
- 32 (F) Pentobarbital
- 33 (G) Secobarbital
- 34 (H) Talbutal
- 35 (I) Thiamyla
- 36 (J) Thiopental
- 37 (K) Tiletamine & Zolazepam
- 38 (L) Vinbarbital

39 *or any salt of any of these drugs and approved by the federal Food*
40 *and Drug Administration for marketing only as a suppository.*

- 1 (3) Any substance which contains any quantity of a derivative
2 of barbituric acid or any salt thereof.
- 3 (4) Chlorhexadol.
- 4 (5) Lysergic acid.
- 5 (6) Lysergic acid amide.
- 6 (7) Methyprylon.
- 7 (8) Sulfondiethylmethane.
- 8 (9) Sulfonethylmethane.
- 9 (10) Sulfonmethane.
- 10 (11) Gamma hydroxybutyric acid, and its salts, isomers and
11 salts of isomers, contained in a drug product for which an
12 application has been approved under Section 505 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).
- 14 (d) Nalorphine.
- 15 (e) Narcotic drugs. Unless specifically excepted or unless listed
16 in another schedule, any material, compound, mixture, or
17 preparation containing any of the following narcotic drugs, or their
18 salts calculated as the free anhydrous base or alkaloid, in limited
19 quantities as set forth below:
- 20 (1) Not more than 1.8 grams of codeine per 100 milliliters or
21 not more than 90 milligrams per dosage unit, with an equal or
22 greater quantity of an isoquinoline alkaloid of opium.
- 23 (2) Not more than 1.8 grams of codeine per 100 milliliters or
24 not more than 90 milligrams per dosage unit, with one or more
25 active, nonnarcotic ingredients in recognized therapeutic amounts.
- 26 (3) Not more than 300 milligrams of dihydrocodeinone per 100
27 milliliters or not more than 15 milligrams per dosage unit, with a
28 fourfold or greater quantity of an isoquinoline alkaloid of opium.
- 29 (4) Not more than 300 milligrams of dihydrocodeinone per 100
30 milliliters or not more than 15 milligrams per dosage unit, with
31 one or more active nonnarcotic ingredients in recognized
32 therapeutic amounts. Additionally, oral liquid preparations of
33 dihydrocodeinone containing the above specified amounts may
34 not contain as its nonnarcotic ingredients two or more
35 antihistamines in combination with each other.
- 36 (5) Not more than 1.8 grams of dihydrocodeine per 100
37 milliliters or not more than 90 milligrams per dosage unit, with
38 one or more active nonnarcotic ingredients in recognized
39 therapeutic amounts.

1 (6) Not more than 300 milligrams of ethylmorphine per 100
2 milliliters or not more than 15 milligrams per dosage unit, with
3 one or more active, nonnarcotic ingredients in recognized
4 therapeutic amounts.

5 (7) Not more than 500 milligrams of opium per 100 milliliters
6 or per 100 grams or not more than 25 milligrams per dosage unit,
7 with one or more active, nonnarcotic ingredients in recognized
8 therapeutic amounts.

9 (8) Not more than 50 milligrams of morphine per 100 milliliters
10 or per 100 grams, with one or more active, nonnarcotic ingredients
11 in recognized therapeutic amounts.

12 (f) Anabolic steroids and chorionic gonadotropin. Any material,
13 compound, mixture, or preparation containing chorionic
14 gonadotropin or an anabolic steroid (excluding anabolic steroid
15 products listed in the “Table of Exempt Anabolic Steroid Products”
16 (Section 1308.34 of Title 21 of the Code of Federal Regulations),
17 as exempt from the federal Controlled Substances Act (Section
18 801 and following of Title 21 of the United States Code)),
19 including, but not limited to, the following:

- 20 (1) Androisoxazole.
- 21 (2) Androstenediol.
- 22 (3) Bolandiol.
- 23 (4) Bolasterone.
- 24 (5) Boldenone.
- 25 (6) *Calusterone*.
- 26 ~~(6)~~
- 27 (7) Chlormethandienone.
- 28 ~~(7)~~
- 29 (8) Clostebol.
- 30 (9) *Dehydrochlormethyltestosterone*.
- 31 (10) *Delta1-dihydrotestosterone*.
- 32 (11) *Desoxymethyltestosterone*.
- 33 ~~(8)~~
- 34 (12) Dihydromesterone.
- 35 ~~(9)~~
- 36 (13) Drostanolone.
- 37 ~~(10)~~
- 38 (14) Ethylestrenol.
- 39 ~~(11)~~
- 40 (15) Fluoxymesterone.

- 1 ~~(12)~~
- 2 (16) Formyldienolone.
- 3 ~~(13)~~
- 4 (17) Furazabol.
- 5 ~~(14)~~
- 6 (18) 4-Hydroxy-19-nortestosterone.
- 7 ~~(15)~~
- 8 (19) Mesterolone.
- 9 ~~(16)~~
- 10 (20) Methandriol.
- 11 ~~(17)~~
- 12 (21) Methandrostenolone.
- 13 ~~(18)~~
- 14 (22) Methenolone.
- 15 ~~(19)~~
- 16 (23) 17-Methyltestosterone.
- 17 ~~(20)~~
- 18 (24) Methyltrienolone.
- 19 (25) *Mibolerone*.
- 20 ~~21~~
- 21 (26) Nandrolone.
- 22 ~~(22)~~
- 23 (27) Norbolethone.
- 24 (28) *Norclostebol*.
- 25 ~~(23)~~
- 26 (29) Norethandrolone.
- 27 ~~(24)~~
- 28 (30) Normethandrolone.
- 29 ~~(24)~~
- 30 (31) Oxandrolone.
- 31 ~~(25)~~
- 32 (32) Oxymestronone.
- 33 ~~(26)~~
- 34 (33) Oxymetholone.
- 35 ~~(27)~~
- 36 (34) Quinbolone.
- 37 ~~(28)~~
- 38 (35) Stanolone.
- 39 ~~(29)~~
- 40 (36) Stanozolol.

- 1 (~~30~~)
- 2 (37) Stenbolone.
- 3 (~~31~~)
- 4 (38) *Testolactone*.
- 5 (~~32~~)
- 6 (39) Testosterone.
- 7 (40) *Tetrahydrogestrinone*.
- 8 (~~33~~)
- 9 (41) Trenbolone.
- 10 (42) Chorionic Gonadotropin (HGC).
- 11 (43) *13Beta-ethyl-17beta-hydroxygon-4-en-3-one*
- 12 (44) *17Alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane*
- 13 (45) *17Alpha-methyl-3beta,17beta-dihydroxy-5alpha-androstane*
- 14 (46) *17Alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene*
- 15 (47) *17Alpha-methyl-4-hydroxynandrolone*
- 16 (*17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one*)
- 17 (48) *17Alpha-methyl-delta1-dihydrotestosterone*
- 18 (*17betahydroxy-17alpha-methyl-5alpha-androst-1-en-3-one*)
- 19 (49) *17Alpha-methyl-1-testosterone*
- 20 (50) *19-Nor-4,9(10)-androstadienedione*
- 21 (51) *19-Nor-4-androstenediol*
- 22 (*3beta,17beta-dihydroxyestr-4-ene*;
- 23 *3alpha,17beta-dihydroxyestr-4-ene*)
- 24 (52) *19-Nor-4-androstenedione (estr-4-en-3,17-dione)*
- 25 (53) *19-Nor-5-androstenediol*
- 26 (*3beta,17beta-dihydroxyestr-5-ene*;
- 27 *3alpha,17beta-dihydroxyestr-5-ene*)
- 28 (54) *19-Nor-5-androstenedione (estr-5-en-3,17-dione)*
- 29 (55) *1-Androstenediol*
- 30 (*3beta,17beta-dihydroxy-5alphaandrost-1-ene*;
- 31 *3alpha,17beta-dihydroxy-5alphaandrost-1-ene*)
- 32 (56) *1-Androstenedione (5alpha-androst-1-en-3,17-dione)*
- 33 (57) *3Alpha,17beta-dihydroxy-5alpha-androstane*
- 34 (58) *3Beta,17beta-dihydroxy-5alpha-androstane*
- 35 (59) *4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene)*
- 36 (60) *4-Androstenedione (androst-4-en-3,17-dione)*
- 37 (61) *4-Dihydrotestosterone (17beta-hydroxyandrost-3-one)*
- 38 (62) *4-Hydroxy-19-nortestosterone*
- 39 (*4,17beta-dihydroxyestr-4-en-3-one*)

1 (6 3) 4 - H y d r o x y t e s t o s t e r o n e
2 (4,17beta-dihydroxyandrost-4-en-3-one)

3 (64) 5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene)

4 (65) 5-Androstenedione (androst-5-en-3,17-dione)

5 (g) Buprenorphine. Any material, compound, mixture, or
6 preparation containing Buprenorphine.

7 (h) Butabarbital. Any material, compound, mixture, or
8 preparation containing Butabarbital.

9 ~~(g)~~

10 (i) Ketamine. Any material, compound, mixture, or preparation
11 containing ketamine.

12 ~~(h)~~

13 (j) Hallucinogenic substances. Any of the following
14 hallucinogenic substances: dronabinol (synthetic) in sesame oil
15 and encapsulated in a soft gelatin capsule in a drug product
16 approved by the federal Food and Drug Administration.

17 SEC. 5. Section 11057 of the Health and Safety Code is
18 amended to read:

19 11057. (a) The controlled substances listed in this section are
20 included in Schedule IV.

21 (b) Schedule IV shall consist of the drugs and other substances,
22 by whatever official name, common or usual name, chemical name,
23 or brand name designated, listed in this section.

24 (c) Narcotic drugs. Unless specifically excepted or unless listed
25 in another schedule, any material, compound, mixture, or
26 preparation containing any of the following narcotic drugs, or their
27 salts calculated as the free anhydrous base or alkaloid, in limited
28 quantities as set forth below:

29 (1) Not more than 1 milligram of difenoxin and not less than
30 25 micrograms of atropine sulfate per dosage unit.

31 (2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,
32 2-diphenyl-3-methyl-2-propionoxybutane).

33 (3) Butorphanol.

34 (d) Depressants. Unless specifically excepted or unless listed
35 in another schedule, any material, compound, mixture, or
36 preparation which contains any quantity of the following
37 substances, including its salts, isomers, and salts of isomers
38 whenever the existence of those salts, isomers, and salts of isomers
39 is possible within the specific chemical designation:

40 (1) Alprazolam.

- 1 (2) Barbital.
- 2 (3) *Bromazepam.*
- 3 (4) *Camazepam.*
- 4 ~~(3)~~
- 5 (5) Chloral betaine.
- 6 ~~(4)~~
- 7 (6) Chloral hydrate.
- 8 ~~(5)~~
- 9 (7) Chlordiazepoxide.
- 10 ~~(6)~~
- 11 (8) Clobazam.
- 12 ~~(7)~~
- 13 (9) Clonazepam.
- 14 ~~(8)~~
- 15 (10) Clorazepate.
- 16 (11) *Clotiazepam.*
- 17 (12) *Cloxazolam.*
- 18 (13) *Delorazepam.*
- 19 (14) *Dexfenfluramine.*
- 20 ~~(9)~~
- 21 (15) Diazepam.
- 22 (16) *Dichloralphenazone.*
- 23 (17) *Diethylpropion.*
- 24 (18) *Difenoxin.*
- 25 ~~(10)~~
- 26 (19) Estazolam.
- 27 ~~(11)~~
- 28 (20) Ethchlorvynol.
- 29 ~~(12)~~
- 30 (21) Ethinamate.
- 31 (22) *Ethyl loflazepate.*
- 32 (23) *Fludiazepam.*
- 33 ~~(13)~~
- 34 (24) Flunitrazepam.
- 35 ~~(14)~~
- 36 (25) Flurazepam.
- 37 (26) *Fospropofol.*
- 38 ~~(15)~~
- 39 (27) Halazepam.
- 40 (28) *Haloxazolam.*

- 1 (29) *Ketazolam*.
- 2 (30) *Loprazolam*.
- 3 ~~(16)~~
- 4 (31) *Lorazepam*.
- 5 (32) *Lormetazepam*.
- 6 ~~(17)~~
- 7 (33) *Mebutamate*.
- 8 (34) *Medazepam*.
- 9 ~~(18)~~
- 10 (35) *Meprobamate*.
- 11 ~~(19)~~
- 12 (36) *Methohexital*.
- 13 ~~(20)~~
- 14 (37) *Methylphenobarbital (Mephobarbital)*.
- 15 ~~(21)~~
- 16 (38) *Midazolam*.
- 17 (39) *Nimetazepam*.
- 18 ~~(22)~~
- 19 (40) *Nitrazepam*.
- 20 (41) *Nordiazepam*.
- 21 ~~(23)~~
- 22 (42) *Oxazepam*.
- 23 (43) *Oxazolam*.
- 24 ~~(24)~~
- 25 (44) *Paraldehyde*.
- 26 (45) *Pentazocine*.
- 27 ~~(25)~~
- 28 (46) *Petrichoral*.
- 29 ~~(26)~~
- 30 (47) *Phenobarbital*.
- 31 (48) *Pinazepam*.
- 32 ~~(27)~~
- 33 (49) *Prazepam*.
- 34 ~~(28)~~
- 35 (50) *Quazepam*.
- 36 ~~(29)~~
- 37 (51) *Temazepam*.
- 38 (52) *Tetrazepam*.
- 39 ~~(30)~~
- 40 (53) *Triazolam*.

- 1 ~~(31)~~
2 (54) Zaleplon.
3 ~~(32)~~
4 (55) Zolpidem.
5 (56) *Zopiclone*.
6 (e) Fenfluramine. Any material, compound, mixture, or
7 preparation which contains any quantity of the following
8 substances, including its salts, isomers (whether optical, position,
9 or geometric), and salts of those isomers, whenever the existence
10 of those salts, isomers, and salts of isomers is possible:
11 (1) Fenfluramine.
12 (f) Stimulants. Unless specifically excepted or unless listed in
13 another schedule, any material, compound, mixture, or preparation
14 which contains any quantity of the following substances having a
15 stimulant effect on the central nervous system, including its salts,
16 isomers (whether optical, position, or geometric), and salts of those
17 isomers is possible within the specific chemical designation:
18 (1) Diethylpropion.
19 (2) *Fencamfamin*.
20 (3) *Fenproporex*.
21 ~~(2)~~
22 (4) Mazindol.
23 (5) *Mefenorex*.
24 ~~(3)~~
25 (6) Modafinil.
26 ~~(4)~~
27 (7) Phentermine.
28 ~~(5)~~
29 (8) Pemoline (including organometallic complexes and chelates
30 thereof).
31 ~~(6)~~
32 (9) Pipradrol.
33 ~~(7)~~
34 (10) SPA ((-)-1-dimethylamino-1,2-diphenylethane).
35 ~~(8)~~
36 (11) Cathine ((+)-norpseudoephedrine).
37 (12) *Subutramine*.
38 (g) Other substances. Unless specifically excepted or unless
39 listed in another schedule, any material, compound, mixture or

1 preparation which contains any quantity of pentazocine, including
2 its salts.

3 *SEC. 6. Section 11161.5 of the Health and Safety Code is*
4 *amended to read:*

5 11161.5. (a) Prescription forms for controlled substance
6 prescriptions shall be obtained from security printers approved by
7 the Department of Justice.

8 (b) The department may approve security printer applications
9 after the applicant has provided the following information:

10 (1) Name, address, and telephone number of the applicant.

11 (2) Policies and procedures of the applicant for verifying the
12 identity of the prescriber ordering controlled substance prescription
13 forms.

14 (3) Policies and procedures of the applicant for verifying
15 delivery of controlled substance prescription forms to prescribers.

16 (4) (A) The location, names, and titles of the applicant’s agent
17 for service of process in this state; all principal corporate officers,
18 if any; ~~and~~ all managing general partners, if any; and *any individual*
19 *owner, partner, corporate officer, manager, agent, representative,*
20 *employee, or subcontractor of the applicant who has direct access*
21 *to, or management or control of, controlled substance prescription*
22 *forms.*

23 (B) A report containing this information shall be made on an
24 annual basis and within 30 days after any change of office,
25 principal corporate officers, ~~or~~ managing general partner, ~~and~~ *or*
26 *of any person described in subparagraph (A).*

27 (5) (A) A signed statement indicating whether the applicant,
28 *any principal corporate officers officer, or any managing general*
29 ~~partners have~~ *partner, or any individual owner, partner, corporate*
30 *officer, manager, agent, representative, employee, or subcontractor*
31 *of the applicant who has direct access to, or management or*
32 *control of, controlled substance prescription forms, has ever been*
33 convicted of, or pled no contest to, a violation of any law of a
34 foreign country, the United States, or any state, or of any local
35 ordinance.

36 (B) The department shall provide the applicant and *any*
37 *individual owner, partner, corporate officer, manager, agent,*
38 *representative, employee, or subcontractor of the applicant who*
39 *has direct access to, or management or control of, controlled*
40 *substance prescription forms, with the means and direction to*

1 provide fingerprints and related information, in a manner specified
2 by the department, for the purpose of completing state, federal, or
3 foreign criminal background checks.

4 (C) Any applicant described in subdivision (b) shall submit his
5 or her fingerprint images and related information to the department,
6 for the purpose of the department obtaining information as to the
7 existence and nature of a record of state, federal, or foreign level
8 convictions and state, federal, or foreign level arrests for which
9 the department establishes that the applicant was released on bail
10 or on his or her own recognizance pending trial, as described in
11 subdivision (l) of Section 11105 of the Penal Code. Requests for
12 federal level criminal offender record information received by the
13 department pursuant to this section shall be forwarded to the
14 Federal Bureau of Investigation by the department.

15 (D) The department shall assess against each *security printer*
16 applicant a fee determined by the department to be sufficient to
17 cover all processing, maintenance, and investigative costs generated
18 from or associated with completing state, federal, or foreign
19 background checks *and inspections of security printers* pursuant
20 to this section with respect to that applicant; the fee shall be paid
21 by the applicant at the time he or she submits *the security printer*
22 *application*, fingerprints, and related information to the department.

23 (E) The department shall retain fingerprint impressions and
24 related information for subsequent arrest notification pursuant to
25 Section 11105.2 of the Penal Code for all applicants.

26 (c) The department may, within 60 calendar days of receipt of
27 the application from the applicant, deny the security printer
28 application.

29 (d) The department may deny a security printer application on
30 any of the following grounds:

31 (1) The applicant, any individual owner, partner, corporate
32 officer, manager, agent, representative, employee, or subcontractor
33 for the applicant, who has direct access, management, or control
34 of controlled substance prescription forms, has been convicted of
35 a crime. A conviction within the meaning of this paragraph means
36 a plea or verdict of guilty or a conviction following a plea of *nolo*
37 *contendere*. Any action which a board is permitted to take
38 following the establishment of a conviction may be taken when
39 the time for appeal has elapsed, the judgment of conviction has
40 been affirmed on appeal, or when an order granting probation is

1 made suspending the imposition of sentence, irrespective of a
2 subsequent order under the provisions of Section 1203.4 of the
3 Penal Code.

4 (2) The applicant committed any act involving dishonesty, fraud,
5 or deceit with the intent to substantially benefit himself, herself,
6 or another, or substantially injure another.

7 (3) The applicant committed any act that would constitute a
8 violation of this division.

9 (4) The applicant knowingly made a false statement of fact
10 required to be revealed in the application to produce controlled
11 substance prescription forms.

12 (5) The department determines that the applicant failed to
13 demonstrate adequate security procedures relating to the production
14 and distribution of controlled substance prescription forms.

15 (6) The department determines that the applicant has submitted
16 an incomplete application.

17 (7) As a condition for its approval as a security printer, an
18 applicant shall authorize the Department of Justice to make any
19 examination of the books and records of the applicant, or to visit
20 and inspect the applicant during business hours, to the extent
21 deemed necessary by the board or department to properly enforce
22 this section.

23 (e) An approved applicant shall submit an exemplar of a
24 controlled substance prescription form, with all security features,
25 to the Department of Justice within 30 days of initial production.

26 (f) The department shall maintain a list of approved security
27 printers and the department shall make this information available
28 to prescribers and other appropriate government agencies, including
29 the Board of Pharmacy.

30 (g) Before printing any controlled substance prescription forms,
31 a security printer shall verify with the appropriate licensing board
32 that the prescriber possesses a license and current prescribing
33 privileges which permits the prescribing of controlled substances
34 *with the federal Drug Enforcement Administration (DEA)*.

35 (h) Controlled substance prescription forms shall be provided
36 directly to the prescriber either in person, by certified mail, or by
37 a means that requires a signature signifying receipt of the package
38 and provision of that signature to the security printer. *Controlled*
39 *substance prescriptions provided in person shall be restricted to*
40 *established customers. Security printers shall obtain a photo*

1 *identification from the customer and maintain a log of this*
2 *information. Controlled substance prescriptions shall be shipped*
3 *only to the prescriber’s address on file and verified with the federal*
4 *Drug Enforcement Administration or the Medical Board of*
5 *California.*

6 (i) Security printers shall retain ordering and delivery records
7 in a readily retrievable manner for individual prescribers for three
8 years.

9 (j) Security printers shall produce ordering and delivery records
10 upon request by an authorized officer of the law as defined in
11 Section 4017 of the Business and Professions Code.

12 (k) *Security printers shall report any theft or loss of controlled*
13 *substance prescriptions to the Department of Justice via fax or*
14 *e-mail within 24 hours of the theft or loss.*

15 ~~(k)~~

16 (l) (1) The department ~~may~~ *shall impose restrictions, sanctions,*
17 *or penalties against security printers who are not in compliance*
18 *with this division pursuant to regulations implemented pursuant*
19 *to this division and shall revoke its approval of a security printer*
20 *for a violation of this division or action that would permit a denial*
21 *pursuant to subdivision (d) of this section.*

22 (2) When the department revokes its approval, it shall notify
23 the appropriate licensing boards and remove the security printer
24 from the list of approved security printers.

25 *SEC. 7. Section 11162.1 of the Health and Safety Code is*
26 *amended to read:*

27 11162.1. (a) The prescription forms for controlled substances
28 shall be printed with the following features:

29 (1) A latent, repetitive “void” pattern shall be printed across the
30 entire front of the prescription blank; if a prescription is scanned
31 or photocopied, the word “void” shall appear in a pattern across
32 the entire front of the prescription.

33 (2) A watermark shall be printed on the backside of the
34 prescription blank; the watermark shall consist of the words
35 “California Security Prescription.”

36 (3) A chemical void protection that prevents alteration by
37 chemical washing.

38 (4) A feature printed in thermochromic ink.

39 (5) An area of opaque writing so that the writing disappears if
40 the prescription is lightened.

- 1 (6) A description of the security features included on each
2 prescription form.
- 3 (7) (A) Six quantity check off boxes shall be printed on the
4 form ~~and so that the prescriber may indicate the quantity by~~
5 *checking the applicable box where* the following quantities shall
6 appear:
- 7 1–24
 - 8 25–49
 - 9 50–74
 - 10 75–100
 - 11 101–150
 - 12 151 and over.
- 13 (B) In conjunction with the quantity boxes, a space shall be
14 provided to designate the units referenced in the quantity boxes
15 when the drug is not in tablet or capsule form.
- 16 (8) Prescription blanks shall contain a statement printed on the
17 bottom of the prescription blank that the “Prescription is void if
18 the number of drugs prescribed is not noted.”
- 19 (9) The preprinted name, category of licensure, license number,
20 federal controlled substance registration number *and address* of
21 the prescribing practitioner.
- 22 (10) Check boxes shall be printed on the form so that the
23 prescriber may indicate the number of refills ordered.
- 24 (11) The date of origin of the prescription.
- 25 (12) A check box indicating the prescriber’s order not to
26 substitute.
- 27 (13) An identifying number assigned to the approved security
28 printer by the Department of Justice.
- 29 (14) (A) A check box by the name of each prescriber when a
30 prescription form lists multiple prescribers.
- 31 (B) Each prescriber who signs the prescription form shall
32 identify himself or herself as the prescriber by checking the box
33 by his or her name.
- 34 (b) Each batch of controlled substance prescription forms shall
35 have the lot number printed on the form and each form within that
36 batch shall be numbered sequentially beginning with the numeral
37 one.
- 38 (c) (1) A prescriber designated by a licensed health care facility,
39 a clinic specified in Section 1200, or a clinic specified in
40 subdivision (a) of Section 1206 that has 25 or more physicians or

1 surgeons may order controlled substance prescription forms for
2 use by prescribers when treating patients in that facility without
3 the information required in paragraph (9) of subdivision (a) or
4 paragraph (3) of this subdivision.

5 (2) Forms ordered pursuant to this subdivision shall have the
6 name, category of licensure, license number, and federal controlled
7 substance registration number of the designated prescriber and the
8 name, address, category of licensure, and license number of the
9 licensed health care facility the clinic specified in Section 1200,
10 or the clinic specified in ~~subdivision (a)~~ of Section 1206 that has
11 25 or more physicians or surgeons preprinted on the form. *Licensed*
12 *health care facilities or clinics exempt under Section 1206 are not*
13 *required to preprint the category of licensure and license number*
14 *of their facility or clinic.*

15 (3) Forms ordered pursuant to this section shall not be valid
16 prescriptions without the name, category of licensure, license
17 number, and federal controlled substance registration number of
18 the prescriber on the form.

19 (4) (A) Except as provided in subparagraph (B), the designated
20 prescriber shall maintain a record of the prescribers to whom the
21 controlled substance prescription forms are issued, that shall
22 include the name, category of licensure, license number, federal
23 controlled substance registration number, and quantity of controlled
24 substance prescription forms issued to each prescriber. The record
25 shall be maintained in the health facility for three years.

26 (B) Forms ordered pursuant to this subdivision that are printed
27 by a computerized prescription generation system shall not be
28 subject to subparagraph (A) or paragraph (7) of subdivision (a).
29 Forms printed pursuant to this subdivision that are printed by a
30 computerized prescription generation system may contain the
31 prescriber's name, category of professional licensure, license
32 number, federal controlled substance registration number, and the
33 date of the prescription.

34 (d) This section shall become operative on ~~July 1, 2004~~ *January*
35 *1, 2012. Prescription forms not in compliance with this division*
36 *shall not be valid or accepted after July 1, 2012.*

37 **SECTION 1.**

38 *SEC. 8.* Section 11165 of the Health and Safety Code is
39 amended to read:

1 11165. (a) To assist law enforcement and regulatory agencies
2 in their efforts to control the diversion and resultant abuse of
3 Schedule II, Schedule III, and Schedule IV controlled substances,
4 and for statistical analysis, education, and research, the Department
5 of Justice shall, contingent upon the availability of adequate funds
6 from the Contingent Fund of the Medical Board of California, the
7 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
8 Board of Registered Nursing Fund, and the Osteopathic Medical
9 Board of California Contingent Fund, maintain the Controlled
10 Substance Utilization Review and Evaluation System (CURES)
11 for the electronic monitoring of, *and Internet access to information*
12 *regarding*, the prescribing and dispensing of Schedule II, Schedule
13 III, and Schedule IV controlled substances by all practitioners
14 authorized to prescribe or dispense these controlled substances.

15 (b) The reporting of Schedule III and Schedule IV controlled
16 substance prescriptions to CURES shall be contingent upon the
17 availability of adequate funds from the Department of Justice. The
18 department may seek and use grant funds to pay the costs incurred
19 from the reporting of controlled substance prescriptions to CURES.
20 Funds shall not be appropriated from the Contingent Fund of the
21 Medical Board of California, the Pharmacy Board Contingent
22 Fund, the State Dentistry Fund, the Board of Registered Nursing
23 Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical
24 Board of California Contingent Fund to pay the costs of reporting
25 Schedule III and Schedule IV controlled substance prescriptions
26 to CURES.

27 (c) CURES shall operate under existing provisions of law to
28 safeguard the privacy and confidentiality of patients. Data obtained
29 from CURES shall only be provided to appropriate state, local,
30 and federal persons or public agencies for disciplinary, civil, or
31 criminal purposes and to other agencies or entities, as determined
32 by the Department of Justice, for the purpose of educating
33 practitioners and others in lieu of disciplinary, civil, or criminal
34 actions. Data may be provided to public or private entities, as
35 approved by the Department of Justice, for educational, peer
36 review, statistical, or research purposes, provided that patient
37 information, including any information that may identify the
38 patient, is not compromised. Further, data disclosed to any
39 individual or agency as described in this subdivision shall not be
40 disclosed, sold, or transferred to any third party.

1 (d) For each prescription for a Schedule II, Schedule III, or
2 Schedule IV controlled substance, the dispensing pharmacy or
3 clinic shall provide the following information to the Department
4 of Justice on a weekly basis and in a format specified by the
5 Department of Justice:

6 (1) Full name, address, and the telephone number of the ultimate
7 user or research subject, or contact information as determined by
8 the Secretary of the United States Department of Health and Human
9 Services, and the gender, and date of birth of the ultimate user.

10 (2) The prescriber's category of licensure and license number;
11 federal controlled substance registration number; and the state
12 medical license number of any prescriber using the federal
13 controlled substance registration number of a government-exempt
14 facility.

15 (3) Pharmacy prescription number, license number, and federal
16 controlled substance registration number.

17 (4) NDC (National Drug Code) number of the controlled
18 substance dispensed.

19 (5) Quantity of the controlled substance dispensed.

20 (6) ICD-9 (diagnosis code), if available.

21 (7) Number of refills ordered.

22 (8) Whether the drug was dispensed as a refill of a prescription
23 or as a first-time request.

24 (9) Date of origin of the prescription.

25 (10) Date of dispensing of the prescription.

26 (e) This section shall become operative on January 1, 2005.

27 *SEC. 9. Section 11165.1 of the Health and Safety Code is*
28 *amended to read:*

29 11165.1. (a) (1) A licensed health care practitioner eligible
30 to prescribe Schedule II, Schedule III, or Schedule IV controlled
31 substances or a pharmacist may ~~make a written request for~~ *provide*
32 *a notarized application developed by the Department of Justice*
33 *to obtain approval to access information stored on the Internet*
34 *regarding the controlled substance history of a patient maintained*
35 *within the Department of Justice, and the Department of Justice*
36 *department may release to that practitioner or pharmacist, the*
37 *electronic history of controlled substances dispensed to an*
38 *individual under his or her care based on data contained in the*
39 *CURES Prescription Drug Monitoring Program (PDMP).*

1 (A) An application may be denied, or a subscriber may be
2 suspended, for reasons which include, but are not limited to, the
3 following:

4 (i) Materially falsifying an application for a subscriber.

5 (ii) Failure to maintain effective controls for access to the
6 patient activity report.

7 (iii) Suspended or revoked federal Drug Enforcement
8 Administration (DEA) registration.

9 (iv) Any subscriber who is arrested for a violation of law
10 governing controlled substances or any other law for which the
11 possession or use of a controlled substance is an element of the
12 crime.

13 (v) Any subscriber accessing information for any other reason
14 than caring for his or her patients.

15 (B) Any authorized subscriber shall notify the Department of
16 Justice within 10 days of any changes to the subscriber account.

17 (2) To allow sufficient time for licensed health care practitioners
18 eligible to prescribe Schedule II, Schedule III, or Schedule IV
19 controlled substances and a pharmacist to apply and receive access
20 to PDMP, a written request may be made, until July 1, 2012, and
21 the Department of Justice may release to that practitioner or
22 pharmacist the history of controlled substances dispensed to an
23 individual under his or her care based on data contained in
24 CURES.

25 ~~(2)~~

26 (b) Any request for, or release of, a controlled substance history
27 pursuant to this section shall be made in accordance with guidelines
28 developed by the Department of Justice.

29 ~~(b)~~

30 (c) In order to prevent the inappropriate, improper, or illegal
31 use of Schedule II, Schedule III, or Schedule IV controlled
32 substances, the Department of Justice may initiate the referral of
33 the history of controlled substances dispensed to an individual
34 based on data contained in CURES to licensed health care
35 practitioners, pharmacists, or both, providing care or services to
36 the individual.

37 ~~(c)~~

38 (d) The history of controlled substances dispensed to an
39 individual based on data contained in CURES that is received by
40 a practitioner or pharmacist from the Department of Justice

1 pursuant to this section shall be considered medical information
2 subject to the provisions of the Confidentiality of Medical
3 Information Act contained in Part 2.6 (commencing with Section
4 56) of Division 1 of the Civil Code.

5 *SEC. 10. Section 11165.2 is added to the Health and Safety*
6 *Code, to read:*

7 *11165.2. (a) The Department of Justice may conduct audits*
8 *of the Prescription Drug Monitoring Program system and its users.*

9 *(b) The Department of Justice may establish, by regulation, a*
10 *system for the issuance to a Prescription Drug Monitoring*
11 *Program subscriber of a citation which may contain an order of*
12 *abatement, or an order to pay an administrative fine assessed by*
13 *the Department of Justice if the subscriber is in violation of any*
14 *provision of this chapter or any regulation adopted by the*
15 *Department of Justice pursuant to this chapter.*

16 *(c) The system shall contain the following provisions:*

17 *(1) Citations shall be in writing and shall describe with*
18 *particularity the nature of the violation, including specific*
19 *reference to the provision of law or regulation of the department*
20 *determined to have been violated.*

21 *(2) Whenever appropriate, the citation shall contain an order*
22 *of abatement establishing a reasonable time for abatement of the*
23 *violation.*

24 *(3) In no event shall the administrative fine assessed by the*
25 *department exceed two thousand five hundred dollars (\$2,500) for*
26 *each violation. In assessing a fine, due consideration shall be given*
27 *to the appropriateness of the amount of the fine with respect to*
28 *such factors as the gravity of the violation, the good faith of the*
29 *subscribers, and the history of previous violations.*

30 *(4) An order of abatement or a fine assessment issued pursuant*
31 *to a citation shall inform the subscriber that if the subscriber*
32 *desires a hearing to contest the finding of a violation, a hearing*
33 *shall be requested by written notice to the CURES Program within*
34 *30 days of the date of issuance of the citation or assessment.*
35 *Hearings shall be held pursuant to Chapter 5 (commencing with*
36 *Section 11500) of Part 1 of Division 3 of Title 2 of the Government*
37 *Code.*

38 *(5) In addition to requesting a hearing, the subscriber may,*
39 *within 10 days after service of the citation, request in writing an*
40 *opportunity for an informal conference with the department*

1 regarding the citation. At the conclusion of the informal
2 conference, the department may affirm, modify, or dismiss the
3 citation, including any fine levied or order of abatement issued.
4 The decision shall be deemed to be a final order with regard to
5 the citation issued, including the fine levied or the order of
6 abatement which could include permanent suspension to the
7 system, a monetary fine, or both, depending on the gravity of the
8 violation which will be stipulated by regulation. However, the
9 subscriber does not waive its right to request a hearing to contest
10 a citation by requesting an informal conference. If the citation is
11 dismissed after the informal conference, the request for a hearing
12 on the matter of the citation shall be deemed to be withdrawn. If
13 the citation, including any fine levied or order of abatement, is
14 modified, the citation originally issued shall be considered
15 withdrawn and a new citation issued. If a hearing is requested for
16 a subsequent citation, it shall be requested within 30 days of service
17 of that subsequent citation.

18 (6) Failure of a subscriber to pay a fine within 30 days of the
19 date of assessment or comply with an order of abatement within
20 the fixed time, unless the citation is being appealed, may result in
21 disciplinary action taken by the department. If a citation is not
22 contested and a fine is not paid, the subscriber account will be
23 terminated:

24 (A) A citation may be issued without the assessment of an
25 administrative fine.

26 (B) Assessment of administrative fines may be limited to only
27 particular violations of law or department regulations.

28 (d) Notwithstanding any other provision of law, if a fine is paid
29 to satisfy an assessment based on the finding of a violation,
30 payment of the fine shall be represented as a satisfactory resolution
31 of the matter for purposes of public disclosure.

32 (e) Administrative fines collected pursuant to this section shall
33 be deposited in the CURES Program Special Fund. These special
34 funds shall provide support for costs associated with informal and
35 formal hearings, maintenance, and updates to the CURES system.

36 (f) The sanctions authorized under this section shall be separate
37 from, and in addition to, any other administrative, civil, or criminal
38 remedies; however, a criminal action may not be initiated for a
39 specific offense if a citation has been issued pursuant to this section
40 for that offense, and a citation may not be issued pursuant to this

1 *section for a specific offense if a criminal action for that offense*
2 *has been filed.*

3 *SEC. 11. Section 11165.3 is added to the Health and Safety*
4 *Code, to read:*

5 *11165.3. The theft or loss of prescription information or forms*
6 *shall be reported immediately to the CURES Program, but no later*
7 *than three days after the discovery of the theft or loss. This*
8 *notification may be done in writing utilizing the Bureau of Narcotic*
9 *Enforcement 1175 Reporting Theft/Loss Form or may be reported*
10 *by the authorized subscriber through the CURES Prescription*
11 *Drug Monitoring Program.*

12 *SEC. 12. Section 11212 of the Health and Safety Code is*
13 *amended to read:*

14 11212. (a) Persons who, under applicable federal laws or
15 regulations, are lawfully entitled to use controlled substances for
16 the purpose of research, instruction, or analysis, may lawfully
17 obtain and use for such purposes those substances classified in
18 paragraphs ~~(45)~~ (81) and ~~(46)~~ (82) of subdivision (b) of Section
19 11054 of the Health and Safety Code, upon registration with and
20 approval by the ~~California~~ Department of Justice for use of those
21 substances in bona fide research, instruction, or analysis.

22 ~~That~~ (b) That research, instruction, or analysis shall be carried
23 on only under the auspices of the individual identified by the
24 registrant as responsible for the research. Complete records of
25 receipts, stocks at hand, and use of these controlled substances
26 shall be kept.

27 ~~The~~ (c) The Department of Justice may withdraw approval of
28 the use of such substances at any time. The department may obtain
29 and inspect at any time the records required to be maintained by
30 this section.

31 *SEC. 13. Section 11350 of the Health and Safety Code is*
32 *amended to read:*

33 11350. (a) Except as otherwise provided in this division, every
34 person who possesses (1) any controlled substance specified in
35 subdivision (b) or (c), or paragraph (1) of subdivision (f) of Section
36 11054, specified in paragraph (14), (15), or (20) of subdivision (d)
37 of Section 11054, or specified in subdivision (b) or (c) of Section
38 11055, or specified in subdivision ~~(h)~~ (j) of Section 11056, or (2)
39 any controlled substance classified in Schedule III, IV, or V which
40 is a narcotic drug, unless upon the written prescription of a

1 physician, dentist, podiatrist, or veterinarian licensed to practice
2 in this state, shall be punished by imprisonment in the state prison.

3 (b) Except as otherwise provided in this division, every person
4 who possesses any controlled substance specified in subdivision
5 (e) of Section 11054 shall be punished by imprisonment in the
6 county jail for not more than one year or in the state prison.

7 (c) Except as otherwise provided in this division, whenever a
8 person who possesses any of the controlled substances specified
9 in subdivision (a) or (b), the judge may, in addition to any
10 punishment provided for pursuant to subdivision (a) or (b), assess
11 against that person a fine not to exceed seventy dollars (\$70) with
12 proceeds of this fine to be used in accordance with Section 1463.23
13 of the Penal Code. The court shall, however, take into consideration
14 the defendant's ability to pay, and no defendant shall be denied
15 probation because of his or her inability to pay the fine permitted
16 under this subdivision.

17 (d) Except in unusual cases in which it would not serve the
18 interest of justice to do so, whenever a court grants probation
19 pursuant to a felony conviction under this section, in addition to
20 any other conditions of probation which may be imposed, the
21 following conditions of probation shall be ordered:

22 (1) For a first offense under this section, a fine of at least one
23 thousand dollars (\$1,000) or community service.

24 (2) For a second or subsequent offense under this section, a fine
25 of at least two thousand dollars (\$2,000) or community service.

26 (3) If a defendant does not have the ability to pay the minimum
27 fines specified in paragraphs (1) and (2), community service shall
28 be ordered in lieu of the fine.

29 *SEC. 14. Section 11351 of the Health and Safety Code is*
30 *amended to read:*

31 11351. Except as otherwise provided in this division, every
32 person who possesses for sale or purchases for purposes of sale
33 (1) any controlled substance specified in subdivision (b), (c), or
34 (e) of Section 11054, specified in paragraph (14), (15), or (20) of
35 subdivision (d) of Section 11054, or specified in subdivision (b)
36 or (c) of Section 11055, or specified in subdivision ~~(h)~~ (j) of
37 Section 11056, or (2) any controlled substance classified in
38 Schedule III, IV, or V which is a narcotic drug, shall be punished
39 by imprisonment in the state prison for two, three, or four years.

1 *SEC. 15. Section 11352 of the Health and Safety Code is*
2 *amended to read:*

3 11352. (a) Except as otherwise provided in this division, every
4 person who transports, imports into this state, sells, furnishes,
5 administers, or gives away, or offers to transport, import into this
6 state, sell, furnish, administer, or give away, or attempts to import
7 into this state or transport (1) any controlled substance specified
8 in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)
9 of Section 11054, specified in paragraph (14), (15), or (20) of
10 subdivision (d) of Section 11054, or specified in subdivision (b)
11 or (c) of Section 11055, or specified in subdivision ~~(h)~~ (j) of
12 Section 11056, or (2) any controlled substance classified in
13 Schedule III, IV, or V which is a narcotic drug, unless upon the
14 written prescription of a physician, dentist, podiatrist, or
15 veterinarian licensed to practice in this state, shall be punished by
16 imprisonment in the state prison for three, four, or five years.

17 (b) Notwithstanding the penalty provisions of subdivision (a),
18 any person who transports for sale any controlled substances
19 specified in subdivision (a) within this state from one county to
20 another noncontiguous county shall be punished by imprisonment
21 in the state prison for three, six, or nine years.

22 *SEC. 16. Section 11353 of the Health and Safety Code is*
23 *amended to read:*

24 11353. Every person 18 years of age or over, (a) who in any
25 voluntary manner solicits, induces, encourages, or intimidates any
26 minor with the intent that the minor shall violate any provision of
27 this chapter or Section 11550 with respect to either (1) a controlled
28 substance which is specified in subdivision (b), (c), or (e), or
29 paragraph (1) of subdivision (f) of Section 11054, specified in
30 paragraph (14), (15), or (20) of subdivision (d) of Section 11054,
31 or specified in subdivision (b) or (c) of Section 11055, or specified
32 in subdivision ~~(h)~~ (j) of Section 11056, or (2) any controlled
33 substance classified in Schedule III, IV, or V which is a narcotic
34 drug, (b) who hires, employs, or uses a minor to unlawfully
35 transport, carry, sell, give away, prepare for sale, or peddle any
36 such controlled substance, or (c) who unlawfully sells, furnishes,
37 administers, gives, or offers to sell, furnish, administer, or give,
38 any such controlled substance to a minor, shall be punished by
39 imprisonment in the state prison for a period of three, six, or nine
40 years.

1 *SEC. 17. Section 11354 of the Health and Safety Code is*
2 *amended to read:*

3 11354. (a) Every person under the age of 18 years who in any
4 voluntary manner solicits, induces, encourages, or intimidates any
5 minor with the intent that the minor shall violate any provision of
6 this chapter or Section 11550, who hires, employs, or uses a minor
7 to unlawfully transport, carry, sell, give away, prepare for sale, or
8 peddle (1) any controlled substance specified in subdivision (b),
9 (c), or (e), or paragraph (1) of subdivision (f) of Section 11054,
10 specified in paragraph (14), (15), or (20) of subdivision (d) of
11 Section 11054, or specified in subdivision (b) or (c) of Section
12 11055, or specified in subdivision ~~(h)~~ (j) of Section 11056, or (2)
13 any controlled substance classified in Schedule III, IV, or V which
14 is a narcotic drug, or who unlawfully sells, furnishes, administers,
15 gives, or offers to sell, furnish, administer, or give, any such
16 controlled substance to a minor shall be punished by imprisonment
17 in the state prison.

18 (b) This section is not intended to affect the jurisdiction of the
19 juvenile court.

20 *SEC. 18. Section 11355 of the Health and Safety Code is*
21 *amended to read:*

22 11355. Every person who agrees, consents, or in any manner
23 offers to unlawfully sell, furnish, transport, administer, or give (1)
24 any controlled substance specified in subdivision (b), (c), or (e),
25 or paragraph (1) of subdivision (f) of Section 11054, specified in
26 paragraph (13), (14), (15), or (20) of subdivision (d) of Section
27 11054, or specified in subdivision (b) or (c) of Section 11055, or
28 specified in subdivision ~~(h)~~ (j) of Section 11056, or (2) any
29 controlled substance classified in Schedule III, IV, or V which is
30 a narcotic drug to any person, or who offers, arranges, or negotiates
31 to have any such controlled substance unlawfully sold, delivered,
32 transported, furnished, administered, or given to any person and
33 who then sells, delivers, furnishes, transports, administers, or gives,
34 or offers, arranges, or negotiates to have sold, delivered,
35 transported, furnished, administered, or given to any person any
36 other liquid, substance, or material in lieu of any such controlled
37 substance shall be punished by imprisonment in the county jail for
38 not more than one year, or in the state prison.

39 *SEC. 19. Section 11377 of the Health and Safety Code is*
40 *amended to read:*

1 11377. (a) Except as authorized by law and as otherwise
2 provided in subdivision (b) or Section 11375, or in Article 7
3 (commencing with Section ~~4211~~ 4110) of Chapter 9 of Division
4 2 of the Business and Professions Code, every person who
5 possesses any controlled substance which is (1) classified in
6 Schedule III, IV, or V, and which is not a narcotic drug, (2)
7 specified in subdivision (d) of Section 11054, except paragraphs
8 (13), (14), (15), and (20) of subdivision (d), (3) specified in
9 paragraph (11) of subdivision (c) of Section 11056, (4) specified
10 in paragraph (2) or (3) of subdivision (f) of Section 11054, or (5)
11 specified in subdivision (d), (e), or (f) of Section 11055, unless
12 upon the prescription of a physician, dentist, podiatrist, or
13 veterinarian, licensed to practice in this state, shall be punished by
14 imprisonment in a county jail for a period of not more than one
15 year or in the state prison.

16 (b) (1) Any person who violates subdivision (a) by unlawfully
17 possessing a controlled substance specified in subdivision (f) of
18 Section 11056, and who has not previously been convicted of a
19 violation involving a controlled substance specified in subdivision
20 (f) of Section 11056, is guilty of a misdemeanor.

21 (2) Any person who violates subdivision (a) by unlawfully
22 possessing a controlled substance specified in subdivision ~~(g)~~ (i)
23 of Section 11056 is guilty of a misdemeanor.

24 (3) Any person who violates subdivision (a) by unlawfully
25 possessing a controlled substance specified in paragraph (7) or (8)
26 of subdivision (d) of Section 11055 is guilty of a misdemeanor.

27 (4) Any person who violates subdivision (a) by unlawfully
28 possessing a controlled substance specified in paragraph ~~(8)~~ (11)
29 of subdivision (f) of Section 11057 is guilty of a misdemeanor.

30 (c) In addition to any fine assessed under subdivision (b), the
31 judge may assess a fine not to exceed seventy dollars (\$70) against
32 any person who violates subdivision (a), with the proceeds of this
33 fine to be used in accordance with Section 1463.23 of the Penal
34 Code. The court shall, however, take into consideration the
35 defendant's ability to pay, and no defendant shall be denied
36 probation because of his or her inability to pay the fine permitted
37 under this subdivision.

38 *SEC. 20. Section 11378 of the Health and Safety Code is*
39 *amended to read:*

1 11378. Except as otherwise provided in Article 7 (commencing
2 with Section 4211) of Chapter 9 of Division 2 of the Business and
3 Professions Code, every person who possesses for sale any
4 controlled substance which is (1) classified in Schedule III, IV, or
5 V and which is not a narcotic drug, except subdivision ~~(g)~~ (i) of
6 Section 11056, (2) specified in subdivision (d) of Section 11054,
7 except paragraphs (13), (14), (15), (20), (21), (22), and (23) of
8 subdivision (d), (3) specified in paragraph (11) of subdivision (c)
9 of Section 11056, (4) specified in paragraph (2) or (3) of
10 subdivision (f) of Section 11054, or (5) specified in subdivision
11 (d), (e), or (f), except paragraph (3) of subdivision (e) and
12 subparagraphs (A) and (B) of paragraph (2) of subdivision (f), of
13 Section 11055, shall be punished by imprisonment in the state
14 prison.

15 *SEC. 21. Section 11379 of the Health and Safety Code is*
16 *amended to read:*

17 11379. (a) Except as otherwise provided in subdivision (b)
18 and in Article 7 (commencing with Section ~~4211~~ 4110) of Chapter
19 9 of Division 2 of the Business and Professions Code, every person
20 who transports, imports into this state, sells, furnishes, administers,
21 or gives away, or offers to transport, import into this state, sell,
22 furnish, administer, or give away, or attempts to import into this
23 state or transport any controlled substance which is (1) classified
24 in Schedule III, IV, or V and which is not a narcotic drug, except
25 subdivision ~~(g)~~ (i) of Section 11056, (2) specified in subdivision
26 (d) of Section 11054, except paragraphs (13), (14), (15), (20), (21),
27 (22), and (23) of subdivision (d), (3) specified in paragraph (11)
28 of subdivision (c) of Section 11056, (4) specified in paragraph (2)
29 or (3) of subdivision (f) of Section 11054, or (5) specified in
30 subdivision (d) or (e), except paragraph (3) of subdivision (e), or
31 specified in subparagraph (A) of paragraph (1) of subdivision (f),
32 of Section 11055, unless upon the prescription of a physician,
33 dentist, podiatrist, or veterinarian, licensed to practice in this state,
34 shall be punished by imprisonment in the state prison for a period
35 of two, three, or four years.

36 (b) Notwithstanding the penalty provisions of subdivision (a),
37 any person who transports for sale any controlled substances
38 specified in subdivision (a) within this state from one county to
39 another noncontiguous county shall be punished by imprisonment
40 in the state prison for three, six, or nine years.

1 *SEC. 22. Section 11379.2 of the Health and Safety Code is*
2 *amended to read:*

3 11379.2. Except as otherwise provided in Article 7
4 (commencing with Section ~~4211~~ 4110) of Chapter 9 of Division
5 2 of the Business and Professions Code, every person who
6 possesses for sale or sells any controlled substance specified in
7 subdivision ~~(g)~~ (i) of Section 11056 shall be punished by
8 imprisonment in the county jail for a period of not more than one
9 year or in the state prison.

10 *SEC. 23. Section 11839.2 of the Health and Safety Code is*
11 *amended to read:*

12 11839.2. The following controlled substances are authorized
13 for use in replacement narcotic therapy by licensed narcotic
14 treatment programs:

15 (a) Methadone.

16 (b) Levoalphacetylmethadol (LAAM) as specified in paragraph
17 ~~(10)~~ (12) of subdivision (c) of Section 11055.

18 *SEC. 24. Section 11875 of the Health and Safety Code is*
19 *amended to read:*

20 11875. The following controlled substances are authorized for
21 use in replacement narcotic therapy by licensed narcotic treatment
22 programs:

23 (a) Methadone.

24 (b) Levoalphacetylmethadol (LAAM) as specified in paragraph
25 ~~(10)~~ (12) of subdivision (c) of Section 11055.

26 (c) Buprenorphine products or combination products approved
27 by the federal Food and Drug Administration for maintenance or
28 detoxification of opioid dependence.

29 (d) Any other federally approved controlled substances used
30 for the purpose of narcotic replacement treatment.

31 *SEC. 25. No reimbursement is required by this act pursuant*
32 *to Section 6 of Article XIII B of the California Constitution because*
33 *the only costs that may be incurred by a local agency or school*
34 *district will be incurred because this act creates a new crime or*
35 *infraction, eliminates a crime or infraction, or changes the penalty*
36 *for a crime or infraction, within the meaning of Section 17556 of*
37 *the Government Code, or changes the definition of a crime within*

- 1 *the meaning of Section 6 of Article XIII B of the California*
- 2 *Constitution.*

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Agenda Item 2d



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 24, 2011
To: Legislation and Regulation Committee
Subject: Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Agenda Item 2.d: Healing Arts/DCA

Below are summaries of bills impacting healing arts board or all programs within DCA. A bill analysis and a copy of the most recent version of the bill are provided in unless otherwise noted.

AB 675 (Hagman) Continuing education

Summary: Would provide, if applicable, that continuing education courses, as specified, that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal.

Recent Action: Assembly Health Committee hearing scheduled for April 5, 2011.

AB 958 (Berryhill) Regulatory boards: limitation periods

Summary: This bill would require the board to file an accusation against a licensee within one year after the board discovers the act or omission alleged as grounds for disciplinary action.

Recent Action: Referred to Assembly Business, Professions and Economic Development Committee.

AB 1003 (Smyth) Professional and vocational licenses

Summary: This is a spot bill.

Recent Action: Referred to Rules Committee.

AB 1328 (Pan) Professions and vocations

Summary: This is a spot bill. Board staff was advised that this measure will not be moving forward.

A copy of the bill and an analysis of the measure are not provided.

SB 231 (Emmerson) Regulatory boards: healing arts

Summary: This is a spot bill. Board staff was advised that this measure will not be moving forward.

A copy of the bill and an analysis of the measure are not provided.

SB 227 (Wyland) Business and professions: licensure

Summary: This is a spot bill.

Recent Action: Referred to Rule Committee

SB 538 (Price) Healing Arts

Summary: This bill was recently amended and is now a sunset extension bill for the Board of Registered Nursing.

A copy of the bill and an analysis of the measure are not provided.

SB 544 (Price) Healing Arts

Summary: This bill was recently amended and is now authorizing the dental board to use a collection fee as specified.

A copy of the bill and an analysis of the measure are not provided.

SB 667 (Wyland) Healing Arts

Summary: This is a spot bill.

Recent Action: Referred to Rules Committee

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 675

VERSION: As Introduced February 17, 2011

AUTHOR: Hagman

SPONSOR: Author

BOARD POSITION: None

SUBJECT: Continuing Education

Affected Sections: Add Section 110.6 of the Business and Professions Code.

CURRENT STATUS: Referred to Assembly Business, Professions and Economic Development Committee.

EXISTING LAW:

1. Establishes continuing education requirements for renewal of a pharmacist license.
2. Established the content of courses that satisfy the requirements.

THIS BILL WOULD:

1. Specify that acceptable education courses must contain only content relevant to the particular practice.
2. Specify that the following types of courses shall not be acceptable:
 - a. Promote or advance labor organizing on behalf of a union
 - b. Advance or promote statutory or regulatory changes
 - c. Promote political candidates, political advocacy or political strategy
3. Specify that courses include institutes, seminars, conferences, workshops and any other public event.
4. Specify that a course provider is prohibiting from advertising that a course is acceptable to meet continuing education requirements when it does not and requires the board to withdraw approval of a provider should a violation occur.
5. Require the board to, after notice and an opportunity to be heard is provided, withdraw the approval of a provider for five years if the board determines that such a violation has occurred.

AUTHOR'S INTENT:

This bill would affirmatively preclude granting Continuing Education (CE) credits for attendance at political rallies, or from offering classes that advance or promote labor organizing, lobbying, candidate or political advocacy.

COMMENTS:

This bill would appear to impact the board's current policy as well as the proposed regulation change currently under promulgation that awards licensees continuing education to attend a board meeting.

PRIOR HISTORY/RELATED BILLS:

Unknown

FISCAL IMPACT:

The board does not anticipate any significant impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Mar. 14 Re-referred to Com. on B., P. & C.P. pursuant to Assembly Rule 96.

Mar. 3 Referred to Coms. on HIGHER ED. and B., P. & C.P.

Feb. 18 From printer. May be heard in committee March 20.

Feb. 17 Read first time. To print.

ASSEMBLY BILL

No. 675

Introduced by Assembly Member Hagman
(Coauthor: Senator Huff)

February 17, 2011

An act to add Section 110.6 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 675, as introduced, Hagman. Continuing education.

Existing law provides for the licensure and regulation of professions and vocations by boards within the Department of Consumer Affairs and these boards may require licensees to satisfy continuing education course requirements.

This bill would provide, if applicable, that continuing education courses, as specified, that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal. The bill would also prohibit, to the extent applicable, an approved provider from representing that such a continuing education course is acceptable for meeting requirements for licensure renewal and would require a board, subject to specified procedural requirements, to withdraw its approval of a provider that violates that requirement for no less than 5 years, as specified.

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

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

1 SECTION 1. Section 110.6 is added to the Business and
2 Professions Code, to read:

3 110.6. Notwithstanding any other provision of law, if a board
4 described in Section 101 requires its licensees to satisfy continuing
5 education requirements by pursuing a course of continuing
6 education, the following shall apply:

7 (a) Continuing education courses shall contain only content
8 relevant to the particular practice regulated by the board pursuant
9 to its laws and regulations. Continuing education courses that
10 advance or promote labor organizing on behalf of a union, or that
11 advance or promote statutory or regulatory changes, political
12 candidates, political advocacy, or political strategy shall not be
13 considered content relevant to the practice regulated by the board
14 and shall not be acceptable for meeting continuing education
15 requirements. For the purposes of this section, “courses” includes
16 institutes, seminars, lectures, conferences, workshops, and any
17 other public events.

18 (b) (1) To the extent applicable, if an approved provider offers
19 a course described in subdivision (a), the provider shall not
20 represent that the course is acceptable for meeting the continuing
21 education requirements. If a provider violates this requirement,
22 the board shall withdraw its approval of the provider, subject to
23 paragraph (2).

24 (2) If, after the board provides the provider notice and an
25 opportunity to be heard, the board finds that the provider violated
26 the requirement in paragraph (1), the board shall withdraw approval
27 of the provider for no less than five years.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 958

VERSION: As Introduced February 18, 2011

AUTHOR: Berryhill

SPONSOR: Author

BOARD POSITION: None

SUBJECT: Regulatory boards: limitations periods

Affected Sections: An act to add Section 110.5 to, and to repeal Sections 1670.2, 2230.5, 2960.05, 3137, 3750.51, 4982.05, 4990.32, 5561, 5661, 7686.5, 9884.20, and 9889.8 of, the Business and Professions Code

CURRENT STATUS: Referred to Assembly Business, Professions and Consumer Protection Committee

EXISTING LAW:

Provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs, and authorizes these boards to pursue disciplinary action for various violations.

THIS BILL WOULD:

1. Require a board to file an accusation against a licensee within one year after the board discovers the act or omission alleged as the ground for disciplinary action, or within four years after the act or omission alleged as the ground for disciplinary action occurs, which occurs first.
2. Specify that if the act or omission involves a minor, the four year limitation period provided shall be tolled until the minor reaches the age of majority.
3. Specify that if a licensee intentionally conceals evidence of wrongdoing, the four-year limitations period provided shall be tolled during that period of concealment.
4. Remove separate statutory timeframes that are currently established for some programs.

AUTHOR'S INTENT:

"In order to foster a more cooperative relationship with business as well as ensure that the public good is met, California should put our licensing laws on the same level as criminal statutes of limitations. Treating Californians who are licensed worse than we

treat most criminals is unacceptable and needs to be changed. AB 958 attempts to make this distinction and treat licensees fairly.”

COMMENTS:

Consumers deserve swift investigations and the intent of this legislation is very consistent with the Consumer Protection Enforcement Initiative (CPEI). With the board’s current resources, board staff would be unable to meet the necessary timelines mandated in this bill, which would result in the board’s inability to pursue disciplinary action against licensees that undermine consumer protection.

The board currently has a 42% vacancy rate in authorized positions in our enforcement unit. The board cannot meet the timeframes necessary within existing resources.

FISCAL IMPACT:

Meeting this mandate is a resource issue. It is unclear at this time the number of additional staff that will be required as we have not have a full compliment of staff nor realized the benefits of the additional PYs that were authorized via the BCP process as part of the CPEI.

The board would also anticipate an increase in the costs associated with the prosecution that occurs through the AG’s Office.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

- Mar. 10 Referred to Com. on B., P. & C.P.
- Feb. 20 From printer. May be heard in committee March 22.
- Feb. 18 Read first time. To print.

ASSEMBLY BILL

No. 958

Introduced by Assembly Member Bill Berryhill

February 18, 2011

An act to add Section 110.5 to, and to repeal Sections 1670.2, 2230.5, 2960.05, 3137, 3750.51, 4982.05, 4990.32, 5561, 5661, 7686.5, 9884.20, and 9889.8 of, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

AB 958, as introduced, Bill Berryhill. Regulatory boards: limitations periods.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law requires these boards to file disciplinary action accusations against licensees for various violations within a specified limitations period particular to each board.

This bill would delete those specified limitations periods for each board and would instead impose a specified limitations period on all boards within the Department of Consumer Affairs.

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

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

- 1 SECTION 1. Section 110.5 is added to the Business and
- 2 Professions Code, to read:
- 3 110.5. (a) Notwithstanding any other provision of law and
- 4 except as provided in subdivisions (b) and (c), any accusation filed

1 against a licensee of a board described in Section 101, pursuant to
2 Section 11503 of the Government Code, shall be filed within one
3 year after the board discovers the act or omission alleged as the
4 ground for disciplinary action, or within four years after the act or
5 omission alleged as the ground for disciplinary action occurs,
6 whichever occurs first.

7 (b) If an alleged act or omission involves a minor, the four-year
8 limitations period provided for by subdivision (a) shall be tolled
9 until the minor reaches the age of majority.

10 (c) If a licensee intentionally conceals evidence of wrongdoing,
11 the four-year limitations period provided for by subdivision (a)
12 shall be tolled during that period of concealment.

13 SEC. 2. Section 1670.2 of the Business and Professions Code
14 is repealed.

15 ~~1670.2. (a) Except as otherwise provided in this section, any~~
16 ~~proceeding initiated by the board against a licensee for the violation~~
17 ~~of any provision of this chapter shall be filed within three years~~
18 ~~after the board discovers the act or omission alleged as the ground~~
19 ~~for disciplinary action, or within seven years after the act or~~
20 ~~omission alleged as the ground for disciplinary action occurs,~~
21 ~~whichever occurs first.~~

22 ~~(b) An accusation filed against a licensee pursuant to Section~~
23 ~~11503 of the Government Code alleging fraud or willful~~
24 ~~misrepresentation is not subject to the limitation in subdivision~~
25 ~~(a).~~

26 ~~(c) An accusation filed against a licensee pursuant to Section~~
27 ~~11503 of the Government Code alleging unprofessional conduct~~
28 ~~based on incompetence, gross negligence, or repeated negligent~~
29 ~~acts of the licensee is not subject to the limitation in subdivision~~
30 ~~(a) upon proof that the licensee intentionally concealed from~~
31 ~~discovery his or her incompetence, gross negligence, or repeated~~
32 ~~negligent acts.~~

33 ~~(d) If an alleged act or omission involves any conduct described~~
34 ~~in subdivision (e) of Section 1680 committed on a minor, the~~
35 ~~seven-year limitations period in subdivision (a) and the 10-year~~
36 ~~limitations period in subdivision (e) shall be tolled until the minor~~
37 ~~reaches the age of majority.~~

38 ~~(e) An accusation filed against a licensee pursuant to Section~~
39 ~~11503 of the Government Code alleging conduct described in~~
40 ~~subdivision (e) of Section 1680 not committed on a minor shall~~

1 be filed within three years after the board discovers the act or
2 omission alleged as the ground for disciplinary action, or within
3 10 years after the act or omission alleged as the ground for
4 disciplinary action occurs, whichever occurs first. This subdivision
5 shall apply to a complaint alleging conduct received by the board
6 on and after January 1, 2005.

7 (f) In any allegation, accusation, or proceeding described in
8 this section, the limitations period in subdivision (a) shall be tolled
9 for the period during which material evidence necessary for
10 prosecuting or determining whether a disciplinary action would
11 be appropriate is unavailable to the board due to an ongoing
12 criminal investigation.

13 SEC. 3. Section 2230.5 of the Business and Professions Code
14 is repealed.

15 2230.5. (a) Except as provided in subdivisions (b), (c), and
16 (e), any accusation filed against a licensee pursuant to Section
17 11503 of the Government Code shall be filed within three years
18 after the board, or a division thereof, discovers the act or omission
19 alleged as the ground for disciplinary action, or within seven years
20 after the act or omission alleged as the ground for disciplinary
21 action occurs, whichever occurs first.

22 (b) An accusation filed against a licensee pursuant to Section
23 11503 of the Government Code alleging the procurement of a
24 license by fraud or misrepresentation is not subject to the limitation
25 provided for by subdivision (a).

26 (c) An accusation filed against a licensee pursuant to Section
27 11503 of the Government Code alleging unprofessional conduct
28 based on incompetence, gross negligence, or repeated negligent
29 acts of the licensee is not subject to the limitation provided for by
30 subdivision (a) upon proof that the licensee intentionally concealed
31 from discovery his or her incompetence, gross negligence, or
32 repeated negligent acts.

33 (d) If an alleged act or omission involves a minor, the seven-year
34 limitations period provided for by subdivision (a) and the 10-year
35 limitations period provided for by subdivision (c) shall be tolled
36 until the minor reaches the age of majority.

37 (e) An accusation filed against a licensee pursuant to Section
38 11503 of the Government Code alleging sexual misconduct shall
39 be filed within three years after the board, or a division thereof,
40 discovers the act or omission alleged as the ground for disciplinary

1 action, or within 10 years after the act or omission alleged as the
 2 ground for disciplinary action occurs, whichever occurs first. This
 3 subdivision shall apply to a complaint alleging sexual misconduct
 4 received by the board on and after January 1, 2002.

5 (f) ~~The limitations period provided by subdivision (a) shall be~~
 6 ~~tolled during any period if material evidence necessary for~~
 7 ~~prosecuting or determining whether a disciplinary action would~~
 8 ~~be appropriate is unavailable to the board due to an ongoing~~
 9 ~~criminal investigation.~~

10 SEC. 4. Section 2960.05 of the Business and Professions Code
 11 is repealed.

12 ~~2960.05.—(a) Except as provided in subdivisions (b), (c), and~~
 13 ~~(e), any accusation filed against a licensee pursuant to Section~~
 14 ~~11503 of the Government Code shall be filed within three years~~
 15 ~~from the date the board discovers the alleged act or omission that~~
 16 ~~is the basis for disciplinary action, or within seven years from the~~
 17 ~~date the alleged act or omission that is the basis for disciplinary~~
 18 ~~action occurred, whichever occurs first.~~

19 (b) ~~An accusation filed against a licensee pursuant to Section~~
 20 ~~11503 of the Government Code alleging the procurement of a~~
 21 ~~license by fraud or misrepresentation is not subject to the~~
 22 ~~limitations set forth in subdivision (a).~~

23 (e) ~~The limitation provided for by subdivision (a) shall be tolled~~
 24 ~~for the length of time required to obtain compliance when a report~~
 25 ~~required to be filed by the licensee or registrant with the board~~
 26 ~~pursuant to Article 11 (commencing with Section 800) of Chapter~~
 27 ~~1 is not filed in a timely fashion.~~

28 (d) ~~If an alleged act or omission involves a minor, the seven-year~~
 29 ~~limitations period provided for by subdivision (a) and the 10-year~~
 30 ~~limitations period provided for by subdivision (e) shall be tolled~~
 31 ~~until the minor reaches the age of majority.~~

32 (e) ~~An accusation filed against a licensee pursuant to Section~~
 33 ~~11503 of the Government Code alleging sexual misconduct shall~~
 34 ~~be filed within three years after the board discovers the act or~~
 35 ~~omission alleged as the ground for disciplinary action, or within~~
 36 ~~10 years after the act or omission alleged as the ground for~~
 37 ~~disciplinary action occurs, whichever occurs first. This subdivision~~
 38 ~~shall apply to a complaint alleging sexual misconduct received by~~
 39 ~~the board on and after January 1, 2002.~~

1 ~~(f) The limitations period provided by subdivision (a) shall be~~
2 ~~tolled during any period if material evidence necessary for~~
3 ~~prosecuting or determining whether a disciplinary action would~~
4 ~~be appropriate is unavailable to the board due to an ongoing~~
5 ~~criminal investigation.~~

6 SEC. 5. Section 3137 of the Business and Professions Code is
7 repealed.

8 ~~3137. (a) Except as otherwise provided in this section, any~~
9 ~~accusation filed against a licensee pursuant to Section 11503 of~~
10 ~~the Government Code for the violation of any provision of this~~
11 ~~chapter shall be filed within three years after the board discovers~~
12 ~~the act or omission alleged as the ground for disciplinary action,~~
13 ~~or within seven years after the act or omission alleged as the ground~~
14 ~~for disciplinary action occurs, whichever occurs first.~~

15 ~~(b) An accusation filed against a licensee pursuant to Section~~
16 ~~11503 of the Government Code alleging fraud or willful~~
17 ~~misrepresentation is not subject to the limitation in subdivision~~
18 ~~(a).~~

19 ~~(c) An accusation filed against a licensee pursuant to Section~~
20 ~~11503 of the Government Code alleging unprofessional conduct~~
21 ~~based on incompetence, gross negligence, or repeated negligent~~
22 ~~acts of the licensee is not subject to the limitation in subdivision~~
23 ~~(a) upon proof that the licensee intentionally concealed from~~
24 ~~discovery his or her incompetence, gross negligence, or repeated~~
25 ~~negligent acts.~~

26 ~~(d) If an alleged act or omission involves any conduct described~~
27 ~~in Section 726 committed on a minor, the 10-year limitations period~~
28 ~~in subdivision (c) shall be tolled until the minor reaches the age~~
29 ~~of majority.~~

30 ~~(e) An accusation filed against a licensee pursuant to Section~~
31 ~~11503 of the Government Code alleging conduct described in~~
32 ~~Section 726 shall be filed within three years after the board~~
33 ~~discovers the act or omission alleged as the ground for disciplinary~~
34 ~~action, or within 10 years after the act or omission alleged as the~~
35 ~~ground for disciplinary action occurs, whichever occurs first. This~~
36 ~~subdivision shall apply to a complaint alleging conduct received~~
37 ~~by the board on and after January 1, 2006.~~

38 ~~(f) In any allegation, accusation, or proceeding described in this~~
39 ~~section, the limitations period in subdivision (a) shall be tolled for~~
40 ~~the period during which material evidence necessary for~~

1 prosecuting or determining whether a disciplinary action would
2 be appropriate is unavailable to the board due to an ongoing
3 criminal investigation.

4 SEC. 6. Section 3750.51 of the Business and Professions Code
5 is repealed.

6 ~~3750.51. (a) Except as provided in subdivisions (b), (c), and~~
7 ~~(c), any accusation filed against a licensee pursuant to Section~~
8 ~~11503 of the Government Code shall be filed within three years~~
9 ~~from the date the board discovers the alleged act or omission that~~
10 ~~is the basis for disciplinary action, or within seven years from the~~
11 ~~date the alleged act or omission that is the basis for disciplinary~~
12 ~~action occurred, whichever occurs first.~~

13 ~~(b) An accusation filed against a licensee pursuant to Section~~
14 ~~11503 of the Government Code alleging the procurement of a~~
15 ~~license by fraud or misrepresentation is not subject to the~~
16 ~~limitations set forth in subdivision (a).~~

17 ~~(c) The limitation provided for by subdivision (a) shall be tolled~~
18 ~~for the length of time required to obtain compliance when a report~~
19 ~~required to be filed by the licensee or registrant with the board~~
20 ~~pursuant to Article 11 (commencing with Section 800) of Chapter~~
21 ~~1 is not filed in a timely fashion.~~

22 ~~(d) If an alleged act or omission involves a minor, the seven-year~~
23 ~~limitations period provided for by subdivision (a) and the 10-year~~
24 ~~limitations period provided for by subdivision (c) shall be tolled~~
25 ~~until the minor reaches the age of majority.~~

26 ~~(e) An accusation filed against a licensee pursuant to Section~~
27 ~~11503 of the Government Code alleging sexual misconduct shall~~
28 ~~be filed within three years after the board discovers the act or~~
29 ~~omission alleged as the ground for disciplinary action, or within~~
30 ~~10 years after the act or omission alleged as the ground for~~
31 ~~disciplinary action occurs, whichever occurs first.~~

32 ~~(f) The limitations period provided by subdivision (a) shall be~~
33 ~~tolled during any period if material evidence necessary for~~
34 ~~prosecuting or determining whether a disciplinary action would~~
35 ~~be appropriate is unavailable to the board due to an ongoing~~
36 ~~criminal investigation.~~

37 SEC. 7. Section 4982.05 of the Business and Professions Code
38 is repealed.

39 ~~4982.05. (a) Except as provided in subdivisions (b), (c), and~~
40 ~~(e), any accusation filed against a licensee pursuant to Section~~

1 11503 of the Government Code shall be filed within three years
2 from the date the board discovers the alleged act or omission that
3 is the basis for disciplinary action, or within seven years from the
4 date the alleged act or omission that is the basis for disciplinary
5 action occurred, whichever occurs first.

6 (b) ~~An accusation filed against a licensee pursuant to Section
7 11503 of the Government Code alleging the procurement of a
8 license by fraud or misrepresentation is not subject to the
9 limitations set forth in subdivision (a).~~

10 (c) ~~The limitation provided for by subdivision (a) shall be tolled
11 for the length of time required to obtain compliance when a report
12 required to be filed by the licensee or registrant with the board
13 pursuant to Article 11 (commencing with Section 800) of Chapter
14 1 is not filed in a timely fashion.~~

15 (d) ~~If an alleged act or omission involves a minor, the seven-year
16 limitations period provided for by subdivision (a) and the 10-year
17 limitations period provided for by subdivision (c) shall be tolled
18 until the minor reaches the age of majority.~~

19 (e) ~~An accusation filed against a licensee pursuant to Section
20 11503 of the Government Code alleging sexual misconduct shall
21 be filed within three years after the board discovers the act or
22 omission alleged as the grounds for disciplinary action, or within
23 10 years after the act or omission alleged as the grounds for
24 disciplinary action occurs, whichever occurs first. This subdivision
25 shall apply to a complaint alleging sexual misconduct received by
26 the board on and after January 1, 2002.~~

27 (f) ~~The limitations period provided by subdivision (a) shall be
28 tolled during any period if material evidence necessary for
29 prosecuting or determining whether a disciplinary action would
30 be appropriate is unavailable to the board due to an ongoing
31 criminal investigation.~~

32 (g) ~~For purposes of this section, “discovers” means the later of
33 the occurrence of any of the following with respect to each act or
34 omission alleged as the basis for disciplinary action:~~

35 (1) ~~The date the board received a complaint or report describing
36 the act or omission.~~

37 (2) ~~The date, subsequent to the original complaint or report, on
38 which the board became aware of any additional acts or omissions
39 alleged as the basis for disciplinary action against the same
40 individual.~~

1 ~~(3) The date the board receives from the complainant a written~~
2 ~~release of information pertaining to the complainant’s diagnosis~~
3 ~~and treatment.~~

4 ~~SEC. 8. Section 4990.32 of the Business and Professions Code~~
5 ~~is repealed.~~

6 ~~4990.32.—(a) Except as otherwise provided in this section, an~~
7 ~~accusation filed pursuant to Section 11503 of the Government~~
8 ~~Code against a licensee or registrant under the chapters the board~~
9 ~~administers and enforces shall be filed within three years from the~~
10 ~~date the board discovers the alleged act or omission that is the~~
11 ~~basis for disciplinary action or within seven years from the date~~
12 ~~the alleged act or omission that is the basis for disciplinary action~~
13 ~~occurred, whichever occurs first.~~

14 ~~(b) An accusation filed against a licensee alleging the~~
15 ~~procurement of a license by fraud or misrepresentation is not~~
16 ~~subject to the limitations set forth in subdivision (a).~~

17 ~~(c) The limitations period provided by subdivision (a) shall be~~
18 ~~tolled for the length of time required to obtain compliance when~~
19 ~~a report required to be filed by the licensee or registrant with the~~
20 ~~board pursuant to Article 11 (commencing with Section 800) of~~
21 ~~Chapter 1 is not filed in a timely fashion.~~

22 ~~(d) An accusation alleging sexual misconduct shall be filed~~
23 ~~within three years after the board discovers the act or omission~~
24 ~~alleged as the grounds for disciplinary action or within 10 years~~
25 ~~after the act or omission alleged as the grounds for disciplinary~~
26 ~~action occurred, whichever occurs first. This subdivision shall~~
27 ~~apply to a complaint alleging sexual misconduct received by the~~
28 ~~board on and after January 1, 2002.~~

29 ~~(e) If an alleged act or omission involves a minor, the seven-year~~
30 ~~limitations period provided for by subdivision (a) and the 10-year~~
31 ~~limitations period provided for by subdivision (d) shall be tolled~~
32 ~~until the minor reaches the age of majority. However, if the board~~
33 ~~discovers an alleged act of sexual contact with a minor under~~
34 ~~Section 261, 286, 288, 288.5, 288a, or 289 of the Penal Code after~~
35 ~~the limitations periods described in this subdivision have otherwise~~
36 ~~expired, and there is independent evidence that corroborates the~~
37 ~~allegation, an accusation shall be filed within three years from the~~
38 ~~date the board discovers that alleged act.~~

39 ~~(f) The limitations period provided by subdivision (a) shall be~~
40 ~~tolled during any period if material evidence necessary for~~

1 prosecuting or determining whether a disciplinary action would
2 be appropriate is unavailable to the board due to an ongoing
3 criminal investigation.

4 (g) For purposes of this section, “discovers” means the latest
5 of the occurrence of any of the following with respect to each act
6 or omission alleged as the basis for disciplinary action:

7 (1) The date the board received a complaint or report describing
8 the act or omission.

9 (2) The date, subsequent to the original complaint or report, on
10 which the board became aware of any additional acts or omissions
11 alleged as the basis for disciplinary action against the same
12 individual.

13 (3) The date the board receives from the complainant a written
14 release of information pertaining to the complainant’s diagnosis
15 and treatment.

16 SEC. 9. Section 5561 of the Business and Professions Code is
17 repealed.

18 ~~5561. All accusations against licensees charging the holder of~~
19 ~~a license issued under this chapter with the commission of any act~~
20 ~~constituting a cause for disciplinary action shall be filed with the~~
21 ~~board within five years after the board discovers, or through the~~
22 ~~use of reasonable diligence should have discovered, the act or~~
23 ~~omission alleged as the ground for disciplinary action, whichever~~
24 ~~occurs first, but not more than 10 years after the act or omission~~
25 ~~alleged as the ground for disciplinary action. However, with respect~~
26 ~~to an accusation alleging a violation of Section 5579, the accusation~~
27 ~~may be filed within three years after the discovery by the board~~
28 ~~of the alleged facts constituting the fraud or misrepresentation~~
29 ~~prohibited by Section 5579.~~

30 SEC. 10. Section 5661 of the Business and Professions Code
31 is repealed.

32 ~~5661. All accusations against a licensee shall be filed within~~
33 ~~three years after the board discovers, or through the use of~~
34 ~~reasonable diligence should have discovered, the act or omission~~
35 ~~alleged as the ground for disciplinary action or within six years~~
36 ~~after the act or omission alleged as the ground for disciplinary~~
37 ~~action, whichever occurs first. However, with respect to an~~
38 ~~accusation alleging a violation of Section 5667, the accusation~~
39 ~~may be filed within three years after the discovery by the board~~

1 of the alleged facts constituting the fraud or misrepresentation
2 prohibited by Section 5667.

3 If any accusation is not filed within the time provided in this
4 section, no action against a licensee shall be commenced under
5 this article.

6 SEC. 11. Section 7686.5 of the Business and Professions Code
7 is repealed.

8 ~~7686.5. All accusations against licensees shall be filed with
9 the bureau within two years after the performance of the act or
10 omission alleged as the ground for disciplinary action; provided,
11 however, that the foregoing provision shall not constitute a defense
12 to an accusation alleging fraud or misrepresentation as a ground
13 for disciplinary action. The cause for disciplinary action in such
14 case shall not be deemed to have accrued until discovery, by the
15 bureau, of the facts constituting the fraud or misrepresentation,
16 and, in such case, the accusation shall be filed within three years
17 after such discovery.~~

18 SEC. 12. Section 9884.20 of the Business and Professions
19 Code is repealed.

20 ~~9884.20. All accusations against automotive repair dealers
21 shall be filed within three years after the performance of the act
22 or omission alleged as the ground for disciplinary action, except
23 that with respect to an accusation alleging fraud or
24 misrepresentation as a ground for disciplinary action, the accusation
25 may be filed within two years after the discovery, by the bureau,
26 of the alleged facts constituting the fraud or misrepresentation.~~

27 SEC. 13. Section 9889.8 of the Business and Professions Code
28 is repealed.

29 ~~9889.8. All accusations against licensees shall be filed within
30 three years after the act or omission alleged as the ground for
31 disciplinary action, except that with respect to an accusation
32 alleging a violation of subdivision (d) of Section 9889.3, the
33 accusation may be filed within two years after the discovery by
34 the bureau of the alleged facts constituting the fraud or
35 misrepresentation prohibited by that section.~~

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1003

VERSION: As Introduced February 18, 2011

AUTHOR: Smyth

SPONSOR:

BOARD POSITION: None

SUBJECT: Regulatory boards: limitations periods

Affected Sections: Intent Language Only

CURRENT STATUS: May be heard in committee March 22, 2010

EXISTING LAW:

Established boards within the Department of Consumer Affairs responsible for the licensure and regulation of various professions and vocations and also provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health.

THIS BILL WOULD:

State that it is the intent of the Legislature to enact legislation that would require that all professional and vocational licenses currently issued by the Department of Consumer Affairs and its affiliate boards, and specified licenses issued by the State Department of Public Health, be issued from one central location and that the current regulatory, oversight, and enforcement authority with respect to holders of those licenses remain with those boards and the department currently performing those functions.

AUTHOR'S INTENT:

The author's office has indicated that this is a spot bill. They do not currently have plans for this bill.

COMMENTS:

Staff will continue to watch this bill for amendments and will bring the legislation back to the board to consideration.

FISCAL IMPACT:

Unknown

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Feb. 20 From printer. May be heard in committee March 22.

Feb. 18 Read first time. To print.

ASSEMBLY BILL

No. 1003

Introduced by Assembly Member Smyth

February 18, 2011

An act relating to professional and vocational licenses.

LEGISLATIVE COUNSEL'S DIGEST

AB 1003, as introduced, Smyth. Professional and vocational licenses.

Under existing law, boards within the Department of Consumer Affairs are responsible for the licensure and regulation of various professions and vocations. Existing law also provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health.

This bill would declare the intent of the Legislature to enact legislation that would require that all professional and vocational licenses currently issued by the Department of Consumer Affairs and its affiliate boards, and specified licenses issued by the State Department of Public Health, be issued from one central location and that the current regulatory, oversight, and enforcement authority with respect to holders of those licenses remain with those boards and the department currently performing those functions.

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

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

- 1 SECTION 1. It is the intent of the Legislature to enact
- 2 legislation that would require that all professional and vocational
- 3 licenses currently issued by the Department of Consumer Affairs

1 and its affiliate boards, bureaus, and commissions, and those
2 licenses issued by the State Department of Public Health pursuant
3 to Chapter 3 (commencing with Section 1200) of Division 2 of
4 the Business and Professions Code be issued from one central
5 location. It is also the intent of the Legislature that the current
6 regulatory, oversight, and enforcement authority with respect to
7 holders of those licenses remain with those boards, bureaus, and
8 commissions and the department currently performing those
9 functions.

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 227

VERSION: As Introduced February 9, 2011

AUTHOR: Wyland

SPONSOR:

BOARD POSITION: None

SUBJECT: Business and Professions: licensure

Affected Sections: Amend Section 23.8 of the Business and Professions Code

CURRENT STATUS: Referred to Rule Committee

EXISTING LAW:

Defines "licentiate" as a person authorized by a license, certificate, registration or other means to engage in a business or profession regulated by this code.

THIS BILL WOULD:

Make technical, nonsubstantive changes to that provision.

AUTHOR'S INTENT:

Author's office indicated that this is a spot bill and may become a two year bill.

FISCAL IMPACT:

Unknown

COMMENTS:

This is currently a spot bill. Staff will continue to watch this pending legislation for amendments, and will bring it to the committee and board for consideration if appropriate.

RELATED/PREVIOUS LEGISLATION:

Unknown

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date Action

Feb. 17 Referred to Com. on RLS.

Feb. 10 From printer. May be acted upon on or after March 12.

Feb. 9 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Wyland

February 9, 2011

An act to amend Section 23.8 of the Business and Professions Code, relating to business and professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 227, as introduced, Wyland. Business and professions: licensure. Existing law, under the Business and Professions Code, provides for the regulation and licensure of various professionals. Existing law provides that the term "licentiate," as used in the Business and Professions Code, refers to any person authorized by a license, certificate, registration, or other means to engage in a business or profession regulated by that code and as specified.

This bill would make technical, nonsubstantive changes to that provision.

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

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

- 1 SECTION 1. Section 23.8 of the Business and Professions
- 2 Code is amended to read:
- 3 23.8. "Licentiate" or "licensee" means any person authorized
- 4 by a license, certificate, registration, or *any* other means to engage
- 5 in a business or profession *that is* regulated by this code or referred
- 6 to in Sections 1000 and 3600.

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 667

VERSION: As Introduced February 18, 2011

AUTHOR: Wyland

SPONSOR:

BOARD POSITION: None

SUBJECT: Pharmacy

Affected Sections: Amend Section 500 of the Business and Professions Code.

CURRENT STATUS:

EXISTING LAW:

Allows for the register or book of registration of the Medical Board of California, the Dental Board of California, or the California State Board of Pharmacy is destroyed, as specified, the board may reproduce it.

THIS BILL WOULD:

Make technical, nonsubstantive changes to that provision.

AUTHOR'S INTENT:

This is currently a spot bill.

COMMENTS:

Staff will continue to watch this bill for amendments and will bring the legislation back to the board to consideration. The author's office indicated that it will most likely not carry this legislation.

PRIOR HISTORY/RELATED BILLS:

Unknown

FISCAL IMPACT:

Unknown

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Mar. 3 Referred to Com. on RLS.

Feb. 19 From printer. May be acted upon on or after March 21.

Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print

Introduced by Senator Wyland

February 18, 2011

An act to amend Section 500 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 667, as introduced, Wyland. Healing arts.

Under existing law, if the register or book of registration of the Medical Board of California, the Dental Board of California, or the California State Board of Pharmacy is destroyed, as specified, the board may reproduce it.

This bill would make technical, nonsubstantive changes to that provision.

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

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

- 1 SECTION 1. Section 500 of the Business and Professions Code
2 is amended to read:
3 500. Whenever the register or book of registration of the
4 Medical Board of California, the ~~Board of Dental Examiners~~ *Dental*
5 *Board of California*, or the ~~Board of California State Board of~~
6 Pharmacy is destroyed by fire or other public calamity, the board,
7 whose duty it is to keep the register or book, may reproduce it so
8 that there may be shown as nearly as possible the record existing
9 in the original at the time of destruction.

O

Agenda Item 2e



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: March 24, 2011
To: Legislation and Regulation Committee
Subject: Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Agenda Item 2.e: Other

Below are summaries of bills that cover a spectrum of pharmacy or pharmacy related issues. A bill analysis and a copy of the most recent version of the bill are provided in unless otherwise noted.

AB 389 (Mitchell) Bleeding disorders: blood clotting products

Summary: This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Recent Action: Assembly Health Committee hearing scheduled for April 5, 2011.

AB 604 (Skinner) Needle exchange program

Summary: This bill would authorize the State Department of Public Health to authorize, as specified, certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

Recent Action: Assembly Health Committee hearing scheduled for March 29, 2011.

SB 41 (Yee) Hypodermic needles and syringes

Summary: 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.

Recent Action: Senate Health Committee hearing scheduled for April 6, 2011.

SB 514 (Simitian) Dextromethorphan: sale to minors prohibited

Summary: This bill would make it an infraction for any person in an over-the-counter sale to, without a prescription, willfully and knowingly deliver to a person under 18 years of age a nonprescription drug containing dextromethorphan.

Recent Action: Senate Public Safety Committee hearing postponed.

SB 850 (Leno) Medical records: confidential information

Summary: Would expand those provisions to require that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records do so in a manner that preserves the confidentiality, accuracy, and integrity of the information contained in the record.

Recent Action: Referred to Senate Judiciary Committee

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 389

VERSION: As Amended March 15, 2011

AUTHOR: Mitchell

SPONSOR: Hemophilia Council of California

BOARD POSITION: None

SUBJECT: Bleeding disorders:

Affected Sections: Amend Section 2191 of the Business and Professions Code and Add Article 5 (commencing with Section 125286.10) to Chapter 2 or Part 5 of Division 106 of the Health and Safety Code

Current Status: Assembly Health Committee Hearing April 5, 2011

EXISTING LAW:

1. Establishes the Holden-Moscone-Garamendi Genetically Handicapped Person's Program within the Department of Health Care Services. [HSC §125125]
2. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically disabling conditions, including hemophilia. [HSC §125130]
3. Requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons as specified and sets forth the criteria that the division shall use in considering courses. [B&PC §2191]

THIS BILL WOULD:

1. Require the division to consider including a course on bleeding disorders with particular emphasis on von Willebrand disease using the latest treatment guidelines adopted by the National Heart, Lung and Blood Institute.
2. Add Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act that includes the following:
 - a. Findings and declarations about bleeding disorders, history of and treatment of such disorders, pharmacies role in the delivery of products, identification of persons eligible for treatment through various programs, and states that this article is necessary for the benefit of persons with bleeding disorders to establish standards of service and to promote cost effective, life saving products for home use.
 - b. Defines various terms for purposes of this article including:

- i. “home nursing services” means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.
 - ii. “provider of blood clotting products for home use” means hospital pharmacies, health systems pharmacies, pharmacies affiliated with treatment centers, specialty home care pharmacies and retail pharmacies. These providers are allowed to provide home nursing services and are required to include a health care service plan and all its affiliated providers if the plan exclusively contracts with a single medication group in a specified areas to provide professional services to enrollees.
- c. Requires that each provider, as defined above, meet the following requirements:
 - i. Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescriber and ensure quality care.
 - ii. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables to the provider to know when patients have an appropriate supply of product on hand as well and understanding about proper storage and refrigeration.
 - iii. Maintain 24-hour on-call service seven days a week, 365 days a years.
 - iv. Have the ability to obtain all brands of the products approved by the FDA in multiple assay ranges as specified.
 - v. Supply all necessary ancillary infusion equipment and supplies as needed.
 - vi. Store, ship, or otherwise deliver, all products in conformity with state and federally mandated standards.
 - vii. Provide home nursing services either directly or via a third party, when determined necessary by the physician.
 - viii. Ship product within two business days to a patient for a nonemergency prescription.
 - ix. For emergencies, deliver products, equipment, medications and home nursing services within 12 hours, for patients living within 100 miles of a major metropolitan airport, or within one days for patients living outside that area.
 - x. Provide contact information to a patient to report problems with delivery.
 - xi. Provide patient with product recall and withdrawal notifications within 24 hours.
 - xii. Provide language interpretive service via phone or in person, as needed.
 - xiii. Have a detailed plan in the event of a natural or manmade disaster.
 - xiv. Provide appropriate record keeping.
 - xv. Comply with HIPAA requirements.
- d. Requires the California Board of Pharmacy to administer and enforce this article.

AUTHOR'S INTENT:

According to the author's office, "AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, von Willebrand disease and other bleeding disorders."

COMMENTS:

Many of these provisions are currently the standard of practice, but are not mandated anywhere. This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received. The board would already have jurisdiction to investigate consumer complaints involving poor service or product delivery that resulted in either patient harm or the potential for harm. We are unaware of any such complaints received by the board.

There are potential challenges in enforcing some of these provisions. Specifically, the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting factor on hand as required. Further, it is unclear if the board would have jurisdiction over the home nursing services and the quality of the care provided.

FISCAL/ECONOMIC IMPACT:

We anticipate a portion of an inspector PY will be necessary to ensure compliance with these provisions. This workload could possibly be absorbed if the board is able to fill all authorized inspector positions. However, because of the bill's specificity and the need for close monitoring of these provisions, the board would need to do frequent inspections. However, because the specialty pharmacies are not required to have a separate license, nor are they required to notify the board that they provide such services, performing inspection on all pharmacies that provide these services would be a challenge.

PREVIOUS/RELATED LEGISLATION

SB 1594 (Steinberg, 2007) would have established standards for providers of blood clotting products. The board had a "Watch" position on the bill. The measure later died after being placed on the Senate Appropriations Suspense File and never passed out of the house of origin.

SB 971 (Pavely, 2010) introduced legislation similar to this proposal. The board did not have a position on this bill. This bill was vetoed by the governor.

"I am returning Senate Bill 971 without my signature. This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards

of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address. For these reasons, I am unable to sign this bill.”

SUPPORT/OPPOSITION:

Support

Hemophilia Council of California (sponsor)
California Society of Health-System Pharmacists
Community Healthcare Services
CSL Behring
Grifols, Inc.
Federal Hemophilia Treatment Centers Region IX
Herndon Pharmacy
National Cornerstone Healthcare Services Inc.
Red Chip Enterprises
Walgreens

Oppose

None on file as of March 22, 2011

HISTORY:

Mar. 22 From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 9. Noes 0.) (March 22). Re-referred to Com. on HEALTH.
Mar. 16 Re-referred to Com. on B., P. & C.P.
Mar. 15 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Mar. 8 Re-referred to Com. on B., P. & C.P.
Mar. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Feb. 24 Referred to Com. on B., P. & C.P.
Feb. 15 From printer. May be heard in committee March 17.
Feb. 14 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 15, 2011

AMENDED IN ASSEMBLY MARCH 7, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 389

Introduced by Assembly Member Mitchell
(Principal coauthor: Senator Pavley)

February 14, 2011

An act to amend Section 2191 of the Business and Professions Code, and to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Existing law requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons.

This bill would require the division to consider including a course on bleeding disorders, as specified, in determining its continuing education requirements.

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

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

1 SECTION 1. Section 2191 of the Business and Professions
2 Code is amended to read:

3 2191. (a) In determining its continuing education requirements,
4 the Division of Licensing shall consider including a course in
5 human sexuality as defined in Section 2090 and nutrition to be
6 taken by those licensees whose practices may require knowledge
7 in those areas.

8 (b) The division shall consider including a course in child abuse
9 detection and treatment to be taken by those licensees whose
10 practices are of a nature that there is a likelihood of contact with
11 abused or neglected children.

12 (c) The division shall consider including a course in acupuncture
13 to be taken by those licensees whose practices may require
14 knowledge in the area of acupuncture and whose education has
15 not included instruction in acupuncture.

16 (d) The division shall encourage every physician and surgeon
17 to take nutrition as part of his or her continuing education,
18 particularly a physician and surgeon involved in primary care.

19 (e) The division shall consider including a course in elder abuse
20 detection and treatment to be taken by those licensees whose
21 practices are of a nature that there is a likelihood of contact with
22 abused or neglected persons 65 years of age and older.

23 (f) In determining its continuing education requirements, the
24 division shall consider including a course in the early detection
25 and treatment of substance abusing pregnant women to be taken
26 by those licensees whose practices are of a nature that there is a
27 likelihood of contact with these women.

28 (g) In determining its continuing education requirements, the
29 division shall consider including a course in the special care needs
30 of drug addicted infants to be taken by those licensees whose
31 practices are of a nature that there is a likelihood of contact with
32 these infants.

1 (h) In determining its continuing education requirements, the
2 division shall consider including a course providing training and
3 guidelines on how to routinely screen for signs exhibited by abused
4 women, particularly for physicians and surgeons in emergency,
5 surgical, primary care, pediatric, prenatal, and mental health
6 settings. In the event the division establishes a requirement for
7 continuing education coursework in spousal or partner abuse
8 detection or treatment, that requirement shall be met by each
9 licensee within no more than four years from the date the
10 requirement is imposed.

11 (i) In determining its continuing education requirements, the
12 division shall consider including a course in the special care needs
13 of individuals and their families facing end-of-life issues, including,
14 but not limited to, all of the following:

- 15 (1) Pain and symptom management.
- 16 (2) The ~~psycho-social~~ *psychosocial* dynamics of death.
- 17 (3) Dying and bereavement.
- 18 (4) Hospice care.

19 (j) In determining its continuation education requirements, the
20 division shall give its highest priority to considering a course on
21 pain management.

22 (k) In determining its continuing education requirements, the
23 division shall consider including a course on bleeding disorders,
24 with particular emphasis on von Willebrand disease using the latest
25 treatment guidelines adopted by the National Heart, Lung, and
26 Blood Institute.

27 SEC. 2. Article 5 (commencing with Section 125286.10) is
28 added to Chapter 2 of Part 5 of Division 106 of the Health and
29 Safety Code, to read:

30
31 Article 5. Standards of Service for Providers of Blood Clotting
32 Products for Home Use Act

33
34 125286.10. This article shall be known, and may be cited, as
35 the Standards of Service for Providers of Blood Clotting Products
36 for Home Use Act.

37 125286.15. The Legislature hereby finds and declares all of
38 the following:

- 1 (a) Hemophilia is a rare, hereditary, bleeding disorder affecting
2 at least 4,000 persons in California and is a chronic, lifelong, and
3 incurable, but treatable, disease.
- 4 (b) Von Willebrand disease is a human bleeding disorder caused
5 by a hereditary deficiency or abnormality of the von Willebrand
6 factor in human blood, which is a protein that helps clot blood.
7 Von Willebrand disease is a chronic, lifelong, incurable, but
8 treatable, disease affecting at least 360,000 Californians.
- 9 (c) Until the 1970s, people with severe hemophilia suffered
10 from uncontrollable internal bleeding, crippling orthopedic
11 deformities, and a shortened lifespan. More recently, the production
12 of highly purified blood clotting factors has provided people with
13 hemophilia and other bleeding disorders the opportunity to lead
14 normal lives, free of pain and crippling arthritis.
- 15 (d) The preferred method of treatment of hemophilia today is
16 intravenous injection, or infusion, of prescription blood clotting
17 products several times per week, along with case management and
18 specialized medical care at a federally designated regional
19 hemophilia treatment center.
- 20 (e) Pharmacies and other entities specializing in the delivery of
21 blood clotting products and related equipment, supplies, and
22 services for home use form a growing enterprise in California.
- 23 (f) Timely access to federally designated regional hemophilia
24 centers and appropriate products and services in the home,
25 including infusion of blood clotting products and related
26 equipment, and supplies and services for persons with hemophilia
27 and other bleeding disorders, reduces mortality and bleeding-related
28 hospitalizations according to the federal Centers for Disease
29 Control and Prevention and the Medical and Scientific Advisory
30 Council of the National Hemophilia Foundation.
- 31 (g) Eligible persons with hemophilia or other bleeding disorders
32 may receive treatment through the Genetically Handicapped
33 Persons Program, the California Children’s Services Program, and
34 the Medi-Cal program.
- 35 (h) For the benefit of persons with hemophilia or other bleeding
36 disorders, the purposes of this article are to do the following:
 - 37 (1) Establish standards of service for entities that deliver blood
38 clotting products and related equipment, supplies, and services for
39 home use.

1 (2) Promote access to a full range of essential, cost-effective,
2 lifesaving, blood clotting products and related equipment, supplies,
3 and high-quality services for home use for persons with hemophilia
4 and other bleeding disorders.

5 125286.20. Unless the context otherwise requires, the following
6 definitions shall apply for purposes of this article:

7 (a) “Assay” means the amount of a particular constituent of a
8 mixture or of the biological or pharmacological potency of a drug.

9 (b) “Ancillary infusion equipment and supplies” means the
10 equipment and supplies required to infuse a blood clotting product
11 into a human vein, including, but not limited to, syringes, needles,
12 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
13 tourniquets, medical tape, sharps or equivalent biohazard waste
14 containers, and cold compression packs.

15 (c) “Bleeding disorder” means a medical condition characterized
16 by a deficiency or absence of one or more essential blood clotting
17 proteins in the human blood, often called “factors,” including all
18 forms of hemophilia and other bleeding disorders that, without
19 treatment, result in uncontrollable bleeding or abnormal blood
20 clotting.

21 (d) “Blood clotting product” means an intravenously
22 administered medicine manufactured from human plasma or
23 recombinant biotechnology techniques, approved for distribution
24 by the federal Food and Drug Administration, that is used for the
25 treatment and prevention of symptoms associated with bleeding
26 disorders. Blood clotting products include, but are not limited to,
27 Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von
28 Willebrand Factor products, bypass products for patients with
29 inhibitors, and activated prothrombin complex concentrates.

30 (e) “Emergency” means care as defined in Section 1317.1.

31 (f) “Hemophilia” means a human bleeding disorder caused by
32 a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII,
33 or XIII blood clotting protein in human blood.

34 (g) “Hemophilia treatment center” means a facility for the
35 treatment of bleeding disorders, including, but not limited to,
36 hemophilia, that receives funding specifically for the treatment of
37 patients with bleeding disorders from federal government sources,
38 including, but not limited to, the federal Centers for Disease
39 Control and Prevention and the federal Health Resources and

1 Services Administration (HRSA) of the United States Department
2 of Health and Human Services.

3 (h) “Home nursing services” means specialized nursing care
4 provided in the home setting to assist a patient in the reconstitution
5 and administration of blood clotting products.

6 (i) “Home use” means infusion or other use of a blood clotting
7 product in a place other than a state-recognized hemophilia
8 treatment center or other clinical setting. Places where home use
9 occurs include, without limitation, a home or other nonclinical
10 setting.

11 (j) “Patient” means a person needing a blood clotting product
12 for home use.

13 (k) (1) “Provider of blood clotting products for home use”
14 means all the following pharmacies, except as described in Section
15 125286.35, that dispense blood clotting factors for home use:

16 (A) Hospital pharmacies.

17 (B) Health system pharmacies.

18 (C) Pharmacies affiliated with hemophilia treatment centers.

19 (D) Specialty home care pharmacies.

20 (E) Retail pharmacies.

21 (2) The providers described in this subdivision may also provide
22 home nursing services for persons with bleeding disorders.

23 (3) The providers described in this subdivision shall include a
24 health care service plan and all its affiliated providers if the health
25 care service plan exclusively contracts with a single medical group
26 in a specified geographic area to provide professional services to
27 its enrollees.

28 125286.25. Each provider of blood clotting products for home
29 use shall meet all of the following requirements:

30 (a) Have sufficient knowledge and understanding of bleeding
31 disorders to accurately follow the instructions of the prescribing
32 physician and ensure high-quality service for the patient and the
33 medical and psychosocial management thereof, including, but not
34 limited to, home therapy.

35 (b) Have access to a provider with sufficient clinical experience
36 providing services to persons with bleeding disorders that enables
37 the provider to know when patients have an appropriate supply of
38 clotting factor on hand and about proper storage and refrigeration
39 of clotting factors.

- 1 (c) Maintain 24-hour on-call service seven days a week for
2 every day of the year, adequately screen telephone calls for
3 emergencies, acknowledge all telephone calls within one hour or
4 less, and have access to knowledgeable pharmacy staffing on call
5 24 hours a day, to initiate emergency requests for clotting factors.
- 6 (d) Have the ability to obtain all brands of blood clotting
7 products approved by the federal Food and Drug Administration
8 in multiple assay ranges (low, medium, and high, as applicable)
9 and vial sizes, including products manufactured from human
10 plasma and those manufactured with recombinant biotechnology
11 techniques, provided manufacturer supply exists and payer
12 authorization is obtained.
- 13 (e) Supply all necessary ancillary infusion equipment and
14 supplies with each prescription, as needed.
- 15 (f) Store and ship, or otherwise deliver, all blood clotting
16 products in conformity with all state and federally mandated
17 standards, including, but not limited to, the standards set forth in
18 the product's approved package insert (PI).
- 19 (g) When home nursing services are necessary, as determined
20 by the treating physician, provide these services either directly or
21 through a qualified third party with experience in treating bleeding
22 disorders and coordinate pharmacy services with the third party
23 when one is used to provide home nursing services.
- 24 (h) Upon receiving approved authorization for a nonemergency
25 prescription, provided manufacturer supply exists, ship the
26 prescribed blood clotting products and ancillary infusion equipment
27 and supplies to the patient within two business days or less for
28 established and new patients.
- 29 (i) Upon receiving approved authorization to dispense a
30 prescription for an emergency situation, provided manufacturer
31 supply exists, deliver prescribed blood products, ancillary infusion
32 equipment and supplies, medications, and home nursing services
33 to the patient within 12 hours for patients living within 100 miles
34 of a major metropolitan airport, and within one day for patients
35 living more than 100 miles from a major metropolitan airport.
- 36 (j) Provide patients who have ordered their products with a
37 designated contact telephone number for reporting problems with
38 a delivery and respond to these calls within a reasonable time
39 period.

1 (k) Provide patients with notification of Class 1 and Class 2
2 recalls and withdrawals of blood clotting products and ancillary
3 infusion equipment within 24 hours of the provider of blood
4 clotting products for home use receiving notification and participate
5 in the National Patient Notification System for blood clotting
6 product recalls.

7 (l) Provide language interpretive services over the ~~phone~~
8 *telephone* or in person, as needed by the patient.

9 (m) Have a detailed plan for meeting the requirements of this
10 article in the event of a natural or manmade disaster or other
11 disruption of normal business operations.

12 ~~(n) Provide the patient with a sharps container and instructions~~
13 ~~on how to dispose of medical waste sharps. However, the provider~~
14 ~~of blood clotting products shall not be liable for any acts or~~
15 ~~omissions of the patient in the handling and disposal of medical~~
16 ~~waste.~~

17 ~~(o)~~

18 (n) Provide appropriate and necessary recordkeeping and
19 documentation as required by state and federal law and retain
20 copies of the patient’s prescriptions.

21 ~~(p)~~

22 (o) Comply with the privacy and confidentiality requirements
23 of the federal Health Insurance Portability and Accountability Act
24 of 1996 (HIPAA).

25 125286.30. The California State Board of Pharmacy shall
26 administer and enforce this article.

27 125286.35. Nothing in this article shall apply to either hospital
28 pharmacies or health system pharmacies that dispense blood
29 clotting products due only to emergency, urgent care, or inpatient
30 encounters, or if an inpatient is discharged with a supply of blood
31 clotting products for home use.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 604

VERSION: As Amended March 17, 2011

AUTHOR: Skinner

SPONSOR:

BOARD POSITION: None

SUBJECT: Needle exchange programs.

Affected Sections: An act to amend Sections 121349, 121349.1, 121349.2, and 121349.3 of the Health and Safety Code

CURRENT STATUS: Assembly Health Committee Hearing March 29, 2011

EXISTING LAW:

Health and Safety Code Section 121349

1. Sets for legislative findings and declarations about needle exchange programs (NEPs).
2. Authorizes a clean needle and syringe exchange project in any city and county as specified.

Health and Safety Code Section 121349.1

Requires a city or county that approves such a project shall, in consultation with the State Department of Public Health, authorize the exchange of clean needles and syringes under conditions as specified.

Health and Safety Code Section 121349.2

Provides for an opportunity to comment on such a program on an annual basis.

Health and Safety Code Section 121349.3

1. Requires that the health officer of the participating jurisdiction shall present annually at an open meeting of the board of supervisors or city council a report detailing the program including, relevant statistics on blood-borne infections associated with needle sharing activity and the use of public funds for these programs.
2. Specifies that law enforcement, other stakeholders and the public be provided ample opportunity to provide comment during this meeting.

THIS BILL WOULD:

1. Allow the California Department of Public Health to also authorize NEPs, consistent with state and federal standards, and set for the application criteria.
2. Require the department to hold a public meeting at least 45 days prior to approving the program, as specified.

3. Clarify that the California Department of Public Health, a city, county or a city and county, with or without a department of public health department, may provide an NEP pursuant to appropriate authorizations. Also specifies that program participants shall not be subject to criminal prosecution for possession.
4. Would require an opportunity for public comment on any city or county program on a biennial basis.
5. Would require the health officer to present on a biennial basis, a report detailing the program relevant statistics on *bloodborne* infections associated with needle sharing activity and the use of public funds for these programs, either to the city or county, or to the department.

AUTHOR'S INTENT:

The author notes that the state lacks the authority to respond to urgent public health and fiscal concerns in parts of the state. Counties without a syringe exchange are amongst the counties with the highest number of AIDS cases related to syringe sharing, and with the highest per capita rate of AIDS from syringe sharing.

FISCAL/ECONOMIC IMPACT:

The bill does not have any significant fiscal impact to the board.

PREVIOUS/RELATED LEGISLATION:

SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 - Furnishing Hypodermic Needles and Syringes Without Prescription authorized until December 31, 2010, a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required. The board had a support position on this bill.

SB 774 (Vasconcellos, 2005) would have authorized a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription as specified. The board supported this bill; however it was vetoed by the governor.

SB 1305 (Figueroa) Chapter 64, Statutes of 2006, prohibited a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

AB 110 (Laird), Chapter 707, Statutes of 2007, permits a public entity that receives General Fund money from the Department of Health Services (now DPH) for HIV prevention and education to use that money to support needle exchange programs. The board had a support position on this bill.

AB 1701 (Chesbro, Chapter 667, Statutes of 2010), extended the Disease Prevention Demonstration Project (DPDP) until December 31, 2018, which permits cities or counties to authorize licensed pharmacists to sell or furnish 10 or fewer hypodermic needles or syringes to a person for use without a prescription, as specified. This will was signed by the governor.

AB 1858 (Blumenfield, 2010) would have allowed the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes. This bill was vetoed by the governor.

“I am returning Assembly Bill 1858 without my signature. I signed legislation in 2005 that reflected a careful balance between good public health policy and local decision-making authority. I remain comfortable with that original decision and do not believe it is appropriate to change this balance and instead give authority to the state Department of Public Health to overrule local decisions regarding syringe exchange programs. For this reason, I am unwilling to sign this bill.”

SB 1029 (Yee, 2010) contained many of the same provisions. The governor vetoed this measure.

“I am returning Senate Bill 1029 without my signature. When I signed legislation my first year in office allowing for a pilot program to allow the sale of syringes through participating counties and registered pharmacies, I was seeking to balance the competing public health, law enforcement and local control issues that this issue requires. I believe this balance was achieved and SB 1029 would remove the ability of local officials to best determine policies in their jurisdiction. Some counties have not sought to implement this pilot program, citing competing priorities, lack of pharmacy interest and law enforcement opposition. I respect these local decisions and while I appreciate the author's hard work and dedication to this issue, I cannot sign this bill.”

SUPPORT/OPPOSITION:

Support

Drug Policy Alliance

Oppose

Unknown

HISTORY:

Mar. 21 Re-referred to Com. on HEALTH.

Mar. 17 Referred to Com. on HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Feb. 17 From printer. May be heard in committee March 19.

Feb. 16 Read first time. To print

AMENDED IN ASSEMBLY MARCH 17, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 604

Introduced by Assembly Member Skinner

February 16, 2011

~~An act relating to public health.~~ *An act to amend Sections 121349, 121349.1, 121349.2, and 121349.3 of the Health and Safety Code, relating to public health.*

LEGISLATIVE COUNSEL'S DIGEST

AB 604, as amended, Skinner. ~~Medical home multipayer program.~~
Needle exchange programs.

Existing law, with certain exceptions, makes it a misdemeanor for a person to deliver, furnish, transfer, possess with intent to deliver, furnish, or transfer, or manufacture with the intent to deliver, furnish, or transfer, drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance. Existing law provides an exception to this general rule by authorizing a city, county, or city and county to conduct a clean needle and syringe exchange project authorized by the public entity to combat the spread of HIV and bloodborne hepatitis. Existing law exempts providers participating in an exchange project from criminal prosecution for possession of needles or syringes during participation in the project. Existing law also provides a specified annual comment and reporting process relating to the needle and syringe exchange projects.

This bill would authorize the State Department of Public Health to authorize, as specified, certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

This bill would exempt staff and volunteers participating in an authorized exchange project from criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project and would exempt program participants from criminal prosecution for possession of needles and syringes acquired from an authorized exchange project entity. The bill would also make the comment and reporting process for the projects biennial.

~~Existing law establishes the State Department of Public Health and sets forth its powers and duties, including, but not limited to, the licensing and regulation of health facilities.~~

~~This bill would declare the intent of the Legislature to subsequently amend this bill to include provisions that would establish a medical home multipayer program to improve patient access to health care services, and to improve the continuity and coordination of health care services.~~

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

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

- 1 SECTION 1. Section 121349 of the Health and Safety Code is
- 2 amended to read:
- 3 121349. (a) The Legislature finds and declares that scientific
- 4 data from needle exchange programs in the United States and in
- 5 Europe have shown that the exchange of used hypodermic needles
- 6 and syringes for clean hypodermic needles and syringes does not
- 7 increase drug use in the population, can serve as an important
- 8 bridge to treatment and recovery from drug abuse, and can curtail
- 9 the spread of human immunodeficiency virus (HIV) infection
- 10 among the intravenous drug user population.
- 11 (b) In order to ~~attempt to~~ reduce the spread of HIV infection
- 12 and ~~blood-borne~~ *bloodborne* hepatitis among the intravenous drug

1 user population within California, the Legislature hereby authorizes
2 a clean needle and syringe exchange project pursuant to this chapter
3 in any city ~~and county~~, county, or city *and county* upon the action
4 of a county board of supervisors and the local health officer or
5 health commission of that county, or upon the action of the city
6 council, the mayor, and the local health officer of a city with a
7 health department, or upon the action of the city council and the
8 mayor of a city without a health department.

9 *(c) In order to reduce the spread of HIV infection, viral hepatitis,*
10 *and other potentially deadly bloodborne infections, the State*
11 *Department of Public Health may, notwithstanding any other law,*
12 *authorize entities that provide services set forth in paragraph (1)*
13 *of subdivision (d), and that have sufficient staff and capacity to*
14 *provide the services described in Section 121349.1, as determined*
15 *by the department, to apply for authorization under this chapter*
16 *to provide hypodermic needle and syringe exchange services*
17 *consistent with state and federal standards, including those of the*
18 *United States Public Health Service, in any location where the*
19 *department determines that the conditions exist for the rapid spread*
20 *of HIV, viral hepatitis, or any other potentially deadly or disabling*
21 *infections that are spread through the sharing of used hypodermic*
22 *needles and syringes.*

23 *(d) In order for an entity to be authorized to conduct a project*
24 *pursuant to this chapter, its application to the department shall*
25 *demonstrate that the entity complies with all of the following*
26 *minimum standards:*

27 *(1) The entity provides, directly or through referral, any of the*
28 *following services:*

29 *(A) Drug abuse treatment services.*

30 *(B) HIV or hepatitis C screening.*

31 *(C) Hepatitis A and hepatitis B vaccination.*

32 *(D) Screening for sexually transmitted infections.*

33 *(E) Housing services for the homeless, for victims of domestic*
34 *violence, or other similar housing services.*

35 *(F) Services related to provision of education and materials for*
36 *the reduction of sexual risk behaviors, including, but not limited*
37 *to, the distribution of condoms.*

38 *(2) The entity has the capacity to commence needle and syringe*
39 *exchange services within three months of authorization.*

1 (3) *The entity has adequate funding to do all of the following*
 2 *at reasonably projected program participation levels:*
 3 (A) *Provide needles and syringe exchange services for all of its*
 4 *participants.*
 5 (B) *Provide HIV and viral hepatitis prevention education*
 6 *services for all of its participants.*
 7 (C) *Provide for the safe recovery and disposal of used syringes*
 8 *and sharps waste from all of its participants.*
 9 (4) *The entity has the capacity, and an established plan, to*
 10 *collect evaluative data in order to assess program impact,*
 11 *including, but not limited to, all of the following:*
 12 (A) *The total number of persons served.*
 13 (B) *The total number of syringes and needles distributed,*
 14 *recovered, and disposed of.*
 15 (C) *The total numbers and types of referrals to drug treatment*
 16 *and other services.*
 17 (5) *If the application is provisionally deemed appropriate by*
 18 *the department, the department shall, at least 45 days prior to*
 19 *approval of the application, provide for a period of public comment*
 20 *as follows:*
 21 (A) *Post on the department’s Internet Web site the name of the*
 22 *applicant, the nature of the services, and the location where the*
 23 *applying entity will provide the services.*
 24 (B) *Send a written and an electronic mail notice to the local*
 25 *health officer of the affected jurisdiction.*
 26 (e) *The department shall establish and maintain on its Internet*
 27 *Web site the address and contact information of programs*
 28 *providing hypodermic needle and syringe exchange services.*
 29 (e)
 30 (f) *The authorization provided under this section shall only be*
 31 *for a clean needle and syringe exchange project as described in*
 32 *Section 121349.1*
 33 *SEC. 2. Section 121349.1 of the Health and Safety Code is*
 34 *amended to read:*
 35 *121349.1. ~~A city and county, or a~~The State Department of*
 36 *Public Health or a city, county, or a city and county with or without*
 37 *a health department, that acts to authorize a clean needle and*
 38 *syringe exchange project pursuant to this chapter shall, in*
 39 *consultation with the State Department of Public Health Services,*
 40 *authorize the exchange of clean hypodermic needles and syringes,*

1 as recommended by the United States ~~Secretary of Health and~~
2 ~~Human Services~~ *Public Health Service*, subject to the availability
3 of funding, as part of a network of comprehensive services,
4 including treatment services, to combat the spread of HIV and
5 ~~blood-borne~~ *bloodborne* hepatitis infection among injection drug
6 users. ~~Providers~~ *Staff and volunteers* participating in an exchange
7 project authorized by the *state*, county, city, or city and county
8 pursuant to this chapter shall not be subject to criminal prosecution
9 for ~~possession or violation of any law related to the possession,~~
10 ~~furnishing, or transfer of hypodermic~~ needles or syringes during
11 participation in an exchange project. *Program participants shall*
12 *not be subject to criminal prosecution for possession of needles*
13 *or syringes acquired from an authorized needle and syringe*
14 *exchange project entity.*

15 *SEC. 3. Section 121349.2 of the Health and Safety Code is*
16 *amended to read:*

17 121349.2. Local government, local ~~public~~ health officials, and
18 law enforcement shall be given the opportunity to comment on
19 clean needle and syringe exchange programs on ~~an annual~~ *a*
20 *biennial* basis. The public shall be given the opportunity to provide
21 input to local leaders to ensure that any potential adverse impacts
22 on the public welfare of clean needle and syringe exchange
23 programs are addressed and mitigated.

24 *SEC. 4. Section 121349.3 of the Health and Safety Code is*
25 *amended to read:*

26 121349.3. The health officer of the participating jurisdiction
27 shall present ~~annually~~ *biennially* at an open meeting of the board
28 of supervisors or city council a report detailing the status of clean
29 needle and syringe exchange programs, including, but not limited
30 to, relevant statistics on ~~blood-borne~~ *bloodborne* infections
31 associated with needle sharing activity and the use of public funds
32 for these programs. Law enforcement, administrators of alcohol
33 and drug treatment programs, other stakeholders, and the public
34 shall be afforded ample opportunity to comment at this ~~annual~~
35 *biennial* meeting. The notice to the public shall be sufficient to
36 assure adequate participation in the meeting by the public. This
37 meeting shall be noticed in accordance with all state and local open
38 meeting laws and ordinances, and as local officials deem
39 appropriate. *For hypodermic needle and syringe exchange services*
40 *authorized by the State Department of Public Health, a biennial*

1 *report shall be provided by the department to the local health*
2 *officer based on the reports to the department from service*
3 *providers within the jurisdiction of that local health officer.*

4 ~~SECTION 1. It is the intent of the Legislature to subsequently~~
5 ~~amend this measure to include provisions that would establish a~~
6 ~~medical home multipayer program to improve patient access to~~
7 ~~health care services, and improve the continuity and coordination~~
8 ~~of health care services.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 41

VERSION: As Introduced December 7, 2010

AUTHOR: Yee

SPONSOR:

BOARD POSITION: None

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Business and Professions Code
Amend Sections 4145 and 4148
Repeal Section 4140
Health and Safety Code
Amend Sections 11364
Add Section 121281
Repeal Chapter 13.5 (commencing with Section 121285)

CURRENT STATUS: Senate Health Committee Hearing April 6, 2011

EXISTING LAW:

1. Allows a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time as specified.
2. Establishes a December 31, 2018 sunset date for this provision.
3. Specified that no person shall possess a hypodermic needle or syringe except when acquired in accordance with specified provisions of the law.
4. Allows a pharmacist or physician to furnish hypodermic needles or syringes for human use without a prescription or permit if the person is known to the furnisher and the furnisher has been previously provided with a prescription or proof of legitimate medical need.
5. Establishes the Disease Prevention Demonstration Project (DPDP) as collaboration between pharmacies and local and state health officials for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.
6. Allows for a person to possess, for personal use, 10 or fewer hypodermic needles and syringes if acquired from an authorized source.
7. Allows local governments, local health officers, and law enforcement, the opportunity to comment on needle exchange programs (NEPs) on an annual basis.

THIS BILL WOULD:

1. Repeal the section prohibiting a person from possessing a hypodermic needle or syringe except as provided in Article 9 (Hypodermic Needles and Syringes).
2. Allow a physician or pharmacist to furnish hypodermic needles and syringes, without a prescription, if the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of the legitimate medical need to administer a medicine or treatment.
3. Allow a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use.
4. Specify that pharmacies shall furnish such products in a manner to ensure that they are only available to authorized personnel.
5. Shall provide consumers with disposal options including an onsite collection program or make available mail-back sharps containers or personal medical sharps disposal containers.
6. Shall provide written information or verbal counseling to patients about access to drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste.
7. Specify that all stocks of needles and syringes shall be confiscated if found outside the licensed premises or found not in the possession or control of a person entitled under these provisions.
8. Make conforming changes to H&SC 11364 allowing for possession of up to 30 needles or syringes.
5. Remove the requirement for local authorization through a vote of a Board of Supervisors or City Council.
6. Require Office of Aids to develop and maintain information on its website about accessing drug treatment, accessing HIV and hepatitis screenings and safe disposal of syringe and sharps waste; require the Board to either post or maintain a link to the same information on its website.

AUTHOR'S INTENT:**FISCAL IMPACT:**

The bill does not have any significant fiscal impact to the board. As the measure may impact a licensee or entity under the board's jurisdiction, it is possible that the board may exercise regulatory authority over any related activities within a licensee's scope of practice or authority. The board could likely utilize existing resources to comply with the posting requirements.

PREVIOUS/CURRENT LEGISLATION:

SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 - Furnishing Hypodermic Needles and Syringes Without Prescription authorized until December 31, 2010, a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required. The board had a support position on this bill.

SB 774 (Vasconcellos, 2005) would have authorized a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription as specified. The board supported this bill; however it was vetoed by the governor.

SB 1305 (Figueroa) Chapter 64, Statutes of 2006, prohibited a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

AB 110 (Laird), Chapter 707, Statutes of 2007, permits a public entity that receives General Fund money from the Department of Health Services (now DPH) for HIV prevention and education to use that money to support needle exchange programs. The board had a support position on this bill.

AB 1701 (Chesbro, Chapter 667, Statutes of 2010), extended the Disease Prevention Demonstration Project (DPDP) until December 31, 2018, which permits cities or counties to authorize licensed pharmacists to sell or furnish 10 or fewer hypodermic needles or syringes to a person for use without a prescription, as specified. This bill was signed by the governor.

AB 1858 (Blumenfield, 2010) would have allowed the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes. This bill was vetoed by the governor.

“I am returning Assembly Bill 1858 without my signature. I signed legislation in 2005 that reflected a careful balance between good public health policy and local decision-making authority. I remain comfortable with that original decision and do not believe it is appropriate to change this balance and instead give authority to the state Department of Public Health to overrule local decisions regarding syringe exchange programs. For this reason, I am unwilling to sign this bill.”

SB 1029 (Yee, 2010) contained many of the same provisions. The governor vetoed this measure.

“I am returning Senate Bill 1029 without my signature. When I signed legislation my first year in office allowing for a pilot program to allow the sale of syringes through participating counties and registered pharmacies, I was seeking to balance the competing public health, law enforcement and local control issues that this issue requires. I believe this balance was achieved and SB 1029 would remove the ability of local officials to best determine policies in their jurisdiction. Some counties have not sought to implement this pilot program, citing competing priorities, lack of pharmacy interest and law enforcement opposition. I respect these local decisions and while I appreciate the author's hard work and dedication to this issue, I cannot sign this bill.”

SUPPORT and OPPOSITION:

Unknown

HISTORY:

Date	Action
Mar. 15	Set for hearing April 6.
Mar. 14	Set, first hearing. Hearing canceled at the request of author.
Mar. 4	Set for hearing March 23.
Jan. 20	Referred to Coms. on HEALTH and PUB. S.
Jan. 3	Read first time. 2010
Dec. 8	From printer. May be acted upon on or after January 7.
Dec. 7	Introduced. To Com. on RLS. for assignment. To print.

Introduced by Senator YeeDecember 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:

1 SECTION 1. It is the intent of the Legislature to improve access
2 to syringes and hypodermic needles so as to remove significant
3 barriers for persons seeking to protect their health and the health
4 of other persons, and to remove barriers for programs or businesses
5 to provide sterile injection equipment and education to adults,
6 thereby reducing the spread of communicable diseases and
7 protecting the public health.

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

10 ~~4140. No person shall possess or have under his or her control~~
11 ~~any hypodermic needle or syringe except when acquired in~~
12 ~~accordance with this article.~~

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

15 4145. (a) Notwithstanding any other provision of law, a
16 pharmacist or physician may, without a prescription or a permit,
17 furnish hypodermic needles and syringes for human use, and a
18 person may, without a prescription or license, obtain hypodermic
19 needles and syringes from a pharmacist or physician for human
20 use, ~~if one~~ *the person is known to the furnisher and the furnisher*
21 *has previously been provided a prescription or other proof of the*
22 ~~following requirements is met:~~ *a legitimate medical need requiring*
23 *a hypodermic needle or syringe to administer a medicine or*
24 *treatment.*

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

5 (2) ~~Pursuant to authorization by a county, with respect to all of~~
6 ~~(b) Notwithstanding any other provision of the territory within~~
7 ~~the county, or a city, with respect to the territory within the city,~~
8 ~~for the period commencing January 1, 2005, and ending December~~
9 ~~31, 2018, law, as a public health measure intended to prevent the~~
10 ~~transmission of HIV, viral hepatitis, and other bloodborne diseases~~
11 ~~among persons who use syringes and hypodermic needles, and to~~
12 ~~prevent subsequent infection of sexual partners, newborn children,~~
13 ~~or other persons, a physician or pharmacist may furnish may,~~
14 ~~without a prescription or sell 10 a permit, furnish 30 or fewer~~
15 ~~hypodermic needles or and syringes at any one time for human~~
16 ~~use to a person 18 years of age or older if the pharmacist works~~
17 ~~for a pharmacy that is registered with the Disease Prevention~~
18 ~~Demonstration Project pursuant to Chapter 13.5 (commencing~~
19 ~~with Section 121285) of Part 4 of Division 105 of the Health and~~
20 ~~Safety Code and the pharmacy complies with the provisions of~~
21 ~~that chapter, and a person 18 years of age or older may, without~~
22 ~~a prescription or license, obtain 30 or fewer hypodermic needles~~
23 ~~and syringes solely for personal use from a physician or~~
24 ~~pharmacist.~~

25 ~~(b)~~

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

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

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

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

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

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

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

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

16 *(1) Access drug treatment.*

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

18 *(3) Safely dispose of sharps waste.*

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

21 4148. All stocks of hypodermic needles or syringes shall be
22 confiscated if found outside the licensed premises of any person
23 holding a permit under Section 4141 and found not in the
24 possession or under the control of a person entitled to an exemption
25 under Section 4143, 4144, or 4145, *or under Section 11364,*
26 *121349, or 121349.1 of the Health and Safety Code.*

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

29 11364. (a) It is unlawful to possess an opium pipe or any
30 device, contrivance, instrument, or paraphernalia used for
31 unlawfully injecting or smoking (1) a controlled substance specified
32 in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)
33 of Section 11054, specified in paragraph (14), (15), or (20) of
34 subdivision (d) of Section 11054, specified in subdivision (b) or
35 (c) of Section 11055, or specified in paragraph (2) of subdivision
36 (d) of Section 11055, or (2) a controlled substance which is a
37 narcotic drug classified in Schedule III, IV, or V.

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

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

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

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

19 121281. In order to assist pharmacists and pharmacy personnel
20 in the education of consumers who are at risk of bloodborne
21 infections regarding methods and opportunities for improving and
22 protecting their health, and thereby protect the public health, the
23 Office of AIDS shall develop and maintain all of the following
24 information, on its Internet Web site, and the California State Board
25 of Pharmacy shall also post, or maintain a link to, the information
26 on its Internet Web site:

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

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

31 (c) How consumers can access drug treatment.

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

34 SEC. 8. No reimbursement is required by this act pursuant to
35 Section 6 of Article XIII B of the California Constitution because
36 the only costs that may be incurred by a local agency or school
37 district will be incurred because this act creates a new crime or
38 infraction, eliminates a crime or infraction, or changes the penalty
39 for a crime or infraction, within the meaning of Section 17556 of
40 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 514

VERSION: As Introduced February 17, 2011

AUTHOR: Simitian

SPONSOR:

BOARD POSITION: None

SUBJECT: Dextromethorphan: sale to minors prohibited

Affected Sections: Add Section 11110 to the Health and Safety Code

CURRENT STATUS: Senate Public Safety Committee hearing postponed.

EXISTING LAW:

1. Health and Safety Code Section 11100 establishes the conditions and reporting requirements for the sale of ephedrine and pseudoephedrine to a person under 18 years of age.
2. Regulates the sale of nonprescription drugs.

THIS BILL WOULD:

1. State that it shall be an infraction to sell willfully and knowingly to a person under 18 years of age, an over-the-counter drug, material, compound, mixture, preparation or substance containing dextromethorphan without a prescription.
2. State it shall be prima facie evidence of a violation if the person making the sale does not require and obtain "proof of age" from anyone presumable younger than 25.
 - a. Defines "proof of age" as any document issued by a government agency that contains a description or photo and provides the person's date of birth.
3. State it shall be affirmative defense to a violation if the defendant can prove all of the following:
 - a. Proof of age was obtained as required
 - b. The purchaser provided false representation of his or her age
 - c. The appearance of the purchaser would lead an ordinary person to believe the purchaser was at least 18 years old.
 - d. The sale was made in good faith based on the information provided.
4. Specify that a retail clerk that fails to obtain proof of age is not guilty of an infraction, subject to civil penalties or subject to disciplinary action or discharge by an employer.
 - a. State that this does not apply to a retail clerk that is willfully participating in an ongoing criminal conspiracy to violate these provisions.

AUTHOR'S INTENT:

FISCAL IMPACT:

Unknown

COMMENTS:

RELATED/PREVIOUS LEGISLATION:

AB 1853 (2003)

SB 307 (2005)

SUPPORT/OPPOSITION:

Support

Oppose

Unknown

HISTORY:

Date Action

Mar. 17 Hearing postponed by committee.

Mar. 9 Set for hearing March 22.

Mar. 3 Referred to Com. on PUB. S.

Feb. 18 From printer. May be acted upon on or after March 20.

Feb. 17 Introduced. Read first time. To Com. on RLS. for assignment.
To print.

Introduced by Senator SimitianFebruary 17, 2011

An act to add Section 11110 to the Health and Safety Code, relating to nonprescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 514, as introduced, Simitian. Dextromethorphan: sale to minors prohibited.

Existing law prohibits a manufacturer, wholesaler, retailer, or other person from selling, transferring, or otherwise furnishing a specified substance, including ephedrine and pseudoephedrine, to a person under 18 years of age, except as specified. A first violation of this provision is a misdemeanor. Existing law further regulates the sale of nonprescription drugs, as specified.

This bill would, in addition, make it an infraction for any person in an over-the-counter sale to, without a prescription, willfully and knowingly deliver to a person under 18 years of age a nonprescription drug containing dextromethorphan. The bill would further provide that a retail clerk who fails to require and obtain proof of age from the purchaser shall not be guilty of an infraction, subject to any civil penalties, or subject to any disciplinary action or discharge by his or her employer, unless the retail clerk is a willful participant in an ongoing criminal conspiracy to violate the provisions prohibiting the sale of dextromethorphan to minors. By creating new crimes, 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:

1 SECTION 1. Section 11110 is added to the Health and Safety
2 Code, to read:

3 11110. (a) It shall be an infraction for any person in an
4 over-the-counter sale to, without a prescription, willfully and
5 knowingly deliver to a person under 18 years of age a drug,
6 material, compound, mixture, preparation, or substance containing
7 any quantity of dextromethorphan (the dextrorotatory isomer of
8 3-methoxy-N-methylmorphinan, including its salts, but not
9 including its racemic or levorotatory forms).

10 (b) (1) It shall be prima facie evidence of a violation of this
11 section if the person making the sale does not require and obtain
12 proof of age from the purchaser, unless from the purchaser’s
13 outward appearance the person making the sale would reasonably
14 presume the purchaser to be 25 years of age or older.

15 (2) For the purposes of this section, “proof of age” means any
16 document issued by a governmental agency that contains a
17 description or photograph of the person and gives the person’s
18 date of birth, including a passport, military identification card, or
19 driver’s license.

20 (c) It shall be an affirmative defense to a violation of this section
21 if the defendant proves, by a preponderance of the evidence, all
22 of the following:

23 (1) The person making the sale required and obtained proof of
24 age from the purchaser.

25 (2) The purchaser falsely represented his or her age by the use
26 of a false, forged, or altered document.

27 (3) The appearance of the purchaser would lead an ordinary and
28 prudent person to believe that the purchaser was at least 18 years
29 of age.

30 (4) The sale was made in good faith and in reliance upon the
31 appearance and representation of proof of age of the purchaser.

32 (d) (1) Notwithstanding any other provision of this section, a
33 retail clerk who fails to require and obtain proof of age from the

1 purchaser shall not be guilty of an infraction pursuant to
2 subdivision (a), subject to any civil penalties, or subject to any
3 disciplinary action or discharge by his or her employer.

4 (2) This subdivision shall not apply to a retail clerk who is a
5 willful participant in an ongoing criminal conspiracy to violate
6 this section.

7 SEC. 2. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the penalty
12 for a crime or infraction, within the meaning of Section 17556 of
13 the Government Code, or changes the definition of a crime within
14 the meaning of Section 6 of Article XIII B of the California
15 Constitution.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 850

VERSION: As Introduced February 18, 2011

AUTHOR: Leno

SPONSOR: Consumer Attorneys of California

BOARD POSITION: None

SUBJECT: Medical Records: Confidential Information

Affected Sections: Amend Section 56.101 of the Civil Code

CURRENT STATUS: Referred to Senate Judiciary Committee

EXISTING LAW:

1. Requires every provider of health care, health care service plan, pharmaceutical company, or contractor that has medical records shall maintain, store or destroy them in a manner that preserves confidentiality.
2. Specifies that providers, as specified, that fail to do so will be subject to remedies and penalties.

THIS BILL WOULD:

Clarify that these provisions apply to both written and electronic medical records and would specify that records must be maintained in a matter that preserves not only confidentiality, but also ensures the accuracy and integrity of the information.

AUTHOR'S INTENT:

The author's office indicated that this legislation is to ensure the integrity of electronic medical records.

FISCAL IMPACT:

This workload could possibly be absorbed if the board is able to fill all authorized inspector positions.

SUPPORT and OPPOSITION:

Unknown

HISTORY:

Date Action

Mar. 10 Referred to Com. on JUD.

Feb. 20 From printer. May be acted upon on or after March 22.

Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Leno

February 18, 2011

An act to amend Section 56.101 of the Civil Code, relating to medical records.

LEGISLATIVE COUNSEL'S DIGEST

SB 850, as introduced, Leno. Medical records: confidential information.

The Confidentiality of Medical Information Act requires that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records do so in a manner that preserves the confidentiality of the information contained in the record, and provides that negligence in conducting these activities may result in damages or an administrative fine or civil penalty, as specified.

This bill would expand those provisions to require that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records do so in a manner that preserves the confidentiality, accuracy, and integrity of the information contained in the record.

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

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

1 SECTION 1. Section 56.101 of the Civil Code is amended to
2 read:

1 56.101. Every provider of health care, health care service plan,
2 pharmaceutical company, or contractor who creates, maintains,
3 preserves, stores, abandons, destroys, or disposes of *written or*
4 *electronic* medical records shall do so in a manner that preserves
5 the confidentiality, *accuracy, and integrity* of the information
6 contained therein. Any provider of health care, health care service
7 plan, pharmaceutical company, or contractor who negligently
8 creates, maintains, preserves, stores, abandons, destroys, or
9 disposes of *written or electronic* medical records shall be subject
10 to the remedies and penalties provided under subdivisions (b) and
11 (c) of Section 56.36.

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