California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Stan Weisser, RPh, Chair
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member
Shirley Wheat, Public Member
Tappan Zee, Public Member

LEGISLATION REPORT AND ACTION

A. Board Sponsored Legislation –For Discussion and Possible Action

ATTACHMENT A

1. FOR DISCUSSION: Review of the Executive Staff's written response to the Chair of the Assembly Committee on Business, Professions and Consumer Protection for a report on board-sponsored legislation for 2009-2010

   Following the January 2010 Board Meeting, the board received a request from Chair Mary Hayashi of the Assembly Business, Professions and Consumer Protection Committee to provide information about board-sponsored legislation for 2009 and 2010. The request stated that the "Committee is concerned that legislative efforts of dubious merit to consumers is taking priority over licensing and enforcement; please explain how consumer protection drives the Board's activities."

   In **Attachment A** is the committee's request and the written response prepared by the board's executive staff and provided to Chair Hayashi in early March.

   Details about the board's consumer protection mandate and legislative program are provided on the first five pages of the report. Details about each provision contained in board-sponsored legislation for 2009 and 2010 follow in the remaining pages of the report.

2. AB 977 (Skinner) – Pharmacists: Immunization Administration
   Proposal to Add §4052.8 to the Business and Professions Code

   Last year, the board approved a legislative proposal to expand the conditions under which a pharmacist could administer certain immunizations. This proposal also strengthened the training requirements for such pharmacists and established reporting requirements. The proposal, as introduced, was defeated early on because of strong objections by the California Medical Association (CMA) and was significantly amended to only include intent language. In early December, board staff resumed work on this proposal and provided amendments to the author's office for consideration. The amendments resulted in a scaled-back version of the original proposal, but still provided improved patient access to life-saving flu vaccinations.

The bill was amended several times. In its current form, this bill establishes a pilot project to allow a pharmacist in administer flu vaccines to any person 18 years of age or older pursuant to a protocol developed by the Medical Board of California in consultation with public health officers. The bill specifies that the protocol must be consistent with the requirements for flu vaccination approved by the Advisory Committee On Immunization Practices (ACIP). The bill retained the training and continuing education requirements from pervious versions of the bill as well as the record keeping requirements and requires the board in concert with the Medical Board, to evaluate the effectiveness of the pilot and sets a sunset date of January 1, 2015.

A copy of the January 25, 2010, version of the bill is provided in Attachment A.

3. Omnibus Provisions SB 1489 (Senate Committee on Business, Professions and Economic Development)

   On January 20, 2010, the board voted to support the inclusion of the following amendments in the Senate Business Professions and Economic Development Committee's Omnibus measure for 2010. SB 1489 was introduced on March 11, 2010 included the board's requested proposals. The April 5, 2010, amendment of the bill did not modify any pharmacy-related provisions. A copy of the latest version of SB 1489 is included in Attachment A.

   a. **§4196(e)** – Veterinary Food Animal Drug Retailer; Designated Representative in Charge
      At its October 2008 Board Meeting, the board approved provisions to be include in the 2009 Omnibus Bill (Senate BP&ED, SB 821). The chaptered version of SB 821 contained a drafting error and the section requires clarification (to be amended as previously approved by the board).

   b. **§4200.1** – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x failure)
      In October 2008, the board approved that the sunset provision within §4200.1 be eliminated. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has, again, been included in the Senate BP&ED Committee's 2010 Omnibus bill.

   c. General Provisions Correcting a Name Change from the Department of Health Services to the State Department of Public Health

      §4017 – Authorized Officers of the Law

      §4028 – Definition of Licensed Hospital

      §4037 – Definition of Pharmacy

      §4052.3(e) – Emergency Contraception Drug Therapy; Requirements and Limitations

      §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

      §4072(b) – Oral or Electronic Transmission of Prescription – Health Care Facility

§4119(a) – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

§4127.1(d) – License to Compound Injectable Sterile Drug Products Required

§4169 – Prohibited Acts (also, strike operative date of 2008)

§4181(a) – License Requirements; Policies and Procedures; Who May Dispense

§4191(a) – Compliance with California Department of Public Health Requirements; Who May Dispense Drugs

d. Provision to Update a Reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

e. Provisions to Update References to the Department of Health Care Services (formerly known as the Department of Health Services)
§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring. Subdivisions (b) (c) and (d) reference DHCS as it relates the calculation and transmission of Medi-Cal pricing to the pharmacy.
§4426 – California Department of Health Care Services to Study Reimbursement Rates. This section specifies that the DHCS shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates.

f. Other nonsubstantive amendments

§4101 – Veterinary Food-Animal Drug Retailer

4. Board Sponsored Provisions Not Included in 2010 Legislation

a. Reverse Distributors – Provisions to Specify the Operations of 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 January 20, 2010, to sponsor legislation to distinguish between a reverse distributor and an integrated waste hauler. Following the board's approval, staff proposed these provisions for inclusion in the Senate Committee on Business, Professions and Economic Development but they were declined by the committee. Likewise, staff was not able to secure an author or identify any measure in which these provisions could be included in the current session.

Staff will again pursue these board-approved provisions in the next legislative session.

- Amend §4040.5 Reverse Distributor
- Amend §4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- Amend §4126.5 Furnishing Dangerous Drugs by a Pharmacy

b. Changes Proposed by the Board for Enhancement of the Board's Enforcement Program
   - Amend §4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
   - Amend §4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures
   - Amend §4112 - Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

c. Changes for the Pharmacist Recovery Program
   - Amend §4362 – Pharmacists Recovery Program

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction – For Discussion and Possible Action

ATTACHMENT B

1. Board of Pharmacy

AB 2104 (Hayashi) – California State Board of Pharmacy

This bill would authorize the Governor to appoint the executive officer and would authorize the Governor to determine whether the executive officer may or may not be a member of the board. This bill would require the board to receive approval from the DCA for prior to sponsoring or taking positions on legislation and would define ex parte communications and the reporting requirements for board members that engage in such communications.

This bill is schedule to be heard in the Assembly Business, Professions and Consumer Protection Committee on April 20, 2010.

SB 1390 (Corbett) – Prescription Container Labels

Allow the board to exempt from the labeling requirements established in regulations, prescriptions dispensed to patients a patient in a long-term health care facility from the requirements of the if the prescriptions are administered by a licensed health care professional.

This bill is scheduled to be heard in Senate Business, Professions and Economic Development on April 19, 2010.

2. Pharmacy Practice

AB 1869 (Anderson) Pharmacy – Spot Bill

This proposal in its current form states that it is the intent of the legislature to address the scope of practice of pharmacists. This is a spot bill. Based on information received by the author's office, there are no immediate plans for this bill.

AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors

This bill was introduced on February 16, 2010, and amended on April 3, 2010. As amended, the bill would require a pharmacy to report to the board any occurrence

known by the pharmacy of a prescription being furnished to a person other than the patient named on the prescription or that patient's representative. The bill would also require the pharmacy to report any adverse reaction that may have occurred as a result of the person to whom the prescription was furnished using the prescribed drug.

The bill was double referred. It was heard in the Assembly Health Committee on April 13, 2010, where it passed (Ayes 13. Noes 5.) and was re-referred to the Assembly Committee on Business, Professions and Consumer Protection.

3. Sunset Review and Legislative Oversight Proposals

AB 1659 (Huber) – State Government, Agency Repeals

This bill was introduced on January 19, 2010 and amended on April 7, 2010. As amended, the bill established a Sunset Review Committee charged with conducting a comprehensive analysis of every agency to determine if it is still necessary and cost effective. It establishes reporting elements that must be addressed by the agencies including its purpose, budget information, programs and projects under its control, its successes and failures, as recommendations for changes to improve better fulfill its mission. The bill defines the committee composition and appointment authorities.

This bill was double referred. It is scheduled to be heard in the Assembly Health Committee on April 13, 2010, and should it pass out of committee it will be referred to the Assembly Committee on Business, Professions and Consumer Protection.

AB 2130 (Huber) – Joint Committee of Boards, Commissions and Consumer Protection.

This bill is the implementation bill for AB 1659 (Huber). It abolishes the Joint Committee of Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Sunset Review Committee established in AB 1659.

This bill was passed by the Assembly Committee on Business, Professions and Consumer Protection (11-0) on April 6, 2010, and then referred to the Assembly Appropriations Committee. The bill has not yet been scheduled for hearing in Appropriations.

SB 954 (Harmon) – Legislative Procedure, Committee Referrals

This bill would enact the Jobs Protection Act. It would rename the Joint Committee on Boards, Commissions, and Consumer Protection as the Joint Committee on Boards, Commissions, and Consumer or Business Protection, and would create a new legislative procedure with regard to any bill, as defined, that may have a statewide economic impact affecting business. The bill would require the Assembly Committee on Rules and the Senate Committee on Rules to refer any bill that may have a statewide economic impact affecting business, as specified, to the joint committee for the preparation of an economic impact analysis and a hearing and approval. The bill would require the joint committee to move a bill estimated to generate a fiscal impact of $10,000 or more on small business, as defined, or

$50,000 or more on any other business, to the suspense file of the joint committee for further consideration, subject to specified procedural requirements. The bill would also require the joint committee to make an annual report in that regard.

This bill has not yet been scheduled for hearing. Board staff was advised that this bill may not be moving forward in its current form, but may move forward in a new direction, placing much of the requirements with the Rules committee of each house.

SB 1171 (Negrete McLeod) – Regulatory Boards, Operations

This bill was introduced on February 18, 2010, and then amended on April 5, 2010. As amended, it makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau under the Department of Consumer Affairs upon sunset, if the sunset date is not extended. This bill establishes reporting requirements for board's undergoing Sunset Review and requires that a review be completed by the appropriate policy committees of the Legislature.

The bill was referred to the Senate Committee on Rules but has not yet been scheduled for hearing.

SB 1172 (Negrete McLeod) – Diversion Programs

This bill was amended April 12, 2010 and is the vehicle being used to facilitate implementation of the SB 1441 Uniform Standards for Substance Abusing Healing Arts Professionals. In its current form, it requires a board, contracting for monitoring services, such as the Pharmacists Recovery Program, to require an audit at least once every three years and specifies that the audit will be provided to the legislature. This bill would require a healing arts board to order a licensee to cease practice if the licensee tests positive for any prohibited substance as specified.

The bill was amended April 12, 2010, and re-referred back to the Senate Committee on Business, Professions and Economic Development. Hearing is set for April 19, 2010, upon adjournment of session.

4. Regulation of Dangerous Drugs and Devices

AB 1455 (Hill) – Pseudoephredrine

AB 1455 implements a statewide electronic tracking program in retail outlets that monitors all California over-the-counter (OTC) pseudoephedrine (PSE) purchases in real-time to prevent individuals from exceeding legal purchase limits. This system would allow retailers to be alerted immediately when a consumer is about to exceed purchase limits, and requires the retailer to deny the sale.

This bill was referred to the Senate Public Safety Committee on January 19, 2010, but has not yet been scheduled for a hearing.

AB 2548 (Block) – CURES – Prescription Drug Monitoring Program

This bill establishes the Prescription Drug Monitoring Program (PDMP) within the DOJ for the purpose of monitoring any prescriber or pharmacist who has obtained access to CURES data via the Internet in order to control the diversion and resultant abuse of, and to ensure the safe and lawful dispensing of Schedule II, Schedule III, and Schedule IV controlled substances.

On April 13, 2010, the bill passed out of Assembly Committee on Public Safety (7-0) and referred to Assembly Appropriations with a recommendation: To Consent Calendar.

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

This bill, sponsored by the Hemophilia Council of California, establishes the "Standards of Service for Providers of Blood Clotting Products for Home Use Act." As amended on April 7, 2010, the bill sets forth requirements for entities that deliver blood clotting products and related equipment, supplies and services for home use. It authorizes the Department of Health Care Services to promulgate regulations necessary for the implementation of these standards, and specifies that the Board of Pharmacy shall enforce the provisions established.

The bill was double-referred to Senate Health and to Senate Committee on Business, Professions and Economic Development and is scheduled for hearing in the Senate Committee on Business, Professions and Economic Development on April 19.

SB 1071 (DeSaulnier) – CURES

As amended on March 24, 2010, this bill creates the CURES Fund in the State Treasury and imposes yearly fee, as determined by the Department of Justice (DOJ), on manufacturers and importers of Schedule II, Schedule III, and Schedule IV controlled substances. This measure specifies what these funds may be used for as it relates to the CURES program. The bill does not, however, define an "importer" of specified controlled substances.

The bill was double-referred to the Senate Committee on Revenue & Taxation, and to the Senate Committee on Health. The April 14 hearing in Senate Revenue & Taxation was postponed by the committee.

SB 1106 (Yee) – Prescribers – Dispensing of Samples

Specifically, SB 1106 will require a prescriber dispensing sample prescription drugs to either (1) provide the patient with a copy of the FDA approved package insert for the drug sample or starter kit or the (2) ensure that the manufacturer's warnings are affixed to the package containing the drug sample or starter kit.

This bill passed from the Senate Committee on Business, Professions and Economic Development (Y:5 N:2 A:2); was amended April 5; and re-referred to Senate Appropriations. The bill was on the Senate third reading file April 15.

5. Pharmacy Licensing Issues

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

AB 2077 makes findings and declarations regarding unit dose packaging and centralized packaging functions, and 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.

On April 13, the bill was amended and re-referred back to the Assembly Committee on Business, Professions and Consumer Protection where it is scheduled to be heard on April 20.

AB 2292 (Lowenthal) – Pharmacy: Clinics

AB 2292 amends pharmacy law to modify the licensing requirements for a board-issued clinic license for a surgical clinic to include (1) licensure by the California Department of Public Health under §1204 of the Health and Safety Code; (2) an outpatient setting accredited by an approved agency as defined in §1248 of the Health and Safety Code; and (3) an ambulatory surgical center certified to participate in the Medicare Program, as specified.

The bill was passed out of Assembly Health (19-0) on March 23, and was re-referred to Assembly Appropriations. A hearing in Appropriations has not yet been set.

AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program

As introduced, AB 2551 states the Legislatures intent to establish a new fee structure for loan repayment of various health professions development programs. Staff has been advised that the bill will be amended to create a scholarship fund for pharmacy technicians.

The bill was referred to the Assembly Committee on Business, Professions and Consumer Protection but has not yet been scheduled for hearing.

6. Distribution of Needles and Syringes

AB 1701 (Chesbro) – Hypodermic Needles and Syringes

AB 1701 removes the 2010 sunset date of the Disease Prevention Demonstration Project (a pilot launched in 2004) within the California Department of Public Health which 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.

The bill passed out of the Assembly on April 5 and awaits assignment from Senate Rules.

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services

AB 1858 expands provisions related to needle exchange programs (NEPs) to allow the California Department of Public Health (CDPH) to authorize NEPs in addition to those currently authorized by counties and cities and specifies other requirements of CDPH related to NEPs (Web site information, reports, etc.). The author states that the measure is intended to compliment the efforts of SB 1029 (Yee) [see below].

The bill passed out of Assembly Health (11-5) on April 12 and was re-referred to Assembly Appropriations.

AB 2139 (Chesbro) – Solid Waste: Product Stewardship

AB 2139 establishes the Product Stewardship Program within the Department of Resources Recycling and Recovery and proposes an Extended Producer Responsibility (ERP) framework for the purpose of establishing one law to address a wide range of toxic products, including home-generated medical waste (including hypodermic needles, pen needles, intravenous needles and lancets), household pesticides, and other hazardous waste found around the home. The bill requires a producer or product stewardship organization, on or before September 30, 2011, to submit a product stewardship plan to the department. The bill makes declarations and findings related to product stewardship, defines terms, requires reports, and specifies other requirements.

As amended April 6, the bill passed out of Assembly Environmental Safety and Toxic Materials on April 13 (6-3) and was re-referred to the Assembly Committee on Natural Resources.

SB 1029 (Yee) – Hypodermic Needles and Syringes

According to the author, this will is an incremental move away from complete prohibition of sale and possession of syringes, allowing an adult to possess 30 or fewer syringes for personal use. The bill allows a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 38 years of age or older. The bill addresses the storage of products to ensure they are available only to authorized personnel; requires that disposal options are provided to consumers; removes the requirement of local authorizations; and makes other related changes.

As amended on April 7, SB 1029 is scheduled for hearing in Senate Business Professions and Economic Development on April 19.

7. General / Other

AB 2112 (Monning) – Prescription Record Privacy Act

AB 2112 would establish the Prescription Record Privacy Act to maintain confidentiality of prescriber information and prohibit the disclosure of prescriber information to a third party unless authorized by law. The bill specifies penalties for non compliance, authorizes the adoption of regulations and defines terms.

Staff was advised that author has pulled the bill from committee and that the author does not plan to move forward on this measure.

8. Other Legislation Impacting the Board's Jurisdiction

Attachment A

Board Sponsored Legislation

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

March 2, 2010

The Honorable Mary Hayashi
Chair, Assembly Business and Professions Committee
State Capitol, Room 3013
Sacramento, CA 95814

Dear Assembly Member Hayashi:

On behalf of the Board of Pharmacy, I am pleased to provide you with the attached report you requested in late January 2010 on the board's sponsored legislation for 2009 and 2010.

I will be happy to meet with you or your staff to respond to questions you may have regarding this report or the board's legislation program.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Brian Stiger
Kim Kirchmeyer

California State
Board of Pharmacy

Legislative Program Overview

A Report to the Chair of the Assembly Business and Professions Committee

February 2010

CALIFORNIA STATE
BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

Forward

This report has been written in response to a January 2010 request from the Chair of the Assembly Committee on Business and Professions seeking information about how the California State Board of Pharmacy develops and sponsors legislation. Executive staff of the board prepared this report.

Accordingly for each bill sponsored by the board, information is organized by topic headings, according to parameters set by the Chair in her request:

- Originator of the bill
- Criteria for sponsorship and consideration of consumer protection factors
- Research and approval timeline
- Summary of issues that arose during the Legislative Process

Introduction

The California State Board of Pharmacy is a consumer protection agency charged with enforcement of the state's Pharmacy Law. The board has 13 major regulatory programs that regulate both the individuals and firms that procure, ship, store and dispense prescription drugs and devices to the state's health care providers and patients, both from within and outside California.

The board is comprised of 13 members; seven pharmacists and six public members. Four of the public members and all seven pharmacists are appointed by the Governor, the Assembly and the Senate each appoint one public member. At the time of this report, the board is comprised of four pharmacists and six public members. There are three pharmacist positions vacant.

The board is mandated under California Business and Professions Code section 4001.1 that:

> Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The Board of Pharmacy organizes its activities according to a strategic plan, which is reviewed and revised annually. This plan is divided into five strategic areas that are managed by a committee of the board:

- Enforcement
- Licensing
- Communication and Public Education
- Legislation and Regulation
- Organizational Development

Committee members and the chairperson are appointed by the board president on an annual basis.

In this report, the functions and activities of the board and its Legislation and Regulation Committee will be discussed.

The goal of the Legislation and Regulation Committee is to advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy. The board's vision is: "Healthy Californians through quality pharmacist's care."

The board's mission is: "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement."

Pursuant to this mission and vision, all legislation advocated by the board, whether sponsored or reviewed, must either benefit the public with respect to pharmacist's care or advance the board's ability to license and enforce provisions that support pharmacist's care. In this vein, consumer protection is more than enforcing licensing standards and initiating enforcement actions. It includes devising and implementing prevention strategies for the misuse of dangerous drugs and devices, and eliminating unnecessary barriers to access to vital health care resources. As a regulator of a dynamic profession, it is necessary for the board to maintain vigilance to ensure outdated laws are updated or repealed, and new laws, reflecting new practices or responding to emerging issues, are enacted. Legislation and regulations involving licensing and enforcement activities of the board must be continually evaluated to ensure that minimum standards for competency in the professions are set and maintained.

Each year, the board typically sponsors at least one bill. The origin of legislative proposals comes from:

1. Issues before the board or Administration,
2. Comments addressed to the board from members, stakeholders and the public,
3. Investigations conducted by the board,
4. Health care issues affecting patients and drug distribution,
5. Board staff.

Legislation and promulgation of regulations are necessary to keep Pharmacy Law current. Health care continues to undergo dramatic changes as new technology and new medications compete with costs to drive down the expenses related to health care. Emerging technology that can provide enhanced health care at lower overall expense to the health care system sometimes cannot be used without changes in law. Emerging enforcement matters and health care issues also are the impetus for board-sponsored legislative proposals. Issues in public health or board initiatives frequently necessitate a legislative or regulation response.

But the board also responds to legislative proposals of others, not by sponsoring the proposal but by providing technical assistance to aid implementation or supporting those proposals that advance or opposing those that compromise the board's consumer protection mandate.

As stated in its 2002 Sunset Report: the rapid advance of health care technology (e.g., automation, communications and clinical innovations), workforce issues (e.g., persistent shortages of pharmacists and other health care professionals, geographic and socioeconomic imbalances in the distribution of pharmacies and pharmacists), demographic changes (e.g., aging population, rapidly increasing numbers of consumers from distinct racial, ethnic and linguistic backgrounds), and marketplace issues (e.g., consolidation, growth in chain pharmacies, direct-to-patient advertising of prescription medications, mail order pharmacies, internet pharmacies, rapidly rising drug costs and rapid increases in prescription volumes) increase the complexity of the board's policymaking activities.

Without a legislative program, the board would have significant challenges in moving forward towards its vision of "healthy Californians through quality pharmacist's care." Without seeking or responding to statutory change, the board would be passive and inactive to emerging health care issues. Outdated laws would remain on the books, and innovation and change to improve the public health would be impeded. This is not characteristic of a dynamic consumer protection program, a vigorous public health program or a desirable characteristic for a program regulating those who provide health care on behalf of California's citizens. Pursuing legislative and regulatory changes therefore are necessary components of the board's consumer protection mandate.

The board does its decision making in public, and seeks the participation of the public and other stakeholders in the process. Meeting agendas are placed online and distributed in hard copy form at least 10 days before a meeting. A "subscriber alert" is also emailed to interested parties who have signed up to be notified about board activities through the board's email contact list. Additionally, meeting materials that are provided to board members are also put online at the same time they are distributed to the board, and the availability of the meeting materials is announced via a subscriber alert.

Each year the board holds at least four full public board meetings, where the board acts on matters before it, including legislative and regulation proposals affecting consumers or the board's jurisdiction. In advance of any board meeting, the board usually schedules a committee meeting of the board's strategic committees so an in-depth

discussion of emerging issues is permitted. These meetings are also accessible to the public. Finally, meeting minutes are posted online to allow those who are interested in following board activities to do so without having to attend the meetings in person.

Administration Review of Proposals

The board works closely with the Department of Consumer Affairs to secure its legislative objectives. As an executive branch agency, concerns of the Administration are important to the board. If unaddressed, such concerns could result in an oppose position or a veto if the legislation reaches the Governor. Accordingly, the board notifies the Administration of its annual legislative proposals once determined (usually following the October or the January board meetings). The board also conducts its decision making in public board meetings where the department is present.

For legislation sponsored in 2009, the board made its decisions at the October 2008 board meeting, and within one day of the meeting, notified the State and Consumer Services Agency as well as the legislative staff of the Department of Consumer Affairs about its proposals.

For legislation the board will sponsor in 2010, the board finalized its legislative agenda at the January 2010 board meeting, and notified the Department of Consumer Affairs Legislative Affairs Office the next business day.

Throughout any legislative session, updates to the Administration are provided in response to their inquiries before bills are up in committee hearings as well as in monthly reports to the DCA director. Additionally the board's staff works closely with departmental legislative and budget staff on all legislative matters as the session progresses.

Board-Sponsored Legislation 2009 and 2010

2009

AB 977 (Skinner), Immunizations (two-year bill)

AB 1071 (Emmerson), Board of Pharmacy Fees, Chapter 270, Statutes of 2009

SB 470 (Corbett), Addition of Purpose to Prescription Labels, Chapter 590, Statutes of 2009

SB 819 (Yee/ Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 308, Statutes of 2009

SB 821 (Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 307, Statutes of 2009

2010

Unnumbered bill – provisions for the Senate Business, Professions and Economic Development Committee Health Boards Care Omnibus Bill

Unnumbered bill – provisions to enhance the board's enforcement program

No bill planned, provisions approved – Standards for reverse distributors/wholesalers

Specific details about each of these proposals are provided on the following pages.

In Closing

The Board of Pharmacy is pleased to share this report with the Chair of the Assembly Business and Professions Committee.

The Board of Pharmacy's legislative program is one component the board activates to fulfill its consumer protection mandate. Legislative proposals are developed during public meetings, with input from stakeholders. During any legislative session, once legislation is introduced, amendments are made to remove opposition or clarify provisions. This is the legislative process.

The board seeks comments that will enable it to maintain or improve its level of excellence in seeking, providing and improving consumer protection. This is part of the public feedback built into every Board Meeting and Legislation and Regulation Committee Meeting.

Finally, activities performed in pursuing legislation support the board's vision of "healthy Californians through quality pharmacist care," and the board's mission.

2009 Legislation Sponsored by the Board of Pharmacy:

AB 977 (Skinner)

Bill Originator

Dr. Jeff Goad, Professor, University of Southern California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Increase access to life-saving vaccinations.

Consumer Protection Factors

1. Vaccines are a safe, effective, and efficient means to prevent sickness and death from infectious diseases as reported by the United States Department of Health and Human Services (HHS).
2. The federal Centers for Disease Control and Prevention report that 220,000,000 persons should get the influenza vaccination annually; however, fewer than 100,000,000 do.
3. According to Families USA, 12.1 millions Californians are uninsured.
4. Pharmacists represent the third largest health professional group in the United States and are on the frontline of preventative care.
5. Pharmacists are trained to screen, administer, and properly deal with any adverse events that may arise from vaccines.
6. Pharmacists are the most accessible health care provider – they interact with patients without an appointment.
7. Pharmacists have four years of professional training post baccalaureate degree to earn their PharmD degree, and many pursue post-doctorate residencies in addition.
8. Pharmacists have a formal national immunization training program based on the CDC's "Pink Book" guidelines.

9. Since 1995, Pharmacy Law has allowed a pharmacist to administer immunizations pursuant to a protocol with a physician. Since that time, pharmacists have safely initiated and administered thousands of immunizations to Californians. Patients seem comfortable obtaining these immunizations from pharmacists.

10. The proposal establishes additional standardized training, continuing education and reporting requirements.

Background

The CDC reports that vaccine-preventable disease levels are at or near record lows; however, the CDC notes that it cannot take high immunization coverage levels for granted. "To continue to protect American's children and adults, we must obtain maximum immunization coverage in all populations, establish effective partnerships, conduct reliable scientific research, implement immunization systems, and ensure vaccine safety."

Research and Approval Timeline

Assembly Bill 977, as initially introduced, would have allowed specially trained pharmacists to administer specific vaccines to patients. These vaccines are those recommended by the Centers for Disease Control. There are 10 of these that are recommended for adolescents aged 7-18, and 10 vaccines that are recommended for adults.

The origin of the concept was a presentation made to the board's Licensing Committee Meeting in March 2007, where the board heard a presentation by USC School of Pharmacy Professor Jeff Goad. Dr. Goad provided information about the CDC's concerns about immunization rates in some patients given the benefits of vaccines. He described the training of pharmacists in today's schools of pharmacy with respect to immunizations. The board agreed to proceed with legislation to allow specially trained pharmacists to administer immunizations pursuant to CDC protocols, and under specific conditions.

Over the following 18 months, the board developed language, but did not initiate work on finding an author due to other workload priorities and staffing commitments.

The immunization legislative proposal was brought by staff to the board in the fall of 2008, where at the October 2008 Board Meeting, the board approved the language. Approval was based on:

1. Improving access of patients to vaccines, should it result in increased immunization rates, is a public health issue that will improve the overall health of the public.

2. The integration of vaccination training as part of the education of pharmacists and ongoing training programs for licensed pharmacists prepares them to administer vaccines.

3. Immunization clinics, especially for flu, are well received by the public, and the board has never received a complaint from a consumer regarding a pharmacist-administered vaccination.

4. The Advisory Committee for Immunization Practices of the CDC develops the parameters for administration of vaccines in the US.

5. The proposal would in part address the objectives of the California Department of Public Health, voiced directly to the board in various board meetings in preparing health care providers to prepare for emergency response situations due to disasters, pandemics (e.g., H1N1 vaccinations) or terrorism. The board has worked over the years on preparing pharmacies and pharmacists to prepare for such emergency responses in accordance with the CDPH's objectives.

Bill History

This bill was introduced on February 26, 2009 and was amended six times, most recently January 25, 2010. The bill is currently referred to the Senate Health Committee and the Senate Business, Professions and Economic Development Committee.

Summary of Issues

The following summary is that of the board's executive staff and provides their opinions and understanding of what has occurred during the deliberations of the legislative process.

The introduced version of AB 977 met with opposition from the California Medical Association, other physicians' groups and the California Nurses Association that was not resolvable. The board scaled back the proposal before the first policy hearing in the Assembly Business and Professions Committee to include only influenza and pneumococcal vaccines. Why was this approach selected?

- Combined – influenza and pneumonia are the 8th leading cause of death in people of all ages and the 7th leading cause of death in people over the age of 65.

- During most influenza seasons, up to 20 percent of the people in the US may be infected with the influenza virus. Influenza immunization can reduce physicians' visits, lost work days and reduce antibiotic use.

- Over 30 percent of Californians were without health insurance in the spring of 2009.
- One of every 20 people who get pneumococcal pneumonia dies from it.
- This would have aided the California Department of Public Health's plans to identify immunizers to administer H1N1 vaccines to Californians.

Thus, this version of the bill contained the focus of the board's goals in seeking this proposal, although substantially scaled back.

However, the two vaccine version of AB 977 was also strongly opposed, and resolution could not be reached in April 2009 before the legislative deadline for policy committees to pass bills in the house of origin. The bill was amended to direct the California Pharmacists Association to do a study of protocols. This version of the bill never had a hearing, nor did the board take a position on it. The bill became a two-year bill.

In an attempt to resolve opposition from the medical community, another approach considered and discussed with the author's office and other proponents of the bill would have resulted in the state (Medical Board and Board of Pharmacy) developing a general protocol under which pharmacists could administer influenza and pneumococcal vaccines. The development of such a protocol had occurred in the past for pharmacists to provide emergency contraception.

This concept became the origin for the provisions in the January 4, 2010 version of the bill, which was drafted by board staff in November 2009, reviewed by AB 977 supporters, and sent to the author's chief of staff on November 24, 2009. The Medical Board's staff was notified of the proposed amendment, and they indicated that their board might have problems with the two immunizations specified in the bill, but a review by their board would not occur until the end of January.

In December 2009, the author's office worked directly with the California Medical Association on resolving the CMA's still strong opposition to the board's proposed draft amendments (for a joint Medical Board/Pharmacy Board protocol for flu and pneumococcal vaccines). The board was not involved in these discussions. At some point, negotiations between the author's office and the CMA resulted in the CMA drafting amendments that if incorporated in AB 977, would change their position to neutral. These amendments were put into the bill on January 5, during the Assembly Health Committee Hearing, and would appear in print as the January 6 version of AB 977.

On January 4, 2010, the bill was amended to authorize pharmacists to administer flu and pneumococcal vaccines to any person 11 years of age and older pursuant to a standardized protocol developed by Board of Pharmacy and the Medical Board of California. This version also specified training, continuing

education requirements and record keeping for any pharmacist immunizing under its provisions.

Next, the bill was amended again during the Assembly Health Committee on January 5 (published as the January 6 version), with CMA's proposed changes. This scaled back version of the bill would require the Board of Pharmacy and the Medical Board to develop a protocol for administration of flu vaccines by a pharmacist to an adult. The program would be a four-year pilot program and mandate a report to the Legislature one year prior to sunset of the provisions.

Because of conflicting schedules and absences over the holidays, combined with the tight legislative deadlines needed to pass two-year bills in the house of origin in January 2010, the board did not actually see the proposed amendments in a mock-up form until immediately before the Assembly Health hearing. As such, the executive officer indicated during the hearing that the board could support the proposed amendments if existing law remained in section 4052, and the proposed new state protocol was created as a new provision. This was the essence of the CMA amendments.

The bill was passed by the Assembly Health Committee, and referred to the Assembly Business and Professions Committee for hearing on January 12.

On January 11, the board learned from the author's office that the chair of the Assembly Business and Professions Committee wanted additional amendments in AB 977 that would be inserted during the Assembly Business and Professions Committee hearing on January 12 to require the Medical Board solely to develop the protocol. The executive officer indicated that she would not testify because she wanted to see the proposed amendment. However, at the request of the author's office, she agreed to come.

During the Assembly Business and Professions Committee hearing, the bill was passed with an amendment during the hearing. The amendments were not in print prior to the hearing, not made available to the board, and had been negotiated without the board's participation or knowledge.

During the hearing, the author's office, the lobbyist for the California Pharmacists Association and the committee chair agreed on the negotiated amendment that the Medical Board would solely be responsible for developing the protocol. The executive officer stated during the hearing that the board could support the amendment but noted that regulations by the Board of Pharmacy would likely be needed to implement the protocol, which had been required for the emergency contraception protocol done five years earlier. The bill was passed by the committee, and amendments printed on January 13.

On January 13, the board's executive officer was contacted by the Assembly Appropriations consultant, to identify the potential fiscal impact of AB 977, and was alerted that AB 977 was a likely candidate for suspense. After January 14, there was no further update from the Appropriations Committee.

Meanwhile, on January 20 and 21, 2010, the January Board Meeting took place. The board also held a Legislation and Regulation Committee meeting at the end of the day on January 20. As one piece of business, the committee reviewed the January 6 version of the bill.

The board staff who prepare meeting materials for the board inadvertently failed to provide the January 13 version of the bill which likely appeared in print as the packet materials were being compiled.

This oversight was repeated during the Legislation and Regulation Committee report during the January 21 Board Meeting. During the Board Meeting on January 21, the board voted to support the January 6 version of the bill, unaware that AB 977 had been more recently amended. Moreover, because the bill had been targeted for suspense, the board's staff thought the bill would die on the suspense file and focused its attention during the meeting to other pressing regulation issues.

Near the end of the January, the board learned that the bill had been passed by the Assembly Appropriations Committee on January 21 while the Board Meeting was underway. Also at the end of January, via a media inquiry from the *Sacramento Bee* seeking clarification on a controversy that occurred during the floor vote, the board learned that AB 977 had been passed by the Assembly.

The current version of the bill (January 25, 2010), substantially scales back what the board initially proposed in October 2008. More recently, on February 23, the Department of Consumer Affairs took an oppose position on the bill because there has been no problem demonstrated with provisions in existing law regarding physician and pharmacist protocols, nor a shortage of locations for patients to receive flu vaccines.

The next meeting of the board is April 21 and 22, 2010, where the board will consider its position on AB 977.

Support
California Pharmacists Association
California Retailers Association

AB 1071 (Emmerson)

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 5: Achieve the board's mission and goals.

Outcome: An effective organization.

Overall Legislative Intent

Ensure the financial solvency of the board.

Consumer Protection Factors

1. Business and Professions Code Section 4001 establishes the California State Board of Pharmacy which is vested with the administration and enforcement of Chapter 9, Division 2 of the Business and Professions Code.
2. The board regulates almost 120,000 licensees.
3. In fiscal year 2008/09, the board received over 16,000 applications, issued almost 12,000 licenses, and renewed over 50,000 licenses.
4. In fiscal year 2008/09, the board initiated over 2,700 investigations, completed over 2,100 investigations, issued 965 citation and fines, referred 136 cases to the Office of the Attorney General, revoked 32 licenses, and formally disciplined an additional 34 licensees. It also collected $1.2 million in citations.

Background

Beginning in 2008, many of the board's fees were increased to their statutory maximum because board-authorized expenditures exceeded annual revenue. This was done via a regulation change pursuant to the Administrative Procedure Act. The statutory maximum fee levels were established in statute in 1987.

A review of the Consumer Price Index reveals that the cost of consumer goods has risen steadily since 1988 by approximately 85 percent; however, board fees have remained unchanged.

The board's licensee population has grown 20 percent over the last five years, yet the size of the board's staff remains relatively constant until July 2009.

Research and Approval Timeline

During each quarterly board meeting, board members are provided with a budget update including a fund condition report. Over the last few years, expenditures have exceeded revenue, resulting in a depletion of the board's fund. In 2008, a DCA fund condition report predicted a fund deficit by 2011/12.

In 2008 the board commissioned an independent fee audit to determine the unit cost to process applications and license renewals. The audit reaffirmed that the board's expenditures were exceeding its revenues resulting in the draining of the contingent fund balance. The audit concluded that the board's current fee structure was insufficient to maintain the legislatively mandated 12-month reserve requirement and noted that the board's fund condition will continue to drop until it eventually exhausts all reserves and a deficit would occur.

During the July 2008 Board Meeting, the board discussed the initiation of an independent fee audit as a precursor to pursuing a statutory change in the board's fees.

In October 2008, the board again publicly discussed the need to pursue a statutory fee increase and noted that a fee audit was underway.

During the January 2009 Board Meeting, the board heard a presentation by the independent auditor on the findings and recommendations of the audit. Also during this meeting, the board voted to increase licensing fees at an amount that would be sufficient to remedy the board's fund condition and fulfill fiduciary requirements for the next five years.

Bill History

The bill was introduced on February 27, 2009. As initially introduced, the bill only addressed the increase in board licensing and renewal fees. The bill was later amended on September 2, 2009 to include provisions to extend the sunset dates for various boards within the Department of Consumer Affairs. The bill was enrolled on September 17, 2009 and chaptered on October 11, 2009.

Summary of Concerns

No concerns were raised and no opposition was on file for this proposal.

SB 470 (Corbett)

Bill Originator

Pharmacy Foundation of California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy

Outcome: Improve the health and safety of Californians.

Goal 4: Provide relevant information to information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Overall Legislative Intent

Reduce medication errors.

Consumer Protection Factors

1. According to the Archives of Internal Medicine Report, in 2004, 34 Americans were being killed each day because of medication errors that occur in their home.
2. The Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.
3. Recommendation 2 from the SCR 49 Panel (see below) provides, "Require that the intended use of a medication be included on all prescriptions and require that the intended use of medications be included on medication labels/labeling unless disapproved by the prescriber or the patient."
4. Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

Background

In 2005, Senator Jackie Speier authored SCR 49 which called for the creation of an expert panel to 1) study the causes of medication errors in the community setting and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting. Over the course of one year, the panel met and heard

testimony from members of academia, consumer groups and various health professionals. The result of the panel's work was a comprehensive report summarizing medication errors and the outcomes of such errors as well as recommendations to mitigate errors.

A copy of the SCR 49 report can be found on the board's Web site.

Subsequent to the SCR 49 report, in 2007 Senator Corbett introduced SB 472, creating the California Patient Medication Safety Act of 2007 to standardize the prescription label and make it patient-centered. Specifically, this bill directed the board to develop a standardized patient-centered prescription label for medicine dispensed to California patients after January 1, 2011.

To facilitate implementation of the requirements contained within SB 472, the board held public meetings to elicit input from consumers as well as conducted individual consumer surveys. The board posted its survey document on its web site to allow for electronic submission, published the survey document in a statewide AARP newsletter, mailed the survey to various consumer groups, and attended and disseminated the surveys at various public events and health fairs statewide. Also, in conjunction with the Pharmacy Foundation of California, the board developed and deployed a radio survey of the public about prescription container labels.

A full report of the board's development of the regulation requirements for prescription container labels as directed by SB 472, including survey results, can be found on the board's Web site.

Research and Approval Timeline

During the July 2008 Board Meeting, the board heard a request from Steve Gray, PharmD, representing the Pharmacy Foundation of California. The Foundation requested that the board sponsor legislation to clarify a pharmacist's authorization within Business and Professions Code § 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. One of the Foundation's primary focuses is on the reduction of medication errors, and the Foundation believes that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient understanding and outcomes.

Consistent with the board's general process to consider legislative proposals, this issue was referred to the Legislation and Regulation Committee for discussion.

During the October 2008 Legislation and Regulation Committee Meeting, the committee discussed the proposal in detail. The proposal was consistent with the recommendations of the SCR 49 Medication Errors Panel. Testimony provided during the meeting included statements that a big problem is that

patients forget what their drugs are for after taking them home and storing them with other medications. Testimony also stated concerns with medication safety for patients in assisted living facilities, which are regulated by the California Department of Social Services. Comments noted that the providers of these facilities who assist seniors with their medications are low paid staff members, and that by adding purpose to the labels on prescription containers would assist patients in such care facilities from duplicate medication therapies and prevent errors. Minutes from this meeting are available at the board's Web site that describes the discussion and deliberation by the board. The committee voted to recommend sponsorship of a proposal to amend section 4076 to include the purpose of the medicine on the prescription label.

Subsequent to the committee meeting, during the October 2008 Board Meeting, the board discussed the issue, heard testimony from the public, deliberated and voted to pursue sponsorship of the proposal as recommended by committee.

A copy of board materials and minutes can be obtained from the board's Web site.

Bill History

After submission to Leg Counsel, the original language was expanded to amend Business and Professions Code section 4040. The bill was introduced on February 26, 2009, and was amended twice. The bill was enrolled on August 27, 2009, and chaptered October 11, 2009.

Summary of Issues

Throughout the process, the board had a broad base of consumer and industry support as detailed below.

Senator Corbett accepted amendments offered by the California Medical Association (CMA) whose original position was Support if Amended.

Senator Corbett accepted amendments offered by the California Retailers Association and National Association of Chain Drug Stores whose original position was Oppose Unless Amended.

Support

California Alliance for Retired Americans

California Medical Association

California Pan Ethnic Health Network

California Retailers Association

California Society of Health-Systems Pharmacists

Kaiser Permanente

National Association of Chain Drug Stores

Pharmacy Foundation of California

UCSF School of Pharmacy

Opposition
None on file

SB 819 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Ensure the continuity of care for patients requiring prescription medications.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC). The PIC is the pharmacist responsible for overall pharmacy operations, including ensuring adherence to pharmacy law.
3. Keep Pharmacy Law current and clear so practitioners know and can comply with legal requirements.

Background

The omnibus provisions included in SB 819 were categorized into four types of changes:

1. Omnibus provisions to correct erroneous code citations resulting from the recodification of Business and Professions Code section 4052 several years before.
2. General omnibus provisions.
3. Authorization to use mobile pharmacies in disaster response activities or during renovation or reconstruction of a damaged pharmacy.

4. Changes resulting from a comprehensive legal review by board staff and counsel on the legal requirements surrounding the pharmacist-in-charge and designated representative-in-charge.

Provisions Contained Within the Proposal

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following references in the Business and Professions Code and Health and Safety Code to §4052 required technical amendments.

The sections affected are:

§733 – Dispensing Prescription Drugs and Devices

§4027 – Skilled Nursing Facility; Intermediate Care Facility; Other Health Care Facilities

§4040 – Prescription; Content Requirements

§4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

§4060 – Controlled Substances – Prescription Required, Exceptions

§4076 – Prescription Container – Requirements for Labeling

§4111 – Restrictions on Prescriber Ownership

§4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner

H&SC §11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Provisions

The following provisions are a miscellaneous aggregation of general modifications to the identified code sections.

Amend §4059.5 - Who May Order Dangerous Drugs or Devices, Exceptions.

This section was amended to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Amend §4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

This section replaced the term “representative-in-charge” with the correct “designated representative-in-charge” as a result of changes in SB 1307 (Chapter 857, Statutes of 2006).

Amend §4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section was amended to clarify who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section was amended to authorize the board to inactivate a pharmacist license when a pharmacist who certifies completion of the required 30 units of continuing education as part of a renewal fails to provide proof of completion of these credits either when audited or when investigated by the board.

Amend §4301 – Unprofessional Conduct

This section was amended to reference the definition of a long-term care facility to the Health and Safety Code section 1418.

Amend H&SC 11165 – Controlled Substance Utilization Review and Evaluation System (CURES): Establishment; Operation; Funding; Reporting to Legislature

This section was amended to require that a clinic that dispenses Schedule III and Schedule IV controlled substances must report this information to the CURES system, consistent with the reporting requirements for pharmacies, hospitals, and others that dispense controlled drug to patients.

Use of Mobile Pharmacies

Amend §4062 Furnishing Dangerous Drugs During an Emergency

This section was amended to allow the use of a mobile pharmacy in the event of a declared natural disaster, if certain criteria are met.

Amend §4110 License Required, Temporary Permit Upon Transfer of Ownership

This section was amended to allow the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed, damaged or otherwise under repair.

Pharmacist-in-Charge and Designated Representative-in-Charge

In 2007 board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge as well that of a designated representative-in-charge. A designated representative-in-charge is the non-pharmacist who is specially licensed by the board to oversee operations in a drug wholesaler. As a result of this review, several changes were recommended including technical changes as well as refining the definitions of the pharmacist-in-charge and designated representative-in-charge, and clarifying the reporting requirements to the board when a change in either occurs.

Amend §4022.5 – Designated Representative; Designated Representative-in-Charge

This section was amended to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

Add §4036.5 – Pharmacist-in-Charge

This section was added to define the term "pharmacist-in-charge" as well as the responsibilities of a pharmacist serving as such.

Amend §4161 – Non-Resident Wholesaler; Requirements

This section was amended to clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043, but was needed here to provide clarity to non-resident wholesaler requirements.

Amend §4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action

This section was amended to specify that failure to meet notification requirements to the board about when a PIC quits serving as a PIC will constitute grounds for disciplinary action.

Amend §4329 – Non-pharmacists; Prohibited Acts

This section was amended to prohibit a non-pharmacist from acting as a supervisor or pharmacist-in-charge.

Amend §4330 – Proprietors; Prohibited Acts

This section was amended to specify that any pharmacy owner that subverts or intends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Research and Approval Timeline

These changes were approved by the board in 2007 and many were incorporated in SB 1779 (2008) as omnibus provisions. This bill was vetoed by the Governor at the end of the 2008 session for reasons unrelated to the contents of the bill.

At the October 2008 Board Meeting, the board voted to again pursue all of the omnibus provisions approved for sponsorship in 2008.

Bill History

This bill was introduced on March 10, 2009 and was amended nine times. The bill was enrolled on September 15, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill also contained provisions for several of the healing arts boards within the DCA. This board is unaware of any concerns with the board's provisions. As a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

SB 821 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Provide a safe and legal manner for Californians to dispose of used sharps.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC) and designated representative-in-charge (DRIC). The PIC is the pharmacist responsible for overall pharmacy operations including ensuring adherence to pharmacy law. The DRIC is a licensee responsible for overall operations of a wholesaler.
3. Provide for an efficient and quick method of communication to notify board-licensed facilities of alerts and other messages from the board.

Background

These proposals were identified over the course of 2008 and were brought to the board for consideration as legislative proposals in October 2008. Several proposals were identified from legal counsel advice to remedy questions on the interpretation of pharmacy law; however, two provisions had specific triggering events detailed below.

1. During the early months of 2008, five separate recalls of heparin were issued by for various manufacturers to remove potentially dangerous heparin from the marketplace. Heparin is a widely used drug in hospitals for anticoagulation therapy. By April 2008, tainted heparin had been

linked to 81 deaths in the US. Board staff sent out a series of e-mail alerts regarding the recalls. However, board staff, conducting specialized inspections of a sample of hospitals, discovered recalled heparin in 40 percent of hospitals initially inspected.

As a result, the board immediately began inspections of all 533 hospitals in the state to ensure that all recalled heparin was removed from patient care areas and had either been returned to the manufacturer or was properly quarantined. By the end of June 2009, the board identified 94 hospitals where recalled heparin had been found by the board at least two months following the last recall (18 percent of California's hospitals).

A recommendation resulting from this series of events was the need to develop a quick and efficient method to contact all board-licensed facilities. As a result, a provision was created that all board-licensed facilities need to join the board's subscriber alert system by July 1, 2010.

2. SB 1305 (Figueroa, Chapter 64, Statutes of 2006) prohibited any person after September 1, 2008 to knowingly place home-generated sharps in residential or commercial waste or recycle containers. This made disposal of used sharps a bit more complex, but pharmacies where not authorized to accept used sharps back from patients. The board drafted a new section to the Business and Professions Code (as section 4146) to allow pharmacies to accept back used sharps in appropriate containers from patients to ensure appropriate disposal and reduce a very serious public health risk.

<u>Provisions Contained Within Bill</u>

Add §4013 – Subscriber Alert

This section added a requirement that all board-licensed facilities must join the board's e-mail notification list. Such a requirement will allow the board to quickly disseminate information to board licensees at minimal cost. The board will also use this system to distribute its biannual newsletter.

Add §4146 – Disposal of Returned Sharps by a Pharmacy

This section was added to authorize a pharmacy to accept returned sharps containers from consumers for disposal.

Amend §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.

This section was amended to clarify about when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she has ceased to serve in such a capacity.

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

This section was amended to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the board.

Amend §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section was amended to clarify procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days.

Amend §4160 – Wholesaler Licenses

This section was amended to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Amend §4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked

This section was amended to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Research and Approval Timeline

At the October 2008 Board Meeting, the board voted to pursue these several new omnibus provisions, which were introduced in SB 821 in 2009.

Bill History

This bill was introduced on March 1, 2009 and was amended six times. The bill was enrolled on September 4, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill contains provisions for several of the healing arts boards within the DCA. We are unaware of any concerns in any of the board's provisions. As a provision in an omnibus bill, any opposition must be resolved or the provision will be removed from the bill.

2010 Legislation Sponsored by the Board of Pharmacy:

Omnibus Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

Keep pharmacy law current.

Background

The omnibus provisions for sponsorship in 2010 are categorized into two types of changes:

1. Amendments to update references to the California Department of Public Health and California Department of Health Care Services (formerly known as the Department of Health Services) and one amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California).
2. General omnibus provisions.

Provisions Contained Within Proposal

Effective July 1, 2007, pursuant to the California Public Health Act of 2006 (Chapter 241, Statutes of 2006), the Department of Health Services was split into two agencies: the Department of Public Health and the Department of Health Care Services. Several sections within the Business and Professions Code require amendment to correctly reference the appropriate agency as a result of this change.

The sections affected are:

§4017 – Authorized Officers of the Law

§4027 – Skilled Nursing Facilities – Intermediate Care Facilities – Other Health Care Facilities

§4028 – Licensed Hospital

§4037 – Pharmacy

§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations

§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

§4072 – Oral or Electronic Transmission of Prescriptions – Health Care Facility

§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

§4127.1 – License to Compound Injectable Sterile Drug Products Required

§4169 – Prohibited Acts

§4181 -- License Requirements; Policies and Procedures; Who May Dispense

§4191 -- Compliance with California Department of Public Health; Who May Dispense Drugs

§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring

§4426 – California Department of Health Care Services to Study Reimbursement Rates

General Omnibus Provisions

Amend Section §4196(e) – Veterinary Food Animal Drug Retailer; Designated Representative in Charge

At its October 2008 Board Meeting, the board approved provisions to be included in the 2009 Omnibus Bill (Senate Business, Professions and Economic Development Committee, SB 821). However, the chaptered version of SB 821 contained a drafting error and the section requires correction.

§4200.1 – Retaking Examinations; Limits; Requirements (North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Examination (CPJE) Four-time Failure)

Since 1998, the Business and Professions Code has required that pharmacist applicants who fail either the CPJE four times or the NAPLEX four times must take 16 semester hours in a school of pharmacy before retaking the examination failed four times.

In October 2008, the board approved a proposal to eliminate a sunset date of January 1, 2010 within §4200.1 that had been extended several times but not repealed. Though the Senate Business, Professions and Economic Development Committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. As a result, the provisions in §4200.1 were repealed.

This amendment to restore §4200.1 has been proposed to the Senate BP&ED Committee for inclusion in the 2010 Omnibus bill.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to pursue the omnibus changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

We are unaware of any concerns with the board's provisions, as the provision has been law for 12 years. However, as a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

Consumer Protection Enforcement Initiative – Board of Pharmacy Specific Provisions

Bill Originator

Department of Consumer Affairs

California State Board of Pharmacy

Strategic Plan Reference

Goal 1: Exercise oversight on all pharmacy activities

Outcome: Improve consumer protection.

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Improved consumer protection

Consumer Protection Factors

1. Reduce time to complete investigations.
2. Ensure licensees providing pharmacy related services to Californians do not have a revoked license.

Background

Over the prior year, the Department of Consumer Affairs has initiated a number of initiatives aimed at strengthening the enforcement activities of the health care boards. These changes were initiated following problems identified at the Board of Registered Nursing by the *Los Angeles Times*.

The first major change was prioritization of fingerprinting of all licensees. Fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. It also enables boards to obtain “subsequent” arrest and conviction information if a licensee is arrested or convicted in California.

The second major problem reported in the *LA Times* was the time it was taking the Board of Registered Nursing to investigate complaints and complete enforcement actions, which exceeded 3.5 years. The BRN uses the department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators there has been a problem. This delayed investigations. Additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

The DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards.

In addition to the efforts of the department, board staff developed provisions to enhance the board's enforcement activities.

Provisions Contained Within Proposal

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

Amend this section to specify that upon request of a board inspector, an owner, corporation officer or manager shall provide requested records within 72 hours unless an extension by the board is granted.

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

Amend this section to clarify that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft of drugs or impairment. The amendment would also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

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

Amend this section to require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist-related services to Californians.

Research and Approval Timeline

At the October 2009 Board Meeting, the board voted to pursue these provisions and seek that they are included in the department's enforcement enhancement proposals.

During the January 2010 Board Meeting, the board reaffirmed sponsorship of these proposed changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

The board has requested that these provisions be included in the DCA health care boards' enforcement program enhancement legislation.

Reverse Distributor Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Specify the operations of reverse distributors, and differentiate these duties from the scope of practice authorized to a California licensed integrated waste hauler.

Consumer Protection Factors

1. Provide a safe and effective method for consumers to dispose of unwanted medicine, besides flushing it down the toilet or throwing it into the trash.

Background

For over two years, the board has been working with state and some local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. In February 2009, the California Integrated Waste Management Board finalized these guidelines, which were developed pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007). The guidelines provide components for three types of drug take back programs: 1) in pharmacies or other stationary locations, 2) at one-time or periodic community events, and 3) return via mail back to a licensed integrated waste hauler.

In 2008 while working with the California Integrated Waste Management Board and the California Department of Public Health on guidelines regarding what types of businesses could pick up aggregated pharmaceutical waste returned by patients, there appeared potential clarity issues about what a reverse drug distributor (licensed by the Board of Pharmacy) and a licensed integrated waste hauler (licensed by the California Department of Public Health) could do. The board began working on provisions to provide clearer delineation for what a reverse distributor could do, and when a reverse distributer desired to perform the duties of an integrated waste hauler, the company would need to be licensed by the CDPH as well.

The California Board of Pharmacy recently disciplined two pharmacies and the pharmacists involved in fraud involving a reverse distributor who submitted claims on behalf of the pharmacies for refunds for the return of drugs to manufacturers where the pharmacies claimed they were returning the drugs from their unused inventory. However, the reverse distributor had actually obtained the drugs from other sources.

Provisions Contained Within Proposal

Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine returned by patients, and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler (it is already classified in the Health and Safety Code as aggregated pharmaceutical waste). A reverse distributor may handle drugs that have never been dispensed by a pharmacy. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

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

Specifies minimum requirements for reverse distributors to document the return of drugs from a pharmacy to include the quantity or weight of the drugs being returned, the date returned and the company to which the drugs were provided. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to provide drugs returned from patients in a take back program to a licensed integrated waste hauler. The provisions will need additional refinement to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. This provision was not previously considered by the board.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to sponsor a bill containing to specify the operations of reverse distributors.

Bill History

These provisions are not yet contained in legislation, and will likely not be pursued until 2011.

Summary of Issues

The board did not seek a sponsor for these provisions for a 2010 introduction.

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January 21, 2010

Ms. Virginia Herold, Executive Officer
Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

RECEIVED BY CALIF
BOARD OF PHARMACY
2010 JAN 26 AM 10: 48

Dear Ms. Herold:

The Assembly Business and Professions Committee plans to examine how the Board of Pharmacy develops and sponsors legislation. Specifically, the committee would like the Board to detail the genesis and approval process for all 2009-2010 Board-sponsored bills.

In this report, please include the originator of the bill, detail the criteria for sponsorship, including consideration of consumer protection factors, the research and approval timeline, coordination with the Department of Consumer Affairs, and a summary of any concerns that developed during the legislative process. The Committee is concerned that legislative efforts of dubious merit to consumers is taking priority over licensing and enforcement; please explain how consumer protection drives the Board's activities.

We look forward to receiving your report by the end of February. If you have any questions, please contact Sarah Weaver, at sarah.huchel@asm.ca.gov, or (916) 319-3301.

Sincerely,

Mary Hayashi

Cc: Laura Zuniga, Deputy Secretary, Legislation, State and Consumer Services Agency
Jennifer Kent, Deputy Legislative Secretary, Office of the Governor

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

January 27, 2010

The Honorable Mary Hayashi
Chair, Assembly Committee on
Business and Professions
State Capitol, Room 3013
Sacramento, CA 95816

Dear Assemblymember Hayashi:

I have received your letter of January 21, 2010, requesting that the board provide specific information about the board's sponsored legislation for 2009 and 2010.

I will be pleased to compile the information for you, and will submit it to you before the end of February as you have specified.

Rest assured that the board takes its consumer protection mandate seriously, and its legislative efforts reflect that mandate. We are confident once you review the material that will be submitted, all your concerns will be assuaged.

In the interim and before this information is provided to you, should you have questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Brian Stiger, Director, Department of Consumer Affairs

AMENDED IN ASSEMBLY JANUARY 25, 2010

AMENDED IN ASSEMBLY JANUARY 13, 2010

AMENDED IN ASSEMBLY JANUARY 6, 2010

AMENDED IN ASSEMBLY JANUARY 4, 2010

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 977

Introduced by Assembly Member Skinner

February 26, 2009

An act to add and repeal Section 4052.8 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 977, as amended, Skinner. Pharmacists: immunization protocols ~~with physicians~~.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime. Existing law, among other things, authorizes a pharmacist to administer immunizations pursuant to a protocol with a prescriber.

This bill, until January 1, 2015, would additionally authorize a pharmacist~~, in consultation with a physician and surgeon,~~ to initiate and administer influenza immunizations to any person 18 years of age or older pursuant to standardized protocols developed and approved by the Medical Board of California in consultation with public health

officers. The bill would, with respect to the development and approval of those standardized protocols, authorize the Medical Board of California to consult with the board. The bill would require a pharmacist, prior to initiating and administering those immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist initiating and administering those immunizations to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require a pharmacist, at the time of administration of that immunization, to provide the patient with a Vaccine Information Statement and to provide the patient and the patient's physician with documentation of administration of the immunization. The bill would also require a pharmacist administering that immunization to maintain a specified immunization record, provide documentation of administration to the appropriate immunization registry, report any adverse event and ensure proper storage and handling of vaccines. The bill would authorize a pharmacist initiating and administering vaccines under these provisions to initiate and administer epinephrine for severe allergic reactions.

This bill would require the board and the Medical Board of California to complete an evaluation of influenza immunizations initiated and administered under the standardized protocols authorized by the bill, and would require the board to report to the appropriate policy committees of the Legislature by January 1, 2014.

Because this bill would create new requirements under the Pharmacy Law, the violation of which would be a crime, it 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 Legislature finds and declares all of the
2 following:

(a) Vaccines are a safe, effective, and efficient means to prevent sickness and death from infectious diseases as reported by the United States Department of Health and Human Services (HHS).

(b) The federal Centers for Disease Control and Prevention report that 220,000,000 persons should get the influenza vaccination annually, however, fewer than 100,000,000 do.

(c) According to the California Health Care Foundation, 6,600,000 Californians are uninsured and may not have access to immunizations.

(d) Pharmacists represent the third largest health professional group in the United States and are on the front line of preventative care.

(e) Pharmacists are trained to screen, administer, and properly deal with any adverse events that may arise from vaccines.

(f) Primary care physicians play an integral role in preventative health care for Californians. This act will provide an adjunct to that preventative health care.

(g) Therefore, in order to achieve greater access to immunization and to protect Californians, it is the intent of the Legislature to provide greater access to lifesaving vaccinations and to ensure that pharmacists may administer influenza vaccinations.

SEC. 2. Section 4052.8 is added to the Business and Professions Code, to read:

4052.8. (a) A pharmacist may~~, in consultation with a physician and surgeon,~~ initiate and administer influenza immunizations, pursuant to standardized protocols developed and approved by the Medical Board of California in consultation with public health officers, to any person 18 years of age or older. With respect to the development and approval of those standardized protocols, the Medical Board of California may consult with the board. The standardized protocols shall be consistent with protocols developed by the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

(b) Prior to initiating and administering immunizations, a pharmacist shall complete the American Pharmacists Association's Pharmacy-Based Immunization Delivery Certificate Training Program or another pharmacy-based immunization training certificate program endorsed by the federal Centers for Disease Control and Prevention or the Accreditation Council for Pharmaceutical Education.

(c) (1) A pharmacist initiating and administering any immunization pursuant to this section shall also complete three hours of immunization-related continuing education coursework annually.

(2) If a pharmacist fails to satisfy this requirement, he or she shall, in addition to any other applicable disciplinary action, retake the training identified in subdivision (b) and also complete the three hours of immunization-related continuing education coursework described in paragraph (1) prior to initiating and administering any further immunizations.

(3) The three hours of immunization-related continuing education may be applied toward the continuing education requirement described in Section 4231.

(d) A pharmacist initiating and administering any immunization pursuant to this section shall at all times be certified in basic life support.

(e) At the time of administration of an immunization, the pharmacist shall do all of the following:

(1) Provide the patient or the patient's agent with the appropriate Vaccine Information Statement, produced by the federal Centers for Disease Control and Prevention, for each immunization administered.

(2) Provide documentation of administration of the immunization to the patient and the patient's physician or primary care provider, if one can be identified.

(3) Provide documentation of administration of the immunization to the appropriate immunization registry.

(f) The pharmacist shall maintain an immunization administration record, which shall include, but not be limited to, the name of the vaccine, the expiration date, the date of administration, the manufacturer and lot number, the administration site and route, the Vaccine Information Statement date, and the name and title of the person administering, for 10 years from the date of administration.

(g) Any pharmacist initiating and administering vaccines may initiate and administer epinephrine by injection for severe allergic reactions.

(h) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the United States Department of Health and Human Services.

(i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible for ensuring that proper vaccine temperatures are maintained during subsequent storage and handling to preserve the potency of the vaccine.

(j) The board and the Medical Board of California shall evaluate the effectiveness of the initiation and administration of immunizations pursuant to this section, and the board shall report to the appropriate policy committees of the Legislature by January 1, 2014.

(k) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

~~SEC. 4.~~

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

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AMENDED IN SENATE APRIL 5, 2010

SENATE BILL No. 1489

Introduced by Committee on Business, Professions and Economic Development (Senators Negrete McLeod (Chair), Aanestad, Calderon, Correa, Florez, Oropeza, Walters, Wyland, and Yee)

March 11, 2010

An act to amend Sections 2065, 2096, 2102, 2103, 2177, 2184, ~~2397~~, 2570.19, 3025.1, 3046, 3057.5, 3147, 3147.6, 3147.7, 4017, 4028, 4037, 4052.3, 4059, 4072, 4101, 4119, 4127.1, 4169, 4181, 4191, 4196, 4425, 4426, 4980.40.5, 4980.43, 4980.80, 4982.25, 4984.8, 4989.54, 4990.02, 4990.12, 4990.18, 4990.22, 4990.30, 4990.38, 4992.36, 4996.17, 4996.23, 4999.46, 4999.58, and 4999.90 of, to add Section 4200.1 to, to add and repeal Sections 4999.57 and 4999.59 of, to repeal Sections *2026,* 4980.07, 4982.2, and 4984.6 of, and to repeal Article 3 (commencing with Section 4994) of Chapter 14 of Division 2 of, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1489, as amended, Committee on Business, Professions and Economic Development. Healing arts.

(1) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California ~~and for the licensure and regulation of podiatrists by the California Board of Podiatric Medicine within the Medical Board of California~~. Existing ~~law exempts a licensee of either of those boards from liability for civil damages for acts or omissions by the licensee in rendering specified emergency care and for injury or death caused in an emergency situation occurring in the licensee's office or a hospital on account of a failure to inform a patient of the possible consequences~~

~~of a medical procedure, as specified. Existing law prohibits construing these provisions to authorize a podiatrist to act beyond certain scope of practice limitations.~~

~~This bill would delete that prohibition.~~

~~Existing~~

law requires an applicant for a physician's and surgeon's certificate whose professional instruction was acquired in a country other than the United States or Canada to provide evidence satisfactory to the board of, among other things, satisfactory completion of at least one year of specified postgraduate training.

This bill would require the applicant to instead complete at least 2 years of that postgraduate training.

Existing law requires an applicant for a physician's and surgeon's certificate to obtain a passing score on the written examination designated by the board and makes passing scores on a written examination valid for 10 years from the month of the examination for purposes of qualification for a license. Existing law authorizes the board to extend this period of validity for good cause or for time spent in a postgraduate training program.

This bill would limit this 10-year period of validity to passing scores obtained on Step 3 of the United States Medical Licensing Examination and would also authorize the board to extend that period for applicants who hold a valid, unlimited license as a physician and surgeon in another state or a Canadian province and have actively practiced medicine in that state or province.

(2) Existing law, the Optometry Practice Act, provides for the licensure and regulation of optometrists by the State Board of Optometry. Existing law authorizes the renewal of an expired license within 3 years after its expiration if the licensee files an application for renewal and pays all accrued and unpaid renewal fees and the delinquency fee prescribed by the board.

This bill would also require the licensee to submit proof of completion of the required hours of continuing education for the last 2 years.

Existing law authorizes the restoration of a license that is not renewed within 3 years after its expiration if the holder of the expired license, among other requirements, passes the clinical portion of the regular examination of applicants, or other clinical examination approved by the board, and pays a restoration fee equal to the renewal fee in effect on the last regular renewal date for licenses.

This bill would instead require the holder of the expired license to take the National Board of Examiners in Optometry's Clinical Skills examination, or other clinical examination approved by the board, and to also pay any delinquency fees prescribed by the board.

Existing law alternatively authorizes the restoration of a license that is not renewed within 3 years after its expiration if the person provides proof that he or she holds an active license from another state, files an application for renewal, and pays the accrued and unpaid renewal fees and the delinquency fee prescribed by the board.

This bill would also require the person to submit proof of completion of the required hours of continuing education for the last 2 years and take and satisfactorily pass the board's jurisprudence examination. The bill would also require that the person not have committed specified crimes or acts constituting grounds for licensure denial.

(3) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and requires an applicant for a license to pass a national licensure examination and the board's jurisprudence examination. Existing law prohibits boards in the Department of Consumer Affairs from restricting an applicant who failed a licensure examination from taking the examination again, except as specified.

This bill would authorize an applicant for a pharmacist license to take the licensure examination and the jurisprudence examination 4 times each. The bill would also authorize the applicant to take those examinations 4 additional times each if additional pharmacy coursework is completed, as specified.

(4) Existing law provides for the licensure and regulation of marriage and family therapists, licensed clinical social workers, educational psychologists, and professional clinical counselors by the Board of Behavioral Sciences. Existing law authorizes a licensed marriage and family therapist, licensed clinical social worker, or licensed educational psychologist whose license has been revoked, suspended, or placed on probation to petition the board for reinstatement or modification of the penalty, as specified. Existing law also authorizes the board to deny an application or suspend or revoke those licenses due to the revocation, suspension, or restriction by the board of a license to practice as a clinical social worker, marriage and family therapist, or educational psychologist.

This bill would make those provisions apply with respect to licensed professional clinical counseling, as specified.

Existing law requires an applicant applying for a marriage and family therapist license to complete a minimum of 3,000 hours of experience during a period of at least 104 weeks. Existing law requires that this experience consist of at least 500 hours of experience in diagnosing and treating couples, families, and children, and requires that an applicant be credited with 2 hours of experience for each hour of therapy provided for the first 150 hours of treating couples and families in conjoint therapy.

This bill would instead require that an applicant receive that 2-hour credit for up to 150 hours of treating couples and families in conjoint therapy.

Existing law requires an applicant for a professional clinical counselor license to complete a minimum of 3,000 hours of clinical mental health experience under the supervision of an approved supervisor and prohibits a supervisor from supervising more than 2 interns.

This bill would prohibit the board from crediting an applicant for experience obtained under the supervision of a spouse or relative by blood or marriage, or a person with whom the applicant has had or currently has a personal, professional, or business relationship that undermines the authority or effectiveness of the supervision. The bill would also delete the provision prohibiting a supervisor from supervising more than 2 interns.

Existing law requires an intern to receive an average of at least one hour of direct supervisor contact for every 10 hours of client contact in each setting and authorizes an intern working in a governmental entity, a school, college, or university, or a nonprofit and charitable institution to obtain up to 30 hours of the required weekly direct supervisor contract via two-way, real time videoconferencing.

This bill would delete that 30-hour limit and would require an intern to receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of face-to-face psychotherapy, as defined, is performed in each setting in which experience is obtained.

Existing law imposes specified requirements with respect to persons who apply for a professional clinical counselor license between January 1, 2011, and December 31, 2013, inclusive. With respect to those applicants, existing law authorizes the board to accept experience gained outside of California if it is substantially equivalent to that required by the Licensed Professional Clinical Counselor Act and if the applicant has gained a minimum of 250 hours of supervised clinical experience

in direct counseling in California while registered as an intern with the board.

This bill would eliminate that 250-hour requirement with respect to persons with a counseling license in another jurisdiction, as specified, who have held that license for at least 2 years immediately prior to applying with the board.

Existing law authorizes the board to refuse to issue or suspend or revoke a professional clinical counselor license or intern registration if the licensee or registrant has been guilty of unprofessional conduct, as specified.

This bill would specify that unprofessional conduct includes (1) engaging in conduct that subverts a licensing examination, (2) revocation, suspension, or restriction by the board of a license to practice as a clinical social worker, educational psychologist, or marriage and family therapist, and (3) conduct in the supervision of an associate clinical social worker that violates the profession's governing professional clinical counseling or regulations of the board.

The bill would make other technical, nonsubstantive changes in various provisions governing the healing arts and would delete certain obsolete and duplicative language.

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 2026 of the Business and Professions*
2 *Code is repealed.*
3 ~~2026. The California Research Bureau (CRB) of the California~~
4 ~~State Library shall study the role of public disclosure in the public~~
5 ~~protection mandate of the board. The ensuing CRB report shall~~
6 ~~include, but not be limited to, considering whether the public is~~
7 ~~adequately informed about physician misconduct by the current~~
8 ~~laws and regulations providing for disclosure. The study shall~~
9 ~~present policy options for improving public access. The board shall~~
10 ~~work cooperatively with the CRB, providing cost-free access and~~
11 ~~reproduction assistance to the board's records while protecting the~~
12 ~~identity and privacy of all persons involved in any complaint. The~~
13 ~~provision of confidential data, information, and case files by the~~
14 ~~board to the CRB shall not constitute a waiver of any exemption~~
15 ~~from disclosure or discovery or of any confidentiality protection~~

~~or privilege otherwise provided by law that is applicable to the data, information, or case files. Data will be presented in aggregate categories. This study shall be commenced as soon as possible and a report to the Legislature completed no later than July 1, 2008.~~

~~SECTION 1.~~

SEC. 2. Section 2065 of the Business and Professions Code is amended to read:

2065. Unless otherwise provided by law, no postgraduate trainee, intern, resident, postdoctoral fellow, or instructor may engage in the practice of medicine, or receive compensation therefor, or offer to engage in the practice of medicine unless he or she holds a valid, unrevoked, and unsuspended physician's and surgeon's certificate issued by the board. However, a graduate of an approved medical school, who is registered with the board and who is enrolled in a postgraduate training program approved by the board, may engage in the practice of medicine whenever and wherever required as a part of the program under the following conditions:

(a) A graduate enrolled in an approved first-year postgraduate training program may so engage in the practice of medicine for a period not to exceed one year whenever and wherever required as a part of the training program, and may receive compensation for that practice.

(b) A graduate who has completed the first year of postgraduate training may, in an approved residency or fellowship, engage in the practice of medicine whenever and wherever required as part of that residency or fellowship, and may receive compensation for that practice. The resident or fellow shall qualify for, take, and pass the next succeeding written examination for licensure, or shall qualify for and receive a physician's and surgeon's certificate by one of the other methods specified in this chapter. If the resident or fellow fails to receive a license to practice medicine under this chapter within one year from the commencement of the residency or fellowship or if the board denies his or her application for licensure, all privileges and exemptions under this section shall automatically cease.

~~SEC. 2.~~

SEC. 3. Section 2096 of the Business and Professions Code is amended to read:

2096. (a) In addition to other requirements of this chapter, before a physician's and surgeon's license may be issued, each applicant, including an applicant applying pursuant to Article 5 (commencing with Section 2100), except as provided in subdivision (b), shall show by evidence satisfactory to the board that he or she has satisfactorily completed at least one year of postgraduate training.

(b) An applicant applying pursuant to Section 2102 shall show by evidence satisfactory to the board that he or she has satisfactorily completed at least two years of postgraduate training.

(c) The postgraduate training required by this section shall include at least four months of general medicine and shall be obtained in a postgraduate training program approved by the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada (RCPSC).

(d) The amendments made to this section at the 1987 portion of the 1987–88 session of the Legislature shall not apply to applicants who completed their one year of postgraduate training on or before July 1, 1990.

~~SEC. 3.~~

SEC. 4. Section 2102 of the Business and Professions Code is amended to read:

2102. An applicant whose professional instruction was acquired in a country other than the United States or Canada shall provide evidence satisfactory to the board of compliance with the following requirements to be issued a physician's and surgeon's certificate:

(a) Completion in a medical school or schools of a resident course of professional instruction equivalent to that required by Section 2089 and issuance to the applicant of a document acceptable to the board that shows final and successful completion of the course. However, nothing in this section shall be construed to require the board to evaluate for equivalency any coursework obtained at a medical school disapproved by the board pursuant to this section.

(b) Certification by the Educational Commission for Foreign Medical Graduates, or its equivalent, as determined by the board. This subdivision shall apply to all applicants who are subject to this section and who have not taken and passed the written examination specified in subdivision (d) prior to June 1, 1986.

(c) Satisfactory completion of the postgraduate training required under subdivision (b) of Section 2096. An applicant shall be required to have substantially completed the professional instruction required in subdivision (a) and shall be required to make application to the board and have passed steps 1 and 2 of the written examination relating to biomedical and clinical sciences prior to commencing any postgraduate training in this state. In its discretion, the board may authorize an applicant who is deficient in any education or clinical instruction required by Sections 2089 and 2089.5 to make up any deficiencies as a part of his or her postgraduate training program, but that remedial training shall be in addition to the postgraduate training required for licensure.

(d) Passage of the written examination as provided under Article 9 (commencing with Section 2170). An applicant shall be required to meet the requirements specified in subdivision (b) prior to being admitted to the written examination required by this subdivision.

(e) Nothing in this section prohibits the board from disapproving a foreign medical school or from denying an application if, in the opinion of the board, the professional instruction provided by the medical school or the instruction received by the applicant is not equivalent to that required in Article 4 (commencing with Section 2080).

~~SEC. 4.~~

SEC. 5. Section 2103 of the Business and Professions Code is amended to read:

2103. An applicant who is a citizen of the United States shall be eligible for a physician's and surgeon's certificate if he or she has completed the following requirements:

(a) Submitted official evidence satisfactory to the board of completion of a resident course or professional instruction equivalent to that required in Section 2089 in a medical school located outside the United States or Canada. However, nothing in this section shall be construed to require the board to evaluate for equivalency any coursework obtained at a medical school disapproved by the board pursuant to Article 4 (commencing with Section 2080).

(b) Submitted official evidence satisfactory to the board of completion of all formal requirements of the medical school for graduation, except the applicant shall not be required to have completed an internship or social service or be admitted or licensed

to practice medicine in the country in which the professional instruction was completed.

(c) Attained a score satisfactory to an approved medical school on a qualifying examination acceptable to the board.

(d) Successfully completed one academic year of supervised clinical training in a program approved by the board pursuant to Section 2104. The board shall also recognize as compliance with this subdivision the successful completion of a one-year supervised clinical medical internship operated by a medical school pursuant to Chapter 85 of the Statutes of 1972 and as amended by Chapter 888 of the Statutes of 1973 as the equivalent of the year of supervised clinical training required by this section.

(1) Training received in the academic year of supervised clinical training approved pursuant to Section 2104 shall be considered as part of the total academic curriculum for purposes of meeting the requirements of Sections 2089 and 2089.5.

(2) An applicant who has passed the basic science and English language examinations required for certification by the Educational Commission for Foreign Medical Graduates may present evidence of those passing scores along with a certificate of completion of one academic year of supervised clinical training in a program approved by the board pursuant to Section 2104 in satisfaction of the formal certification requirements of subdivision (b) of Section 2102.

(e) Satisfactorily completed the postgraduate training required under Section 2096.

(f) Passed the written examination required for certification as a physician and surgeon under this chapter.

~~SEC. 5.~~

SEC. 6. Section 2177 of the Business and Professions Code is amended to read:

2177. (a) A passing score is required for an entire examination or for each part of an examination, as established by resolution of the board.

(b) Applicants may elect to take the written examinations conducted or accepted by the board in separate parts.

(c) (1) An applicant shall have obtained a passing score on Step 3 of the United States Medical Licensing Examination within not more than four attempts in order to be eligible for a physician's and surgeon's certificate.

(2) Notwithstanding paragraph (1), an applicant who obtains a passing score on Step 3 of the United States Medical Licensing Examination in more than four attempts and who meets the requirements of Section 2135.5 shall be eligible to be considered for issuance of a physician's and surgeon's certificate.

~~SEC. 6.~~

SEC. 7. Section 2184 of the Business and Professions Code is amended to read:

2184. (a) Each applicant shall obtain on the written examination a passing score, established by the board pursuant to Section 2177.

(b) (1) Passing scores on Step 3 of the United States Medical Licensing Examination shall be valid for a period of 10 years from the month of the examination for purposes of qualification for licensure in California.

(2) The period of validity provided for in paragraph (1) may be extended by the board for any of the following:

(A) For good cause.

(B) For time spent in a postgraduate training program, including, but not limited to, residency training, fellowship training, remedial or refresher training, or other training that is intended to maintain or improve medical skills.

(C) For an applicant who holds a valid, unlimited license as a physician and surgeon in another state or a Canadian province and has actively practiced medicine in that state or province.

(3) Upon expiration of the 10-year period plus any extension granted by the board under paragraph (2), the applicant shall pass the Special Purpose Examination of the Federation of State Medical Boards or a clinical competency written examination determined by the board to be equivalent.

~~SEC. 7. Section 2397 of the Business and Professions Code is amended to read:~~

~~2397. (a) A licensee shall not be liable for civil damages for injury or death caused in an emergency situation occurring in the licensee's office or in a hospital on account of a failure to inform a patient of the possible consequences of a medical procedure where the failure to inform is caused by any of the following:~~

~~(1) The patient was unconscious.~~

~~(2) The medical procedure was undertaken without the consent of the patient because the licensee reasonably believed that a~~

~~medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient.~~

~~(3) A medical procedure was performed on a person legally incapable of giving consent, and the licensee reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.~~

~~(b) This section is applicable only to actions for damages for injuries or death arising because of a licensee's failure to inform, and not to actions for damages arising because of a licensee's negligence in rendering or failing to render treatment.~~

~~(c) As used in this section:~~

~~(1) "Hospital" means a licensed general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.~~

~~(2) "Emergency situation occurring in the licensee's office" means a situation occurring in an office, other than a hospital, used by a licensee for the examination or treatment of patients, requiring immediate services for alleviation of severe pain, or immediate diagnosis and treatment of unforeseeable medical conditions, which, if not immediately diagnosed and treated, would lead to serious disability or death.~~

~~(3) "Emergency situation occurring in a hospital" means a situation occurring in a hospital, whether or not it occurs in an emergency room, requiring immediate services for alleviation of severe pain, or immediate diagnosis and treatment of unforeseeable medical conditions, which, if not immediately diagnosed and treated, would lead to serious disability or death.~~

SEC. 8. Section 2570.19 of the Business and Professions Code is amended to read:

2570.19. (a) There is hereby created a California Board of Occupational Therapy, hereafter referred to as the board. The board shall enforce and administer this chapter.

(b) The members of the board shall consist of the following:

(1) Three occupational therapists who shall have practiced occupational therapy for five years.

(2) One occupational therapy assistant who shall have assisted in the practice of occupational therapy for five years.

(3) Three public members who shall not be licentiates of the board or of any board referred to in Section 1000 or 3600.

(c) The Governor shall appoint the three occupational therapists and one occupational therapy assistant to be members of the board. The Governor, the Senate Committee on Rules, and the Speaker of the Assembly shall each appoint a public member. Not more than one member of the board shall be appointed from the full-time faculty of any university, college, or other educational institution.

(d) All members shall be residents of California at the time of their appointment. The occupational therapist and occupational therapy assistant members shall have been engaged in rendering occupational therapy services to the public, teaching, or research in occupational therapy for at least five years preceding their appointments.

(e) The public members may not be or have ever been occupational therapists or occupational therapy assistants or in training to become occupational therapists or occupational therapy assistants. The public members may not be related to, or have a household member who is, an occupational therapist or an occupational therapy assistant, and may not have had, within two years of the appointment, a substantial financial interest in a person regulated by the board.

(f) The Governor shall appoint two board members for a term of one year, two board members for a term of two years, and one board member for a term of three years. Appointments made thereafter shall be for four-year terms, but no person shall be appointed to serve more than two consecutive terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the first appointed members who shall serve through the last calendar day of the year in which they are appointed, before commencing the terms prescribed by this section. Vacancies shall be filled by appointment for the unexpired term. The board shall annually elect one of its members as president.

(g) The board shall meet and hold at least one regular meeting annually in the Cities of Sacramento, Los Angeles, and San Francisco. The board may convene from time to time until its business is concluded. Special meetings of the board may be held at any time and place designated by the board.

(h) Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act (Article 9

(commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(i) Members of the board shall receive no compensation for their services, but shall be entitled to reasonable travel and other expenses incurred in the execution of their powers and duties in accordance with Section 103.

(j) The appointing power shall have the power to remove any member of the board from office for neglect of any duty imposed by state law, for incompetency, or for unprofessional or dishonorable conduct.

(k) This section shall become inoperative on July 1, 2013, and, as of January 1, 2014, is repealed, unless a later enacted statute that is enacted before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 9. Section 3025.1 of the Business and Professions Code is amended to read:

3025.1. The board may adopt rules and regulations that are, in its judgment, reasonable and necessary to ensure that optometrists have the knowledge to adequately protect the public health and safety by establishing educational requirements for admission to the examinations for licensure.

SEC. 10. Section 3046 of the Business and Professions Code is amended to read:

3046. In order to obtain a license to practice optometry in California, an applicant shall have graduated from an accredited school of optometry, passed the required examinations for licensure, and not have met any of the grounds for denial established in Section 480. The proceedings under this section shall be in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 11. Section 3057.5 of the Business and Professions Code is amended to read:

3057.5. Notwithstanding any other provision of this chapter, the board shall permit a person who meets all of the following requirements to take the examinations for a certificate of registration as an optometrist:

(a) Is over the age of 18 years.

(b) Is not subject to denial of a certificate under Section 480.

(c) Has a degree as a doctor of optometry issued by a university located outside of the United States.

SEC. 12. Section 3147 of the Business and Professions Code is amended to read:

3147. Except as otherwise provided by Section 114, an expired license may be renewed at any time within three years after its expiration by filing an application for renewal on a form prescribed by the board, paying all accrued and unpaid renewal fees, paying any delinquency fees prescribed by the board, and submitting proof of completion of the required number of hours of continuing education for the last two years, as prescribed by the board pursuant to Section 3159. Renewal under this section shall be effective on the date on which all of those requirements are satisfied. If so renewed, the license shall continue as provided in Sections 3146 and 3147.5.

SEC. 13. Section 3147.6 of the Business and Professions Code is amended to read:

3147.6. Except as otherwise provided by Section 114, a license that is not renewed within three years after its expiration may be restored thereafter, if no fact, circumstance, or condition exists that, if the license were restored, would justify its revocation or suspension, provided all of the following conditions are met:

(a) The holder of the expired license is not subject to denial of a license under Section 480.

(b) The holder of the expired license applies in writing for its restoration on a form prescribed by the board.

(c) The holder of the expired license pays the fee or fees as would be required of him or her if he or she were then applying for a license for the first time.

(d) The holder of the expired license satisfactorily passes both of the following examinations:

(1) The National Board of Examiners in Optometry's Clinical Skills examination or other clinical examination approved by the board.

(2) The board's jurisprudence examination.

(e) After taking and satisfactorily passing the examinations identified in subdivision (d), the holder of the expired license pays a restoration fee equal to the sum of the license renewal fee in effect on the last regular renewal date for licenses and any delinquency fees prescribed by the board.

SEC. 14. Section 3147.7 of the Business and Professions Code is amended to read:

3147.7. The provisions of Section 3147.6 shall not apply to a person holding a license that has not been renewed within three years of expiration, if the person provides satisfactory proof that he or she holds an active license from another state and meets all of the following conditions:

(a) Is not subject to denial of a license under Section 480.

(b) Applies in writing for restoration of the license on a form prescribed by the board.

(c) Pays all accrued and unpaid renewal fees and any delinquency fees prescribed by the board.

(d) Submits proof of completion of the required number of hours of continuing education for the last two years.

(e) Takes and satisfactorily passes the board's jurisprudence examination.

SEC. 15. Section 4017 of the Business and Professions Code is amended to read:

4017. "Authorized officers of the law" means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State Department of Public Health, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

SEC. 16. Section 4028 of the Business and Professions Code is amended to read:

4028. "Licensed hospital" means an institution, place, building, or agency that maintains and operates organized facilities for one or more persons for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay, and includes any institution classified under regulations issued by the State Department of Public Health as a general or specialized hospital, as a maternity hospital, or as a tuberculosis hospital, but does not include a sanitarium, rest home, a nursing or convalescent home, a maternity home, or an institution for treating alcoholics.

SEC. 17. Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises

1 described in a license issued by the board wherein controlled
2 substances, dangerous drugs, or dangerous devices are stored,
3 possessed, prepared, manufactured, derived, compounded, or
4 repackaged, and from which the controlled substances, dangerous
5 drugs, or dangerous devices are furnished, sold, or dispensed at
6 retail.
7 (b) "Pharmacy" shall not include any area in a facility licensed
8 by the State Department of Public Health where floor supplies,
9 ward supplies, operating room supplies, or emergency room
10 supplies of dangerous drugs or dangerous devices are stored or
11 possessed solely for treatment of patients registered for treatment
12 in the facility or for treatment of patients receiving emergency care
13 in the facility.
14 SEC. 18. Section 4052.3 of the Business and Professions Code
15 is amended to read:
16 4052.3. (a) Notwithstanding any other provision of law, a
17 pharmacist may furnish emergency contraception drug therapy in
18 accordance with either of the following:
19 (1) Standardized procedures or protocols developed by the
20 pharmacist and an authorized prescriber who is acting within his
21 or her scope of practice.
22 (2) Standardized procedures or protocols developed and
23 approved by both the board and the Medical Board of California
24 in consultation with the American College of Obstetricians and
25 Gynecologists, the California Pharmacist Association, and other
26 appropriate entities. Both the board and the Medical Board of
27 California shall have authority to ensure compliance with this
28 clause, and both boards are specifically charged with the
29 enforcement of this provision with respect to their respective
30 licensees. Nothing in this clause shall be construed to expand the
31 authority of a pharmacist to prescribe any prescription medication.
32 (b) Prior to performing a procedure authorized under this
33 paragraph, a pharmacist shall complete a training program on
34 emergency contraception that consists of at least one hour of
35 approved continuing education on emergency contraception drug
36 therapy.
37 (c) A pharmacist, pharmacist's employer, or pharmacist's agent
38 may not directly charge a patient a separate consultation fee for
39 emergency contraception drug therapy services initiated pursuant
40 to this paragraph, but may charge an administrative fee not to

1 exceed ten dollars ($10) above the retail cost of the drug. Upon an
2 oral, telephonic, electronic, or written request from a patient or
3 customer, a pharmacist or pharmacist's employee shall disclose
4 the total retail price that a consumer would pay for emergency
5 contraception drug therapy. As used in this subparagraph, total
6 retail price includes providing the consumer with specific
7 information regarding the price of the emergency contraception
8 drugs and the price of the administrative fee charged. This
9 limitation is not intended to interfere with other contractually
10 agreed-upon terms between a pharmacist, a pharmacist's employer,
11 or a pharmacist's agent, and a health care service plan or insurer.
12 Patients who are insured or covered and receive a pharmacy benefit
13 that covers the cost of emergency contraception shall not be
14 required to pay an administrative fee. These patients shall be
15 required to pay copayments pursuant to the terms and conditions
16 of their coverage. The provisions of this subparagraph shall cease
17 to be operative for dedicated emergency contraception drugs when
18 these drugs are reclassified as over-the-counter products by the
19 federal Food and Drug Administration.
20 (d) A pharmacist may not require a patient to provide
21 individually identifiable medical information that is not specified
22 in Section 1707.1 of Title 16 of the California Code of Regulations
23 before initiating emergency contraception drug therapy pursuant
24 to this section.
25 (e) For each emergency contraception drug therapy initiated
26 pursuant to this section, the pharmacist shall provide the recipient
27 of the emergency contraception drugs with a standardized factsheet
28 that includes, but is not limited to, the indications for use of the
29 drug, the appropriate method for using the drug, the need for
30 medical followup, and other appropriate information. The board
31 shall develop this form in consultation with the State Department
32 of Public Health, the American College of Obstetricians and
33 Gynecologists, the California Pharmacists Association, and other
34 health care organizations. The provisions of this section do not
35 preclude the use of existing publications developed by nationally
36 recognized medical organizations.
37 SEC. 19. Section 4059 of the Business and Professions Code
38 is amended to read:
39 4059. (a) A person may not furnish any dangerous drug, except
40 upon the prescription of a physician, dentist, podiatrist, optometrist,

1 veterinarian, or naturopathic doctor pursuant to Section 3640.7. A
2 person may not furnish any dangerous device, except upon the
3 prescription of a physician, dentist, podiatrist, optometrist,
4 veterinarian, or naturopathic doctor pursuant to Section 3640.7.
5 (b) This section does not apply to the furnishing of any
6 dangerous drug or dangerous device by a manufacturer, wholesaler,
7 or pharmacy to each other or to a physician, dentist, podiatrist,
8 optometrist, veterinarian, or naturopathic doctor pursuant to Section
9 3640.7, or to a laboratory under sales and purchase records that
10 correctly give the date, the names and addresses of the supplier
11 and the buyer, the drug or device, and its quantity. This section
12 does not apply to the furnishing of any dangerous device by a
13 manufacturer, wholesaler, or pharmacy to a physical therapist
14 acting within the scope of his or her license under sales and
15 purchase records that correctly provide the date the device is
16 provided, the names and addresses of the supplier and the buyer,
17 a description of the device, and the quantity supplied.
18 (c) A pharmacist, or a person exempted pursuant to Section
19 4054, may distribute dangerous drugs and dangerous devices
20 directly to dialysis patients pursuant to regulations adopted by the
21 board. The board shall adopt any regulations as are necessary to
22 ensure the safe distribution of these drugs and devices to dialysis
23 patients without interruption thereof. A person who violates a
24 regulation adopted pursuant to this subdivision shall be liable upon
25 order of the board to surrender his or her personal license. These
26 penalties shall be in addition to penalties that may be imposed
27 pursuant to Section 4301. If the board finds any dialysis drugs or
28 devices distributed pursuant to this subdivision to be ineffective
29 or unsafe for the intended use, the board may institute immediate
30 recall of any or all of the drugs or devices distributed to individual
31 patients.
32 (d) Home dialysis patients who receive any drugs or devices
33 pursuant to subdivision (c) shall have completed a full course of
34 home training given by a dialysis center licensed by the State
35 Department of Public Health. The physician prescribing the dialysis
36 products shall submit proof satisfactory to the manufacturer or
37 wholesaler that the patient has completed the program.
38 (e) A pharmacist may furnish a dangerous drug authorized for
39 use pursuant to Section 2620.3 to a physical therapist. A record
40 containing the date, name and address of the buyer, and name and

quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Board of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

SEC. 20. Section 4072 of the Business and Professions Code is amended to read:

4072. (a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the State Department of Public Health in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

SEC. 21. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

(b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application by the wholesaler or veterinary food-animal drug retailer and approval by the board. Any designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.

SEC. 22. Section 4119 of the Business and Professions Code is amended to read:

4119. (a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

SEC. 23. Section 4127.1 of the Business and Professions Code is amended to read:

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board

and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

SEC. 24. Section 4169 of the Business and Professions Code is amended to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has 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 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) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

SEC. 25. Section 4181 of the Business and Professions Code is amended to read:

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 26. Section 4191 of the Business and Professions Code is amended to read:

4191. (a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

SEC. 27. Section 4196 of the Business and Professions Code is amended to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

SEC. 28. Section 4200.1 is added to the Business and Professions Code, to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at a minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the

California Practice Standards and Jurisprudence Examination for Pharmacists.

SEC. 29. Section 4425 of the Business and Professions Code is amended to read:

4425. (a) As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Care Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal reimbursement rate for over-the-counter medications or compounded prescriptions.

(b) The State Department of Health Care Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section.

(c) The State Department of Health Care Services shall monitor pharmacy participation with the requirements of subdivision (a).

(d) The State Department of Health Care Services shall conduct an outreach program to inform Medicare beneficiaries of their right to participate in the program described in subdivision (a), including, but not limited to, the following:

(1) Including on its Internet Web site the Medi-Cal reimbursement rate for, at minimum, 200 of the most commonly prescribed medicines and updating this information monthly.

(2) Providing a sign to participating pharmacies that the pharmacies shall prominently display at the point of service and at the point of sale, reminding the Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and providing the department's telephone number, e-mail address, and Internet Web site address to access information about the program.

(e) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the

need to continue the implementation of this article under those circumstances.

(f) This section shall not apply to a prescription that is covered by insurance.

SEC. 30. Section 4426 of the Business and Professions Code is amended to read:

4426. The State Department of Health Care Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

SEC. 31. Section 4980.07 of the Business and Professions Code is repealed.

SEC. 32. Section 4980.40.5 of the Business and Professions Code is amended to read:

4980.40.5. (a) A doctor's or master's degree in marriage, family, and child counseling, marital and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling, or marriage and family therapy, obtained from a school, college, or university approved by the Bureau for Private Postsecondary and Vocational Education as of June 30, 2007, shall be considered by the board to meet the requirements necessary for licensure as a marriage and family therapist and for registration as a marriage and family therapist intern provided that the degree is conferred on or before July 1, 2010.

(b) As an alternative to meeting the qualifications specified in subdivision (a) of Section 4980.40, the board shall accept as equivalent degrees those doctor's or master's degrees that otherwise meet the requirements of this chapter and are conferred by educational institutions accredited by any of the following associations:

(1) Northwest Commission on Colleges and Universities.

(2) Middle States Association of Colleges and Secondary Schools.

(3) New England Association of Schools and Colleges.

(4) North Central Association of Colleges and Secondary Schools.

(5) Southern Association of Colleges and Schools.

SEC. 33. Section 4980.43 of the Business and Professions Code is amended to read:

4980.43. (a) Prior to applying for licensure examinations, each applicant shall complete experience that shall comply with the following:

(1) A minimum of 3,000 hours completed during a period of at least 104 weeks.

(2) Not more than 40 hours in any seven consecutive days.

(3) Not less than 1,700 hours of supervised experience completed subsequent to the granting of the qualifying master's or doctor's degree.

(4) Not more than 1,300 hours of supervised experience obtained prior to completing a master's or doctor's degree.

The applicant shall not be credited with more than 750 hours of counseling and direct supervisor contact prior to completing the master's or doctor's degree.

(5) No hours of experience may be gained prior to completing either 12 semester units or 18 quarter units of graduate instruction and becoming a trainee except for personal psychotherapy.

(6) No hours of experience gained more than six years prior to the date the application for examination eligibility was filed, except that up to 500 hours of clinical experience gained in the supervised practicum required by subdivision (c) of Section 4980.37 and subparagraph (B) of paragraph (1) of subdivision (d) of Section 4980.36 shall be exempt from this six-year requirement.

(7) Not more than a combined total of 1,250 hours of experience in the following:

(A) Direct supervisor contact.

(B) Professional enrichment activities. For purposes of this chapter, "professional enrichment activities" include the following:

(i) Workshops, seminars, training sessions, or conferences directly related to marriage and family therapy attended by the applicant that are approved by the applicant's supervisor. An applicant shall have no more than 250 hours of verified attendance at these workshops, seminars, training sessions, or conferences.

(ii) Participation by the applicant in personal psychotherapy, which includes group, marital or conjoint, family, or individual psychotherapy by an appropriately licensed professional. An applicant shall have no more than 100 hours of participation in personal psychotherapy. The applicant shall be credited with three hours of experience for each hour of personal psychotherapy.

(C) Client centered advocacy.

(8) Not more than 500 hours of experience providing group therapy or group counseling.

(9) Not more than 250 hours of experience administering and evaluating psychological tests, writing clinical reports, writing progress notes, or writing process notes.

(10) Not less than 500 total hours of experience in diagnosing and treating couples, families, and children. For up to 150 hours of treating couples and families in conjoint therapy, the applicant shall be credited with two hours of experience for each hour of therapy provided.

(11) Not more than 375 hours of experience providing personal psychotherapy, crisis counseling, or other counseling services via telemedicine in accordance with Section 2290.5.

(b) All applicants, trainees, and registrants shall be at all times under the supervision of a supervisor who shall be responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who shall be responsible to the board for compliance with all laws, rules, and regulations governing the practice of marriage and family therapy. Supervised experience shall be gained by interns and trainees either as an employee or as a volunteer. The requirements of this chapter regarding gaining hours of experience and supervision are applicable equally to employees and volunteers. Experience shall not be gained by interns or trainees as an independent contractor.

(1) If employed, an intern shall provide the board with copies of the corresponding W-2 tax forms for each year of experience claimed upon application for licensure.

(2) If volunteering, an intern shall provide the board with a letter from his or her employer verifying the intern's employment as a volunteer upon application for licensure.

(c) Supervision shall include at least one hour of direct supervisor contact in each week for which experience is credited in each work setting, as specified:

(1) A trainee shall receive an average of at least one hour of direct supervisor contact for every five hours of client contact in each setting.

(2) An individual supervised after being granted a qualifying degree shall receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of client

contact is gained in each setting. No more than five hours of supervision, whether individual or group, shall be credited during any single week.

(3) For purposes of this section, "one hour of direct supervisor contact" means one hour per week of face-to-face contact on an individual basis or two hours per week of face-to-face contact in a group.

(4) Direct supervisor contact shall occur within the same week as the hours claimed.

(5) Direct supervisor contact provided in a group shall be provided in a group of not more than eight supervisees and in segments lasting no less than one continuous hour.

(6) Notwithstanding paragraph (3), an intern working in a governmental entity, a school, a college, or a university, or an institution that is both nonprofit and charitable may obtain the required weekly direct supervisor contact via two-way, real-time videoconferencing. The supervisor shall be responsible for ensuring that client confidentiality is upheld.

(7) All experience gained by a trainee shall be monitored by the supervisor as specified by regulation.

(d) (1) A trainee may be credited with supervised experience completed in any setting that meets all of the following:

(A) Lawfully and regularly provides mental health counseling or psychotherapy.

(B) Provides oversight to ensure that the trainee's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.

(C) Is not a private practice owned by a licensed marriage and family therapist, a licensed psychologist, a licensed clinical social worker, a licensed physician and surgeon, or a professional corporation of any of those licensed professions.

(2) Experience may be gained by the trainee solely as part of the position for which the trainee volunteers or is employed.

(e) (1) An intern may be credited with supervised experience completed in any setting that meets both of the following:

(A) Lawfully and regularly provides mental health counseling or psychotherapy.

(B) Provides oversight to ensure that the intern's work at the setting meets the experience and supervision requirements set forth

in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.

(2) An applicant shall not be employed or volunteer in a private practice, as defined in subparagraph (C) of paragraph (1) of subdivision (d), until registered as an intern.

(3) While an intern may be either a paid employee or a volunteer, employers are encouraged to provide fair remuneration to interns.

(4) Except for periods of time during a supervisor's vacation or sick leave, an intern who is employed or volunteering in private practice shall be under the direct supervision of a licensee that has satisfied the requirements of subdivision (g) of Section 4980.03. The supervising licensee shall either be employed by and practice at the same site as the intern's employer, or shall be an owner or shareholder of the private practice. Alternative supervision may be arranged during a supervisor's vacation or sick leave if the supervision meets the requirements of this section.

(5) Experience may be gained by the intern solely as part of the position for which the intern volunteers or is employed.

(f) Except as provided in subdivision (g), all persons shall register with the board as an intern in order to be credited for postdegree hours of supervised experience gained toward licensure.

(g) Except when employed in a private practice setting, all postdegree hours of experience shall be credited toward licensure so long as the applicant applies for the intern registration within 90 days of the granting of the qualifying master's or doctor's degree and is thereafter granted the intern registration by the board.

(h) Trainees, interns, and applicants shall not receive any remuneration from patients or clients, and shall only be paid by their employers.

(i) Trainees, interns, and applicants shall only perform services at the place where their employers regularly conduct business, which may include performing services at other locations, so long as the services are performed under the direction and control of their employer and supervisor, and in compliance with the laws and regulations pertaining to supervision. Trainees and interns shall have no proprietary interest in their employers' businesses and shall not lease or rent space, pay for furnishings, equipment or supplies, or in any other way pay for the obligations of their employers.

(j) Trainees, interns, or applicants who provide volunteered services or other services, and who receive no more than a total, from all work settings, of five hundred dollars ($500) per month as reimbursement for expenses actually incurred by those trainees, interns, or applicants for services rendered in any lawful work setting other than a private practice shall be considered an employee and not an independent contractor. The board may audit applicants who receive reimbursement for expenses, and the applicants shall have the burden of demonstrating that the payments received were for reimbursement of expenses actually incurred.

(k) Each educational institution preparing applicants for licensure pursuant to this chapter shall consider requiring, and shall encourage, its students to undergo individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Each supervisor shall consider, advise, and encourage his or her interns and trainees regarding the advisability of undertaking individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Insofar as it is deemed appropriate and is desired by the applicant, the educational institution and supervisors are encouraged to assist the applicant in locating that counseling or psychotherapy at a reasonable cost.

SEC. 34. Section 4980.80 of the Business and Professions Code is amended to read:

4980.80. (a) This section applies to persons who apply for licensure between January 1, 2010, and December 31, 2013, inclusive.

(b) The board may issue a license to a person who, at the time of application, holds a valid license issued by a board of marriage counselor examiners, marriage therapist examiners, or corresponding authority of any state, if all of the following requirements are satisfied:

(1) The person has held that license for at least two years immediately preceding the date of application.

(2) The education and supervised experience requirements are substantially the equivalent of this chapter.

(3) The person complies with Section 4980.76, if applicable.

(4) The person successfully completes the board administered licensing examinations as specified by subdivision (d) of Section 4980.40 and pays the fees specified.

(5) The person completes all of the following coursework or training:

(A) (i) An applicant who completed a two semester or three quarter unit course in law and professional ethics for marriage and family therapists that included areas of study as specified in Section 4980.41 as part of his or her qualifying degree shall complete an 18-hour course in California law and professional ethics that includes, but is not limited to, the following subjects: advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous patients, psychotherapist-patient privilege, recordkeeping, patient access to records, requirements of the Health Insurance Portability and Accountability Act of 1996, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to patients.

(ii) An applicant who has not completed a two semester or three quarter unit course in law and professional ethics for marriage and family therapists that included areas of study as specified in Section 4980.41 as part of his or her qualifying degree, shall complete a two semester or three quarter unit course in California law and professional ethics that includes, at minimum, the areas of study specified in Section 4980.41.

(B) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28 and any regulations promulgated thereunder.

(C) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25 and any regulations promulgated thereunder.

(D) A minimum of 15 contact hours of training or coursework in alcoholism and other chemical substance dependency as specified by regulation.

(E) (i) Instruction in spousal or partner abuse assessment, detection, and intervention. This instruction may be taken either in fulfillment of other requirements for licensure or in a separate course.

(ii) A minimum of 15 contact hours of coursework or training in spousal or partner abuse assessment, detection, and intervention strategies.

(F) A minimum of a two semester or three quarter unit survey course in psychological testing. This course may be taken either in fulfillment of other requirements for licensure or in a separate course.

(G) A minimum of a two semester or three quarter unit survey course in psychopharmacology. This course may be taken either in fulfillment of other requirements for licensure or in a separate course.

(H) With respect to human sexuality, alcoholism and other chemical substance dependency, spousal or partner abuse assessment, detection, and intervention, psychological testing, and psychopharmacology, the board may accept training or coursework acquired out of state.

(c) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 35. Section 4982.2 of the Business and Professions Code is repealed.

SEC. 36. Section 4982.25 of the Business and Professions Code is amended to read:

4982.25. The board may deny an application, or may suspend or revoke a license or registration issued under this chapter, for any of the following:

(a) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory or possession of the United States, or by any other governmental agency, on a license, certificate, or registration to practice marriage and family therapy, or any other healing art, shall constitute unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

(b) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a clinical social worker, professional clinical counselor, or educational psychologist shall also constitute grounds for disciplinary action for unprofessional conduct against the licensee or registrant under this chapter.

SEC. 37. Section 4984.6 of the Business and Professions Code is repealed.

SEC. 38. Section 4984.8 of the Business and Professions Code is amended to read:

4984.8. (a) A licensee may apply to the board to request that his or her license be placed on inactive status.

(b) A licensee on inactive status shall be subject to this chapter and shall not engage in the practice of marriage and family therapy in this state.

(c) A licensee who holds an inactive license shall pay a biennial fee in the amount of one-half of the standard renewal fee and shall be exempt from continuing education requirements.

(d) A licensee on inactive status who has not committed an act or crime constituting grounds for denial of licensure may, upon request, restore his or her license to practice marriage and family therapy to active status.

(1) A licensee requesting to restore his or her license to active status between renewal cycles shall pay the remaining one-half of his or her renewal fee.

(2) A licensee requesting to restore his or her license to active status, whose license will expire less than one year from the date of the request, shall complete 18 hours of continuing education as specified in Section 4980.54.

(3) A licensee requesting to restore his or her license to active status, whose license will expire more than one year from the date of the request, shall complete 36 hours of continuing education as specified in Section 4980.54.

SEC. 39. Section 4989.54 of the Business and Professions Code is amended to read:

4989.54. The board may deny a license or may suspend or revoke the license of a licensee if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) Conviction of a crime substantially related to the qualifications, functions, and duties of an educational psychologist.

(1) The record of conviction shall be conclusive evidence only of the fact that the conviction occurred.

(2) The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee under this chapter.

(3) A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee under this chapter

shall be deemed to be a conviction within the meaning of this section.

(4) The board may order a license suspended or revoked, or may decline to issue a license when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty or setting aside the verdict of guilty or dismissing the accusation, information, or indictment.

(b) Securing a license by fraud, deceit, or misrepresentation on an application for licensure submitted to the board, whether engaged in by an applicant for a license or by a licensee in support of an application for licensure.

(c) Administering to himself or herself a controlled substance or using any of the dangerous drugs specified in Section 4022 or an alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to himself or herself or to any other person or to the public or to the extent that the use impairs his or her ability to safely perform the functions authorized by the license. The board shall deny an application for a license or revoke the license of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing educational psychology.

(d) Failure to comply with the consent provisions in Section 2290.5.

(e) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(f) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(g) Commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee.

(h) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory or possession of the United States or by any other governmental agency, on a license, certificate, or registration to practice educational psychology or any other healing art. A certified copy

of the disciplinary action, decision, or judgment shall be conclusive evidence of that action.

(i) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a clinical social worker, professional clinical counselor, or marriage and family therapist.

(j) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(k) Gross negligence or incompetence in the practice of educational psychology.

(*l*) Misrepresentation as to the type or status of a license held by the licensee or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(m) Intentionally or recklessly causing physical or emotional harm to any client.

(n) Engaging in sexual relations with a client or a former client within two years following termination of professional services, soliciting sexual relations with a client, or committing an act of sexual abuse or sexual misconduct with a client or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed educational psychologist.

(o) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services or the basis upon which that fee will be computed.

(p) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients.

(q) Failing to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(r) Performing, holding himself or herself out as being able to perform, or offering to perform any professional services beyond the scope of the license authorized by this chapter or beyond his

or her field or fields of competence as established by his or her education, training, or experience.

(s) Reproducing or describing in public, or in any publication subject to general public distribution, any psychological test or other assessment device the value of which depends in whole or in part on the naivete of the subject in ways that might invalidate the test or device. An educational psychologist shall limit access to the test or device to persons with professional interests who can be expected to safeguard its use.

(t) Aiding or abetting an unlicensed person to engage in conduct requiring a license under this chapter.

(u) When employed by another person or agency, encouraging, either orally or in writing, the employer's or agency's clientele to utilize his or her private practice for further counseling without the approval of the employing agency or administration.

(v) Failing to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(w) Failing to comply with the elder and adult dependent abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(x) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(y) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(z) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of the examination as described in Section 123.

(aa) Impersonation of another by any licensee or applicant for a license, or, in the case of a licensee, allowing any other person to use his or her license.

(ab) Permitting a person under his or her supervision or control to perform, or permitting that person to hold himself or herself out as competent to perform, professional services beyond the level of education, training, or experience of that person.

SEC. 40. Section 4990.02 of the Business and Professions Code is amended to read:

4990.02. "Board," as used in this chapter, Chapter 13 (commencing with Section 4980), Chapter 13.5 (commencing with Section 4989.10), Chapter 14 (commencing with Section 4991), and Chapter 16 (commencing with Section 4999.10) means the Board of Behavioral Sciences.

SEC. 41. Section 4990.12 of the Business and Professions Code is amended to read:

4990.12. The duty of administering and enforcing this chapter, Chapter 13 (commencing with Section 4980), Chapter 13.5 (commencing with Section 4989.10), Chapter 14 (commencing with Section 4991), and Chapter 16 (commencing with Section 4999.10) is vested in the board and the executive officer subject to, and under the direction of, the board. In the performance of this duty, the board and the executive officer have all the powers and are subject to all the responsibilities vested in, and imposed upon, the head of a department by Chapter 2 (commencing with Section 11150) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 42. Section 4990.18 of the Business and Professions Code is amended to read:

4990.18. It is the intent of the Legislature that the board employ its resources for each and all of the following functions:

(a) The licensure of marriage and family therapists, clinical social workers, professional clinical counselors, and educational psychologists.

(b) The development and administration of licensure examinations and examination procedures consistent with prevailing standards for the validation and use of licensing and

1 certification tests. Examinations shall measure knowledge and
2 abilities demonstrably important to the safe, effective practice of
3 the profession.
4 (c) Enforcement of laws designed to protect the public from
5 incompetent, unethical, or unprofessional practitioners.
6 (d) Consumer education.
7 SEC. 43. Section 4990.22 of the Business and Professions
8 Code is amended to read:
9 4990.22. (a) The Behavioral Sciences Fund shall be used for
10 the purposes of carrying out and enforcing the provisions of this
11 chapter and the chapters listed in Section 4990.12. All moneys in
12 the fund shall be expended by the board for the purposes of the
13 programs under its jurisdiction.
14 (b) The board shall keep records that reasonably ensure that
15 funds expended in the administration of each licensure or
16 registration category shall bear a reasonable relation to the revenue
17 derived from each category and report to the department no later
18 than May 31 of each year on those expenditures.
19 (c) Surpluses, if any, may be used by the board in a manner that
20 bears a reasonable relation to the revenue derived from each
21 licensure or registration category and may include, but not be
22 limited to, expenditures for education and research related to each
23 of the licensing or registration categories.
24 SEC. 44. Section 4990.30 of the Business and Professions
25 Code is amended to read:
26 4990.30. (a) A licensed marriage and family therapist, marriage
27 and family therapist intern, licensed clinical social worker,
28 associate clinical social worker, licensed professional clinical
29 counselor, professional clinical counselor intern, or licensed
30 educational psychologist whose license or registration has been
31 revoked, suspended, or placed on probation, may petition the board
32 for reinstatement or modification of the penalty, including
33 modification or termination of probation. The petition shall be on
34 a form provided by the board and shall state any facts and
35 information as may be required by the board including, but not
36 limited to, proof of compliance with the terms and conditions of
37 the underlying disciplinary order. The petition shall be verified by
38 the petitioner who shall file an original and sufficient copies of
39 the petition, together with any supporting documents, for the

members of the board, the administrative law judge, and the Attorney General.

(b) The licensee or registrant may file the petition on or after the expiration of the following timeframes, each of which commences on the effective date of the decision ordering the disciplinary action or, if the order of the board, or any portion of it, is stayed by the board itself or by the superior court, from the date the disciplinary action is actually implemented in its entirety:

(1) Three years for reinstatement of a license or registration that was revoked for unprofessional conduct, except that the board may, in its sole discretion, specify in its revocation order that a petition for reinstatement may be filed after two years.

(2) Two years for early termination of any probation period of three years or more.

(3) One year for modification of a condition, reinstatement of a license or registration revoked for mental or physical illness, or termination of probation of less than three years.

(c) The petition may be heard by the board itself or the board may assign the petition to an administrative law judge pursuant to Section 11512 of the Government Code.

(d) The petitioner may request that the board schedule the hearing on the petition for a board meeting at a specific city where the board regularly meets.

(e) The petitioner and the Attorney General shall be given timely notice by letter of the time and place of the hearing on the petition and an opportunity to present both oral and documentary evidence and argument to the board or the administrative law judge.

(f) The petitioner shall at all times have the burden of production and proof to establish by clear and convincing evidence that he or she is entitled to the relief sought in the petition.

(g) The board, when it is hearing the petition itself, or an administrative law judge sitting for the board, may consider all activities of the petitioner since the disciplinary action was taken, the offense for which the petitioner was disciplined, the petitioner's activities during the time his or her license or registration was in good standing, and the petitioner's rehabilitative efforts, general reputation for truth, and professional ability.

(h) The hearing may be continued from time to time as the board or the administrative law judge deems appropriate but in no case

may the hearing on the petition be delayed more than 180 days from its filing without the consent of the petitioner.

(i) The board itself, or the administrative law judge if one is designated by the board, shall hear the petition and shall prepare a written decision setting forth the reasons supporting the decision. In a decision granting a petition reinstating a license or modifying a penalty, the board itself, or the administrative law judge, may impose any terms and conditions that the agency deems reasonably appropriate, including those set forth in Sections 823 and 4990.40. If a petition is heard by an administrative law judge sitting alone, the administrative law judge shall prepare a proposed decision and submit it to the board. The board may take action with respect to the proposed decision and petition as it deems appropriate.

(j) The petitioner shall pay a fingerprinting fee and provide a current set of his or her fingerprints to the board. The petitioner shall execute a form authorizing release to the board or its designee, of all information concerning the petitioner's current physical and mental condition. Information provided to the board pursuant to the release shall be confidential and shall not be subject to discovery or subpoena in any other proceeding, and shall not be admissible in any action, other than before the board, to determine the petitioner's fitness to practice as required by Section 822.

(k) The board may delegate to its executive officer authority to order investigation of the contents of the petition.

(*l*) No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole or the petitioner is required to register pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.

(m) Except in those cases where the petitioner has been disciplined for violation of Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.

SEC. 45. Section 4990.38 of the Business and Professions Code is amended to read:

4990.38. The board may deny an application or may suspend or revoke a license or registration issued under the chapters it administers and enforces for any disciplinary action imposed by another state or territory or possession of the United States, or by a governmental agency on a license, certificate or registration to practice marriage and family therapy, clinical social work, educational psychology, professional clinical counseling, or any other healing art. The disciplinary action, which may include denial of licensure or revocation or suspension of the license or imposition of restrictions on it, constitutes unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

SEC. 46. Section 4992.36 of the Business and Professions Code is amended to read:

4992.36. The board may deny an application, or may suspend or revoke a license or registration issued under this chapter, for any of the following:

(a) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory of the United States, or by any other governmental agency, on a license, certificate, or registration to practice clinical social work or any other healing art shall constitute grounds for disciplinary action for unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

(b) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice marriage and family therapy, professional clinical counseling, or educational psychology against a licensee or registrant shall also constitute grounds for disciplinary action for unprofessional conduct under this chapter.

SEC. 47. Article 3 (commencing with Section 4994) of Chapter 14 of Division 2 of the Business and Professions Code is repealed.

SEC. 48. Section 4996.17 of the Business and Professions Code is amended to read:

4996.17. (a) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially the equivalent of the requirements of this chapter.

(b) The board may issue a license to any person who, at the time of application, holds a valid active clinical social work license issued by a board of clinical social work examiners or

corresponding authority of any state, if the person passes the board administered licensing examinations as specified in Section 4996.1 and pays the required fees. Issuance of the license is conditioned upon all of the following:

(1) The applicant has supervised experience that is substantially the equivalent of that required by this chapter. If the applicant has less than 3,200 hours of qualifying supervised experience, time actively licensed as a clinical social worker shall be accepted at a rate of 100 hours per month up to a maximum of 1,200 hours.

(2) Completion of the following coursework or training in or out of this state:

(A) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28, and any regulations promulgated thereunder.

(B) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25, and any regulations promulgated thereunder.

(C) A minimum of 15 contact hours of training or coursework in alcoholism and other chemical substance dependency, as specified by regulation.

(D) A minimum of 15 contact hours of coursework or training in spousal or partner abuse assessment, detection, and intervention strategies.

(3) The applicant's license is not suspended, revoked, restricted, sanctioned, or voluntarily surrendered in any state.

(4) The applicant is not currently under investigation in any other state, and has not been charged with an offense for any act substantially related to the practice of social work by any public agency, entered into any consent agreement or been subject to an administrative decision that contains conditions placed by an agency upon an applicant's professional conduct or practice, including any voluntary surrender of license, or been the subject of an adverse judgment resulting from the practice of social work that the board determines constitutes evidence of a pattern of incompetence or negligence.

(5) The applicant shall provide a certification from each state where he or she holds a license pertaining to licensure, disciplinary action, and complaints pending.

(6) The applicant is not subject to denial of licensure under Section 480, 4992.3, 4992.35, or 4992.36.

(c) The board may issue a license to any person who, at the time of application, holds a valid, active clinical social work license issued by a board of clinical social work examiners or a corresponding authority of any state, if the person has held that license for at least four years immediately preceding the date of application, the person passes the board administered licensing examinations as specified in Section 4996.1, and the person pays the required fees. Issuance of the license is conditioned upon all of the following:

(1) Completion of the following coursework or training in or out of state:

(A) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28, and any regulations promulgated thereunder.

(B) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25, and any regulations promulgated thereunder.

(C) A minimum of 15 contact hours of training or coursework in alcoholism and other chemical substance dependency, as specified by regulation.

(D) A minimum of 15 contact hours of coursework or training in spousal or partner abuse assessment, detection, and intervention strategies.

(2) The applicant has been licensed as a clinical social worker continuously for a minimum of four years prior to the date of application.

(3) The applicant's license is not suspended, revoked, restricted, sanctioned, or voluntarily surrendered in any state.

(4) The applicant is not currently under investigation in any other state, and has not been charged with an offense for any act substantially related to the practice of social work by any public agency, entered into any consent agreement or been subject to an administrative decision that contains conditions placed by an agency upon an applicant's professional conduct or practice, including any voluntary surrender of license, or been the subject of an adverse judgment resulting from the practice of social work that the board determines constitutes evidence of a pattern of incompetence or negligence.

(5) The applicant provides a certification from each state where he or she holds a license pertaining to licensure, disciplinary action, and complaints pending.

(6) The applicant is not subject to denial of licensure under Section 480, 4992.3, 4992.35, or 4992.36.

SEC. 49. Section 4996.23 of the Business and Professions Code is amended to read:

4996.23. The experience required by subdivision (c) of Section 4996.2 shall meet the following criteria:

(a) All persons registered with the board on and after January 1, 2002, shall have at least 3,200 hours of post-master's degree supervised experience providing clinical social work services as permitted by Section 4996.9. At least 1,700 hours shall be gained under the supervision of a licensed clinical social worker. The remaining required supervised experience may be gained under the supervision of a licensed mental health professional acceptable to the board as defined by a regulation adopted by the board. This experience shall consist of the following:

(1) A minimum of 2,000 hours in clinical psychosocial diagnosis, assessment, and treatment, including psychotherapy or counseling.

(2) A maximum of 1,200 hours in client-centered advocacy, consultation, evaluation, and research.

(3) Of the 2,000 clinical hours required in paragraph (1), no less than 750 hours shall be face-to-face individual or group psychotherapy provided to clients in the context of clinical social work services.

(4) A minimum of two years of supervised experience is required to be obtained over a period of not less than 104 weeks and shall have been gained within the six years immediately preceding the date on which the application for licensure was filed.

(5) Experience shall not be credited for more than 40 hours in any week.

(b) "Supervision" means responsibility for, and control of, the quality of clinical social work services being provided. Consultation or peer discussion shall not be considered to be supervision.

(c) (1) Prior to the commencement of supervision, a supervisor shall comply with all requirements enumerated in Section 1870 of Title 16 of the California Code of Regulations and shall sign under

1 penalty of perjury the "Responsibility Statement for Supervisors
2 of an Associate Clinical Social Worker" form.
3 (2) Supervised experience shall include at least one hour of
4 direct supervisor contact for a minimum of 104 weeks. For
5 purposes of this subdivision, "one hour of direct supervisor contact"
6 means one hour per week of face-to-face contact on an individual
7 basis or two hours of face-to-face contact in a group conducted
8 within the same week as the hours claimed.
9 (3) An associate shall receive an average of at least one hour of
10 direct supervisor contact for every week in which more than 10
11 hours of face-to-face psychotherapy is performed in each setting
12 in which experience is gained. No more than five hours of
13 supervision, whether individual or group, shall be credited during
14 any single week.
15 (4) Group supervision shall be provided in a group of not more
16 than eight supervisees and shall be provided in segments lasting
17 no less than one continuous hour.
18 (5) Of the 104 weeks of required supervision, 52 weeks shall
19 be individual supervision, and of the 52 weeks of required
20 individual supervision, not less than 13 weeks shall be supervised
21 by a licensed clinical social worker.
22 (6) Notwithstanding paragraph (2), an associate clinical social
23 worker working for a governmental entity, school, college, or
24 university, or an institution that is both a nonprofit and charitable
25 institution, may obtain the required weekly direct supervisor
26 contact via live two-way videoconferencing. The supervisor shall
27 be responsible for ensuring that client confidentiality is preserved.
28 (d) The supervisor and the associate shall develop a supervisory
29 plan that describes the goals and objectives of supervision. These
30 goals shall include the ongoing assessment of strengths and
31 limitations and the assurance of practice in accordance with the
32 laws and regulations. The associate shall submit to the board the
33 initial original supervisory plan upon application for licensure.
34 (e) Experience shall only be gained in a setting that meets both
35 of the following:
36 (1) Lawfully and regularly provides clinical social work, mental
37 health counseling, or psychotherapy.
38 (2) Provides oversight to ensure that the associate's work at the
39 setting meets the experience and supervision requirements set forth

in this chapter and is within the scope of practice for the profession as defined in Section 4996.9.

(f) Experience shall not be gained until the applicant has been registered as an associate clinical social worker.

(g) Employment in a private practice as defined in subdivision (h) shall not commence until the applicant has been registered as an associate clinical social worker.

(h) A private practice setting is a setting that is owned by a licensed clinical social worker, a licensed marriage and family therapist, a licensed psychologist, a licensed physician and surgeon, or a professional corporation of any of those licensed professions.

(i) If volunteering, the associate shall provide the board with a letter from his or her employer verifying his or her voluntary status upon application for licensure.

(j) If employed, the associate shall provide the board with copies of his or her W-2 tax forms for each year of experience claimed upon application for licensure.

(k) While an associate may be either a paid employee or volunteer, employers are encouraged to provide fair remuneration to associates.

(*l*) An associate shall not do the following:

(1) Receive any remuneration from patients or clients and shall only be paid by his or her employer.

(2) Have any proprietary interest in the employer's business.

(3) Lease or rent space, pay for furnishings, equipment, or supplies, or in any other way pay for the obligations of his or her employer.

(m) An associate, whether employed or volunteering, may obtain supervision from a person not employed by the associate's employer if that person has signed a written agreement with the employer to take supervisory responsibility for the associate's social work services.

(n) Notwithstanding any other provision of law, associates and applicants for examination shall receive a minimum of one hour of supervision per week for each setting in which he or she is working.

SEC. 50. Section 4999.46 of the Business and Professions Code is amended to read:

4999.46. (a) To qualify for licensure, applicants shall complete clinical mental health experience under the general supervision of an approved supervisor as defined in Section 4999.12.

(b) The experience shall include a minimum of 3,000 postdegree hours of supervised clinical mental health experience related to the practice of professional clinical counseling, performed over a period of not less than two years (104 weeks) which shall include:

(1) Not more than 40 hours in any seven consecutive days.

(2) Not less than 1,750 hours of direct counseling with individuals or groups in a clinical mental health counseling setting using a variety of psychotherapeutic techniques and recognized counseling interventions within the scope of practice of licensed professional clinical counselors.

(3) Not more than 500 hours of experience providing group therapy or group counseling.

(4) Not more than 250 hours of experience providing counseling or crisis counseling on the telephone.

(5) Not less than 150 hours of clinical experience in a hospital or community mental health setting.

(6) Not more than a combined total of 1,250 hours of experience in the following related activities:

(A) Direct supervisor contact.

(B) Client centered advocacy.

(C) Not more than 250 hours of experience administering tests and evaluating psychological tests of clients, writing clinical reports, writing progress notes, or writing process notes.

(D) Not more than 250 hours of verified attendance at workshops, training sessions, or conferences directly related to professional clinical counseling that are approved by the applicant's supervisor.

(c) No hours of clinical mental health experience may be gained more than six years prior to the date the application for examination eligibility was filed.

(d) An applicant shall register with the board as an intern in order to be credited for postdegree hours of experience toward licensure. Postdegree hours of experience shall be credited toward licensure, provided that the applicant applies for intern registration within 90 days of the granting of the qualifying degree and is registered as an intern by the board.

(e) All applicants and interns shall be at all times under the supervision of a supervisor who shall be responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who shall be responsible to the board for compliance with all laws, rules, and regulations governing the practice of professional clinical counseling.

(f) Experience obtained under the supervision of a spouse or relative by blood or marriage shall not be credited toward the required hours of supervised experience. Experience obtained under the supervision of a supervisor with whom the applicant has had or currently has a personal, professional, or business relationship that undermines the authority or effectiveness of the supervision shall not be credited toward the required hours of supervised experience.

(g) Supervision shall include at least one hour of direct supervisor contact in each week for which experience is credited in each work setting.

(1) No more than five hours of supervision, whether individual or group, shall be credited during any single week.

(2) An intern shall receive at least one additional hour of direct supervisor contact for every week in which more than 10 hours of face-to-face psychotherapy is performed in each setting in which experience is gained.

(3) For purposes of this section, "one hour of direct supervisor contact" means one hour of face-to-face contact on an individual basis or two hours of face-to-face contact in a group of not more than eight persons in segments lasting no less than one continuous hour.

(4) Notwithstanding paragraph (3), an intern working in a governmental entity, a school, a college, or a university, or an institution that is both nonprofit and charitable, may obtain the required weekly direct supervisor contact via two-way, real-time videoconferencing. The supervisor shall be responsible for ensuring that client confidentiality is upheld.

SEC. 51. Section 4999.57 is added to the Business and Professions Code, to read:

4999.57. (a) This section applies to a person who applies for examination eligibility or registration between January 1, 2011,

1 and December 31, 2013, inclusive, who does not hold a license
2 described in subdivision (a) of Section 4999.58.
3 (b) Experience gained outside of California shall be accepted
4 toward the licensure requirements if it is substantially equivalent
5 to that required by this chapter, if the applicant complies with
6 Section 4999.40, if applicable, and if the applicant has gained a
7 minimum of 250 hours of supervised experience in direct
8 counseling within California while registered as an intern with the
9 board.
10 (c) Education gained while residing outside of California shall
11 be accepted toward the licensure requirements if it is substantially
12 equivalent to the education requirements of this chapter, if the
13 applicant has completed the training or coursework required under
14 subdivision (e) of Section 4999.32, and if the applicant completes,
15 in addition to the course described in subparagraph (I) of paragraph
16 (1) of subdivision (c) of Section 4999.32, an 18-hour course in
17 California law and professional ethics that includes, but is not
18 limited to, instruction in advertising, scope of practice, scope of
19 competence, treatment of minors, confidentiality, dangerous clients,
20 psychotherapist-client privilege, recordkeeping, client access to
21 records, the Health Insurance Portability and Accountability Act,
22 dual relationships, child abuse, elder and dependent adult abuse,
23 online therapy, insurance reimbursement, civil liability, disciplinary
24 actions and unprofessional conduct, ethics complaints and ethical
25 standards, termination of therapy, standards of care, relevant family
26 law, and therapist disclosures to clients.
27 (d) For purposes of this section, the board may, in its discretion,
28 accept education as substantially equivalent if the applicant's
29 education meets the requirements of Section 4999.32. If the
30 applicant's degree does not contain the content or the overall units
31 required by Section 4999.32, the board may, in its discretion, accept
32 the applicant's education as substantially equivalent if the following
33 criteria are satisfied:
34 (1) The applicant's degree contains the required number of
35 practicum units under paragraph (3) of subdivision (c) of Section
36 4999.32.
37 (2) The applicant remediates his or her specific deficiency by
38 completing the course content and units required by Section
39 4999.32.
40 (3) The applicant's degree otherwise complies with this section.

(e) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

~~SEC. 52. Section 4999.58 of the Business and Professions Code is amended to read:~~

~~4999.58. (a) This section applies to a person who applies for examination eligibility between January 1, 2011, and December 31, 2013, inclusive, who meets both of the following requirements:~~

~~(1) At the time of application, holds a valid license as a professional clinical counselor, or other counseling license that allows the applicant to independently provide clinical mental health services, in another jurisdiction of the United States.~~

~~(2) Has held the license described in paragraph (1) for at least two years immediately preceding the date of application.~~

~~(b) The board may issue a license to a person described in subdivision (a) if all of the following requirements are satisfied:~~

~~(1) The education and supervised experience requirements of the other jurisdiction are substantially the equivalent of this chapter, as described in subdivision (c) and in Section 4999.46.~~

~~(2) The person complies with subdivision (b) of Section 4999.40, if applicable.~~

~~(3) The person successfully completes the examinations required by the board pursuant to paragraph (3) of subdivision (a) of Section 4999.50.~~

~~(4) The person pays the required fees.~~

~~(c) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter. The board shall consider hours of experience obtained in another state during the six-year period immediately preceding the applicant's initial licensure by that state as a licensed professional clinical counselor.~~

~~(d) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, if the applicant has completed the training or coursework required under subdivision (c) of Section 4999.32, and if the applicant completes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics that includes, but is not limited to, instruction in advertising, scope of practice, scope of~~

~~competence, treatment of minors, confidentiality, dangerous clients, psychotherapist-client privilege, recordkeeping, client access to records, the Health Insurance Portability and Accountability Act, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to clients.~~

~~(e) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:~~

~~(1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.~~

~~(2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.~~

~~(3) The applicant's degree otherwise complies with this section.~~

~~(f) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.~~

SEC. 52. Section 4999.58 of the Business and Professions Code is amended to read:

4999.58. (a) This section applies to ~~persons who apply~~ *a person who applies* for examination eligibility between January 1, 2011, and December 31, 2013, ~~inclusive.~~ *inclusive, and who meets both of the following requirements:*

(1) At the time of application, holds a valid license as a professional clinical counselor, or other counseling license that allows the applicant to independently provide clinical mental health services, in another jurisdiction of the United States.

(2) Has held the license described in paragraph (1) for at least two years immediately preceding the date of application.

(b) The board may issue a license to a person ~~who, at the time of application, has held for at least two years, a valid license as a professional clinical counselor, or other counseling license that~~

~~allows the applicant to independently provide clinical mental health services, in another jurisdiction of the United States, if the~~ *described in subdivision (a) if all of the following requirements are satisfied:*

(1) The education and supervised experience requirements *of the other jurisdiction* are substantially the equivalent of this chapter, as described in subdivision (e) and in Section 4999.46~~, the~~.

(2) The person complies with subdivision (b) of Section 4999.40, if applicable~~, the~~.

(3) The person successfully completes the examinations required by the board pursuant to paragraph (3) of subdivision (a) of Section 4999.50~~, and the~~.

(4) The person pays the required fees.

(c) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter~~ and if the applicant has gained a minimum of 250 hours of supervised clinical experience in direct counseling within California while registered as an intern with the board~~. The board shall consider hours of experience obtained in another state during the six-year period immediately preceding the applicant's initial licensure by that state as a licensed professional clinical counselor.

(d) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, if the applicant has completed the training or coursework required under subdivision (e) of Section 4999.32, and if the applicant completes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics that includes, but is not limited to, instruction in advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous clients, psychotherapist-client privilege, recordkeeping, client access to records, the Health Insurance Portability and Accountability Act, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to clients.

(e) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:

(1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.

(2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.

(3) The applicant's degree otherwise complies with this section.

(f) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

SEC. 53. Section 4999.59 is added to the Business and Professions Code, to read:

4999.59. (a) This section applies to a person who applies for examination eligibility or registration between January 1, 2011, and December 31, 2013, inclusive, who meets both of the following requirements:

(1) At the time of application, holds a valid license described in paragraph (1) of subdivision (a) of Section 4999.58.

(2) Has held the license described in paragraph (1) for less than two years immediately preceding the date of application.

(b) Experience gained outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to that required by this chapter, if the applicant complies with Section 4999.40, if applicable, and if the applicant has gained a minimum of 250 hours of supervised experience in direct counseling within California while registered as an intern with the board. The board shall consider hours of experience obtained in another state during the six-year period immediately preceding the applicant's initial licensure in that state as a professional clinical counselor.

(c) Education gained while residing outside of California shall be accepted toward the licensure requirements if it is substantially equivalent to the education requirements of this chapter, if the

applicant has completed the training or coursework required under subdivision (e) of Section 4999.32, and if the applicant completes, in addition to the course described in subparagraph (I) of paragraph (1) of subdivision (c) of Section 4999.32, an 18-hour course in California law and professional ethics that includes, but is not limited to, instruction in advertising, scope of practice, scope of competence, treatment of minors, confidentiality, dangerous clients, psychotherapist-client privilege, recordkeeping, client access to records, the Health Insurance Portability and Accountability Act, dual relationships, child abuse, elder and dependent adult abuse, online therapy, insurance reimbursement, civil liability, disciplinary actions and unprofessional conduct, ethics complaints and ethical standards, termination of therapy, standards of care, relevant family law, and therapist disclosures to clients.

(d) For purposes of this section, the board may, in its discretion, accept education as substantially equivalent if the applicant's education meets the requirements of Section 4999.32. If the applicant's degree does not contain the content or the overall units required by Section 4999.32, the board may, in its discretion, accept the applicant's education as substantially equivalent if the following criteria are satisfied:

(1) The applicant's degree contains the required number of practicum units under paragraph (3) of subdivision (c) of Section 4999.32.

(2) The applicant remediates his or her specific deficiency by completing the course content and units required by Section 4999.32.

(3) The applicant's degree otherwise complies with this section.

(e) This section shall become inoperative on January 1, 2014, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2014, deletes or extends that date.

SEC. 54. Section 4999.90 of the Business and Professions Code is amended to read:

4999.90. The board may refuse to issue any registration or license, or may suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter shall be deemed to be a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022, or any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license, or the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this subdivision, or any combination thereof. The board shall deny an application for a registration or license or revoke the license or registration of any person, other than one

who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing licensed professional clinical counseling services.

(d) Gross negligence or incompetence in the performance of licensed professional clinical counseling services.

(e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(f) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(g) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee or registrant, allowing any other person to use his or her license or registration.

(h) Aiding or abetting, or employing, directly or indirectly, any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(i) Intentionally or recklessly causing physical or emotional harm to any client.

(j) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(k) Engaging in sexual relations with a client, or a former client within two years following termination of therapy, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed professional clinical counselor.

(*l*) Performing, or holding oneself out as being able to perform, or offering to perform, or permitting any clinical counselor trainee or intern under supervision to perform, any professional services beyond the scope of the license authorized by this chapter.

(m) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client which is obtained from tests or other means.

(n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional clinical counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (n).

(p) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(q) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device.

`(r) Any conduct in the supervision of a registered intern, associate clinical social worker, or clinical counselor trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(s) Performing or holding oneself out as being able to perform professional services beyond the scope of one's competence, as established by one's education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(t) Permitting a clinical counselor trainee or intern under one's supervision or control to perform, or permitting the clinical counselor trainee or intern to hold himself or herself out as competent to perform, professional services beyond the clinical counselor trainee's or intern's level of education, training, or experience.

(u) The violation of any statute or regulation of the standards of the profession, and the nature of the services being rendered, governing the gaining and supervision of experience required by this chapter.

(v) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(w) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(x) Failing to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(y) Repeated acts of negligence.

(z) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(aa) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of an examination as described in Section 123.

(ab) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a clinical social worker, educational psychologist, or marriage and family therapist.

O

Attachment B

Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2104 **VERSION: As Amended April 8, 2010**

AUTHOR: Hayashi **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: California State Board of Pharmacy

Affected Sections: Amend Business and Professions Code Section 4003
Add Business and Professions Code Sections 4008.1 & 4008.2

EXISTING LAW:

1. Authorizes of the board to appoint an executive officer who shall exercise powers and perform duties delegated by the board.
2. Specifies that the executive officer may or may not be a member of the board as determined by the board.

THIS BILL WOULD:

1. Authorize the governor to appoint the executive officer.
2. Authorize the governor to determine if a member of the board may serve as the executive officer.
3. Require the board to submit to the department for approval all legislation it plans to sponsor, support or oppose.
4. Require the board to submit to the department for approval on the same legislation after any substantive amendments.
5. Establishes the reporting requirements for board members who engage in ex parte communication in the following ways:

- Provide a full report to the executive officer or during a public board meeting if it occurs within seven days of the next board meeting or hearing. This report will be made to the board and made part of the record for the meeting or hearing.
- Specify that if two or more members receive substantially the same written or oral communication from the same party, one board member fully discloses the communication on behalf of all members and makes the report part of the record.
- Require the executive officer to place in the public record any report of an ex parte communication.
- Specify that communications shall no longer be considered ex parte when the matter is fully disclosed and placed in the board's record of the meeting.

6. Defines ex parte communication as any written or oral communication between a board member and a person with an interest in a matter before the board that does not occur in a public proceeding on matters that fall into one of the following categories
    - Communication that occurs in a meeting or other conference, including telephone calls, that begins at a scheduled time.
    - Written communication including electronic mail or text messages.
    - Communication that occurs on calendar days when the board has a scheduled meeting or hearing.
    - Communication qualifies as an additional ex parte communications, as may be defined by the board by regulation.
    - Communication by or from any agent, officer, or employee of a licensee or any agent, officer, or employee of any civic, environmental, neighborhood, business, consumer, labor, trade, or similar organization.
7. Defines person of interest to include any person (as defined) who has a matter before the board who intends to influence the decision of a board member or any person with a financial interest in a matter before the board or a consumer or licensee who intends to influence the decision of a board member.
8. ~~Authorizes~~ Requires the board to promulgate regulations providing requirements for ex parte communication and appropriate sanctions for noncompliance.
9. Specifies reporting parameters to be included in the regulation including the date, time and location, the form of communication, identity of the initiator and receiver as well as all others present, a brief description of the information being provided as well as copies of any written materials provided as part of the communication.

AUTHOR'S INTENT:

According to a written statement by the author, "The California Board of Pharmacy has been sponsoring legislation that appears to conflict with its regulatory role, as well as its mission to protect the health and safety of Californians." This bill would require the board to get approval from the Department of Consumer Affairs before sponsoring legislation.

FISCAL IMPACT:

We do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS:

The board works closely with the Department of Consumer Affairs to secure its legislative objectives. As an executive branch agency, concerns of the Administration are important to the board. If unaddressed, such concerns could result in an oppose position or a veto if the legislation reaches the Governor. Accordingly, the board notifies the Administration of its

annual legislative proposals once determined (usually following the October or the January board meetings). The board also conducts its decision making in public board meetings where the department is present.

Throughout any legislative session, updates to the Administration are provided in response to their inquiries before bills are up in committee hearings as well as until recently, in monthly reports to the DCA director. Additionally, the board's staff works closely with departmental legislative and budget staff on all legislative matters as the session progresses.

There is no current requirement that *ex parte* communications (meaning discussions apart from a noticed meeting with members of the public) are disclosed at the next open session. What is not permitted is for the members to have "meetings" on board business that are not formally noticed. This means a majority of the Board cannot discuss Board topics at the same time or "serially" (chain of contacts) without it being placed on an agenda and discussed at a Board meeting. This majority requirement also applies to members of Committees, so no majority of a Committee of the Board can discuss at the same time or serially a topic that would come before the Committee without it being noticed and discussed at a committee meeting.

Ex parte communications with persons with disciplinary cases pending before the board are expressly prohibited by the Administrative Procedure Act (not the Open Meetings Act) and require mandatory disclosure and reporting to all parties of record. (Gov. Code, sections 11430.10, 11430.40, 11430.50, 11430.80). Such a communication also is grounds for disqualification of the board member from participating in the decision. (Gov. Code section 11430.60.)

SUPPORT and OPPOSITION:

SUPPORT

California Labor Federation
California Nurses Association

OPPOSITION

None on file.

HISTORY:

Date	Action
Apr. 12	Re-referred to Com. on B.,P. & C.P.
Apr. 8	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
Mar. 11	Referred to Com. on B. & P.
Feb. 21	From printer. May be heard in committee March 23.
Feb. 18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 8, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 2104

Introduced by Assembly Member Hayashi

February 18, 2010

An act to amend Section 4003 of, and to add Sections 4008.1 and 4008.2 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2104, as amended, Hayashi. California State Board of Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy within the Department of Consumer Affairs. Under existing law, the board is comprised of 13 members and the Governor appoints 11 of those members and one member each is appointed by the Senate Committee on Rules and the Speaker of the Assembly. Existing law authorizes the board to appoint a person exempt from civil service designated as the executive officer who performs the duties delegated by the board. Under existing law, the executive officer may or may not be a member of the board, as determined by the board. Existing law prohibits any board from submitting to the Legislature any fiscal impact analysis relating to legislation pending before the Legislature until the analysis has been submitted to the Director of Consumer Affairs for review and comment.

This bill would instead authorize the Governor to appoint the executive officer and would authorize the Governor to determine whether the executive officer may or may not be a member of the board. The bill would require the board to submit to the Department of Consumer Affairs and receive prior approval for every piece of state

legislation the board seeks to sponsor, support, or oppose and would require that same submittal and approval process after subsequent substantive amendments to legislation. The bill would also ~~authorize~~ *require* a board member, acting in his or her official capacity, ~~and engaging~~ *who engages* in an ex parte communication~~, as defined,~~ with a person with an interest, as defined, in a matter before the board to disclose that communication in *a* specified ~~manners~~ *manner*. The bill would ~~authorize~~ *require* the board to promulgate regulations providing requirements for reporting ex parte communications and sanctions for noncompliance.

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 4003 of the Business and Professions
2 Code is amended to read:
3 4003. (a) The Governor may appoint a person exempt from
4 civil service who shall be designated as an executive officer and
5 who shall exercise the powers and perform the duties delegated
6 by the board and vested in him or her by this chapter. The executive
7 officer may or may not be a member of the board as the Governor
8 may determine.
9 (b) The executive officer shall receive the compensation as
10 established by the board with the approval of the Director of
11 Finance. The executive officer shall also be entitled to travel and
12 other expenses necessary in the performance of his or her duties.
13 (c) The executive officer shall maintain and update in a timely
14 fashion records containing the names, titles, qualifications, and
15 places of business of all persons subject to this chapter.
16 (d) The executive officer shall give receipts for all money
17 received by him or her and pay it to the Department of Consumer
18 Affairs, taking its receipt therefor. Besides the duties required by
19 this chapter, the executive officer shall perform other duties
20 pertaining to the office as may be required of him or her by the
21 board.
22 (e) In accordance with Sections 101.1 and 473.1, this section
23 shall remain in effect only until January 1, 2013, and as of that
24 date is repealed, unless a later enacted statute, that is enacted before
25 January 1, 2013, deletes or extends that date.

SEC. 2. Section 4008.1 is added to the Business and Professions Code, to read:

4008.1. The board shall submit to the department and receive prior approval for every piece of state legislation the board seeks to sponsor, support, or oppose. The board shall resubmit and receive subsequent approval from the department on the same legislation after any substantive amendments.

SEC. 3. Section 4008.2 is added to the Business and Professions Code, to read:

4008.2. (a) A board member who is acting in his or her official capacity ~~and~~ *who* engages in an ex parte communication with a person with an interest in a matter before the board~~, may~~ *shall* disclose that communication in one of the following ways:

(1) The board member or the person discloses the communication pursuant to this section and makes public the ex parte communication by providing a full report of the communication to the executive officer or, if the communication occurs within seven days of the next board meeting or hearing, to the board on the record of the proceeding of that meeting or hearing.

(2) When two or more board members receive substantially the same written communication or receive the same oral communication from the same party on the same matter, one of the board members fully discloses the communication on behalf of the other board member or members who received the communication and requests in writing that it be placed in the board's official record of the proceeding.

(3) The executive officer shall place in the public record any report of an ex parte communication.

(4) Communications shall cease to be ex parte communications when fully disclosed and placed in the board's minutes pursuant to this section.

(b) For purposes of this section, "ex parte communication" means any oral or written communication between a board member and a person with an interest in a matter before the board, concerning substantive~~,~~ but not procedural issues, that does not occur in a public hearing, workshop, or other public proceeding, or on the official record of the proceeding on the matter and falls into one of the following categories:

(1) The communication occurs in a meeting or other conference, including telephone calls, that begins at a scheduled time.

(2) The communication is in writing, including electronic mail or text messages.

(3) The communication occurs on calendar days when the board has a scheduled meeting or hearing.

(4) The communication qualifies as an additional ex parte ~~communications~~ *communication*, as may be defined by the board by regulation.

(5) The communication is by or from any agent, officer, or employee of a licensee or any agent, officer, or employee of any civic, environmental, neighborhood, business, consumer, labor, trade, or similar organization.

(c) "Person with an interest," for purposes of this section, means any of the following:

(1) Any agent, officer, or employee of a licensee, or a person receiving consideration for representing the licensee, or a participant in the proceeding on any matter before the board who intends to influence the decision of a board member on a matter before the board.

(2) Any agent, officer, or employee of any civic, environmental, neighborhood, business, consumer, labor, trade, or similar organization who intends to influence the decision of a board member on a matter before the board.

(3) Any person with a financial interest, as described in Article 1 (commencing with Section 87100) of Chapter 7 of Title 9 of the Government Code, in a matter before the board, or an agent, officer, or employee of the person with a financial interest, or a person receiving consideration for representing the person with a financial interest who intends to influence the decision of a board member on a matter before the board.

(4) A consumer or licensee representing himself or herself who intends to influence the decision of a board member on a matter before the board.

(d) The board ~~may~~ *shall* promulgate regulations providing requirements for reporting of ex parte communications and appropriate sanctions for noncompliance with any rule proscribing ex parte communications. The regulation shall provide that reportable communications shall be reported by the board member or person with an interest before the board, whether the

1 communication was initiated by the person or the board member,
2 and that the report shall include all of the following information:
3 (1) The date, time, and location of the communication, and
4 whether it was oral, written, or a combination.
5 (2) The identity of the recipient and the person initiating the
6 communication, as well as the identity of any persons present
7 during the communication.
8 (3) A brief description of the interested person's, but not the
9 board member's, communication and its content, to which shall
10 be attached a copy of any written material or text used during the
11 communication.
12 (e) Nothing in this section shall be construed to affect the
13 requirements of Sections 11425.10 and 11430.10 of the
14 Government Code regarding quasi-adjudicatory proceedings.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1390 **VERSION: As Amended April 5, 2010**

AUTHOR: Corbett **SPONSOR: California Association of Health Facilities**

BOARD POSITION:

SUBJECT: Prescription Labeling Exemptions

Affected Sections: Business and Professions Code Section 4076.5

EXISTING LAW:

1. Establishes the labeling requirements for a prescription drug container.
2. Requires the board to develop a patient-centered prescription label via regulation.

THIS BILL WOULD:

Allow the board to exempt from the labeling requirements established in regulations, prescriptions dispensed to patients a patient in a long-term health care facility from the requirements of the if the prescriptions are administered by a licensed health care professional.

FISCAL IMPACT:

We do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS:

SB 470 (Corbett, Statutes of 2008) required the board to develop a patient-centered prescription label via regulation. These regulations are currently under a 15-day notice period and awaiting action by the board at the April 2010 Board Meeting.

SUPPORT and OPPOSITION:

Support
California Associate of Health Facilities
California Pharmacists Association
California Hospital Association
Omnicare

Oppose
None of file

HISTORY:

Date	Action
Apr. 5	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
Mar. 16	Set for hearing April 14.
Mar. 11	To Coms. on HEALTH and B., P. & E.D.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 19	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL No. 1390

Introduced by Senator Corbett

February 19, 2010

An act to amend Section 4076.5 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1390, as amended, Corbett. Prescription drug labels.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California.

This bill would authorize the board to exempt *from these regulatory requirements* certain prescriptions dispensed to patients in a long-term *health* care facility ~~from these regulatory 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 4076.5 of the Business and Professions
2 Code is amended to read:
3 4076.5. (a) The board shall promulgate regulations that require,
4 on or before January 1, 2011, a standardized, patient-centered,
5 prescription drug label on all prescription medicine dispensed to
6 patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt ~~certain~~ *from the requirements of regulations promulgated pursuant to subdivision (a)* prescriptions dispensed to ~~patients~~ *a patient* in a long-term *health* care facility ~~from the requirements of the~~ *if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a long-term health care facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the associated regulations. As used in this subdivision, "long-term health care facility" has the meaning as defined in Section 1418 of the Health and Safety Code.* regulations promulgated pursuant to subdivision (a).

(e) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1869 **VERSION: As introduced**

AUTHOR: Anderson **SPONSOR:**

BOARD POSITION:

SUBJECT: **Pharmacists Scope of Practice**

Affected Sections: NA - - Intent Language Only

EXISTING LAW:

Defines the scope of practice for a pharmacist.

THIS BILL WOULD:

States that it is the intent of the legislature to address the scope of practice of pharmacists.

COMMENTS:

This is a spot bill. Based on information received by the author's office, there are no immediate plans for this bill. Staff will continue to track.

HISTORY:

Feb. 16 From printer. May be heard in committee March 18.
Feb. 12 Read first time. To print.

ASSEMBLY BILL No. 1869

Introduced by Assembly Member Anderson

February 12, 2010

An act relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1869, as introduced, Anderson. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy.

This bill would declare the intent of the Legislature to address the scope of practice of pharmacists.

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 address the
2 scope of practice of pharmacists.

O

ASSEMBLY BILL No. 1869

Introduced by Assembly Member Anderson

February 12, 2010

An act relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1869, as introduced, Anderson. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy.

This bill would declare the intent of the Legislature to address the scope of practice of pharmacists.

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 address the
2 scope of practice of pharmacists.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1916 **VERSION: As Amended April 8, 2010**

AUTHOR: Davis **SPONSOR: Author**

BOARD POSITION:

SUBJECT: **Pharmacy Reporting**

Affected Sections: Add Section 4126.7 of the Business and Professions Code

EXISTING LAW:

1. Requires every pharmacy to establish a quality assurance plan to document medication errors attributable to the pharmacist or its personnel.
2. Defines a medication error as any variation from a prescription or drug order not authorized by the prescriber as specified.
3. Establishes the parameters of the quality assurance plan.

THIS BILL WOULD:

1. Require a pharmacy to promptly report to the board any occurrence known by the pharmacy of a prescription being furnished to a person other than the patient named on the prescription or that patient's representative.
2. Specify that report shall include any adverse reaction that may have occurred as a result of the person to whom the prescription was furnished using the prescribed drug.

FISCAL IMPACT:

If the board decides to investigate such reports, the board estimates that an additional part-time inspector will be required to investigate all such reports. It is possible that this associated workload could be absorbed if the additional inspector staff is received through the Consumer Protection Enforcement Initiative. In addition, the board estimates a part-time analyst will be needed to perform administrative and analytical functions resulting from these additional investigations including opening and closing the investigations and issuing letters of admonishment or citation and fines as appropriate and compiling reports.

COMMENTS:

Under current law, pharmacies are not required to notify the board of such errors, but rather to complete a quality assurance review, identify the cause of the error and make changes to ensure that such an error does not occur again. As part of an inspection of a pharmacy, board inspectors review the quality assurance plan to ensure compliance with those provisions of the law. Currently, the only investigations initiated based on this type of medication error are when a consumer notifies the board that it occurred.

Over the last several years, the board has heard presentations on how to reduce medication errors and recently the department developed brief video advising patients on actions they can take to reduce medication errors. One such action is to confirm that the medicine they receive at the pharmacy is theirs.

SUPPORT and OPPOSITION:

Unknown

HISTORY:

Date	Action
Apr. 12	Re-referred to Com. on HEALTH.
Apr. 8	Referred to Coms. on HEALTH and B.,P. & C.P. 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 APRIL 8, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1916

Introduced by Assembly Member Davis

February 16, 2010

~~An act to relating to pharmacy.~~ *An act to add Section 4126.7 to the Business and Professions Code, relating to pharmacies.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1916, as amended, Davis. Pharmacies: *prescriptions:* reports.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. ~~Existing law requires any pharmacy that contracts to compound a drug for parenteral therapy for delivery to another pharmacy to report that contractual arrangement to the board.~~ *Existing law authorizes a pharmacy to furnish dangerous drugs only to, among others, a patient or another pharmacy pursuant to a prescription or as otherwise authorized by law. Existing law requires every pharmacy to establish a quality assurance program to assess errors in dispensing or furnishing prescription drugs. A knowing violation of the Pharmacy Law is a crime unless otherwise specified.*

~~This bill would declare the intent of the Legislature to require a pharmacy to report to the board when a patient is given a prescription that belongs to another person.~~

This bill would require a pharmacy to report to the board any occurrence known by the pharmacy of a prescription being furnished to a person other than the patient named on the prescription or that patient's representative. The bill would also require the pharmacy to report any adverse reaction that may have occurred as a result of the

person to whom the prescription was furnished using the prescribed drug. Because a knowing violation of these 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: ~~no~~ *yes*. State-mandated local program: no.

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

1 *SECTION 1. Section 4126.7 is added to the Business and*
2 *Professions Code, to read:*
3 *4126.7. A pharmacy shall promptly report to the board any*
4 *occurrence known by the pharmacy of a prescription being*
5 *furnished to a person other than the patient named on the*
6 *prescription or that patient's representative. That report shall*
7 *include any adverse reaction that may have occurred as a result*
8 *of the person to whom the prescription was furnished using the*
9 *prescribed drug.*
10 *SEC. 2. No reimbursement is required by this act pursuant to*
11 *Section 6 of Article XIII B of the California Constitution because*
12 *the only costs that may be incurred by a local agency or school*
13 *district will be incurred because this act creates a new crime or*
14 *infraction, eliminates a crime or infraction, or changes the penalty*
15 *for a crime or infraction, within the meaning of Section 17556 of*
16 *the Government Code, or changes the definition of a crime within*
17 *the meaning of Section 6 of Article XIII B of the California*
18 *Constitution.*
19 ~~SECTION 1. It is the intent of the Legislature to enact~~
20 ~~legislation requiring a pharmacy to report to the California State~~
21 ~~Board of Pharmacy when a patient is given a prescription that~~
22 ~~belongs to another person, in order to determine how to possibly~~
23 ~~decrease the number of mix-ups and thereby save lives.~~

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1659 **VERSION: As Amended 4/7/2010**

AUTHOR: Huber **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: Joint Sunset Review Committee

Affected Sections: Add Article 7.5 (commencing with §9147.7) to the Government Code

EXISTING LAW:

1. Provides a sunset date of January 1, 2013 for the Board of Pharmacy.
2. Establishes the Joint Committee on Boards, Commissions, and Consumer Protection and, until January 1, 2012, requires the committee to hold public hearings to evaluate whether a board or regulatory program has demonstrated a need for its continued existence.

THIS BILL WOULD:

1. State the Legislature's intent to enact legislation that provides for the repeal of every entity of state government, excluding constitutionally created or agencies related to higher education.
2. State the Legislature's intent to create a special committee specifically composed to conduct a periodic review and evaluation of every entity of state government, as defined regarding the continued existence of state governmental agencies or their consolidation or reorganization.
3. Add Article 7.5. Sunset Review to the Government Code to
    a. Establish the Joint Sunset Review Committee;
    b. Require that defined entities submit to the committee a report that includes the following:
        i. The purpose and necessity of the agency
        ii. A description of its budget, priorities and job descriptions of its employees
        iii. All programs and projects under the direction of the agency
        iv. Measures of the success or failures of the agency and the justification for the metrics used to evaluate successes and failures and
        v. Recommendations for changes or reorganization in order to better fulfill its purpose

c. Specify that the committee shall take public testimony and evaluate the agency before a sunset date, and specify that the agency shall be eliminated unless the Legislature enacts a law to extend consolidate or reorganize the agency.
d. Specify that no agency shall be extended in perpetuity.
e. Allow for a one-year extension of a sunset date to allow the committee more time to evaluate the agency.
f. As amended, a committee of 10 shall be comprised of five members appointed by the Senate and five members appointed by the Assembly, as specified.
g. Specify when the committee shall convene and for the appointment of a chairperson of the committee.

RELATED LEGISLATION:

AB 2130 (Huber) is the implementation bill for AB 1659.

AUTHOR'S INTENT:

This author-sponsored bill seeks to establish a process through which the Legislature can conduct a comprehensive analysis of state entities to determine if an agency is still necessary, should be reorganized or is cost effective. The stated intent is that automatic sunset dates would be established for entities scheduled for review and that prior to the committee's recommendation, each agency would be required to report to the committee.

According to the author, there is no comprehensive listing of the entities that make up state government and this measure seeks to identify and eliminate waste, duplication and inefficiency in government agencies by creating the Joint Sunset Review Committee within the Legislature. The author states that the law needs to specify an enforcement mechanism to ensure that oversight work is part of annual legislative action.

FISCAL IMPACT:

The board does not anticipate any significant fiscal impact.

HISTORY:

Date	Action
Apr. 7	Read second time and amended.
Apr. 6	From committee: Amend, do pass as amended, and re-refer to Com. on APPR (Ayes 11. Noes 0.)
Feb. 4	Referred to Com. on B&P
Jan. 20	From Printer. May be heard in committee February 19.
Jan. 19	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 7, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1659

Introduced by Assembly Member Huber

January 19, 2010

An act to add Article 7.5 (commencing with Section 9147.7) to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code, relating to state government.

LEGISLATIVE COUNSEL'S DIGEST

AB 1659, as amended, Huber. State government: agency repeals.

Existing law establishes the Joint Committee on Boards, Commissions, and Consumer Protection and, until January 1, 2012, requires the committee to hold public hearings at specified times and to evaluate whether a board or regulatory program has demonstrated a need for its continued existence. Existing law states the intent of the Legislature that all existing and proposed state boards be subject to review every 4 years to evaluate and determine whether each has demonstrated a public need for its continued existence, as specified.

This bill would create the Joint Sunset Review Committee to identify and eliminate waste, duplication, and inefficiency in government agencies, as defined, and to conduct a comprehensive analysis of every agency to determine if the agency is still necessary and cost effective. The bill would require each agency scheduled for repeal to submit a report to the committee containing specified information. The bill would require the committee to take public testimony and evaluate the agency prior to the date the agency is scheduled to be repealed, and would require that an agency be eliminated unless the Legislature enacts a law~~, based upon a recommendation endorsed by a vote of the majority~~

~~of the members of the committee,~~ to extend, consolidate, or reorganize the agency. The bill would specify the composition of the committee, which would be appointed by the President pro Tempore of the Senate~~,~~ *and* the Speaker of the Assembly, ~~and the Governor,~~ and certain aspects of its operating procedure. The bill would also make a statement of legislative intent to enact legislation that provides for the repeal of every entity of state government, excluding an agency that is constitutionally created or an agency related to higher education.

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. (a) It is the intent of the Legislature to enact
2 legislation that provides for the repeal of every entity of state
3 government, excluding an agency that is constitutionally created
4 or an agency related to higher education, in order to eliminate
5 waste, duplication, and inefficiency in state government, subject
6 to a review and a subsequent affirmative act of the Legislature to
7 extend, consolidate, or reorganize the entity.
8 (b) It is further the intent of the Legislature to create a special
9 committee specifically composed to conduct a periodic review and
10 evaluation of every entity described in subdivision (a), which
11 would make recommendations, after appropriate factfinding and
12 evaluation, regarding the continued existence of state governmental
13 agencies or their consolidation or reorganization.
14 SEC. 2. Article 7.5 (commencing with Section 9147.7) is added
15 to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
16 Code, to read:
17
18 Article 7.5. Sunset Review
19
20 9147.7. (a) For the purpose of this section, "agency" means
21 any agency, authority, board, bureau, commission, conservancy,
22 council, department, division, or office of state government,
23 however denominated, excluding an agency that is constitutionally
24 created or an agency related to postsecondary education.
25 (b) The Joint Sunset Review Committee is hereby created to
26 identify and eliminate waste, duplication, and inefficiency in
27 government agencies. The purpose of the committee is to conduct

a comprehensive analysis of every agency to determine if the agency is still necessary and cost effective.

(c) Each agency scheduled for repeal shall submit to the committee, on or before December 1 prior to the year it is set to be repealed, a complete agency report covering the entire period since last reviewed, including, but not limited to, the following:

(1) The purpose and necessity of the agency.

(2) A description of the agency budget, priorities, and job descriptions of employees of the agency.

(3) All programs and projects under the direction of the agency.

(4) Measures of the success or failures of the agency and justifications for the metrics used to evaluate successes and failures.

(5) Any recommendations of the agency for changes or reorganization in order to better fulfill its purpose.

(d) The committee shall take public testimony and evaluate the agency prior to the date the agency is scheduled to be repealed. An agency shall be eliminated unless the Legislature enacts a law~~,~~ ~~based upon a recommendation endorsed by a vote of the majority of the members of the committee,~~ to extend, consolidate, or reorganize the agency. No agency shall be extended in perpetuity unless specifically exempted from the provisions of this section. The committee may recommend that the Legislature extend the statutory sunset date for no more than one year to allow the committee more time to evaluate the agency.

(e) The committee shall be comprised of ~~nine~~ *10* members of the Legislature. The President pro Tempore of the Senate shall appoint ~~three~~ *five* members of the Senate to the committee, not more than ~~two~~ *three* of whom shall be members of the same political party. The Speaker of the Assembly shall appoint ~~three~~ *five* members of the Assembly to the committee, not more than ~~two~~ *three* of whom shall be members of the same political party. ~~The Governor, with the advice and consent of the Senate, shall appoint three members to the committee, not more than two of whom shall be members of the same political party.~~ Members shall be appointed within 15 days after the commencement of the regular session. Each member of the committee who is appointed by the President pro Tempore of the Senate or the Speaker of the Assembly shall serve during that committee member's term of office or until that committee member no longer is a Member of the Senate or the Assembly, whichever is applicable. ~~Each member~~

~~of the committee who is appointed by the Governor shall serve a two-year term that ends on the 30th day of November in even number years.~~ A vacancy on the committee shall be filled in the same manner as the original appointment. ~~Five~~ *Six* members of the committee shall constitute a quorum for the conduct of committee business. Members of the committee shall receive no compensation for their work with the committee.

(f) The committee shall meet not later than 30 days after the first day of the regular session to choose a chairperson and to establish the schedule for agency review provided for in the statutes governing the agencies. The chairperson of the committee shall alternate every two years between a Member of the Senate and a Member of the Assembly, and the vice chairperson of the committee shall be a member of the opposite house as the chairperson.

(g) This section shall not be construed to change the existing jurisdiction of the budget or policy committees of the Legislature.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2130 **VERSION: As Introduced 2/18/2010**

AUTHOR: Huber **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: Sunset Review Act Implementation

Affected Sections: Amend Business and Professions Code Section 4001

EXISTING LAW:

1. Provides a sunset date of January 1, 2013 for the Board of Pharmacy.
2. Establishes the Joint Committee on Boards, Commissions, and Consumer Protection to hold public hearings to evaluate whether a board or regulatory program has demonstrated a need for its continued existence.
3. States legislative intent that all existing and proposed state boards be subject to review every four years to evaluate and determine whether each has demonstrated a public need for its continued existence, as specified.

THIS BILL WOULD:

1. Repeal Business and Professions Code section 473 – thereby eliminating the Joint Committee on Boards, Commissions, and Consumer Protection.
2. Serve as the implementation bill for AB 1659 (Huber) which creates the Joint Sunset Review Committee (JSRC).
3. Require boards and bureaus under the Department of Consumer Affairs that already contain a sunset date to be reviewed by the new JSRC (Article 7.5 commencing with section 9147.7 of the Government Code).
4. Double-joints this measure to AB 1659 (Huber).

AUTHOR'S INTENT:

According to the author, AB 2130 seeks to establish long-term accountability and oversight for government entities by requiring a systematic review and evaluation to determine if there is a public need for an existing or proposed state board or bureau. This measure (AB 2130) is the implementation bill for AB 1659 (Huber) which adds Article 7.5 to the Government Code and therein creates the Joint Sunset Review Committee (JSRC) related to professions and vocations.

FISCAL IMPACT:

The board does not anticipate any significant fiscal impact.

SUPPORT and OPPOSITION:

Support

Oppose

HISTORY:

Date	Action
Apr. 6	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 11. Noes 0.)
Mar. 11	Referred to ASM Com. on B. & P.
Feb. 19	From Printer. May be heard in committee March 21.
Feb. 18	Read first time. To print.

HEARING:

Affected DCA Boards and Bureaus:

Board of Pharmacy
Dental Board
Dental Hygiene Committee of the Dental Board
Medical Board
Guide Dogs for the Blind
Osteopathic Medical Board
California Board of Podiatric Medicine
Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board
Board of Occupational Therapy
Dispensing Opticians
Physical Therapy Board
Registered Nursing
Vocational Nursing and Psychiatric Technicians
Optometry
Physician Assistant Committee of the Medical Board
Naturopathic Medicine Committee
Respiratory Care Board
Massage Therapists
Veterinary Medical Board
Licensed Educational Psychologists
Board of Behavioral Sciences
Marriage and Family Therapists
Board of Accountancy
Architects Board
Interior Designers
Professional Fiduciaries Bureau
Board for Professional Engineers and Land Surveyors
Board of Barbering and Cosmetology
Bureau of Security and Investigative Services
Funeral Directors and Embalmers
Electronic and Appliance Repair
Bureau of Automotive Repair
Tax Preparers

Last updated: 03/25/2010

Background Sheet
AB 2130 (Huber)
Sunset Review Act Implementation

SUMMARY

AB 2130 serves as the implementation bill for the Joint Sunset Review Committee created in AB 1659 (Huber) by defining which government entities will be subject to the Committee's review over a long term cycle.

AB 2130 is contingent on the passage of AB 1659.

BACKGROUND

AB 2130 seeks to establish accountability and oversight for government entities by requiring a systematic review and evaluation of state entities.

Under current law the Joint Committee on Boards, Commissions, and Consumer Protection is granted the power to hold public hearings at specified times and to evaluate whether a board or regulatory program under the Department of Consumer Affairs has demonstrated a need for its continued existence. Committee members have not been appointed to this committee since 2006 and the jurisdiction is limited to the boards and commissions that fall under the Business and Professions code.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection and move the functions of this Committee to the Joint Sunset Review Committee created by AB 1659.

Furthermore, AB 2130 defines which government entities will be subject to the Committee established by AB 1659 and sets the timetable for sunset pursuant to the policy set forth in AB 1659.

The purpose of AB 1659 and AB 2130 is to establish a long term process through which the state can conduct routine reviews of entities and determine if they are still necessary.

It is not the intention of AB 1659 or AB 2130 to prohibit standing committees from conducting their own periodic reviews of boards and commissions under their jurisdiction.

STATUS

AB 2130 will be heard in the Assembly Committee on Business and Professions on April 6.

SPONSOR

Author

SUPPORT

- None on file.

OPPOSITION

- None on file.

CONTACT

Jennifer Wonnacott, Legislative Director 916/319-2010

ASSEMBLY BILL No. 2130

Introduced by Assembly Member Huber

February 18, 2010

An act to amend Sections 22, 101.1, 1917.2, 2001, 2450.3, 2460, 2531, 2569, 2570.19, 2602, 2607.5, 2701, 2841, 3010.5, 3502.1, 3504, 3685, 3710, 4001, 4615, 4800, 4809.8, 4989, 4990.24, 5000, 5510, 5810, 6510, 6710, 7304, 7501, 8710, 9882, 11506, and 22259 of, to amend and repeal Section 1601.1 of, to add Sections 7200.2, 7611, and 9815 to, and to repeal Division 1.2 (commencing with Section 473) of, the Business and Professions Code, and to amend Sections 9148.51 and 9148.52 of the Government Code, relating to professions and vocations.

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LEGISLATIVE COUNSEL'S DIGEST

AB 2130, as introduced, Huber. Professions and vocations: sunset review.

Existing law establishes the Joint Committee on Boards, Commissions, and Consumer Protection and, until January 1, 2012, requires the committee to hold public hearings at specified times and to evaluate whether a board or regulatory program has demonstrated a need for its continued existence. Existing law states the intent of the Legislature that all existing and proposed state boards be subject to review every 4 years to evaluate and determine whether each has demonstrated a public need for its continued existence, as specified.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection. The bill would instead make specified boards and regulatory programs subject to review by the Joint Sunset Review Committee. The bill would provide that its provisions would not become

operative unless Assembly Bill 1659 is enacted and establishes the Joint Sunset Review Committee.

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 22 of the Business and Professions Code
2 is amended to read:
3 22. (a) "Board," as used in any provision of this code, refers
4 to the board in which the administration of the provision is vested,
5 and unless otherwise expressly provided, shall include "bureau,"
6 "commission," "committee," "department," "division," "examining
7 committee," "program," and "agency."
8 (b) Whenever the regulatory program of a board that is subject
9 to review by the Joint *Sunset Review* Committee~~ on Boards,~~
10 ~~Commissions, and Consumer Protection~~, as provided for in
11 ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5*
12 *(commencing with Section 9147.7) of Chapter 1.5 of Part 1 of*
13 *Division 2 of Title 2 of the Government Code*, is taken over by the
14 department, that program shall be designated as a "bureau."
15 SEC. 2. Section 101.1 of the Business and Professions Code
16 is amended to read:
17 101.1. (a) It is the intent of the Legislature that all existing
18 and proposed consumer-related boards or categories of licensed
19 professionals be subject to a review every four years to evaluate
20 and determine whether each board has demonstrated a public need
21 for the continued existence of that board in accordance with
22 enumerated factors and standards as set forth in~~ Division 1.2~~
23 ~~(commencing with Section 473)~~ *Article 7.5 (commencing with*
24 *Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2*
25 *of the Government Code.*
26 (b) (1) ~~In the event that~~ *If* any board, as defined in Section ~~477~~
27 *22*, becomes inoperative or is repealed in accordance with the act
28 that added this section, or by subsequent acts, the Department of
29 Consumer Affairs shall succeed to and is vested with all the duties,
30 powers, purposes, responsibilities and jurisdiction not otherwise
31 repealed or made inoperative of that board and its executive officer.
32 (2) Any provision of existing law that provides for the
33 appointment of board members and specifies the qualifications

and tenure of board members shall not be implemented and shall have no force or effect while that board is inoperative or repealed. Every reference to the inoperative or repealed board, as defined in Section ~~477~~ *22*, shall be deemed to be a reference to the department.

(3) Notwithstanding Section 107, any provision of law authorizing the appointment of an executive officer by a board subject to the review described in ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code*, or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable board is inoperative or repealed. Any reference to the executive officer of an inoperative or repealed board shall be deemed to be a reference to the director or his or her designee.

(c) It is the intent of the Legislature that subsequent legislation to extend or repeal the inoperative date for any board shall be a separate bill for that purpose.

SEC. 3. Division 1.2 (commencing with Section 473) of the Business and Professions Code is repealed.

SEC. 4. Section 1601.1 of the Business and Professions Code, as added by Section 1 of Chapter 35 of the Statutes of 2008, is amended to read:

1601.1. (a) There shall be in the Department of Consumer Affairs the Dental Board of California in which the administration of this chapter is vested. The board shall consist of eight practicing dentists, one registered dental hygienist, one registered dental assistant, and four public members. Of the eight practicing dentists, one shall be a member of a faculty of any California dental college, and one shall be a dentist practicing in a nonprofit community clinic. The appointing powers, described in Section 1603, may appoint to the board a person who was a member of the prior board. The board shall be organized into standing committees dealing with examinations, enforcement, and other subjects as the board deems appropriate.

(b) For purposes of this chapter, any reference in this chapter to the Board of Dental Examiners shall be deemed to refer to the Dental Board of California.

(c) The board shall have all authority previously vested in the existing board under this chapter. The board may enforce all disciplinary actions undertaken by the previous board.

(d) This section shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 5. Section 1601.1 of the Business and Professions Code, as added by Section 3 of Chapter 31 of the Statutes of 2008, is repealed.

~~1601.1. (a) There shall be in the Department of Consumer Affairs the Dental Board of California in which the administration of this chapter is vested. The board shall consist of eight practicing dentists, one registered dental hygienist, one registered dental assistant, and four public members. Of the eight practicing dentists, one shall be a member of a faculty of any California dental college and one shall be a dentist practicing in a nonprofit community clinic. The appointing powers, described in Section 1603, may appoint to the board a person who was a member of the prior board. The board shall be organized into standing committees dealing with examinations, enforcement, and other subjects as the board deems appropriate.~~

~~(b) For purposes of this chapter, any reference in this chapter to the Board of Dental Examiners shall be deemed to refer to the Dental Board of California.~~

~~(c) The board shall have all authority previously vested in the existing board under this chapter. The board may enforce all disciplinary actions undertaken by the previous board.~~

~~(d) This section shall remain in effect only until January 1, 2012, and as of that date, is repealed, unless a later enacted statute that is enacted before January 1, 2012, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 6. Section 1917.2 of the Business and Professions Code is amended to read:

1917.2. (a) The committee shall license as a registered dental hygienist a third- or fourth-year dental student who is in good

standing at an accredited California dental school and who satisfies the following requirements:

(1) Satisfactorily performs on a clinical examination and an examination in California law and ethics as prescribed by the committee.

(2) Satisfactorily completes a national written dental hygiene examination approved by the committee.

(b) A dental student who is granted a registered dental hygienist license pursuant to this section may only practice in a dental practice that serves patients who are insured under Denti-Cal, the Healthy Families Program, or other government programs, or a dental practice that has a sliding scale fee system based on income.

(c) Upon receipt of a license to practice dentistry pursuant to Section 1634, a registered dental hygienist license issued pursuant to this ~~subdivision~~ *section* is automatically revoked.

(d) The dental hygienist license is granted for two years upon passage of the dental hygiene examination, without the ability for renewal.

(e) Notwithstanding subdivision (d), if a dental student fails to remain in good standing at an accredited California dental school, or fails to graduate from the dental program, a registered dental hygienist license issued pursuant to this section shall be revoked. The student shall be responsible for submitting appropriate verifying documentation to the committee.

(f) The provisions of this section shall be reviewed pursuant to ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code*. However, the review shall be limited to the fiscal feasibility and impact on the committee.

(g) This section shall become inoperative ~~as of~~ *on* January 1, 2012.

SEC. 7. Section 2001 of the Business and Professions Code is amended to read:

2001. (a) There is in the Department of Consumer Affairs a Medical Board of California that consists of 15 members, seven of whom shall be public members.

(b) The Governor shall appoint 13 members to the board, subject to confirmation by the Senate, five of whom shall be public

members. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(c) Notwithstanding any other provision of law, to reduce the membership of the board to 15, the following shall occur:

(1) Two positions on the board that are public members having a term that expires on June 1, 2010, shall terminate instead on January 1, 2008.

(2) Two positions on the board that are not public members having a term that expires on June 1, 2008, shall terminate instead on August 1, 2008.

(3) Two positions on the board that are not public members having a term that expires on June 1, 2011, shall terminate instead on January 1, 2008.

(d) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 8. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, 2013, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the Naturopathic Medicine Committee subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 9. Section 2460 of the Business and Professions Code is amended to read:

2460. (a) There is created within the jurisdiction of the Medical Board of California the California Board of Podiatric Medicine.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The

repeal of this section renders the California Board of Podiatric Medicine subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 10. Section 2531 of the Business and Professions Code is amended to read:

2531. (a) There is in the Department of Consumer Affairs a Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board in which the enforcement and administration of this chapter are vested. The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board shall consist of nine members, three of whom shall be public members.

(b) This section shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 11. Section 2569 of the Business and Professions Code is amended to read:

2569. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.* ~~The review shall be performed as if this chapter were scheduled to become inoperative on July 1, 2003, and would be repealed as of January 1, 2004, as described in Section 473.1.~~

SEC. 12. Section 2570.19 of the Business and Professions Code is amended to read:

2570.19. (a) There is hereby created a California Board of Occupational Therapy, hereafter referred to as the board. The board shall enforce and administer this chapter.

(b) The members of the board shall consist of the following:

(1) Three occupational therapists who shall have practiced occupational therapy for five years.

(2) One occupational therapy assistant who shall have assisted in the practice of occupational therapy for five years.

(3) Three public members who shall not be licentiates of the board or of any board referred to in Section 1000 or 3600.

(c) The Governor shall appoint the three occupational therapists and one occupational therapy assistant to be members of the board. The Governor, the Senate Rules Committee, and the Speaker of the Assembly shall each appoint a public member. Not more than one member of the board shall be appointed from the full-time faculty of any university, college, or other educational institution.

(d) All members shall be residents of California at the time of their appointment. The occupational therapist and occupational therapy assistant members shall have been engaged in rendering occupational therapy services to the public, teaching, or research in occupational therapy for at least five years preceding their appointments.

(e) The public members may not be or have ever been occupational therapists or occupational therapy assistants or in training to become occupational therapists or occupational therapy assistants. The public members may not be related to, or have a household member who is, an occupational therapist or an occupational therapy assistant, and may not have had, within two years of the appointment, a substantial financial interest in a person regulated by the board.

(f) The Governor shall appoint two board members for a term of one year, two board members for a term of two years, and one board member for a term of three years. Appointments made thereafter shall be for four-year terms, but no person shall be appointed to serve more than two consecutive terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the first appointed members who shall serve through the last calendar day of the year in which they are appointed, before commencing the terms prescribed by this section. Vacancies shall be filled by appointment for the unexpired term. The board shall annually elect one of its members as president.

(g) The board shall meet and hold at least one regular meeting annually in the Cities of Sacramento, Los Angeles, and San Francisco. The board may convene from time to time until its business is concluded. Special meetings of the board may be held at any time and place designated by the board.

(h) Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(i) Members of the board shall receive no compensation for their services, but shall be entitled to reasonable travel and other expenses incurred in the execution of their powers and duties in accordance with Section 103.

(j) The appointing power shall have the power to remove any member of the board from office for neglect of any duty imposed by state law, for incompetency, or for unprofessional or dishonorable conduct.

(k) A loan is hereby authorized from the General Fund to the Occupational Therapy Fund on or after July 1, 2000, in an amount of up to one million dollars ($1,000,000) to fund operating, personnel, and other startup costs of the board. Six hundred ten thousand dollars ($610,000) of this loan amount is hereby appropriated to the board to use in the 2000–01 fiscal year for the purposes described in this subdivision. In subsequent years, funds from the Occupational Therapy Fund shall be available to the board upon appropriation by the Legislature in the annual Budget Act. The loan shall be repaid to the General Fund over a period of up to five years, and the amount paid shall also include interest at the rate accruing to moneys in the Pooled Money Investment Account. The loan amount and repayment period shall be minimized to the extent possible based upon actual board financing requirements as determined by the Department of Finance.

(*l*) This section shall become inoperative on July 1, 2013, and, as of January 1, 2014, is repealed, unless a later enacted statute that is enacted before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 13. Section 2602 of the Business and Professions Code is amended to read:

2602. The Physical Therapy Board of California, hereafter referred to as the board, shall enforce and administer this chapter. This section shall become inoperative on July 1, 2013, and, as of

January 1, 2014, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed.

The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 14. Section 2607.5 of the Business and Professions Code is amended to read:

2607.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall become inoperative on July 1, 2013, and, as of January 1, 2014, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed.

~~The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 15. Section 2701 of the Business and Professions Code is amended to read:

2701. (a) There is in the Department of Consumer Affairs the Board of Registered Nursing consisting of nine members.

(b) Within the meaning of this chapter, board, or the board, refers to the Board of Registered Nursing. Any reference in state law to the Board of Nurse Examiners of the State of California or California Board of Nursing Education and Nurse Registration shall be construed to refer to the Board of Registered Nursing.

(c) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 16. Section 2841 of the Business and Professions Code is amended to read:

2841. (a) There is in the Department of Consumer Affairs a Board of Vocational Nursing and Psychiatric Technicians of the State of California, consisting of 11 members.

(b) Within the meaning of this chapter, "board," or "the board," refers to the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(c) This section shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 17. Section 3010.5 of the Business and Professions Code is amended to read:

3010.5. (a) There is in the Department of Consumer Affairs a State Board of Optometry in which the enforcement of this chapter is vested. The board consists of 11 members, five of whom shall be public members.

Six members of the board shall constitute a quorum.

(b) The board shall, with respect to conducting investigations, inquiries, and disciplinary actions and proceedings, have the authority previously vested in the board as created pursuant to Section 3010. The board may enforce any disciplinary actions undertaken by that board.

(c) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 18. Section 3502.1 of the Business and Professions Code is amended to read:

3502.1. (a) In addition to the services authorized in the regulations adopted by the board, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) "Drug order" for purposes of this section means an order for medication that is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription or order of the supervising physician, (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians and surgeons, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be approved by the supervising physician and surgeon before it is filled or carried out.

(1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under

the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.

(2) A physician assistant may not administer, provide, or issue a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for that particular patient unless the physician assistant has completed an education course that covers controlled substances and that meets standards, including pharmacological content, approved by the committee. The education course shall be provided either by an accredited continuing education provider or by an approved physician assistant training program. If the physician assistant will administer, provide, or issue a drug order for Schedule II controlled substances, the course shall contain a minimum of three hours exclusively on Schedule II controlled substances. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established by the committee prior to the physician assistant's use of a registration number issued by the United States Drug Enforcement Administration to the physician assistant to administer, provide, or issue a drug order to a patient for a controlled substance without advance approval by a supervising physician and surgeon for that particular patient.

(3) Any drug order issued by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon's practice.

(d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient's medical record in a health facility or medical practice, shall contain the printed name, address, and phone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug order in a patient's medical record in a health facility or a medical practice, shall include the federal controlled substances registration number of the physician assistant and shall otherwise comply with the provisions of Section 11162.1 of the Health and Safety Code.

Except as otherwise required for written drug orders for controlled substances under Section 11162.1 of the Health and Safety Code, the requirements of this subdivision may be met through stamping or otherwise imprinting on the supervising physician and surgeon's prescription blank to show the name, license number, and if applicable, the federal controlled substances number of the physician assistant, and shall be signed by the physician assistant. When using a drug order, the physician assistant is acting on behalf of and as the agent of a supervising physician and surgeon.

(e) The medical record of any patient cared for by a physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out shall be reviewed and countersigned and dated by a supervising physician and surgeon within seven days.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The committee shall consult with the Medical Board of California and report during its sunset review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code* the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 19. Section 3504 of the Business and Professions Code is amended to read:

3504. There is established a Physician Assistant Committee of the Medical Board of California. The committee consists of nine members. This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the committee subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 20. Section 3685 of the Business and Professions Code is amended to read:

3685. ~~(a)~~ The repeal of this chapter renders the committee subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

~~(b) The committee shall prepare the report required by Section 473.2 no later than September 1, 2010.~~

SEC. 21. Section 3710 of the Business and Professions Code is amended to read:

3710. (a) The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 22. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a

"chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) ~~In accordance with Sections 101.1 and 473.1, this~~ *This* section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 23. Section 4615 of the Business and Professions Code is amended to read:

4615. This chapter shall be subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 24. Section 4800 of the Business and Professions Code is amended to read:

4800. There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of seven members, three of whom shall be public members.

This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.

The repeal of this section renders the board subject to the review provided for by ~~Division 1.2 (commencing with Section 473)~~

Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 25. Section 4809.8 of the Business and Professions Code is amended to read:

4809.8. (a) The board shall appoint a voluntary, advisory multidisciplinary committee to assist, advise, and make recommendations for the implementation of rules and regulations necessary to ensure proper administration and enforcement of this chapter. Members of the committee shall be appointed from lists of nominees solicited by the board. The committee shall consist of no more than nine members.

(b) The committee shall be subject to the requirements of Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(c) Committee members shall receive a per diem as provided in Section 103 and shall be compensated for their actual travel expenses in accordance with the rules and regulations adopted by the Department of Personnel Administration.

(d) This section shall become inoperative on July 1, 2011, and as of January 1, 2012, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the committee subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 26. Section 4989 of the Business and Professions Code is amended to read:

4989. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by ~~Division 1.2 (commencing with Section 473). The review shall be performed as if this chapter were scheduled to become inoperative on July 1, 2005, and would be repealed as of January 1, 2006, as described in Section 473.1~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 27. Section 4990.24 of the Business and Professions Code is amended to read:

4990.24. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by ~~Division~~

~~1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 28. Section 5000 of the Business and Professions Code is amended to read:

5000. There is in the Department of Consumer Affairs the California Board of Accountancy, which consists of 15 members, seven of whom shall be licensees, and eight of whom shall be public members who shall not be licentiates of the board or registered by the board. The board has the powers and duties conferred by this chapter.

The Governor shall appoint four of the public members, and the seven licensee members as provided in this section. The Senate Rules Committee and the Speaker of the Assembly shall each appoint two public members. In appointing the seven licensee members, the Governor shall appoint members representing a cross section of the accounting profession with at least two members representing a small public accounting firm. For the purposes of this chapter, a small public accounting firm shall be defined as a professional firm that employs a total of no more than four licensees as partners, owners, or full-time employees in the practice of public accountancy within the State of California.

This section shall become inoperative on July 1, 2011, and as of January 1, 2012, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2012, deletes or extends the dates on which this section becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.* However, the review of the board shall be limited to reports or studies specified in this chapter and those issues identified by the Joint *Sunset Review* Committee ~~on Boards, Commissions, and Consumer Protection~~ and the board regarding the implementation of new licensing requirements.

SEC. 29. Section 5510 of the Business and Professions Code is amended to read:

5510. There is in the Department of Consumer Affairs a California Architects Board which consists of 10 members.

Any reference in law to the California Board of Architectural Examiners shall mean the California Architects Board.

This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 30. Section 5810 of the Business and Professions Code is amended to read:

5810. (a) This chapter shall be subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

(b) This chapter shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 31. Section 6510 of the Business and Professions Code is amended to read:

6510. (a) There is within the jurisdiction of the department the Professional Fiduciaries Bureau. The bureau is under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief of the bureau, who is responsible to the director. Every power granted or duty imposed upon the director under this chapter may be exercised or performed in the name of the director by a deputy director or by the chief, subject to conditions and limitations as the director may prescribe.

(b) The Governor shall appoint, subject to confirmation by the Senate, the chief of the bureau, at a salary to be fixed and determined by the director with the approval of the Director of Finance. The chief shall serve under the direction and supervision of the director and at the pleasure of the Governor.

(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, that becomes operative on or before January 1, ~~2011~~ *2012*, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the bureau subject to the review required by ~~Division 1.2 (commencing with Section~~

~~473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

Notwithstanding any other provision of law, upon the repeal of this section, the responsibilities and jurisdiction of the bureau shall be transferred to the Professional Fiduciaries Advisory Committee, as provided by Section 6511.

SEC. 32. Section 6710 of the Business and Professions Code is amended to read:

6710. (a) There is in the Department of Consumer Affairs a Board for Professional Engineers and Land Surveyors, which consists of 13 members.

(b) Any reference in any law or regulation to the Board of Registration for Professional Engineers and Land Surveyors is deemed to refer to the Board for Professional Engineers and Land Surveyors.

(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 33. Section 7200.2 is added to the Business and Professions Code, to read:

7200.2. The board shall be subject to the review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 34. Section 7304 of the Business and Professions Code is amended to read:

7304. The board shall be subject to review pursuant to ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 35. Section 7501 of the Business and Professions Code is amended to read:

7501. *(a)* There is in the Department of Consumer Affairs a Bureau of Security and Investigative Services. The bureau is under the supervision and control of the director. The director shall administer and enforce the provisions of this chapter.

(b) The bureau shall be subject to the review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 36. Section 7611 is added to the Business and Professions Code, to read:

7611. The bureau shall be subject to the review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 37. Section 8710 of the Business and Professions Code is amended to read:

8710. (a) The Board for Professional Engineers and Land Surveyors is vested with power to administer the provisions and requirements of this chapter, and may make and enforce rules and regulations that are reasonably necessary to carry out its provisions.

(b) The board may adopt rules and regulations of professional conduct that are not inconsistent with state and federal law. The rules and regulations may include definitions of incompetence and negligence. Every person who holds a license or certificate issued by the board pursuant to this chapter, or a license or certificate issued to a civil engineer pursuant to Chapter 7 (commencing with Section 6700), shall be governed by these rules and regulations.

(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section shall render the board subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

SEC. 38. Section 9815 is added to the Business and Professions Code, to read:

9815. The bureau shall be subject to the review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 39. Section 9882 of the Business and Professions Code is amended to read:

9882. (a) There is in the Department of Consumer Affairs a Bureau of Automotive Repair under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief who is responsible to the director. The director

may adopt and enforce those rules and regulations that he or she determines are reasonably necessary to carry out the purposes of this chapter and declaring the policy of the bureau, including a system for the issuance of citations for violations of this chapter as specified in Section 125.9. These rules and regulations shall be adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(b) In 2003 and every four years thereafter, the Joint *Sunset Review* Committee ~~on Boards, Commissions, and Consumer Protection~~ shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the bureau. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare. The committee shall evaluate and review the effectiveness and efficiency of the bureau ~~based on factors and minimum standards of performance that are specified in Section 473.4. The committee~~ *and* shall report its findings and recommendations *to the Legislature* as specified in ~~Section 473.5~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code*. The bureau shall prepare an analysis and submit a report to the committee as specified in ~~Section 473.2~~ *subdivision (c) of Section 9147.7 of the Government Code.*

SEC. 40. Section 11506 of the Business and Professions Code is amended to read:

11506. This part shall be subject to the review required by ~~Division 1.2 (commencing with Section 473)~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code*. This part shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date.

SEC. 41. Section 22259 of the Business and Professions Code is amended to read:

22259. This chapter shall be subject to the review required by ~~Division 1.2 (commencing with Section 473). This~~ *Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code.*

This chapter shall remain in effect only until January 1, 2012, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2012, deletes or extends that date.

SEC. 42. Section 9148.51 of the Government Code is amended to read:

9148.51. (a) It is the intent of the Legislature that all existing and proposed state boards be subject to review every four years to evaluate and determine whether each has demonstrated a public need for its continued existence in accordance with enumerated factors and standards as set forth in ~~Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code~~ *Article 7.5 (commencing with Section 9147.7)*.

(b) ~~In the event that~~ *If* any state board becomes inoperative or is repealed in accordance with the act that added this section, any provision of existing law that provides for the appointment of board members and specifies the qualifications and tenure of board members shall not be implemented and shall have no force or effect while that state board is inoperative or repealed.

(c) Any provision of law authorizing the appointment of an executive officer by a state board subject to the review described ~~in Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code~~ *Article 7.5 (commencing with Section 9147.7)*, or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable state board is inoperative or repealed.

(d) It is the intent of the Legislature that subsequent legislation to extend or repeal the inoperative date for any state board shall be a separate bill for that purpose.

SEC. 43. Section 9148.52 of the Government Code is amended to read:

9148.52. (a) The Joint *Sunset Review* Committee ~~on Boards, Commissions, and Consumer Protection~~ established pursuant to Section ~~473 of the Business and Professions Code~~ *9147.7* shall review all state boards, as defined in Section 9148.2, ~~other than a board subject to review pursuant to Chapter 1 (commencing with Section 473) of Division 1.2 of the Business and Professions Code,~~ every four years.

(b) The committee shall evaluate and make determinations pursuant to ~~Chapter 2 (commencing with Section 474) of Division~~

1 ~~1.2 of the Business and Professions Code~~ *Article 7.5 (commencing*
2 *with Section 9147.7).*
3 SEC. 44. This act shall not become operative unless Assembly
4 Bill 1659 of the 2009–10 Regular Session is also enacted and
5 becomes operative on or before January 1, 2011, and adds Article
6 7.5 (commencing with Section 9147.7) to Chapter 1.5 of Part 1 of
7 Division 2 of Title 2 of the Government Code to establish the Joint
8 Sunset Review Committee.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: **SB 954** **VERSION: Introduced 2/4/2010**

AUTHOR: **Harman (Coauthor: Dutton)** **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: **Legislative Procedure: Committee Referrals**

Affected Sections of Law:

Amend Chapters 1 and 2 of Division 1.2. of the Business and Professions Code re: the Joint Committee on Boards, Commissions, and Consumer Protection
Add Chapter 3 to Division 1.2. of the Business and Professions Code
Business and Professions Code §4001.5, §4200.1, and §4200.3

EXISTING LAW:

1. The California Constitution authorizes each house of the Legislature to provide for the selection of committees necessary for the conduct of its business, including committees.

THIS BILL WOULD:

1. Create the Jobs Protection Act
2. Rename the Joint Committee on Boards, Commissions, and Consumer Protection as the "Joint Committee on Boards, Commissions, and Consumer ***or Business*** Protection."
3. Create a new legislative procedure with regard to any bill, as defined, that may have a statewide impact affecting business.
4. Require the Assembly Committee on Rules and the Senate Committee on Rules to refer any bill that may have a statewide economic impact affecting business, as specified, to the joint committee for the preparation of an economic impact report and a hearing and approval.
5. Require the joint committee to move a bill estimated to generate a fiscal impact of $10,000 or more on small business, as defined, or $50,000 or more on any other business, to the suspense file of the joint committee for further consideration, subject to specified procedural requirements and to make an annual report in that regard.

AUTHOR'S INTENT:

According to the author, SB 954 is in response to the ever-growing burdensome regulations and mandates, in addition to the high tax rates and red tape that have made California a hostile climate in which to do business.

The author states that California's business community is the starting point for job creation and getting our economy back on track. In order to protect jobs, we must protect businesses and that overregulation has been driving businesses and jobs out of this state for years.

Further, the author provides that the Jobs Protection Act will require that any bill that has an economic impact on California business be sent to an existing joint committee for the preparation of an Economic Impact Report (EIR) and hearing.

STAFF COMMENTS:

Senator Harman authored a like measure, SB 60, which was heard in the 8th Extraordinary Session; which failed. The Senate Committee on Rules' analysis raised concerns regarding the potential cost to the Legislature, procedural issues regarding the progression of legislation, and stated that while determining the potential effect on consumers and businesses may be desirable, there may be other ways to accomplish that goal within the existing legislative structure.

Senator Harman's staff indicated they are working to determine how best to move forward to achieve the goals of the Jobs Protection Act.

HISTORY:

Date	**Action**
2010	
Feb. 18	To Com. on RLS and APPR..
Feb. 5	From print. May be acted upon on or after March 7.
Feb. 4	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 954

Introduced by Senator Harman
(Coauthor: Senator Dutton)
(Coauthor: Assembly Member Smyth)

February 4, 2010

An act to amend Sections 22, 102.3, 473, 473.15, 473.16, 473.2, 473.3, 473.4, 473.5, 473.6, 474, 474.1, 474.2, 474.3, 474.4, 1620.1, 1632.5, 1634.2, 1638.1, 1638.7, 4001.5, 4200.1, 4200.3, 4934.2, 5000, 5811, 6704.1, 7000.5, 7303.2, 9882, 18824, and 18882 of, to amend the heading of Division 1.2 (commencing with Section 473) of, and to add Chapter 3 (commencing with Section 474.5) to Division 1.2 of, the Business and Professions Code, and to amend Sections 9148.52 and 9148.8 of the Government Code, relating to legislative procedure.

LEGISLATIVE COUNSEL'S DIGEST

SB 954, as introduced, Harman. Legislative procedure: committee referrals: Joint Committee on Boards, Commissions, and Consumer or Business Protection.

The California Constitution authorizes each house of the Legislature to provide for the selection of committees necessary for the conduct of its business, including committees to ascertain facts and make recommendations to the Legislature on a subject within the scope of legislative control.

Existing law generally makes various regulatory boards within the Department of Consumer Affairs inoperative and repealed on specified dates, and, until January 1, 2012, subjects those boards and other specified boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection.

This bill would enact the Jobs Protection Act. The bill would rename the Joint Committee on Boards, Commissions, and Consumer Protection

as the Joint Committee on Boards, Commissions, and Consumer or Business Protection, and would create a new legislative procedure with regard to any bill, as defined, that may have a statewide economic impact affecting business. The bill would require the Assembly Committee on Rules and the Senate Committee on Rules to refer any bill that may have a statewide economic impact affecting business, as specified, to the joint committee for the preparation of an economic impact analysis and a hearing and approval. The bill would require the joint committee to move a bill estimated to generate a fiscal impact of $10,000 or more on small business, as defined, or $50,000 or more on any other business, to the suspense file of the joint committee for further consideration, subject to specified procedural requirements. The bill would also require the joint committee to make an annual report in that regard. The bill would make conforming changes to related provisions.

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. This act shall be known and may be cited as the
2 Jobs Protection Act.
3 SEC. 2. Section 22 of the Business and Professions Code is
4 amended to read:
5 22. (a) "Board," as used in any provision of this code, refers
6 to the board in which the administration of the provision is vested,
7 and unless otherwise expressly provided, shall include "bureau,"
8 "commission," "committee," "department," "division," "examining
9 committee," "program," and "agency."
10 (b) Whenever the regulatory program of a board that is subject
11 to review by the Joint Committee on Boards, Commissions, and
12 Consumer *or Business* Protection, as provided for in Division 1.2
13 (commencing with Section 473), is taken over by the department,
14 that program shall be designated as a "bureau."
15 SEC. 3. Section 102.3 of the Business and Professions Code
16 is amended to read:
17 102.3. (a) The director may enter into an interagency
18 agreement with an appropriate entity within the Department of
19 Consumer Affairs as provided for in Section 101 to delegate the
20 duties, powers, purposes, responsibilities, and jurisdiction that
21 have been succeeded and vested with the department, of a board,

as defined in Section 477, which became inoperative and was repealed in accordance with Chapter 908 of the Statutes of 1994.

(b) (1) Where, pursuant to subdivision (a), an interagency agreement is entered into between the director and that entity, the entity receiving the delegation of authority may establish a technical committee to regulate, as directed by the entity, the profession subject to the authority that has been delegated. The entity may delegate to the technical committee only those powers that it received pursuant to the interagency agreement with the director. The technical committee shall have only those powers that have been delegated to it by the entity.

(2) Where the entity delegates its authority to adopt, amend, or repeal regulations to the technical committee, all regulations adopted, amended, or repealed by the technical committee shall be subject to the review and approval of the entity.

(3) The entity shall not delegate to a technical committee its authority to discipline a licentiate who has violated the provisions of the applicable chapter of the Business and Professions Code that is subject to the director's delegation of authority to the entity.

(c) An interagency agreement entered into, pursuant to subdivision (a), shall continue until such time as the licensing program administered by the technical committee has undergone a review by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection to evaluate and determine whether the licensing program has demonstrated a public need for its continued existence. Thereafter, at the director's discretion, the interagency agreement may be renewed.

SEC. 4. The heading of Division 1.2 (commencing with Section 473) of the Business and Professions Code is amended to read:

DIVISION 1.2. JOINT COMMITTEE ON BOARDS, COMMISSIONS, AND CONSUMER *OR BUSINESS* PROTECTION

SEC. 5. Section 473 of the Business and Professions Code is amended to read:

473. (a) There is hereby established the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection.

(b) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall consist of three members

appointed by the Senate Committee on Rules and three members appointed by the Speaker of the Assembly. No more than two of the three members appointed from either the Senate or the Assembly shall be from the same party. The Joint Rules Committee shall appoint the chairperson of the committee.

(c) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall have and exercise all of the rights, duties, and powers conferred upon investigating committees and their members by the Joint Rules of the Senate and Assembly as they are adopted and amended from time to time, which provisions are incorporated herein and made applicable to this committee and its members.

(d) The Speaker of the Assembly and the Senate Committee on Rules may designate staff for the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection.

(e) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection is authorized to act until January 1, 2012, at which time the committee's existence shall terminate.

SEC. 6. Section 473.15 of the Business and Professions Code is amended to read:

473.15. (a) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection established pursuant to Section 473 shall review the following boards established by initiative measures, as provided in this section:

(1) The State Board of Chiropractic Examiners established by an initiative measure approved by electors November 7, 1922.

(2) The Osteopathic Medical Board of California established by an initiative measure approved June 2, 1913, and acts amendatory thereto approved by electors November 7, 1922.

(b) The Osteopathic Medical Board of California shall prepare an analysis and submit a report as described in subdivisions (a) to (e), inclusive, of Section 473.2, to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection on or before September 1, 2010.

(c) The State Board of Chiropractic Examiners shall prepare an analysis and submit a report as described in subdivisions (a) to (e), inclusive, of Section 473.2, to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection on or before September 1, 2011.

(d) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall, during the interim recess of 2004 for the Osteopathic Medical Board of California, and during the interim recess of 2011 for the State Board of Chiropractic Examiners, hold public hearings to receive testimony from the Director of Consumer Affairs, the board involved, the public, and the regulated industry. In that hearing, each board shall be prepared to demonstrate a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall evaluate and make determinations pursuant to Section 473.4 and shall report its findings and recommendations to the department as provided in Section 473.5.

(f) In the exercise of its inherent power to make investigations and ascertain facts to formulate public policy and determine the necessity and expediency of contemplated legislation for the protection of the public health, safety, and welfare, it is the intent of the Legislature that the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California be reviewed pursuant to this section.

(g) It is not the intent of the Legislature in requiring a review under this section to amend the initiative measures that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 7. Section 473.16 of the Business and Professions Code is amended to read:

473.16. The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall examine the composition of the Medical Board of California and its initial and biennial fees and report to the Governor and the Legislature its findings no later than July 1, 2008.

SEC. 8. Section 473.2 of the Business and Professions Code is amended to read:

473.2. All boards to which this chapter applies shall, with the assistance of the Department of Consumer Affairs, prepare an analysis and submit a report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection no later than

22 months before that board shall become inoperative. The analysis and report shall include, at a minimum, all of the following:

(a) A comprehensive statement of the board's mission, goals, objectives and legal jurisdiction in protecting the health, safety, and welfare of the public.

(b) The board's enforcement priorities, complaint and enforcement data, budget expenditures with average- and median-costs per case, and case aging data specific to post and preaccusation cases at the Attorney General's office.

(c) The board's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(d) The board's description of its licensing process including the time and costs required to implement and administer its licensing examination, ownership of the license examination, relevancy and validity of the licensing examination, and passage rate and areas of examination.

(e) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.

SEC. 9. Section 473.3 of the Business and Professions Code is amended to read:

473.3. (a) Prior to the termination, continuation, or reestablishment of any board or any of the board's functions, the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall, during the interim recess preceding the date upon which a board becomes inoperative, hold public hearings to receive testimony from the Director of Consumer Affairs, the board involved, and the public and regulated industry. In that hearing, each board shall have the burden of demonstrating a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(b) In addition to subdivision (a), in 2002 and every four years thereafter, the committee, in cooperation with the California Postsecondary Education Commission, shall hold a public hearing to receive testimony from the Director of Consumer Affairs, the Bureau for Private Postsecondary and Vocational Education, private postsecondary educational institutions regulated by the

bureau, and students of those institutions. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.

(c) The committee, in cooperation with the California Postsecondary Education Commission, shall evaluate and review the effectiveness and efficiency of the Bureau for Private Postsecondary and Vocational Education, based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.

(d) In addition to subdivision (a), in 2003 and every four years thereafter, the committee shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the Bureau of Automotive Repair. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The committee shall evaluate and review the effectiveness and efficiency of the Bureau of Automotive Repair based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.

SEC. 10. Section 473.4 of the Business and Professions Code is amended to read:

473.4. (a) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall evaluate and determine whether a board or regulatory program has demonstrated a public need for the continued existence of the board or regulatory program and for the degree of regulation the board or regulatory program implements based on the following factors and minimum standards of performance:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial licensing or regulation of a practice or profession have changed.

(3) Whether other conditions have arisen that would warrant increased, decreased, or the same degree of regulation.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether the board rules enhance the public interest and are within the scope of legislative intent.

(5) Whether the board operates and enforces its regulatory responsibilities in the public interest and whether its regulatory mission is impeded or enhanced by existing statutes, regulations, policies, practices, or any other circumstances, including budgetary, resource, and personnel matters.

(6) Whether an analysis of board operations indicates that the board performs its statutory duties efficiently and effectively.

(7) Whether the composition of the board adequately represents the public interest and whether the board encourages public participation in its decisions rather than participation only by the industry and individuals it regulates.

(8) Whether the board and its laws or regulations stimulate or restrict competition, and the extent of the economic impact the board's regulatory practices have on the state's business and technological growth.

(9) Whether complaint, investigation, powers to intervene, and disciplinary procedures adequately protect the public and whether final dispositions of complaints, investigations, restraining orders, and disciplinary actions are in the public interest; or if it is, instead, self-serving to the profession, industry or individuals being regulated by the board.

(10) Whether the scope of practice of the regulated profession or occupation contributes to the highest utilization of personnel and whether entry requirements encourage affirmative action.

(11) Whether administrative and statutory changes are necessary to improve board operations to enhance the public interest.

(b) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall consider alternatives to placing responsibilities and jurisdiction of the board under the Department of Consumer Affairs.

(c) Nothing in this section precludes any board from submitting other appropriate information to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection.

SEC. 11. Section 473.5 of the Business and Professions Code is amended to read:

473.5. The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall report its findings and preliminary recommendations to the department for its review, and, within 90 days of receiving the report, the department shall report its findings and recommendations to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection during the next year of the regular session that follows the hearings described in Section 473.3. The committee shall then meet to vote on final recommendations. A final report shall be completed by the committee and made available to the public and the Legislature. The report shall include final recommendations of the department and the committee and whether each board or function scheduled for repeal shall be terminated, continued, or reestablished, and whether its functions should be revised. If the committee or the department deems it advisable, the report may include proposed bills to carry out its recommendations.

SEC. 12. Section 473.6 of the Business and Professions Code is amended to read:

473.6. The chairpersons of the appropriate policy committees of the Legislature may refer to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection for review of any legislative issues or proposals to create new licensure or regulatory categories, change licensing requirements, modify scope of practice, or create a new licensing board under the provisions of this code or pursuant to Chapter 1.5 (commencing with Section 9148) of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 13. Section 474 of the Business and Professions Code is amended to read:

474. The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection established pursuant to Section 473 shall review all state boards as defined in Section 9148.2 of the Government Code, in addition to boards subject to review pursuant to Chapter 1 (commencing with Section 473), every four years or over another time period as determined by the committee.

SEC. 14. Section 474.1 of the Business and Professions Code is amended to read:

474.1. Prior to recommending the termination, continuation, or reestablishment of any board or any of the state board's functions, the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall hold public hearings to receive testimony from the board involved and the public. In that hearing, each board shall have the burden of demonstrating a compelling public need for the continued existence of the board.

SEC. 15. Section 474.2 of the Business and Professions Code is amended to read:

474.2. All state boards to which this chapter applies shall prepare an analysis and submit a report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection not later than 22 months before that state board is scheduled to be reviewed by the committee. The analysis and report shall include, at a minimum, all of the following:

(a) A comprehensive statement of the state board's mission, goals, objectives, and legal jurisdiction in protecting the health, safety, and welfare of the public.

(b) The board's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(c) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.

(d) A complete cost-benefit analysis of the board's operation for each of the four years preceding the date of the report or over a time period specified by the committee.

SEC. 16. Section 474.3 of the Business and Professions Code is amended to read:

474.3. (a) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall evaluate and determine whether a state board as defined in Section 9148.2 of the Government Code, other than a board, subject to review pursuant to Chapter 1 (commencing with Section 473), has demonstrated a public need for its continued existence based on, but not limited to, the following factors and minimum standards of performance:

(1) Whether the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial creation of the state board have changed.

(3) If the state board is necessary, whether existing statutes and regulations establish the most effective regulation consistent with the public interest, considering other available regulatory mechanisms, and whether the board rules enhance the public interest and are within the scope of legislative intent.

(4) Whether the state board operates and enforces its responsibilities in the public interest and whether its mission is impeded or enhanced by existing statutes, regulations, policies, practices, or any other circumstances, including budgetary, resource, and personnel matters.

(5) Whether an analysis of the state board indicates that it performs its statutory duties efficiently and effectively.

(6) Whether the composition of the state board adequately represents the public interest and whether it encourages public participation in its decisions rather than participation only by the entities it regulates or advises.

(7) Whether the state board and its laws or regulations stimulate or restrict competition, and the extent of the economic impact the board's regulatory practices have on the state's business and technological growth.

(8) Whether administrative and statutory changes are necessary to improve the state board operations to enhance the public interest.

(b) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall consider the appropriateness of eliminating and consolidating responsibilities between state boards.

(c) Nothing in this section precludes any state board or, if requested by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection, the Legislative Analyst's Office, from submitting other appropriate information to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection.

SEC. 17. Section 474.4 of the Business and Professions Code is amended to read:

474.4. The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall meet to vote on final recommendations. A final report shall be completed by the committee and made available to the public and the Legislature.

The report shall include final recommendations of the committee and whether each board or function shall be terminated, or continued, and whether its functions should be revised or consolidated with those of other state boards. If the committee deems it advisable, the report may include proposed bills to carry out its recommendations.

SEC. 18. Chapter 3 (commencing with Section 474.5) is added to Division 1.2 of the Business and Professions Code, to read:

CHAPTER 3. REFERRAL OF LEGISLATION AFFECTING BUSINESSES

474.5. (a) The Assembly Committee on Rules and the Senate Committee on Rules shall refer any bill that may have a statewide economic impact affecting business to the Joint Committee on Boards, Commissions, and Consumer or Business Protection for review and approval.

(b) (1) The referral specified in subdivision (a) shall not affect any other referral made by the rules committees to any other policy committee or appropriations committee, if any. However, the bill shall remain with the Joint Committee on Boards, Commissions, and Consumer or Business Protection until approved by the joint committee.

(2) Notwithstanding paragraph (1), any hearing conducted under this section by the joint committee shall commence after any hearing or hearings conducted by any policy committee or, if double-referred, by any policy committees of the house of the Legislature for which the bill is proceeding, and shall commence before any hearing conducted by the appropriations committee, if any, of the house of the Legislature for which the bill is proceeding. The hearing shall, insofar as consistent with theis chapter, be conducted in the same manner as the hearing of a standing committee.

(c) For purposes of this chapter, the following definitions shall apply:

(1) "Bill" means a bill, resolution, or constitutional amendment.

(2) "Business" means any other business not defined as a small business.

(3) "Small business" means an independently owned and operated business that is not dominant in its field of operation, the principal office of which is located in California, the officers of

which are domiciled in California, and which, together with affiliates, has 100 or fewer employees, and average annual gross receipts of ten million dollars ($10,000,000) or less over the previous three years, or is a manufacturer, as defined in subdivision (c) of Section 14837 of the Government Code, with 100 or fewer employees.

474.6. For purposes of Section 474.5, "statewide economic impact" shall be construed broadly, and the factors the Assembly Rules Committee and the Senate Rules Committee shall consider when making a determination of "statewide economic impact" shall include, but not be limited to, the following:

(a) Whether the proposed bill contains language that includes a tax or a fee, directly provides for the regulation of a specific industry, provides for environmental mitigation or regulation, adds burdens to the state economy, imposes additional burdens on insurers, increases workers' compensation, disability, or health insurance requirements, or affects housing costs or the housing market.

(b) Any other provision included in the bill that may affect the statewide economy.

474.7. Once a bill is referred to the joint committee pursuant to this chapter, the following shall apply:

(a) The joint committee shall prepare an economic impact analysis on the bill prior to the joint committee hearing on that bill and shall make a determination of fiscal effect.

(b) (1) If the bill relates to, or may affect, a small business or small businesses, the economic impact analysis shall include, but not be limited to, all of the following:

(A) An estimate of the number of small businesses that will be subject to, or affected by, the bill.

(B) The estimated annual average cost of compliance by a small business subject to, or affected by, the bill.

(C) A description of reasonable alternatives that would lessen any adverse impact on a small business subject to the bill, including, but not limited to:

(D) The establishment of less burdensome compliance or reporting requirements for small businesses.

(E) The establishment of less burdensome schedules or deadlines for compliance or reporting requirements for small businesses.

(F) The consolidation or simplification of compliance or reporting requirements for small businesses.

(G) The use of performance standards for small businesses, instead of design or prescriptive standards.

(2) If the bill relates to, or may affect, any other business not defined as a small business, the economic impact analysis shall include, but not be limited to, all of the following:

(A) An estimate of the number of businesses that will be subject to, or affected by, the bill.

(B) The estimated annual average cost of compliance by a business subject to, or affected by, the bill.

(C) A description of reasonable alternatives that would lessen any adverse impact on a business subject to the bill, including, but not limited to:

(D) The establishment of less burdensome compliance or reporting requirements for businesses.

(E) The establishment of less burdensome schedules or deadlines for compliance or reporting requirements for businesses.

(F) The consolidation or simplification of compliance or reporting requirements for businesses.

(G) The use of performance standards for businesses, instead of design or prescriptive standards.

(c) (1) The joint committee shall move a bill under paragraph (1) of subdivision (b) that is estimated to generate a fiscal impact of ten thousand dollars ($10,000) or more to the suspense file of the joint committee, without prejudice, for further consideration.

(2) The joint committee shall move a bill under paragraph (2) of subdivision (b) that is estimated to generate a fiscal impact of fifty thousand dollars ($50,000) or more to the suspense file of the joint committee, without prejudice, for further consideration.

(d) A bill may be amended after being placed and while on the suspense file. Any amendments proposed or accepted by the author of a bill that is moved to the suspense file must be submitted no later than eight calendar days prior to the joint committee hearing at which the suspense file will be heard. Failure to meet this deadline will result in that bill not being considered for passage off the suspense file.

(e) An author shall present all testimony at the time of the first regularly scheduled hearing on a bill, even though the bill's provisions indicate that a referral to the suspense file under this

1 section is in order. No testimony shall be taken during the joint
2 committee hearing while the suspense file is being heard.
3 (f) At the discretion of the chair, the joint committee may not
4 move any bill to the suspense file during any joint committee
5 hearing held within three weeks before adjournment for interim
6 study recess or final recess.
7 (g) A bill may be moved off the suspense file upon a majority
8 vote of the members of each house of the joint committee, subject
9 to quorum requirements and as otherwise provided in the joint
10 rules.
11 474.8. After a bill is heard in either house of the Legislature,
12 and the joint committee has already approved the bill, while in the
13 other house of the Legislature the bill shall not be rereferred to the
14 joint committee, unless the bill has been amended since the date
15 it was first heard by the joint committee. If the bill has been
16 amended by either house, and it still has, or has been amended to
17 have, a statewide economic impact affecting business, it shall be
18 rereferred to the joint committee pursuant to the same procedures
19 specified in Section 474.5 in the house of the Legislature for which
20 it has been moved.
21 474.9. In addition to the analysis prepared under subdivisions
22 (a) and (b) of Section 474.7, the joint committee shall annually
23 prepare a report to the public on or before January 1, that provides
24 a compilation of the bills referred to the joint committee under this
25 chapter during the regular session of the Legislature or under any
26 extraordinary session, the economic impact analyses described in
27 subdivisions (a) and (b) of Section 474.7, a copy of the history and
28 vote counts for each bill, and a synopsis of the actions taken by
29 the joint committee with regard to that session or sessions.
30 474.95. (a) The Assembly Committee on Rules and the Senate
31 Committee on Rules shall incorporate these procedures into the
32 Joint Rules of the Senate and Assembly and the legislative calendar
33 regarding committee deadlines.
34 (b) All other Standing Rules of the Assembly, Standing Rules
35 of the Senate, and Joint Rules of the Assembly and Senate shall
36 apply to the joint committee in exercising its authority under this
37 chapter.
38 SEC. 19. Section 1620.1 of the Business and Professions Code
39 is amended to read:

1620.1. The Department of Consumer Affairs, in conjunction with the board and the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection, shall review the scope of practice for dental auxiliaries. The department shall employ the services of an independent consultant to perform this comprehensive analysis. The department shall be authorized to enter into an interagency agreement or be exempted from obtaining sole source approval for a sole source contract. The board shall pay for all of the costs associated with this comprehensive analysis. The department shall report its findings and recommendations to the Legislature by September 1, 2002.

SEC. 20. Section 1632.5 of the Business and Professions Code is amended to read:

1632.5. (a) Prior to implementation of paragraph (2) of subdivision (c) of Section 1632, the department's Office of Professional Examination Services shall review the Western Regional Examining Board examination to ensure compliance with the requirements of Section 139 and to certify that the examination process meets those standards. If the department determines that the examination process fails to meet those standards, paragraph (2) of subdivision (c) of Section 1632 shall not be implemented. The review of the Western Regional Examining Board examination shall be conducted during or after the Dental Board of California's occupational analysis scheduled for the 2004–05 fiscal year, but not later than September 30, 2005. However, an applicant who successfully completes the Western Regional Examining Board examination on or after January 1, 2005, shall be deemed to have met the requirements of subdivision (c) of Section 1632 if the department certifies that the Western Regional Examining Board examination meets the standards set forth in this subdivision.

(b) The Western Regional Examining Board examination process shall be regularly reviewed by the department pursuant to Section 139.

(c) The Western Regional Examining Board examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) As part of its next scheduled review by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection, the Dental Board of California shall report to that committee and

the department on the pass rates of applicants who sat for the Western Regional Examining Board examination, compared with the pass rates of applicants who sat for the state clinical and written examination administered by the Dental Board of California. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 21. Section 1634.2 of the Business and Professions Code is amended to read:

1634.2. (a) An advanced education program's compliance with subdivision (c) of Section 1634.1 shall be regularly reviewed by the department pursuant to Section 139.

(b) An advanced education program described in subdivision (c) of Section 1634.1 shall meet the requirements of subdivision (a) of Section 12944 of the Government Code.

(c) The clinical residency program completion certification required by subdivision (c) of Section 1634.1 shall include a list of core competencies commensurate to those found in the board's examinations. The board, together with the department's Office of Professional Examination Services, shall ensure the alignment of the competencies stated in the clinical residency program completion certification with the board's current occupational analysis. The board shall implement use of the clinical residency program completion certification form and use of the core competency list through the adoption of emergency regulations by January 1, 2008.

(d) As part of its next scheduled review after January 1, 2007, by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection, the board shall report to that committee and to the department the number of complaints received for those dentists who have obtained licensure by passing the state clinical examination and for those dentists who have obtained licensure through an advanced education program. The report shall also contain tracking information on these complaints and their disposition. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 22. Section 1638.1 of the Business and Professions Code is amended to read:

1638.1. (a) (1) A person licensed pursuant to Section 1634 who wishes to perform elective facial cosmetic surgery shall first apply for and receive a permit to perform elective facial cosmetic surgery from the board.

(2) A permit issued pursuant to this section shall be valid for a period of two years and must be renewed by the permitholder at the time his or her license is renewed. Every six years, prior to renewal of the permitholder's license and permit, the permitholder shall submit evidence acceptable to the credentialing committee that he or she has maintained continued competence to perform the procedures authorized by the permit. The credentialing committee may limit a permit consistent with paragraph (1) of subdivision (e) if it is not satisfied that the permitholder has established continued competence.

(b) The board may adopt regulations for the issuance of the permit that it deems necessary to protect the health, safety, and welfare of the public.

(c) A licensee may obtain a permit to perform elective facial cosmetic surgery by furnishing all of the following information on an application form approved by the board:

(1) Proof of successful completion of an oral and maxillofacial surgery residency program accredited by the Commission on Dental Accreditation of the American Dental Association.

(2) Proof that the applicant has satisfied the criteria specified in either subparagraph (A) or (B):

(A) (i) Is certified, or is a candidate for certification, by the American Board of Oral and Maxillofacial Surgery.

(ii) Submits to the board a letter from the program director of the accredited residency program, or from the director of a postresidency fellowship program accredited by the Commission on Dental Accreditation of the American Dental Association, stating that the licensee has the education, training, and competence necessary to perform the surgical procedures that the licensee has notified the board he or she intends to perform.

(iii) Submits documentation to the board of at least 10 operative reports from residency training or proctored procedures that are representative of procedures that the licensee intends to perform from both of the following categories:

(I) Cosmetic contouring of the osteocartilaginous facial structure, which may include, but is not limited to, rhinoplasty and otoplasty.

(II) Cosmetic soft tissue contouring or rejuvenation, which may include, but is not limited to, facelift, blepharoplasty, facial skin resurfacing, or lip augmentation.

(iv) Submits documentation to the board showing the surgical privileges the applicant possesses at any licensed general acute care hospital and any licensed outpatient surgical facility in this state.

(B) (i) Has been granted privileges by the medical staff at a licensed general acute care hospital to perform the surgical procedures set forth in paragraph (A) at that hospital.

(ii) Submits to the board the documentation described in clause (iii) of subparagraph (A).

(3) Proof that the applicant is on active status on the staff of a general acute care hospital and maintains the necessary privileges based on the bylaws of the hospital to maintain that status.

(d) The application shall be accompanied by an application fee of five hundred dollars ($500) for an initial permit. The fee to renew a permit shall be two hundred dollars ($200).

(e) (1) The board shall appoint a credentialing committee to review the qualifications of each applicant for a permit. Upon completion of the review of an applicant, the committee shall make a recommendation to the board on whether to issue or not issue a permit to the applicant. The permit may be unqualified, entitling the permitholder to perform any facial cosmetic surgical procedure authorized by this section, or it may contain limitations if the credentialing committee is not satisfied that the applicant has the training or competence to perform certain classes of procedures, or if the applicant has not requested to be permitted for all procedures authorized by this section.

(2) The credentialing committee shall be comprised of five members, as follows:

(A) A physician and surgeon with a specialty in plastic and reconstructive surgery who maintains active status on the staff of a licensed general acute care hospital in this state.

(B) A physician and surgeon with a specialty in otolaryngology who maintains active status on the staff of a licensed general acute care hospital in this state.

(C) Three oral and maxillofacial surgeons licensed by the board who are board certified by the American Board of Oral and Maxillofacial Surgeons, and who maintain active status on the

staff of a licensed general acute care hospital in this state, at least one of whom shall be licensed as a physician and surgeon in this state. Two years after the effective date of this section, any oral and maxillofacial surgeon appointed to the committee who is not licensed as a physician and surgeon shall hold a permit pursuant to this section.

(3) The board shall solicit from the following organizations input and recommendations regarding members to be appointed to the credentialing committee:

(A) The Medical Board of California.

(B) The California Dental Association.

(C) The California Association of Oral and Maxillofacial Surgeons.

(D) The California Medical Association.

(E) The California Society of Plastic Surgeons.

(F) Any other source that the board deems appropriate.

(4) The credentialing committee shall meet at a time and place directed by the board to evaluate applicants for permits. A quorum of three members shall be required for the committee to consider applicants and make recommendations to the board.

(f) A licensee may not perform any elective, facial cosmetic surgical procedure except at a general acute care hospital, a licensed outpatient surgical facility, or an outpatient surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Association for Ambulatory Health Care (AAAHC), the Medicare program, or an accreditation agency approved by the Medical Board of California pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Elective cosmetic surgery" means any procedure defined as cosmetic surgery in subdivision (d) of Section 1367.63 of the Health and Safety Code, and excludes any procedure that constitutes reconstructive surgery, as defined in subdivision (c) of Section 1367.63 of the Health and Safety Code.

(2) "Facial" means those regions of the human body described in Section 1625 and in any regulations adopted pursuant to that section by the board.

(h) A holder of a permit issued pursuant to this section shall not perform elective facial cosmetic surgical procedures unless he or

she has malpractice insurance or other financial security protection that would satisfy the requirements of Section 2216.2 and any regulations adopted thereunder.

(i) A holder of a permit shall comply with the requirements of subparagraph (D) of paragraph (2) of subdivision (a) of Section 1248.15 of the Health and Safety Code, and the reporting requirements specified in Section 2240, with respect to any surgical procedure authorized by this section, in the same manner as a physician and surgeon.

(j) Any violation of this section constitutes unprofessional conduct and is grounds for the revocation or suspension of the person's permit, license, or both, or the person may be reprimanded or placed on probation. Proceedings initiated by the board under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein.

(k) On or before January 1, 2009, and every four years thereafter, the board shall report to the Joint Committee on Boards, Commissions and Consumer *or Business* Protection on all of the following:

(1) The number of persons licensed pursuant to Section 1634 who apply to receive a permit to perform elective facial cosmetic surgery from the board pursuant to subdivision (a).

(2) The recommendations of the credentialing committee to the board.

(3) The board's action on recommendations received by the credentialing committee.

(4) The number of persons receiving a permit from the board to perform elective facial cosmetic surgery.

(5) The number of complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.

(6) Action taken by the board resulting from complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.

SEC. 23. Section 1638.7 of the Business and Professions Code is amended to read:

1638.7. The next occupational analysis of dental licensees and oral and maxillofacial facial surgeons pursuant to Section 139 shall include a survey of the training and practices of oral and maxillofacial surgeons and, upon completion of that analysis, a report shall be made to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection regarding the findings.

SEC. 24. Section 4001.5 of the Business and Professions Code is amended to read:

4001.5. The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination.

SEC. 25. Section 4200.1 of the Business and Professions Code is amended to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

SEC. 26. Section 4200.3 of the Business and Professions Code is amended to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 27. Section 4934.2 of the Business and Professions Code is amended to read:

4934.2. The board shall conduct the following studies and reviews, and shall report its findings and recommendations to the department and the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection no later ~~that~~ *than* September 1, 2004:

(a) The board shall conduct a comprehensive study of the use of unlicensed acupuncture assistants and the need to license and regulate those assistants.

(b) The board shall study and recommend ways to improve the frequency and consistency of their auditing and the quality and relevance of their courses.

SEC. 28. Section 5000 of the Business and Professions Code is amended to read:

5000. There is in the Department of Consumer Affairs the California Board of Accountancy, which consists of 15 members, seven of whom shall be licensees, and eight of whom shall be public members who shall not be licentiates of the board or registered by the board. The board has the powers and duties conferred by this chapter.

The Governor shall appoint four of the public members, and the seven licensee members as provided in this section. The Senate Rules Committee and the Speaker of the Assembly shall each appoint two public members. In appointing the seven licensee members, the Governor shall appoint members representing a cross section of the accounting profession with at least two members representing a small public accounting firm. For the purposes of this chapter, a small public accounting firm shall be defined as a professional firm that employs a total of no more than four licensees as partners, owners, or full-time employees in the practice of public accountancy within the State of California.

This section shall become inoperative on July 1, 2011, and as of January 1, 2012, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2012, deletes or extends the dates on which this section becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473). However, the review of the board shall be limited to reports or studies specified in this chapter and those issues identified by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection and the board regarding the implementation of new licensing requirements.

SEC. 29. Section 5811 of the Business and Professions Code is amended to read:

5811. An interior design organization issuing stamps under Section 5801 shall provide to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection by September 1, 2008, a report that reviews and assesses the costs and benefits associated with the California Code and Regulations Examination and explores feasible alternatives to that examination.

SEC. 30. Section 6704.1 of the Business and Professions Code is amended to read:

6704.1. (a) The Department of Consumer Affairs, in conjunction with the board, and the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall review the engineering branch titles specified in Section 6732 to determine whether certain title acts should be eliminated from this chapter, retained, or converted to practice acts similar to civil, electrical, and mechanical engineering, and whether supplemental engineering work should be permitted for all branches of engineering. The

department shall contract with an independent consulting firm to perform this comprehensive analysis of title act registration.

(b) The independent consultant shall perform, but not be limited to, the following: (1) meet with representatives of each of the engineering branches and other professional groups; (2) examine the type of services and work provided by engineers in all branches of engineering and interrelated professions within the marketplace, to determine the interrelationship that exists between the various branches of engineers and other interrelated professions; (3) review and analyze educational requirements of engineers; (4) identify the degree to which supplemental or "overlapping" work between engineering branches and interrelated professions occurs; (5) review alternative methods of regulation of engineers in other states and what impact the regulations would have if adopted in California; (6) identify the manner in which local and state agencies utilize regulations and statutes to regulate engineering work; and (7) recommend changes to existing laws regulating engineers after considering how these changes may affect the health, safety, and welfare of the public.

(c) The board shall reimburse the department for costs associated with this comprehensive analysis. The department shall report its findings and recommendations to the Legislature by September 1, 2002.

SEC. 31. Section 7000.5 of the Business and Professions Code is amended to read:

7000.5. (a) There is in the Department of Consumer Affairs a Contractors' State License Board, which consists of 15 members.

(b) The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473). However, the review of this board by the department shall be limited to only those unresolved issues identified by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection.

(c) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 32. Section 7303.2 of the Business and Professions Code is amended to read:

7303.2. The board shall conduct the following studies and reviews, and shall report its findings and recommendations to the department and the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection no later than September 1, 2005:

(a) The board, pursuant to Section 139 and in conjunction with the Office of Professional Examination Services of the department, shall review the 1600 hour training requirement for cosmetologists.

(b) The board, in conjunction with the Office of Professional Examination Services of the department, shall evaluate the equivalency of the national exam.

(c) The board shall conduct a study to assess the costs and benefits associated with requiring all applicants to submit fingerprint cards for background investigations.

(d) The board, in coordination with the Department of Industrial Relations, shall review all components of the apprenticeship program, including, but not limited to, the following:

(1) Apprenticeship curriculum requirements.

(2) The standards for the preapprentice trainers, program sponsors, trainers, and placement establishments. The board shall pay particular attention to ways to eliminate duplicative regulations.

(e) The board shall review all components of the externship program. In addition to structural changes, the board shall address the following:

(1) Whether the program should be eliminated.

(2) Whether the program should be available to all students, not just cosmetology students attending private schools.

(3) Whether the students should be paid.

(f) The board shall assess the costs and benefits associated with same day licensing. If the board determines that the benefits of same day licensing outweigh the costs, the board shall immediately plan and implement safety measures to protect site staff and undispersed licenses.

(g) The board, in conjunction with the Office of Professional Examination Services of the department, shall assess the validity of aggregate scoring for board applicants.

SEC. 33. Section 9882 of the Business and Professions Code is amended to read:

9882. (a) There is in the Department of Consumer Affairs a Bureau of Automotive Repair under the supervision and control

of the director. The duty of enforcing and administering this chapter is vested in the chief who is responsible to the director. The director may adopt and enforce those rules and regulations that he or she determines are reasonably necessary to carry out the purposes of this chapter and declaring the policy of the bureau, including a system for the issuance of citations for violations of this chapter as specified in Section 125.9. These rules and regulations shall be adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(b) In 2003 and every four years thereafter, the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the bureau. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare. The committee shall evaluate and review the effectiveness and efficiency of the bureau based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.

SEC. 34. Section 18824 of the Business and Professions Code is amended to read:

18824. (a) Except as provided in Sections 18646 and 18832, every person who conducts a contest or wrestling exhibition shall, within five working days after the determination of every contest or wrestling exhibition for which admission is charged and received, furnish to the commission the following:

(1) A written report executed under penalty of perjury by one of the officers, showing the amount of the gross receipts, not to exceed two million dollars ($2,000,000), and the gross price for the contest or wrestling exhibition charged directly or indirectly and no matter by whom received, for the sale, lease, or other exploitation of broadcasting and television rights of the contest or wrestling exhibition, and without any deductions, except for expenses incurred for one broadcast announcer, telephone line connection, and transmission mobile equipment facility, which

may be deducted from the gross taxable base when those expenses are approved by the commission.

(2) A fee of 5 percent, exclusive of any federal taxes paid thereon, of the amount paid for admission to the contest or wrestling exhibition, except that for any one contest, the fee shall not exceed the amount of one hundred thousand dollars ($100,000). The commission shall report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection on the fiscal impact of the one hundred thousand dollar ($100,000) limit on fees collected by the commission for admissions revenues.

(A) The amount of the gross receipts upon which the fee provided for in paragraph (2) is calculated shall not include any assessments levied by the commission under Section 18711.

(B) (i) If the fee for any one boxing contest exceeds seventy thousand dollars ($70,000), the amount in excess of seventy thousand dollars ($70,000) shall be paid one-half to the commission and one-half to the Boxers' Pension Fund.

(ii) If the report required by subdivision (b) of Section 18618 recommends that the Boxers' Pension Fund shall be expanded to include all athletes licensed under this chapter, the commission, by regulation, shall require, for all contests where the fee exceeds seventy thousand dollars ($70,000), the amount in excess of seventy thousand dollars ($70,000) shall be paid one-half to the commission and one-half to the Boxers' Pension Fund only if all athletes licensed under this chapter are made eligible for the Boxers' Pension Fund.

(C) The fee shall apply to the amount actually paid for admission and not to the regular established price.

(D) No fee is due in the case of a person admitted free of charge. However, if the total number of persons admitted free of charge to a boxing, kickboxing, or martial arts contest, or wrestling exhibition exceeds 33 percent of the total number of spectators, then a fee of one dollar ($1) per complimentary ticket or pass used to gain admission to the contest shall be paid to the commission for each complimentary ticket or pass that exceeds the numerical total of 33 percent of the total number of spectators.

(E) The minimum fee for an amateur contest or exhibition shall not be less than five hundred dollars ($500).

(3) A fee of up to 5 percent, to be established by the commission through regulations to become operative on or before July 1, 2008,

and updated periodically as needed, of the gross price, exclusive of any federal taxes paid thereon, for the sale, lease, or other exploitation of broadcasting or television rights thereof, except that in no case shall the fee be less than one thousand dollars ($1,000) or more than twenty-five thousand dollars ($25,000).

(b) As used in this section, "person" includes a promoter, club, individual, corporation, partnership, association, or other organization, and "wrestling exhibition" means a performance of wrestling skills and techniques by two or more individuals, to which admission is charged or which is broadcast or televised, in which the participating individuals are not required to use their best efforts in order to win, and for which the winner may have been selected before the performance commences.

SEC. 35. Section 18882 of the Business and Professions Code is amended to read:

18882. (a) At the time of payment of the fee required by Section 18824, a promoter shall pay to the commission all amounts scheduled for contribution to the pension plan. If the commission, in its discretion, requires pursuant to Section 18881, that contributions to the pension plan be made by the boxer and his or her manager, those contributions shall be made at the time and in the manner prescribed by the commission.

(b) All contributions to finance the pension plan shall be deposited in the State Treasury and credited to the Boxers' Pension Fund, which is hereby created. Notwithstanding the provisions of Section 13340 of the Government Code, all moneys in the Boxers' Pension Fund are hereby continuously appropriated to be used exclusively for the purposes and administration of the pension plan.

(c) The Boxers' Pension Fund is a retirement fund, and no moneys within it shall be deposited or transferred to the General Fund.

(d) The commission has exclusive control of all funds in the Boxers' Pension Fund. No transfer or disbursement in any amount from this fund shall be made except upon the authorization of the commission and for the purpose and administration of the pension plan.

(e) Except as otherwise provided in this subdivision, the commission or its designee shall invest the money contained in the Boxers' Pension Fund according to the same standard of care

as provided in Section 16040 of the Probate Code. The commission has exclusive control over the investment of all moneys in the Boxers' Pension Fund. Except as otherwise prohibited or restricted by law, the commission may invest the moneys in the fund through the purchase, holding, or sale of any investment, financial instrument, or financial transaction that the commission in its informed opinion determines is prudent.

(f) The administrative costs associated with investing, managing, and distributing the Boxers' Pension Fund shall be limited to no more than 20 percent of the average annual contribution made to the fund in the previous two years, not including any investment income derived from the corpus of the fund. Diligence shall be exercised by administrators in order to lower the fund's expense ratio as far below 20 percent as feasible and appropriate. The commission shall report to the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection on the impact of this provision during the next regularly scheduled sunset review after January 1, 2007.

SEC. 36. Section 9148.52 of the Government Code is amended to read:

9148.52. (a) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection established pursuant to Section 473 of the Business and Professions Code shall review all state boards, as defined in Section 9148.2, other than a board subject to review pursuant to Chapter 1 (commencing with Section 473) of Division 1.2 of the Business and Professions Code, every four years.

(b) The committee shall evaluate and make determinations pursuant to Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code.

SEC. 37. Section 9148.8 of the Government Code is amended to read:

9148.8. (a) The Joint Committee on Boards, Commissions, and Consumer *or Business* Protection, acting pursuant to a request from the chairperson of the appropriate policy committee, shall evaluate a plan prepared pursuant to Section 9148.4 or 9148.6.

(b) Evaluations prepared by the Joint Committee on Boards, Commissions, and Consumer *or Business* Protection pursuant to this section shall be provided to the respective policy and fiscal

1 committees of the Legislature pursuant to rules adopted by each
2 committee for this purpose.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1171 **VERSION: As amended April 5, 2010**

AUTHOR: Negrete McLeod **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: **Regulatory boards: Operations**

Affected Sections: Amend Sections 22, 473.1, 473.15, 473.2, 473.3, 473.4, 473.6 & 9882
Add Section s473.12 and 473.7
Repeal Sections 473.16 and 473.5
Repeal and add Section 101.1 and 473 of the Business and Professions Code

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs (DCA) shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Provide that if the terms of office of the members of the board are terminated, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor members shall be appointed by the same appointing authorities for the remainder of the previous members' terms.
2. Require that if the term of office for a bureau chief is terminated, a successor bureau chief shall be appointed who shall succeed to and be vested with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor shall be appointed by the same appointing authorities for the remainder of the previous bureau chief's terms.

3. Specify that provisions referring to the Joint Committee on Boards, Commissions and Consumer Protection shall mean reference to the appropriate policy committees of the Legislature.
4. Specify that the provisions apply to all boards, bureaus and entities as listed, including the Board of Pharmacy.
5. Establishes new, yet to be determined sunset dates.
6. Requires that the appropriate policy committees of the Legislature shall review boards and bureaus as specified.
7. Require all boards and bureaus to prepare an analysis and submit a report to the appropriate policy committees of the Legislature no later than ~~22~~ 16 months before the termination of the terms of office of the membership.
8. Specify the content of the report to include:
   - The number of complaints received annually, the number that proceeded to investigation, the number of accusations filed per year and the number and kind of disciplinary actions taken.
   - The average processing times for complaints and administrative case resolution as specified.
   - The average processing time per year between the final disposition of a complaint and notice to the complainant.
   - A copy of the enforcement priorities including criteria for seeking an interim suspension order.
   - Brief description of the board or bureau's fund condition, sources of revenue and expenditures for the last four fiscal years by program component.
   - A brief description of the cost per year required to implement and administer a licensing examination, ownership of the license examination, the last assessment of the relevancy and validity of the licensing examination and passage rates for each of the last four years.
   - A copy of sponsored legislation and description of budget change proposals.
   - A brief assessment of licensing fees as to whether they are sufficient, too high or too low.
   - A brief statement detailing how enforcement, public disclosure, accessibility to the public has improved over the last four years.
   - Allow for the annual submission of these elements to the appropriate committees and require posting of such reports on the board's Web site.
9. Specify that the appropriate policy committees may hold public hearings to receive testimony regarding whether the board's or bureau's policies and practices are sufficient to protect consumers and are fair to licensees and prospective licensees and whether licensure of the profession is required to protect the public and whether an enforcement monitor is necessary to obtain further information on operations.

10. Allow the appropriate policy committees of the Legislature to evaluate and determine whether a board or program has a demonstrated public need for the continued existence of the regulatory program.
11. Allows the chairperson of the appropriate policy committees to refer to interim study review, any legislative issues or proposals to create new licensure or regulatory categories, change licensing requirements, modify the scope of practice or create a new licensing board.

AUTHOR'S INTENT:

SB 1171 is needed to update and streamline the sunset review process. The Author states that the bill revises the sunset process in two significant ways: First, by providing that when a professional licensing board in the Department of Consumer Affairs becomes inoperative or is repealed, a successor board is created to succeed to, and be vested with all of the duties, powers, purposes, responsibilities, and jurisdiction of the prior board. In effect, this bill makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau under the Department. Second, it removes references to the Joint Committee on Boards Commissions and Consumer Protection and allows for standing policy committees of the Legislature to conduct sunset review hearings.

FISCAL IMPACT:

The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS:

This bill provides that when a professional licensing board in the Department of Consumer Affairs becomes inoperative or is repealed, a successor board is created to succeed to, and be vested with all of the duties, powers, purposes, responsibilities, and jurisdiction of the prior board. In effect, this bill makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau under the Department of Consumer Affairs.

This bill removes references to the Joint Committee on Boards Commissions and Consumer Protection, and instead, would provide that the relevant Legislative policy committees shall review the regulatory boards under DCA. The bill revises the review schedule for regulatory boards, and also provides for the review of DCA bureaus.

The board currently collects and reports several of the elements detailed above as part of its quarterly and annual statistics.

This bill mirrors many of the provisions contained in SB 638 (Negrete McLeod, 2009). The board had a support position on the bill.

SUPPORT/OPPOSITION

None of file.

HISTORY:

Apr. 5	Read second time. Amended. Re-referred to Com. on RLS.
Mar. 25	From committee: Do pass as amended, but first amend, and re-refer to Com. on RLS. (Ayes 6. Noes 2. Page 2986.)
Mar. 9	Set for hearing March 22.
Mar. 4	To Coms. on B., P. & E.D. and RLS.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL No. 1171

Introduced by Senator Negrete McLeod

February 18, 2010

An act to amend Sections 22, 473.1, 473.15, 473.2, 473.3, 473.4, 473.6, and 9882 of, to add Sections 473.12 and 473.7 to, to repeal Sections 473.16 and 473.5 of, and to repeal and add Sections 101.1 and 473 of, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

SB 1171, as amended, Negrete McLeod. Regulatory boards: operations.

Existing law creates various regulatory boards, as defined, within the Department of Consumer Affairs, with board members serving specified terms of office. Existing law generally makes the regulatory boards inoperative and repealed on specified dates, unless those dates are deleted or extended by subsequent legislation, and subjects these boards that are scheduled to become inoperative and repealed as well as other boards in state government, as specified, to review by the Joint Committee on Boards, Commissions, and Consumer Protection. Under existing law, that committee, following a specified procedure, recommends whether the board should be continued or its functions modified. Existing law requires the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California to submit certain analyses and reports to the committee on specified dates and requires the committee to review those boards and hold hearings as specified, and to make certain evaluations and findings.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection and would authorize the appropriate policy

committees of the Legislature to carry out its duties. The bill would terminate the terms of office of each board member or bureau chief within the department on unspecified dates and would authorize successor board members and bureau chiefs to be appointed, as specified. The bill would also subject interior design organizations, the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, the Tax Education Council, ~~and~~ the Naturopathic Medical Committee, *and the certification of common interest development managers and massage therapists* to review on unspecified dates. The bill would authorize the appropriate policy committees of the Legislature to review the boards, bureaus, or entities that are scheduled to have their board membership or bureau chief so terminated or reviewed, as specified, and would authorize the appropriate policy committees of the Legislature to investigate their operations and to hold specified public hearings. The bill would require a board, bureau, or entity, if its annual report contains certain information, to post that report on its Internet Web site. The bill would make other conforming changes.

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 22 of the Business and Professions Code
2 is amended to read:
3 22. "Board," as used in any provision of this code, refers to
4 the board in which the administration of the provision is vested,
5 and unless otherwise expressly provided, shall include "bureau,"
6 "commission," "committee," "department," "division," "examining
7 committee," "program," and "agency."
8 SEC. 2. Section 101.1 of the Business and Professions Code
9 is repealed.
10 SEC. 3. Section 101.1 is added to the Business and Professions
11 Code, to read:
12 101.1. (a) Notwithstanding any other provision of law, if the
13 terms of office of the members of a board are terminated in
14 accordance with the act that added this section or by subsequent
15 acts, successor members shall be appointed that shall succeed to,
16 and be vested with, all the duties, powers, purposes,
17 responsibilities, and jurisdiction not otherwise repealed or made
18 inoperative of the members that they are succeeding. The successor

members shall be appointed by the same appointing authorities, for the remainder of the previous members' terms, and shall be subject to the same membership requirements as the members they are succeeding.

(b) Notwithstanding any other provision of law, if the term of office for a bureau chief is terminated in accordance with the act that added this section or by subsequent acts, a successor bureau chief shall be appointed who shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the bureau chief that he or she is succeeding. The successor bureau chief shall be appointed by the same appointing ~~authorities, for the remainder of the previous bureau chief's term,~~ *authority* and shall be subject to the same requirements as the bureau chief he or she is succeeding.

SEC. 4. Section 473 of the Business and Professions Code is repealed.

SEC. 5. Section 473 is added to the Business and Professions Code, to read:

473. Whenever the provisions of this code refer to the Joint Committee on Boards, Commissions, and Consumer Protection, the reference shall be construed to be a reference to the appropriate policy committees of the Legislature.

SEC. 6. Section 473.1 of the Business and Professions Code is amended to read:

473.1. This chapter shall apply to all of the following:

(a) Every board, as defined in Section 22, that is scheduled to have its membership reconstituted on a specified date as provided by subdivision (a) of Section 473.12.

(b) Every bureau that is named in subdivision (b) of Section 473.12.

(c) Every entity that is named in subdivision (c) of Section 473.12.

SEC. 7. Section 473.12 is added to the Business and Professions Code, to read:

473.12. (a) Notwithstanding any other provision of law, the term of office of each member of the following boards in the department shall terminate on the date listed, unless a later enacted statute, that is enacted before the date listed for that board, deletes or extends that date:

(1) The Dental Board of California: January 1, ____.
(2) The Medical Board of California: January 1, ____.
(3) The State Board of Optometry: January 1, ____.
(4) The California State Board of Pharmacy: January 1, ____.
(5) The Veterinary Medical Board: January 1, ____.
(6) The California Board of Accountancy: January 1, ____.
(7) The California Architects Board: January 1, ____.
(8) The State Board of Barbering and Cosmetology: January 1, ____.
(9) The Board for Professional Engineers and Land Surveyors: January 1, ____.
(10) The Contractors' State License Board: January 1, ____.
(11) The Board of Registered Nursing: January 1, ____.
(12) The Board of Behavioral Sciences: January 1, ____.
(13) The State Athletic Commission: January 1, ____.
(14) The State Board of Guide Dogs for the Blind: January 1, ____.
(15) The Court Reporters Board of California: January 1, ____.
(16) The Board of Vocational Nursing and Psychiatric Technicians: January 1, ____.
(17) The Landscape Architects Technical Committee: January 1, ____.
(18) The Respiratory Care Board of California: January 1, ____.
(19) The Acupuncture Board: January 1, ____.
(20) The Board of Psychology: January 1, ____.
(21) The California Board of Podiatric Medicine: January 1, ____.
(22) The Physical Therapy Board of California: January 1, ____.
(23) The Physician Assistant Committee of the Medical Board of California: January 1, ____.
(24) The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board: January 1, ____.
(25) The California Board of Occupational Therapy: January 1, ____.
(26) The Dental Hygiene Committee of California: January 1, ____.

(b) Notwithstanding any other provision of law, the term of office for the bureau chief of each of the following bureaus shall terminate on the date listed, unless a later enacted statute, that is

enacted before the date listed for that bureau, deletes or extends that date:

(1) Arbitration Review Program: January 1, ____.

(2) Bureau for Private Postsecondary Education: January 1, ____.

(3) Bureau of Automotive Repair: January 1, ____.

(4) Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation: January 1, ____.

(5) Bureau of Security and Investigative Services: January 1, ____.

(6) Cemetery and Funeral Bureau: January 1, ____.

(7) Professional Fiduciaries Bureau: January 1, ____.

(8) Telephone Medical Advice Services Bureau: January 1, ____.

(9) Division of Investigation: January 1, ____.

(c) Notwithstanding any other provision of law, the following shall be subject to review under this chapter on the following dates:

(1) Interior design certification organizations: January 1, ____.

(2) State Board of Chiropractic Examiners pursuant to Section 473.15: January 1, ____.

(3) Osteopathic Medical Board of California pursuant to Section 473.15: January 1, ____.

(4) California Tax Education Council: January 1, ____.

(5) Naturopathic Medicine Committee, Osteopathic Medical Board of California: January 1, ____.

(6) Common interest development manager certification: January 1, ____.

(7) Massage therapy certification law: January 1, ____.

(d) Nothing in this section or in Section 101.1 shall be construed to preclude, prohibit, or in any manner alter the requirement of Senate confirmation of a board member, chief officer, or other appointee that is subject to confirmation by the Senate as otherwise required by law.

(e) It is not the intent of the Legislature in enacting this section to amend the initiative measure that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 8. Section 473.15 of the Business and Professions Code is amended to read:

473.15. (a) The appropriate policy committees of the Legislature shall review the following boards established by initiative measures, as provided in this section:

(1) The State Board of Chiropractic Examiners established by an initiative measure approved by electors November 7, 1922.

(2) The Osteopathic Medical Board of California established by an initiative measure approved June 2, 1913, and acts amendatory thereto approved by electors November 7, 1922.

(b) The Osteopathic Medical Board of California shall prepare an analysis and submit a report as described in subdivision (a) of Section 473.2, to the appropriate policy committees of the Legislature on or before September 1, 2010.

(c) The State Board of Chiropractic Examiners shall prepare an analysis and submit a report as described in subdivision (a), of Section 473.2, to the appropriate policy committees of the Legislature on or before September 1, 2011.

(d) The appropriate policy committees of the Legislature shall, during the interim recess of 2011, hold public hearings to receive testimony from the Director of Consumer Affairs, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the public, and the regulated industry. In those hearings, each board shall be prepared to demonstrate a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The appropriate policy committees of the Legislature shall evaluate and make determinations pursuant to Section 473.4.

(f) In the exercise of its inherent power to make investigations and ascertain facts to formulate public policy and determine the necessity and expediency of contemplated legislation for the protection of the public health, safety, and welfare, it is the intent of the Legislature that the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California be reviewed pursuant to this section.

(g) It is not the intent of the Legislature in enacting this section to amend the initiative measures that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 9. Section 473.16 of the Business and Professions Code is repealed.

SEC. 10. Section 473.2 of the Business and Professions Code is amended to read:

473.2. (a) All boards or bureaus listed in Section 473.12 shall, with the assistance of the Department of Consumer Affairs, prepare an analysis and submit a report to the appropriate policy committees of the Legislature no later than ~~22~~ *16* months before that board's membership or the bureau chief's term shall be terminated pursuant to Section 473.12. The analysis and report shall include, at a minimum, all of the following:

(1) The number of complaints it received per year, the number of complaints per year that proceeded to investigation, the number of accusations filed per year, and the number and kind of disciplinary actions taken, including, but not limited to, interim suspension orders, revocations, probations, and suspensions.

(2) The average amount of time per year that elapsed between receipt of a complaint and the complaint being closed or referred to investigation; the average amount of time per year elapsed between the commencement of an investigation and the complaint either being closed or an accusation being filed; the average amount of time elapsed per year between the filing of an accusation and a final decision, including appeals; and the average and median costs per case.

(3) The average amount of time per year between final disposition of a complaint and notice to the complainant.

(4) A copy of the enforcement priorities including criteria for seeking an interim suspension order.

(5) A brief description of the board's or bureau's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(6) A brief description of the cost per year required to implement and administer its licensing examination, ownership of the license examination, the last assessment of the relevancy and validity of the licensing examination, the passage rate for each of the last four years, and areas of examination.

(7) A copy of sponsored legislation and a description of its budget change proposals.

(8) A brief assessment as to whether its licensing fees are sufficient, too high, or too low.

(9) A brief statement detailing how the board or bureau over the prior four years has improved its enforcement, public

disclosure, accessibility to the public, including, but not limited to, Internet Web casts of its proceedings, and fiscal condition.

(b) If an annual report contains information that is required by this section, a board or bureau may submit the annual report to the committees and shall post that report on the board's or bureau's Internet Web site.

SEC. 11. Section 473.3 of the Business and Professions Code is amended to read:

473.3. Prior to the termination of the terms of office of the membership of any board or the chief of any bureau described in Section 473.12, the appropriate policy committees of the Legislature, during the interim recess preceding the date upon which a board member's or bureau chief's term of office is to be terminated, may hold public hearings to receive and consider testimony from the Director of Consumer Affairs, the board or bureau involved, the Attorney General, members of the public, and representatives of the regulated industry regarding whether the board's or bureau's policies and practices, including enforcement, disclosure, licensing examination, and fee structure, are sufficient to protect consumers and are fair to licensees and prospective licensees, whether licensure of the profession is required to protect the public, and whether an enforcement monitor may be necessary to obtain further information on operations.

SEC. 12. Section 473.4 of the Business and Professions Code is amended to read:

473.4. (a) The appropriate policy committees of the Legislature may evaluate and determine whether a board or regulatory program has demonstrated a public need for the continued existence of the regulatory program and for the degree of regulation the board or regulatory program implements based on the following factors and minimum standards of performance:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial licensing or regulation of a practice or profession have changed.

(3) Whether other conditions have arisen that would warrant increased, decreased, or the same degree of regulation.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest,

1 considering other available regulatory mechanisms, and whether
2 the board rules enhance the public interest and are within the scope
3 of legislative intent.
4 (5) Whether the board operates and enforces its regulatory
5 responsibilities in the public interest and whether its regulatory
6 mission is impeded or enhanced by existing statutes, regulations,
7 policies, practices, or any other circumstances, including budgetary,
8 resource, and personnel matters.
9 (6) Whether an analysis of board operations indicates that the
10 board performs its statutory duties efficiently and effectively.
11 (7) Whether the composition of the board adequately represents
12 the public interest and whether the board encourages public
13 participation in its decisions rather than participation only by the
14 industry and individuals it regulates.
15 (8) Whether the board and its laws or regulations stimulate or
16 restrict competition, and the extent of the economic impact the
17 board's regulatory practices have on the state's business and
18 technological growth.
19 (9) Whether complaint, investigation, powers to intervene, and
20 disciplinary procedures adequately protect the public and whether
21 final dispositions of complaints, investigations, restraining orders,
22 and disciplinary actions are in the public interest; or if it is, instead,
23 self-serving to the profession, industry, or individuals being
24 regulated by the board.
25 (10) Whether the scope of practice of the regulated profession
26 or occupation contributes to the highest utilization of personnel
27 and whether entry requirements encourage affirmative action.
28 (11) Whether administrative and statutory changes are necessary
29 to improve board operations to enhance the public interest.
30 (b) Nothing in this section precludes any board from submitting
31 other appropriate information to the appropriate policy committees
32 of the Legislature.
33 SEC. 13. Section 473.5 of the Business and Professions Code
34 is repealed.
35 SEC. 14. Section 473.6 of the Business and Professions Code
36 is amended to read:
37 473.6. The chairpersons of the appropriate policy committees
38 of the Legislature may refer to interim study review of any
39 legislative issues or proposals to create new licensure or regulatory
40 categories, change licensing requirements, modify scope of

practice, or create a new licensing board under the provisions of this code or pursuant to Chapter 1.5 (commencing with Section 9148) of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 15. Section 473.7 is added to the Business and Professions Code, to read:

473.7. The appropriate policy committees of the Legislature may, through their oversight function, investigate the operations of any entity to which this chapter applies and hold public hearings on any matter subject to public hearing under Section 473.3.

SEC. 16. Section 9882 of the Business and Professions Code is amended to read:

9882. (a) There is in the Department of Consumer Affairs a Bureau of Automotive Repair under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief who is responsible to the director. The director may adopt and enforce those rules and regulations that he or she determines are reasonably necessary to carry out the purposes of this chapter and declaring the policy of the bureau, including a system for the issuance of citations for violations of this chapter as specified in Section 125.9. These rules and regulations shall be adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(b) In 2003 and every four years thereafter, the appropriate policy committees of the Legislature may hold a public hearing to receive and consider testimony from the Director of Consumer Affairs, the bureau, the Attorney General, members of the public, and representatives of this industry regarding the bureau's policies and practices as specified in Section 473.3. The appropriate policy committees of the Legislature may evaluate and review the effectiveness and efficiency of the bureau based on factors and minimum standards of performance that are specified in Section 473.4. The bureau shall prepare an analysis and submit a report to the appropriate policy committees of the Legislature as specified in Section 473.2.

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AMENDED IN SENATE APRIL 5, 2010

SENATE BILL No. 1171

Introduced by Senator Negrete McLeod

February 18, 2010

An act to amend Sections 22, 473.1, 473.15, 473.2, 473.3, 473.4, 473.6, and 9882 of, to add Sections 473.12 and 473.7 to, to repeal Sections 473.16 and 473.5 of, and to repeal and add Sections 101.1 and 473 of, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

SB 1171, as amended, Negrete McLeod. Regulatory boards: operations.

Existing law creates various regulatory boards, as defined, within the Department of Consumer Affairs, with board members serving specified terms of office. Existing law generally makes the regulatory boards inoperative and repealed on specified dates, unless those dates are deleted or extended by subsequent legislation, and subjects these boards that are scheduled to become inoperative and repealed as well as other boards in state government, as specified, to review by the Joint Committee on Boards, Commissions, and Consumer Protection. Under existing law, that committee, following a specified procedure, recommends whether the board should be continued or its functions modified. Existing law requires the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California to submit certain analyses and reports to the committee on specified dates and requires the committee to review those boards and hold hearings as specified, and to make certain evaluations and findings.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection and would authorize the appropriate policy

committees of the Legislature to carry out its duties. The bill would terminate the terms of office of each board member or bureau chief within the department on unspecified dates and would authorize successor board members and bureau chiefs to be appointed, as specified. The bill would also subject interior design organizations, the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, the Tax Education Council, ~~and~~ the Naturopathic Medical Committee, *and the certification of common interest development managers and massage therapists* to review on unspecified dates. The bill would authorize the appropriate policy committees of the Legislature to review the boards, bureaus, or entities that are scheduled to have their board membership or bureau chief so terminated or reviewed, as specified, and would authorize the appropriate policy committees of the Legislature to investigate their operations and to hold specified public hearings. The bill would require a board, bureau, or entity, if its annual report contains certain information, to post that report on its Internet Web site. The bill would make other conforming changes.

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 22 of the Business and Professions Code
2 is amended to read:
3 22. "Board," as used in any provision of this code, refers to
4 the board in which the administration of the provision is vested,
5 and unless otherwise expressly provided, shall include "bureau,"
6 "commission," "committee," "department," "division," "examining
7 committee," "program," and "agency."
8 SEC. 2. Section 101.1 of the Business and Professions Code
9 is repealed.
10 SEC. 3. Section 101.1 is added to the Business and Professions
11 Code, to read:
12 101.1. (a) Notwithstanding any other provision of law, if the
13 terms of office of the members of a board are terminated in
14 accordance with the act that added this section or by subsequent
15 acts, successor members shall be appointed that shall succeed to,
16 and be vested with, all the duties, powers, purposes,
17 responsibilities, and jurisdiction not otherwise repealed or made
18 inoperative of the members that they are succeeding. The successor

members shall be appointed by the same appointing authorities, for the remainder of the previous members' terms, and shall be subject to the same membership requirements as the members they are succeeding.

(b) Notwithstanding any other provision of law, if the term of office for a bureau chief is terminated in accordance with the act that added this section or by subsequent acts, a successor bureau chief shall be appointed who shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the bureau chief that he or she is succeeding. The successor bureau chief shall be appointed by the same appointing ~~authorities, for the remainder of the previous bureau chief's term,~~ *authority* and shall be subject to the same requirements as the bureau chief he or she is succeeding.

SEC. 4. Section 473 of the Business and Professions Code is repealed.

SEC. 5. Section 473 is added to the Business and Professions Code, to read:

473. Whenever the provisions of this code refer to the Joint Committee on Boards, Commissions, and Consumer Protection, the reference shall be construed to be a reference to the appropriate policy committees of the Legislature.

SEC. 6. Section 473.1 of the Business and Professions Code is amended to read:

473.1. This chapter shall apply to all of the following:

(a) Every board, as defined in Section 22, that is scheduled to have its membership reconstituted on a specified date as provided by subdivision (a) of Section 473.12.

(b) Every bureau that is named in subdivision (b) of Section 473.12.

(c) Every entity that is named in subdivision (c) of Section 473.12.

SEC. 7. Section 473.12 is added to the Business and Professions Code, to read:

473.12. (a) Notwithstanding any other provision of law, the term of office of each member of the following boards in the department shall terminate on the date listed, unless a later enacted statute, that is enacted before the date listed for that board, deletes or extends that date:

(1) The Dental Board of California: January 1, ____.
(2) The Medical Board of California: January 1, ____.
(3) The State Board of Optometry: January 1, ____.
(4) The California State Board of Pharmacy: January 1, ____.
(5) The Veterinary Medical Board: January 1, ____.
(6) The California Board of Accountancy: January 1, ____.
(7) The California Architects Board: January 1, ____.
(8) The State Board of Barbering and Cosmetology: January 1, ____.
(9) The Board for Professional Engineers and Land Surveyors: January 1, ____.
(10) The Contractors' State License Board: January 1, ____.
(11) The Board of Registered Nursing: January 1, ____.
(12) The Board of Behavioral Sciences: January 1, ____.
(13) The State Athletic Commission: January 1, ____.
(14) The State Board of Guide Dogs for the Blind: January 1, ____.
(15) The Court Reporters Board of California: January 1, ____.
(16) The Board of Vocational Nursing and Psychiatric Technicians: January 1, ____.
(17) The Landscape Architects Technical Committee: January 1, ____.
(18) The Respiratory Care Board of California: January 1, ____.
(19) The Acupuncture Board: January 1, ____.
(20) The Board of Psychology: January 1, ____.
(21) The California Board of Podiatric Medicine: January 1, ____.
(22) The Physical Therapy Board of California: January 1, ____.
(23) The Physician Assistant Committee of the Medical Board of California: January 1, ____.
(24) The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board: January 1, ____.
(25) The California Board of Occupational Therapy: January 1, ____.
(26) The Dental Hygiene Committee of California: January 1, ____.

(b) Notwithstanding any other provision of law, the term of office for the bureau chief of each of the following bureaus shall terminate on the date listed, unless a later enacted statute, that is

enacted before the date listed for that bureau, deletes or extends that date:

(1) Arbitration Review Program: January 1, ____.

(2) Bureau for Private Postsecondary Education: January 1, ____.

(3) Bureau of Automotive Repair: January 1, ____.

(4) Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation: January 1, ____.

(5) Bureau of Security and Investigative Services: January 1, ____.

(6) Cemetery and Funeral Bureau: January 1, ____.

(7) Professional Fiduciaries Bureau: January 1, ____.

(8) Telephone Medical Advice Services Bureau: January 1, ____.

(9) Division of Investigation: January 1, ____.

(c) Notwithstanding any other provision of law, the following shall be subject to review under this chapter on the following dates:

(1) Interior design certification organizations: January 1, ____.

(2) State Board of Chiropractic Examiners pursuant to Section 473.15: January 1, ____.

(3) Osteopathic Medical Board of California pursuant to Section 473.15: January 1, ____.

(4) California Tax Education Council: January 1, ____.

(5) Naturopathic Medicine Committee, Osteopathic Medical Board of California: January 1, ____.

(6) Common interest development manager certification: January 1, ____.

(7) Massage therapy certification law: January 1, ____.

(d) Nothing in this section or in Section 101.1 shall be construed to preclude, prohibit, or in any manner alter the requirement of Senate confirmation of a board member, chief officer, or other appointee that is subject to confirmation by the Senate as otherwise required by law.

(e) It is not the intent of the Legislature in enacting this section to amend the initiative measure that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 8. Section 473.15 of the Business and Professions Code is amended to read:

473.15. (a) The appropriate policy committees of the Legislature shall review the following boards established by initiative measures, as provided in this section:

(1) The State Board of Chiropractic Examiners established by an initiative measure approved by electors November 7, 1922.

(2) The Osteopathic Medical Board of California established by an initiative measure approved June 2, 1913, and acts amendatory thereto approved by electors November 7, 1922.

(b) The Osteopathic Medical Board of California shall prepare an analysis and submit a report as described in subdivision (a) of Section 473.2, to the appropriate policy committees of the Legislature on or before September 1, 2010.

(c) The State Board of Chiropractic Examiners shall prepare an analysis and submit a report as described in subdivision (a), of Section 473.2, to the appropriate policy committees of the Legislature on or before September 1, 2011.

(d) The appropriate policy committees of the Legislature shall, during the interim recess of 2011, hold public hearings to receive testimony from the Director of Consumer Affairs, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the public, and the regulated industry. In those hearings, each board shall be prepared to demonstrate a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The appropriate policy committees of the Legislature shall evaluate and make determinations pursuant to Section 473.4.

(f) In the exercise of its inherent power to make investigations and ascertain facts to formulate public policy and determine the necessity and expediency of contemplated legislation for the protection of the public health, safety, and welfare, it is the intent of the Legislature that the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California be reviewed pursuant to this section.

(g) It is not the intent of the Legislature in enacting this section to amend the initiative measures that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 9. Section 473.16 of the Business and Professions Code is repealed.

SEC. 10. Section 473.2 of the Business and Professions Code is amended to read:

473.2. (a) All boards or bureaus listed in Section 473.12 shall, with the assistance of the Department of Consumer Affairs, prepare an analysis and submit a report to the appropriate policy committees of the Legislature no later than ~~22~~ *16* months before that board's membership or the bureau chief's term shall be terminated pursuant to Section 473.12. The analysis and report shall include, at a minimum, all of the following:

(1) The number of complaints it received per year, the number of complaints per year that proceeded to investigation, the number of accusations filed per year, and the number and kind of disciplinary actions taken, including, but not limited to, interim suspension orders, revocations, probations, and suspensions.

(2) The average amount of time per year that elapsed between receipt of a complaint and the complaint being closed or referred to investigation; the average amount of time per year elapsed between the commencement of an investigation and the complaint either being closed or an accusation being filed; the average amount of time elapsed per year between the filing of an accusation and a final decision, including appeals; and the average and median costs per case.

(3) The average amount of time per year between final disposition of a complaint and notice to the complainant.

(4) A copy of the enforcement priorities including criteria for seeking an interim suspension order.

(5) A brief description of the board's or bureau's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(6) A brief description of the cost per year required to implement and administer its licensing examination, ownership of the license examination, the last assessment of the relevancy and validity of the licensing examination, the passage rate for each of the last four years, and areas of examination.

(7) A copy of sponsored legislation and a description of its budget change proposals.

(8) A brief assessment as to whether its licensing fees are sufficient, too high, or too low.

(9) A brief statement detailing how the board or bureau over the prior four years has improved its enforcement, public

disclosure, accessibility to the public, including, but not limited to, Internet Web casts of its proceedings, and fiscal condition.

(b) If an annual report contains information that is required by this section, a board or bureau may submit the annual report to the committees and shall post that report on the board's or bureau's Internet Web site.

SEC. 11. Section 473.3 of the Business and Professions Code is amended to read:

473.3. Prior to the termination of the terms of office of the membership of any board or the chief of any bureau described in Section 473.12, the appropriate policy committees of the Legislature, during the interim recess preceding the date upon which a board member's or bureau chief's term of office is to be terminated, may hold public hearings to receive and consider testimony from the Director of Consumer Affairs, the board or bureau involved, the Attorney General, members of the public, and representatives of the regulated industry regarding whether the board's or bureau's policies and practices, including enforcement, disclosure, licensing examination, and fee structure, are sufficient to protect consumers and are fair to licensees and prospective licensees, whether licensure of the profession is required to protect the public, and whether an enforcement monitor may be necessary to obtain further information on operations.

SEC. 12. Section 473.4 of the Business and Professions Code is amended to read:

473.4. (a) The appropriate policy committees of the Legislature may evaluate and determine whether a board or regulatory program has demonstrated a public need for the continued existence of the regulatory program and for the degree of regulation the board or regulatory program implements based on the following factors and minimum standards of performance:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial licensing or regulation of a practice or profession have changed.

(3) Whether other conditions have arisen that would warrant increased, decreased, or the same degree of regulation.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest,

1 considering other available regulatory mechanisms, and whether
2 the board rules enhance the public interest and are within the scope
3 of legislative intent.
4 (5) Whether the board operates and enforces its regulatory
5 responsibilities in the public interest and whether its regulatory
6 mission is impeded or enhanced by existing statutes, regulations,
7 policies, practices, or any other circumstances, including budgetary,
8 resource, and personnel matters.
9 (6) Whether an analysis of board operations indicates that the
10 board performs its statutory duties efficiently and effectively.
11 (7) Whether the composition of the board adequately represents
12 the public interest and whether the board encourages public
13 participation in its decisions rather than participation only by the
14 industry and individuals it regulates.
15 (8) Whether the board and its laws or regulations stimulate or
16 restrict competition, and the extent of the economic impact the
17 board's regulatory practices have on the state's business and
18 technological growth.
19 (9) Whether complaint, investigation, powers to intervene, and
20 disciplinary procedures adequately protect the public and whether
21 final dispositions of complaints, investigations, restraining orders,
22 and disciplinary actions are in the public interest; or if it is, instead,
23 self-serving to the profession, industry, or individuals being
24 regulated by the board.
25 (10) Whether the scope of practice of the regulated profession
26 or occupation contributes to the highest utilization of personnel
27 and whether entry requirements encourage affirmative action.
28 (11) Whether administrative and statutory changes are necessary
29 to improve board operations to enhance the public interest.
30 (b) Nothing in this section precludes any board from submitting
31 other appropriate information to the appropriate policy committees
32 of the Legislature.
33 SEC. 13. Section 473.5 of the Business and Professions Code
34 is repealed.
35 SEC. 14. Section 473.6 of the Business and Professions Code
36 is amended to read:
37 473.6. The chairpersons of the appropriate policy committees
38 of the Legislature may refer to interim study review of any
39 legislative issues or proposals to create new licensure or regulatory
40 categories, change licensing requirements, modify scope of

practice, or create a new licensing board under the provisions of this code or pursuant to Chapter 1.5 (commencing with Section 9148) of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 15. Section 473.7 is added to the Business and Professions Code, to read:

473.7. The appropriate policy committees of the Legislature may, through their oversight function, investigate the operations of any entity to which this chapter applies and hold public hearings on any matter subject to public hearing under Section 473.3.

SEC. 16. Section 9882 of the Business and Professions Code is amended to read:

9882. (a) There is in the Department of Consumer Affairs a Bureau of Automotive Repair under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief who is responsible to the director. The director may adopt and enforce those rules and regulations that he or she determines are reasonably necessary to carry out the purposes of this chapter and declaring the policy of the bureau, including a system for the issuance of citations for violations of this chapter as specified in Section 125.9. These rules and regulations shall be adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(b) In 2003 and every four years thereafter, the appropriate policy committees of the Legislature may hold a public hearing to receive and consider testimony from the Director of Consumer Affairs, the bureau, the Attorney General, members of the public, and representatives of this industry regarding the bureau's policies and practices as specified in Section 473.3. The appropriate policy committees of the Legislature may evaluate and review the effectiveness and efficiency of the bureau based on factors and minimum standards of performance that are specified in Section 473.4. The bureau shall prepare an analysis and submit a report to the appropriate policy committees of the Legislature as specified in Section 473.2.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1172 **VERSION: As Amended April 12, 2010**

AUTHOR: Negrete McLeod **SPONSOR: Department of Consumer Affairs**

BOARD POSITION:

SUBJECT: Regulatory boards: Operations

Affected Sections: ~~Amend Sections 156, 1695, 2360, 2662, 2770, 3534, 4360, and 4860 of the Business and Professions Code~~
Amend Section 156.1 and add Sections 315.2, 315.4 and 315.6 of the Business and Professions Code.

EXISTING LAW:

1. Allows the director for the Department of Consumer Affairs to enter into contracts on behalf of any board.
2. Requires the board to operate a pharmacist's recovery program to rehabilitate pharmacists or intern pharmacists whose competency may be impaired due to alcohol, drug abuse or mental illness.

THIS BILL WOULD:

1. Require an external independent audit of an entity contracting with the department to provide monitoring services for substance abusing health care professionals, at least once every three years as specified.
2. Require that an audit report shall be prepared and provided to the Legislature, the department and the board and shall including findings and identify noncompliance with the terms of the contract.
3. Require the vendor, the department and the board to respond to the findings.
4. Require a board to order a licensee to cease practice if a licensee tests positive for any prohibited substance as specified.
5. Authorizes the board to order a licensee on probation or in a diversion program to cease practice for major violations or when the board orders a licensee to undergo a clinical diagnostic evaluation as specified.
6. Prohibits the board from disclosing to the public that a licensee is participating in a diversion program, unless the participation was ordered as part of the terms and conditions of probation. However it requires the board to disclose any

restrictions placed on a license as a result of their participation on the diversion program.

AUTHOR'S INTENT:

To facilitate implementation of those uniform standards developed that require legislation to enact.

FISCAL IMPACT:

The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS:

In 2008, Senator Ridley-Thomas sponsored legislation establishing the Substance Abuse Coordination Committee in SB 1441. This committee is largely composed of executive officers from the healing arts board within the Department of Consumer Affairs, was charged with developing uniform standards to be used when dealing with substance abusing licensees.

This bill is currently a spot bill. It will be amended to incorporate the legislative changes necessary to implement the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees resulting from SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

SUPPORT/OPPOSITION

None of file.

HISTORY:

Date	Action
Apr. 12	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
Apr. 7	Set for hearing April 19.
Mar. 4	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 12, 2010

SENATE BILL No. 1172

Introduced by Senator Negrete McLeod

February 18, 2010

~~An act to amend Sections 156, 1695, 2360, 2662, 2770, 3534, 4360, and 4860 of the Business and Professions Code, relating to regulatory boards.~~ *An act to amend Section 156.1 of, and to add Sections 315.2, 315.4, and 315.6 to, the Business and Professions Code, relating to regulatory boards.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1172, as amended, Negrete McLeod. Regulatory ~~boards.~~ *boards: diversion programs.*

~~Existing~~

(1) Existing law provides for the regulation of specified professions and vocations by various boards, as defined, within the Department of Consumer Affairs. ~~The department is under the control of the Director of Consumer Affairs. Existing law authorizes the director to enter into contracts for and on behalf of any board within the department.~~ *Under existing law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs are required to retain all records and documents pertaining to those services for 3 years or until they are audited, whichever occurs first. Under existing law, those records and documents are required to be kept confidential and are not subject to discovery or subpoena.*

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

This bill would specify that those records and documents shall be kept for 3 years and are not subject to discovery or subpoena unless otherwise expressly provided by law and would prohibit the licentiate from waiving confidentiality. The bill would require the department or board contracting for those services to have an audit conducted at least once every 3 years by a specified independent reviewer or review team, would require that reviewer or review team to prepare an audit report and to submit it to the Legislature, the department, and the board by June 30 every 3 years, with the first report due in 2013, and would require the department, the contract vendor, and the board to respond to the report, as specified.

(2) Existing law provides for the licensure and regulation of various healing arts by boards within the Department of Consumer Affairs. Under existing law, these boards are authorized to issue, deny, suspend, and revoke licenses based on various grounds and to take disciplinary action against their licensees.

Existing law establishes diversion and recovery programs to identify and rehabilitate dentists, osteopathic physicians and surgeons, physical therapists, physical therapy assistants, registered nurses, physician assistants, pharmacists and intern pharmacists, veterinarians, and registered veterinary technicians whose competency may be impaired due to, among other things, alcohol and drug abuse.

~~This bill would, with respect to those programs, revise references to alcohol and drug abuse to include other substances.~~

The bill would require a healing arts board to order a licensee to cease practice if the licensee tests positive for any prohibited substance under the terms of the licensee's probation or diversion program. The bill would also authorize a board to adopt regulations authorizing it to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation, as specified. Except as provided, the bill would prohibit a healing arts board from disclosing to the public that a licensee is participating in a board diversion program.

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

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

SECTION 1. Section 156.1 of the Business and Professions Code is amended to read:

156.1. (a) Notwithstanding any other provision of law, individuals or entities contracting with the department or any board within the department for the provision of services relating to the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs~~,~~ shall retain all records and documents pertaining to those services until such time as these records and documents have been reviewed for audit ~~by the department~~ *pursuant to subdivision (c)*. These records and documents shall be retained for ~~a maximum of~~ three years from the date of the last treatment or service rendered to that licentiate, ~~or until such time as the records pertaining to treatment or services rendered to that licentiate are audited, whichever occurs first,~~ after which time the records and documents may be purged and destroyed by the contract vendor. This provision shall supersede any other provision of law relating to the purging or destruction of records pertaining to those treatment and rehabilitation programs.

(b) ~~Notwithstanding any other provision of law, all~~ *Unless otherwise expressly provided by statute or regulation, all* records and documents pertaining to services for the treatment and rehabilitation of licentiates impaired by alcohol or dangerous drugs provided by any contract vendor to the department or to any board within the department shall be kept confidential and are not subject to discovery or subpoena. *A licentiate may not waive confidentiality pursuant to this subdivision.*

(c) (1) An external independent audit of an individual or entity contracting with the department pursuant to subdivision (a) shall be conducted at least once every three years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the contractor providing the services. The independent reviewer or review team shall be competent in the professional practice of internal auditing and assessment processes.

(2) The independent reviewer or review team shall prepare an audit report that assesses the contractor's performance in adhering to any standards established by the department or the board and shall submit that report to the Legislature, the department, and

the board by June 30 every three years, with the first report due in 2013. The audit report shall make findings and identify any material inadequacies, deficiencies, irregularities, or any other noncompliance with the terms of the contract.

(3) The department, contract vendor, and the board shall respond to the assessment and findings in the audit report prior to submission to the Legislature.

~~(c)~~

(d) With respect to all other contracts for services with the department or any board within the department other than those set forth in subdivision (a), the director or chief deputy director may request an examination and audit by the department's internal auditor of all performance under the contract. For this purpose, all documents and records of the contract vendor in connection with such performance shall be retained by such vendor for a period of three years after final payment under the contract. Nothing in this section shall affect the authority of the State Auditor to conduct any examination or audit under the terms of Section 8546.7 of the Government Code.

SEC. 2. Section 315.2 is added to the Business and Professions Code, to read:

315.2. (a) A board, as described in Section 315, shall order a licensee of the board to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) A licensee may petition to return to practice pursuant to the uniform and specific standards adopted and authorized under Section 315.

SEC. 3. Section 315.4 is added to the Business and Professions Code, to read:

315.4. (a) A board, as described in Section 315, may adopt regulations authorizing the board to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical

diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

(b) An order to cease practice under this section shall not be governed by the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) A cease practice order under this section shall not constitute disciplinary action.

(d) The regulations shall also include provisions for a licensee to petition to return to practice pursuant to the uniform and specific standards adopted and authorized under Section 315.

SEC. 4. Section 315.6 is added to the Business and Professions Code, to read:

315.6. Unless otherwise authorized by statute or regulation, a board, as described in Section 315, shall not disclose to the public that a licensee is participating in a board diversion program unless participation was ordered as a term of probation. However, a board shall disclose to the public any restrictions that are placed on a licensee's practice as a result of the licensee's participation in a board diversion program provided that the disclosure does not contain information linking the restriction to the licensee's participation in the board's diversion program.

~~SECTION 1. Section 156 of the Business and Professions Code is amended to read:~~

~~156. (a) The director may, for the department and at the request and with the consent of a board or bureau within the department on whose behalf the contract is to be made, enter into contracts pursuant to Chapter 3 (commencing with Section 11250) of Part 1 of Division 3 of Title 2 of the Government Code or Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code for and on behalf of any board or bureau within the department.~~

~~(b) In accordance with subdivision (a), the director may, in his or her discretion, negotiate and execute contracts for examination purposes that include provisions that hold harmless a contractor where liability resulting from a contract between a board in the department and the contractor is traceable to the state or its officers, agents, or employees.~~

~~SEC. 2. Section 1695 of the Business and Professions Code is amended to read:~~

~~1695. It is the intent of the Legislature that the Dental Board of California seek ways and means to identify and rehabilitate licensees whose competency may be impaired due to abuse of dangerous drugs or alcohol or other substances, so that licensees so afflicted may be treated and returned to the practice of dentistry in a manner that will not endanger the public health and safety. It is also the intent of the Legislature that the Dental Board of California shall implement this legislation in part by establishing a diversion program as a voluntary alternative approach to traditional disciplinary actions.~~

~~SEC. 3. Section 2360 of the Business and Professions Code is amended to read:~~

~~2360. It is the intent of the Legislature that the Osteopathic Medical Board of California seek ways and means to identify and rehabilitate osteopathic physicians and surgeons whose competency may be impaired due to abuse of dangerous drugs or alcohol or other substances, so that osteopathic physicians and surgeons so afflicted may be treated and returned to the practice of medicine in a manner that will not endanger the public health and safety. It is also the intent of the Legislature that the Osteopathic Medical Board of California shall implement this legislation by establishing a diversion program as a voluntary alternative approach to traditional disciplinary actions.~~

~~SEC. 4. Section 2662 of the Business and Professions Code is amended to read:~~

~~2662. It is the intent of the Legislature that the board shall seek ways and means to identify and rehabilitate physical therapists and physical therapist assistants whose competency is impaired due to abuse of dangerous drugs or alcohol or other substances so that they may be treated and returned to the practice of physical therapy in a manner that will not endanger the public health and safety.~~

~~SEC. 5. Section 2770 of the Business and Professions Code is amended to read:~~

~~2770. It is the intent of the Legislature that the Board of Registered Nursing seek ways and means to identify and rehabilitate registered nurses whose competency may be impaired due to abuse of alcohol or drugs or other substances, or due to mental illness so that registered nurses so afflicted may be rehabilitated and returned to the practice of nursing in a manner~~

~~that will not endanger the public health and safety. It is also the intent of the Legislature that the Board of Registered Nursing shall implement this legislation by establishing a diversion program as a voluntary alternative to traditional disciplinary actions.~~

~~SEC. 6. Section 3534 of the Business and Professions Code is amended to read:~~

~~3534. (a) It is the intent of the Legislature that the examining committee shall seek ways and means to identify and rehabilitate physician assistants whose competency is impaired due to abuse of dangerous drugs or alcohol or other substances so that they may be treated and returned to the practice of medicine in a manner that will not endanger the public health and safety.~~

~~SEC. 7. Section 4360 of the Business and Professions Code is amended to read:~~

~~4360. The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol or other substances, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.~~

~~SEC. 8. Section 4860 of the Business and Professions Code is amended to read:~~

~~4860. It is the intent of the Legislature that the Veterinary Medical Board seek ways and means to identify and rehabilitate veterinarians and registered veterinary technicians with impairment due to abuse of dangerous drugs or alcohol or other substances, affecting competency so that veterinarians and registered veterinary technicians so afflicted may be treated and returned to the practice of veterinary medicine in a manner that will not endanger the public health and safety.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1455 **VERSION:** **As Introduced 2/19/2010**

AUTHOR: Block **SPONSOR:** **California Department of Justice**

BOARD POSITION:

SUBJECT: **Electronic Tracking of Pseudoephedrine (PSE) Purchases**

Affected Sections: Health & Safety Code §11100 and
Health & Safety Code §11100.02

EXISTING LAW:

1. Existing federal law provides for limited regulation of the retail sale of pseudoephedrine (PSE) products which prohibit the sale of more than 3.6 grams in a single transaction, and more than 9.0 grams in a one-month period without a valid prescription.
2. Existing state law specifies limitations on sales, recordkeeping, and reporting requirements of the sale, transfer or furnishing of pseudoephedrine.
3. The Uniform Controlled Substances Act (Act) classifies controlled substances into five schedules, with the most restrictive limitations place on Schedule I controlled substances and the least restrictive limitations placed on Schedule V controlled substances.
4. Does not classify pseudoephedrine (PSE) or PSE products within any of the five schedules, but does 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:

1. Be implemented as an emergency statute, and remain in effect only until January 1, 2017.
2. Provide that it is a misdemeanor, punishable as specified, for any retail distributor, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority, to sell or distribute to a person specified amounts of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within specified time limits, to sell or distribute any of those substances to a person whose information has generated an alert, or, except under specified conditions, to sell or distribute to any purchaser a nonprescription product containing any amount of those substances.
2. Provide for the secure storage of PSE products, as specified.
3. Provide that the information in the system may not be used for any purpose other than to meet the requirements of, or comply with, this act or a certain federal act, as specified. The bill would specify legislative findings, declarations, and intent.

AUTHOR'S INTENT:

According to the author, AB 1455 will implement a statewide electronic "real time" tracking program funded by the retail industry in which it will be used to monitor all California over-the-counter (OTC) purchases of pseudoephedrine (PSE). This tracking system will be administered by the National Association of Drug Diversion Investigators (NADDI).

When a customer attempts a purchase, retailers will be required to enter *specified data through either a web-based interface or a direct interface with the database. The system will alert a retailer at the point of sale if the consumer is ineligible to make the purchase, as specified. If so alerted, the retailer is precluded from completing the sale.

*The data required to be entered is the same data that is required pursuant to federal law to be kept as to transactions on the sale of PSE products, as specified.

Such a system will alert retailers when a purchaser attempts to exceed purchase limits, and the retailer would be required to deny the sale.

FISCAL IMPACT:

As amended, 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 would likely utilize existing resources and incorporate into its inspection program any compliance with the provisions of this measure, if enacted.

SUPPORT and OPPOSITION (as of April 14, 2010):
None known.

HISTORY:

Date	Action
2010	
Jan. 19	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on PUB. S.
2009	
Aug. 24	In committee: Set, first hearing. Hearing canceled at the request of author.
Aug. 19	Re-referred to Coms. on PUB. S. and JUD.
Aug. 18	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on RLS.
Aug. 17	Read second time. To third reading. Re-referred to Com. on RLS. pursuant to Senate Rule 29.10(c).
Aug. 17	Re-referred to Com. on APPR. pursuant to Joint Rule 10.5.
July 23	From inactive file. To second reading. Read second time and amended. Ordered returned to second reading.
June 29	To inactive file on motion of Senator Yee.
June 23	Read second time, amended, and to third reading.
June 22	From committee: Amend, and do pass as amended. (Ayes 6. Noes 1.) (June 17).
May 21	Referred to Com. on ED.
May 14	In Senate. Read first time. To Com. on RLS. for assignment.
May 14	Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 1447.)
May 11	Read second time. To third reading.
May 7	Read second time and amended. Ordered returned to second reading.
May 6	From committee: Amend, and do pass as amended. (Ayes 9. Noes 0.) (May 5).
Apr. 23	Re-referred to Com. on HIGHER ED.
Apr. 22	From committee chair, with author's amendments: Amend, and re-refer to Com. on HIGHER ED. Read second time and amended.
Apr. 21	In committee: Set, first hearing. Hearing canceled at the request of author.
Apr. 15	Re-referred to Com. on HIGHER ED.
Apr. 13	Referred to Com. on HIGHER ED. From committee chair, with author's amendments: Amend, and re-refer to Com. on HIGHER ED. Read second time and amended.
Mar. 2	Read first time.
Mar. 1	From printer. May be heard in committee March 30.
Feb. 27	Introduced. To print.

HEARING:

AMENDED IN SENATE JANUARY 19, 2010

AMENDED IN SENATE AUGUST 18, 2009

AMENDED IN SENATE JULY 23, 2009

AMENDED IN SENATE JUNE 23, 2009

AMENDED IN ASSEMBLY MAY 7, 2009

AMENDED IN ASSEMBLY APRIL 22, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1455

Introduced by Assembly Member Hill
(Principal coauthor: Senator Leno)
(Coauthors: Assembly Members *Anderson,* Gilmore, Hagman, Jones, Ma, Miller, ~~and Nielsen~~ *Nielsen, and Salas*)
~~(Coauthor: Senator Benoit)~~ *(Coauthors: Senators Cox and Huff)*

February 27, 2009

An act to amend, repeal, and add Section 11100 of, and to add and repeal Section 11100.02 of, the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1455, as amended, Hill. Ephedrine: retail sale.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on

controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified. Existing law prohibits the sale of more than 3 packages or 9 grams of a nonprescription product containing ephedrine or the other drugs, as specified.

This bill would instead provide that it is a misdemeanor, punishable as specified, for any retail distributor, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority, to sell or distribute to a person specified amounts of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within specified time limits, to sell or distribute any of those substances to a person whose information has generated an alert, or, except under specified conditions, to sell or distribute to any purchaser a nonprescription product containing any amount of those substances. The bill would contain provisions requiring the secure storage of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and providing for the creation of an electronic authorization and monitoring system for the collection of, access to, and sharing of information regarding these transactions, as specified. *The bill would provide that the information in the system may not be used for any purpose other than to meet the requirements of, or comply with, this act or a certain federal act, as specified. The bill would specify legislative findings, declarations, and intent.* The bill's provisions would remain in effect only until January 1, 2017. By creating a new crime, this bill would impose a state-mandated local program.

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

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

(3) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. 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.
31 (24) Thionylchloride.
32 (25) Benzyl cyanide.
33 (26) Ergonovine maleate.

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

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

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

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

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

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which

includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

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

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

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

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

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

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

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

(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to

the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

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

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

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

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

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

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

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

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

(h) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

SEC. 2. Section 11100 is added to the Health and Safety Code, to read:

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

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

(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.

(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).

(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).

(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

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

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

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

exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

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

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

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

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

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

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

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

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

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

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

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

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

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

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by

imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

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

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

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

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

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

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

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

(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial

Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

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

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

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

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

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

(j) This section shall become operative on January 1, 2017.

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

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

(1) To sell or distribute to the same purchaser within any 30-day period more than nine grams, or within any ~~24-hour period~~ *day* more than 3.6 grams, of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

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

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

~~(A) The purchaser shall produce a valid federal- or state-issued identification or document relating to identification that is acceptable for purposes of Section 274a.2(b)(1)(v)(A) or Section 274a.2(b)(1)(v)(B) of Title 8 of the Code of Federal Regulations, in effect on or after March 9, 2006.~~

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

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

(i) The date of the transaction.

(ii) The identification number presented.

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

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

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

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

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

(A) The date of the transaction.

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

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

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

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

(2) Upon recording the transaction information, the retail distributor shall transmit the information immediately to the electronic authorization and monitoring system for purposes of determining whether the proposed sale would violate this section and therefore may not proceed. *The transaction information shall not be accessed or used by the retail distributor for any purpose other than to meet the requirements set forth in this section or to comply with the provisions of the federal Combat Methamphetamine Epidemic Act, or any regulation adopted pursuant to this section or that act.*

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

(d) (1) The Bureau of Narcotic Enforcement shall enter into a memorandum of understanding (MOU) with the National Association of Drug Diversion Investigators ~~or other comparable organization~~ to provide retail distributors of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in this state ~~with access~~ *access without charge* to an electronic authorization and monitoring system for the sale of those products.

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

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

(4) Neither the bureau nor any state agency shall bear any cost for the development, installation, or maintenance of the system.

(5) The state shall impose no fee on a retail distributor or manufacturer to defray administrative or other costs for oversight or use of the system.

(6) The MOU shall state that no party to the MOU nor any entity under contract to provide the electronic authorization and monitoring system shall be authorized to use the information contained in the system for any purpose other than those set forth in this section, the federal Combat Methamphetamine Epidemic Act, or any regulation adopted pursuant to this section or that act. However, the system operator shall be authorized to analyze the information for the sole purpose of assessing and improving the performance and efficacy of the system.

(e) The bureau is authorized to enter into a cooperative endeavor, MOU, contract, or any other agreement with any other law enforcement agency in order to provide instant access to the information collected under this section regarding the sale of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

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

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

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

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

(1) "Bureau" means Bureau of Narcotic Enforcement of the Department of Justice.

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

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

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

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

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

(i) The provisions of this section shall not become operative unless all of the following conditions have been met:

(1) The Bureau of Narcotic Enforcement enters into a MOU with the National Association of Drug Diversion Investigators or other comparable organization, as set forth in subdivision (d).

(2) The Bureau of Narcotic Enforcement determines that a substantial number of retail distributors have access to the electronic authorization and monitoring system pursuant to the provisions of the MOU.

(3) A period of 180 days has expired from the date the bureau made the determination specified in paragraph (2).

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

(k) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

SEC. 4. (a) The Legislature finds and declares all of the following:

(1) The National Association of Drug Diversion Investigators (NADDI) is the only organization prepared to implement, and capable of implementing, a statewide electronic tracking system for retail sales of medicines containing pseudoephedrine as soon as would be mandated by this act.

(2) Only NADDI is positioned to implement the system as specified in this act because manufacturers of these medicines have entered into a contractual relationship with NADDI to provide access to the system, without charge, to all retailers and to appropriate state and local law enforcement agencies.

(b) It is the intent of the Legislature in enacting this act to mandate a statewide electronic tracking system for retail sales of medicines containing pseudoephedrine without incurring cost to the state to run the system because manufacturers of pseudoephedrine products will fund the system.

~~SEC. 4.~~

SEC. 5. 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.

~~SEC. 5.~~

SEC. 6. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to effectively and expeditiously control the distribution of ephedrine and like substances in order to reduce their use in the manufacture of methamphetamine, it is necessary that this act go into immediate effect.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2548 **VERSION: As Introduced 2/19/2010**

AUTHOR: Block **SPONSOR: California Department of Justice**

RECOMMENDED POSITION:

SUBJECT: Prescription Drug Monitoring Program (CURES)

Affected Sections: **Uniform Controlled Substances Act**
Amend Health & Safety Code §11165
Add Health & Safety Code §11165.05

EXISTING LAW:

1. The Controlled Substance Utilization Review and Evaluation System (CURES) is maintained by the California Department of Justice. The system's maintenance is contingent upon availability of the following Contingent Funds: Medical Board, Pharmacy Board, Dentistry, Board of Registered Nursing and Osteopathic.
2. Requires prescriptions for Schedule II and III controlled substances be reported to DOJ.
3. Requires that a dispensing pharmacy or clinic weekly report specified information to DOJ on a form specified by that department.
4. Allows an eligible prescriber or a pharmacist to request/receive CURES data (a patient's history of controlled substances dispensed to the patient) and allows the DOJ to initiate the referral of that information to an individual.
5. Provides that CURES data received by a practitioner or pharmacist is considered medical information subject to the provisions of the Confidentiality of Medical Information Act.

THIS BILL WOULD:

1. Adds HSC Section 11165.2 to establish the Prescription Drug Monitoring Program (PDMP) within the DOJ for the purpose of monitoring any prescriber or pharmacist who has obtained access to CURES data.
2. Provide that the DOJ maintain CURES for monitoring <u>and Internet accessing</u> of data.
3. Adds provisions to provide for a manual or electronic application (to DOJ) for an eligible practitioner or pharmacist to access CURES data via the Internet, and for the discretionary approval thereof by DOJ.

4. Provides the criteria that DOJ may utilize to deny an application or to suspend access to an approved subscriber to CURES data.
5. Defines a "PDMP subscriber" as a practitioner or pharmacist who has obtained approval under Section 11165.1 to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
6. Provides authority for the DOJ to promulgate regulations to establish a Citation and Fine system for a PDMP subscriber who violates any provision of the chapter, and further defines the parameters of that system. Additionally, the bill provides that sanctions authorized by the measure are separate from and in addition to any other administrative, civil, or criminal remedies.
7. Adds HSC Section 11165.3 to require a PDMP subscriber to manually or electronically report to CURES the theft or loss of prescription information or prescription forms within three days; and that such notification may be made on a form approved by the DOJ.

RELATED LEGISLATION:

SB 1071 (DeSaulnier) – Establishes the "CURES Fund" to sustain the CURES program by imposing an annual fee on manufacturers or importers of Schedule II, III or IV controlled substances.

AUTHOR'S INTENT:

According to the author, AB 2548 seeks to provide authority to the DOJ/PDMP Program to monitor and report any suspicious behavior by PDMP Subscribers (pharmacists, practitioners and any other authorized user of CURES data) and would establish a system for issuing citations for PDMP Subscribers who violate any provision of the Uniform Controlled Substances Act. The measure also requires any reports of theft of prescription information or forms must be reported to DOJ within three days.

FISCAL IMPACT:

The board does not anticipate any significant fiscal impact to its operations as a result of this legislation.

SUPPORT and OPPOSITION (as of April 7, 2010):
None known.

HISTORY:

Date	Action
Mar. 18	Referred to Com. on Public Safety
Feb. 22	Read first time.
Feb. 21	From Printer. May be heard in committee on March 23.
Feb. 19	Introduced. To print.

HEARING:

Committee:	ASM Public Safety
Hearing Date:	April 13, 2010

ASSEMBLY BILL No. 2548

Introduced by Assembly Member Block

February 19, 2010

An act to amend Sections 11165 and 11165.1 of, and to add Sections 11165.2 and 11165.3 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2548, as introduced, Block. CURES: Prescription Drug Monitoring Program.

Existing law, the Uniform Controlled Substances Act, provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program. The act further provides that in order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual. A violation of any of these provisions is a misdemeanor, punishable as specified.

This bill would establish the Prescription Drug Monitoring Program (PDMP) in state government under the Department of Justice to monitor any practitioner or pharmacist (PDMP subscriber) who has obtained approval, as specified, to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, as well as the number, amount,

and type of controlled substances being dispensed to an individual under his or her care, in order to control the diversion and resultant abuse of, and to ensure the safe and lawful dispensing of, Schedule II, Schedule III, and Schedule IV controlled substances. This bill would provide that the Department of Justice may establish, by regulation, a system for the issuance to a PDMP subscriber of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the department, if the subscriber is in violation of any provision of, or any regulation adopted by the department pursuant to, the Uniform Controlled Substances Act. This bill would further provide that the theft or loss of prescription information or prescription forms shall be reported, as specified, no later than 3 days after the discovery of the theft or loss. By creating a new 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. Section 11165 of the Health and Safety Code is
2 amended to read:
3 11165. (a) To assist law enforcement and regulatory agencies
4 in their efforts to control the diversion and resultant abuse of
5 Schedule II, Schedule III, and Schedule IV controlled substances,
6 and for statistical analysis, education, and research, the Department
7 of Justice shall, contingent upon the availability of adequate funds
8 from the Contingent Fund of the Medical Board of California, the
9 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
10 Board of Registered Nursing Fund, and the Osteopathic Medical
11 Board of California Contingent Fund, maintain the Controlled
12 Substance Utilization Review and Evaluation System (CURES)
13 for the electronic monitoring *and Internet accessing* of the
14 prescribing and dispensing of Schedule II, Schedule III, and
15 Schedule IV controlled substances by all practitioners authorized
16 to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 2. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may ~~make a written request for~~ *manually or electronically submit to the Department of Justice a notarized application developed by the department to obtain approval to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES*, and the Department of Justice may, *upon approval of the application,* release to that practitioner or pharmacist, the *electronic* history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(3) An application by a practitioner or pharmacist may be denied, or access authorized pursuant to this section for a practitioner or pharmacist may be suspended, for cause, including, but not limited to, the following:

(A) Materially falsifying an application.

(B) Failure to maintain effective controls for access to the patient activity report.

(C) The suspension or revocation of a Drug Enforcement Agency registration.

(D) An arrest or conviction for any controlled substance offense or violation of this section.

(E) Accessing information pursuant to this section for any reason not related to the care of a patient.

(4) Any practitioner or pharmacist authorized pursuant to this section to access a patient's history of dispensed controlled substances shall notify the department within 10 days of any change of pertinent information regarding the practitioner or pharmacist.

~~(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.~~

~~(c)~~

(b) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 3. Section 11165.2 is added to the Health and Safety Code, to read:

11165.2. (a) This section may be cited and known as the Prescription Drug Monitoring Program (PDMP).

(b) The PDMP shall be established in state government under the Department of Justice to monitor any practitioner or pharmacist who has obtained approval under Section 11165.1 to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, as well as the number, amount, and type of controlled substances being dispensed to an individual under his or her care, in order to control the diversion and resultant abuse of, and to ensure the safe and lawful dispensing of, Schedule II, Schedule III, and Schedule IV controlled substances. For the purposes of this section, a "PDMP subscriber" means a practitioner or pharmacist who has obtained approval under Section 11165.1 to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(c) The Department of Justice may establish, by regulation, a system for the issuance to a PDMP subscriber of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the department, if the subscriber is in violation of any provision of this chapter or any regulation adopted by the department pursuant to this chapter.

(d) A citation system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscriber, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the CURES program of the Department of Justice within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied and the order of abatement. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of

abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action being taken by the department. If a citation is not contested and a fine is not paid, the subscriber account shall be terminated.

(7) A citation may be issued without the assessment of an administrative fine.

(8) Assessment of administrative fines may be limited to only particular violations of the law or department regulations.

(9) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in a fund under the Department of Justice relating to CURES. These special funds shall be utilized to provide support for costs associated with informal and formal hearings under, maintenance of, and updates to CURES.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action shall not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

SEC. 4. Section 11165.3 is added to the Health and Safety Code, to read:

11165.3. (a) A PDMP subscriber, as defined in Section 11165.2, shall manually or electronically report any theft or loss of prescription information or prescription forms to the CURES program no later than three days after the discovery of the theft or loss.

(b) The notification may be, reported electronically or in writing utilizing a form approved by the Department of Justice.

1 SEC. 5. 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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ASSEMBLY BILL No. 2548

Introduced by Assembly Member Block

February 19, 2010

An act to amend Sections 11165 and 11165.1 of, and to add Sections 11165.2 and 11165.3 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2548, as introduced, Block. CURES: Prescription Drug Monitoring Program.

Existing law, the Uniform Controlled Substances Act, provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program. The act further provides that in order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual. A violation of any of these provisions is a misdemeanor, punishable as specified.

This bill would establish the Prescription Drug Monitoring Program (PDMP) in state government under the Department of Justice to monitor any practitioner or pharmacist (PDMP subscriber) who has obtained approval, as specified, to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, as well as the number, amount,

and type of controlled substances being dispensed to an individual under his or her care, in order to control the diversion and resultant abuse of, and to ensure the safe and lawful dispensing of, Schedule II, Schedule III, and Schedule IV controlled substances. This bill would provide that the Department of Justice may establish, by regulation, a system for the issuance to a PDMP subscriber of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the department, if the subscriber is in violation of any provision of, or any regulation adopted by the department pursuant to, the Uniform Controlled Substances Act. This bill would further provide that the theft or loss of prescription information or prescription forms shall be reported, as specified, no later than 3 days after the discovery of the theft or loss. By creating a new 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. Section 11165 of the Health and Safety Code is
2 amended to read:
3 11165. (a) To assist law enforcement and regulatory agencies
4 in their efforts to control the diversion and resultant abuse of
5 Schedule II, Schedule III, and Schedule IV controlled substances,
6 and for statistical analysis, education, and research, the Department
7 of Justice shall, contingent upon the availability of adequate funds
8 from the Contingent Fund of the Medical Board of California, the
9 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
10 Board of Registered Nursing Fund, and the Osteopathic Medical
11 Board of California Contingent Fund, maintain the Controlled
12 Substance Utilization Review and Evaluation System (CURES)
13 for the electronic monitoring *and Internet accessing* of the
14 prescribing and dispensing of Schedule II, Schedule III, and
15 Schedule IV controlled substances by all practitioners authorized
16 to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 2. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may ~~make a written request for~~ *manually or electronically submit to the Department of Justice a notarized application developed by the department to obtain approval to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES*, and the Department of Justice may, *upon approval of the application,* release to that practitioner or pharmacist, the *electronic* history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(3) An application by a practitioner or pharmacist may be denied, or access authorized pursuant to this section for a practitioner or pharmacist may be suspended, for cause, including, but not limited to, the following:

(A) Materially falsifying an application.

(B) Failure to maintain effective controls for access to the patient activity report.

(C) The suspension or revocation of a Drug Enforcement Agency registration.

(D) An arrest or conviction for any controlled substance offense or violation of this section.

(E) Accessing information pursuant to this section for any reason not related to the care of a patient.

(4) Any practitioner or pharmacist authorized pursuant to this section to access a patient's history of dispensed controlled substances shall notify the department within 10 days of any change of pertinent information regarding the practitioner or pharmacist.

~~(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.~~

~~(c)~~

(b) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 3. Section 11165.2 is added to the Health and Safety Code, to read:

11165.2. (a) This section may be cited and known as the Prescription Drug Monitoring Program (PDMP).

(b) The PDMP shall be established in state government under the Department of Justice to monitor any practitioner or pharmacist who has obtained approval under Section 11165.1 to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES, as well as the number, amount, and type of controlled substances being dispensed to an individual under his or her care, in order to control the diversion and resultant abuse of, and to ensure the safe and lawful dispensing of, Schedule II, Schedule III, and Schedule IV controlled substances. For the purposes of this section, a "PDMP subscriber" means a practitioner or pharmacist who has obtained approval under Section 11165.1 to access, using the Internet, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(c) The Department of Justice may establish, by regulation, a system for the issuance to a PDMP subscriber of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the department, if the subscriber is in violation of any provision of this chapter or any regulation adopted by the department pursuant to this chapter.

(d) A citation system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscriber, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the CURES program of the Department of Justice within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied and the order of abatement. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of

abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action being taken by the department. If a citation is not contested and a fine is not paid, the subscriber account shall be terminated.

(7) A citation may be issued without the assessment of an administrative fine.

(8) Assessment of administrative fines may be limited to only particular violations of the law or department regulations.

(9) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in a fund under the Department of Justice relating to CURES. These special funds shall be utilized to provide support for costs associated with informal and formal hearings under, maintenance of, and updates to CURES.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action shall not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

SEC. 4. Section 11165.3 is added to the Health and Safety Code, to read:

11165.3. (a) A PDMP subscriber, as defined in Section 11165.2, shall manually or electronically report any theft or loss of prescription information or prescription forms to the CURES program no later than three days after the discovery of the theft or loss.

(b) The notification may be, reported electronically or in writing utilizing a form approved by the Department of Justice.

1 SEC. 5. 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 971** **VERSION: Amended April 7, 2010**

AUTHOR: **Pavely** **SPONSOR: Hemophilia Council of California**

BOARD POSITION:

SUBJECT: **Bleeding disorders: blood clotting products**

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 and further provides that the director shall adopt regulations that are necessary for the implementation of this article. [HSC §125130]

THIS BILL WOULD:

1. Add Article 5 "Standards of Service for Providers of Blood Clotting Products for Home Use Act" to the Health and Safety Code relating to genetic disease services (commencing with Section 125286.1) for the purpose of:
    a. establishing standards of service for entities that deliver blood clotting products and related equipment, supplies and services for home use, and
    b. promoting access to a full range of essential and cost effective blood clotting products, related equipment, supplies, and services for home use for persons with hemophilia and other bleeding disorders.
2. Require the Board of Pharmacy to administer and enforce the provisions of the article.
3. Define "Ancillary infusion equipment and supplies," "blood clotting product," "emergency," "provider of blood clotting products for home use" and other terms used in the article.
4. Require that each provider of blood clotting products as defined, have knowledgeable pharmacy staffing on call 24 hours a day to initiate emergency requests for clotting factors.
5. Require a provider of blood clotting products as defined to:

a. have sufficient knowledge and understanding of bleeding disorders and sufficient clinical experience providing services to persons with bleeding orders, as specified; and ensure customer service staff meet these requirements;
b. have knowledgeable pharmacy staffing on call 24 hours a day to initiate emergency requests for clotting factors;
c. supply blood clotting products and home nursing services as prescribed, unless permitted by the prescriber to substitute or adjust a product;
d. require a prescriber to indicate in a prescription which specific product is intended;
e. supply all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, as specified, as well as all necessary infusion equipment and supplies with each prescription;
f. maintain adequate stocks of blood clotting products, equipment and supplies and ship the product, infusion equipment and supplies to consumers within specified timeframes, as specified;
g. provide language translation services, as needed by the consumer, maintain a 24-hour on-call service to screen phone calls for emergencies, and provide a designated contact phone number for consumers to report problems with product delivery.
h. participate in national notification systems for product recalls, notify patients of the recall within 24-hours and establish plans to meet the requirements of the bill in the event of a disaster;
i. inform consumers about co-pay, deductible and coinsurance payment responsibilities when a product is ordered / dispensed initially and also when there is a change in the consumer's insurance, health plan or other third-party payer; and provide the consumer with copies of billing invoices and necessary and appropriate recordkeeping and documentation; and
j. meet various state and federal laws relating to the storage and shipping of products and the proper collection, removal and disposal of hazardous waste, recordkeeping and documentation and patient privacy.

AUTHOR'S INTENT:

According to the author, intravenous injection or infusion of prescribed blood clotting products, coupled with case management and specialized medical care, is the preferred method of treatment of hemophilia. The author states that the number of providers delivering blood clotting products and related equipment, supplies, and services for home use is rising and that while these providers are either pharmacies licensed by the state, or providers located in federally-designated hemophilia treatment centers, there are currently no formal standards of service in California for providers of blood clotting products for home use. The author states that this bill will enact needed standards for the benefit of persons with hemophilia and other bleeding disorders, and will maintain the current cost effective model of hemophilia care for future generations.

This measure specifies that the Board of Pharmacy will enforce the provisions of this bill.

COMMENTS:

In 2007-2008, Senator Darryl Steinberg introduced SB 1594 to establish standards for providers of blood clotting products. In April 2008 the Legislation and Regulation Committee discussed SB 1594 but did not make a recommendation to the board. The board discussed this bill at is April 2008 Board Meeting and subsequently took 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.

SUPPORT/OPPOSITION: *(according to the author)*

(Sponsor) Hemophelia Counsel of California
California Medical Association
CSL Behring
Grifols, Inc.
Plasma Protein Therapeutics Association
Herndon 1 Pharmacy

NEUTRAL:

California Society of Health Systems Pharmacists (CSHP)

OPPOSE UNLESS AMENDED: (Introduced version)

California Pharmacists Association

HISTORY:

2010

Apr. 7	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on Health.
Mar. 12	Set for hearing April 14.
Feb. 18	To Coms. on HEALTH and B., P. & E.D.
Feb. 9	From print. May be acted upon on or after March 11.
Feb. 8	Introduced. Read first time. To Com. on RLS. for assignment. To print.

HEARING: *(As of 4/10/2010)*

Apr. 14 Senate Health

AMENDED IN SENATE APRIL 7, 2010

SENATE BILL No. 971

Introduced by Senator Pavley

February 8, 2010

An act to add Article 5 (commencing with Section 125286.1) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic disease services.

LEGISLATIVE COUNSEL'S DIGEST

SB 971, as amended, Pavley. Bleeding disorders: blood clotting products.

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 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.

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. Article 5 (commencing with Section 125286.1)
2 is added to Chapter 2 of Part 5 of Division 106 of the Health and
3 Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.1. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.2. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand Factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors have provided people with hemophilia and other bleeding disorders with the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California. All of these entities are licensed by the state or are located at federally designated regional hemophilia treatment centers, or both.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations, and is extremely cost effective, according to the federal Centers for Disease Control and Prevention and the Medical

and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and Medi-Cal. Access to quality blood clotting products for home use and related equipment, supplies, and services for people with hemophilia or other bleeding disorders promotes cost containment in each of these publicly funded programs as well as in the health insurance and health care industries more generally.

(h) For the benefit of persons with hemophilia or other bleeding disorders, as well as for cost containment in health care, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.3. Unless context otherwise requires, the following definitions shall apply for purposes of this article:

~~(a) "340B Program" means an outpatient pharmacy licensed to dispense blood clotting products in California and that is conditionally or fully designated as a covered entity under the Veterans Health Care Act of 1992 (Public Law 102-585), which enacted Section 340B of the Public Health Service Act (41 U.S.C. Sec. 201 et seq.).~~

~~(b)~~

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

~~(c)~~

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

~~(d)~~

(c) "Bleeding disorder" means a medical condition characterized by a ~~severe~~ deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting *without treatment.*

~~(c)~~

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

~~(f)~~

(e) "Consumer" means a person needing a blood clotting product for home use.

~~(g)~~

(f) "Emergency" means a situation in which a prudent layperson could reasonably believe that the consumer's condition requires immediate medical attention.

~~(h)~~

(g) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

~~(i)~~

(h) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding from the federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

~~(j)~~

(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.

~~(k)~~

(j) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center. Places where home use occurs include, without limitation, a home or physician office.

~~(l)~~

(k) "Provider of blood clotting products for home use" means a seller and provider of blood clotting products, ancillary infusion equipment, home nursing services, and patient assistance for the management of bleeding disorders for home use. ~~These providers include, without limitation, 340B programs, other pharmacies, and, when treatment is not provided onsite, hemophilia treatment centers.~~

125286.4. Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have sufficient clinical experience providing services to persons with bleeding disorders and a sufficient nonclinical understanding of bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper refrigeration of clotting factors.

(c) Ensure that its customer service staff meets the requirements of subdivisions (a) and (b).

(d) Have ~~a pharmacist available at all times,~~ *knowledgeable pharmacy staffing on call* 24 hours a day, ~~seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products.~~ *to initiate emergency requests for clotting factors.*

(e) Supply blood clotting products and home nursing services, as prescribed by the consumer's treating physician, and, pursuant to Section 4073 of the Business and Professions Code, not make any substitutions of blood clotting products or assay amounts.

(f) ~~Ask the~~ *The* prescribing physician *shall indicate* which specific blood clotting product is intended whenever a prescription ~~does not indicate the specific product and then use the product named in the physician's response.~~ *is written.*

(g) Supply all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including

products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, *provided manufacturer supply exists and payer authorization is approved.*

(h) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(i) Maintain adequate stocks of blood clotting products and ancillary infusion equipment and supplies.

(j) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(k) When home nursing services are prescribed by the treating physician, provide these services either directly or through a qualified third party with experience in infusing bleeding disorders and coordinate pharmacy services with the third party when one is used to provide home nursing services.

(*l*) Upon receiving *approved authorization for* a nonemergency prescription, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the consumer within~~:~~ *two business days or less for established and new consumers.*

~~(1) Two business days or less for established consumers.~~

~~(2) Three business days or less for new consumers.~~

(m) Upon receiving *approved authorization to dispense* a prescription for an emergency situation, deliver prescribed blood products, ancillary infusion equipment and supplies, medications, and home nursing services to the consumer within 12 hours ~~after receipt of the prescription~~ *for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.*

(n) Maintain 24-hour oncall service seven days a week for every day of the year, adequately screen phone calls for emergencies, and respond to all phone calls within one hour or less.

(o) Provide consumers who have ordered their products with a designated contact phone number for reporting problems with a delivery and respond to these calls immediately.

(p) Provide patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours and participate in the National Patient Notification System for blood clotting product recalls.

(q) Provide language translation services, both over the phone and in person, as needed by the consumer.

(r) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(s) Provide for proper collection, removal, and disposal of hazardous waste pursuant to state and federal law, including, but not limited to, sharps containers for the removal and disposal of medical waste.

(t) ~~Clearly inform the~~ *Inform a* consumer of his or her copay, deductible, and coinsurance payment responsibilities ~~each time he or she orders a blood clotting product.~~ *initially and when changed by the consumer's insurance, health plan, or other third-party payer.*

(u) Provide consumers with a copy of all billing invoices.

(v) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(w) Comply with the privacy and confidentiality requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.5. The California State Board of Pharmacy shall administer and enforce this article.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: **SB 1071** **VERSION:** **Amended 3/24/2010**

AUTHOR: **DeSaulnier** **SPONSOR:** **California Department of Justice**

BOARD POSITION:

SUBJECT: **CURES**

Affected Sections of Pharmacy Law: Business and Professions Code sections 4040 and 4076.

EXISTING LAW:

1. Provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule II, and Schedule IV controlled substances pursuant to the Controlled Substances Utilization Review and Evaluation System (CURES)
2. Provides that the maintenance of CURES is contingent upon available funds from the Pharmacy Board Contingent Fund and that of four other DCA boards.
3. Provides that the and reporting of Schedule III and Schedule IV controlled substances to CURES is contingent upon available funds from the Department of Justice, not those boards listed above.
4. Provides for the privacy and confidentiality of patient data maintained in CURES.
5. Specifies information that is to be provided to the Department of Justice upon the dispensing of a Schedule II, III or IV controlled substance.

THIS BILL WOULD:

1. Require the California Department of Justice, beginning January 1, 2011, and annually thereafter, to impose a fee on manufacturers or importers of Schedule II, III, and IV controlled substances to pay for ongoing costs of the CURES program.
2. Creates the CURES Fund in the State Treasury to be administered by the State Board of Equalization. BOE shall collect quarterly the fees imposed by the DOJ.
3. Specifies that the CURES Fund may reimburse the DOJ for the following expenses:
    a. The cost of the administration of the CURES program, as specified;
    b. The cost of maintenance of, and any improvements to, the CURES program;
    c. The cost of education and outreach related to the CURES program; and
    d. The cost of investigation of abuses of the CURES program.

4. Provide that the maintenance of CURES is contingent upon available funds from the Pharmacy Board Contingent Fund and that of four other DCA boards, *as well as the CURES Fund.*
5. Makes Legislative findings and declarations as to the stated value of the CURES program as an investigative, preventive, and educational tool for law enforcement, regulatory boards, educational researchers and the health care community.

RELATED LEGISLATION / NOTES:

AB 2548 (Block) will establish the Prescription Drug Monitoring Program within the DOJ for the purpose of monitoring any prescriber or pharmacist who has obtained access to CURES data, and includes authority and provisions to address violations related to the illegal accessing or use of CURES data, as specified.

SB 1071 does not define an "importer" of controlled substances for purposes of this measure.

BACKGROUND:

The California Department of Justice, Bureau of Narcotic Enforcement is responsible for all state controlled substance enforcement activities and currently administers and enforces the CURES database via the Internet. The program provides authorized agencies and users with Patient Activity Reports (CURES data) to assist prescribers and pharmacists in making informed decisions as to the prescribing and dispensing of controlled substances to individuals.

AUTHOR'S INTENT:

SB 734 (Torlakson) Chapter 487, Statutes of 2005, authorized tamper resistant online access to the CURES system for authorized physicians, pharmacists and law enforcement pending the acquisition of private funding.

According to the author, SB 1071 will provide the necessary revenue to make the Controlled Substance Utilization Review and Evaluation System (CURES) database sustainable and that CURES will remain accessible to all practitioners authorized to prescribe or dispense specified controlled substances, including pharmacists.

FISCAL IMPACT:

The board does not anticipate any significant fiscal impact to its operations as a result of this legislation. Any minor impact could be absorbed within existing resources.

HISTORY:

Date	Action
2010	
Apr. 7	Set for hearing April 14.
Apr. 5	Re-referred to Coms. on REV. & TAX. and HEALTH.
Mar. 24	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on RLS.
Feb. 25	To Com. on RLS.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

HEARING:

Apr. 14 Senate Revenue and Taxation

AMENDED IN SENATE MARCH 24, 2010

SENATE BILL No. 1071

Introduced by Senator DeSaulnier

February 17, 2010

An act to amend Section 11165 of, *and add Section 11165.05 to,* the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1071, as amended, DeSaulnier. Controlled Substance Utilization Review and Evaluation System.

Existing law provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would *require the Department of Justice, beginning January 1, 2011, and annually thereafter, to determine and impose a fee on manufacturers and importers of controlled substances classified in Schedules II, III, and IV, as specified. The bill would require the State Board of Equalization to administer and collect the fee, as specified, and to deposit the fee in the CURES Fund established by the bill. The moneys in the CURES Fund would be available for expenditure, upon appropriation by the Legislature, only for reimbursement of the department for specified costs related to the CURES program. The bill would require that the fee imposed shall be consistent with all applicable legal requirements for imposing fees, as specified. The bill would* make technical, nonsubstantive changes to ~~these~~ *specified* provisions *relating to the CURES program.*

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. The Legislatures finds and declares all of the*
2 *following:*
3 *(a) The CURES program is a valuable investigative, preventive,*
4 *and educational tool for law enforcement, regulatory boards,*
5 *educational researchers, and the health care community.*
6 *(b) Each year the CURES program responds to more than*
7 *60,000 requests from practitioners and pharmacists to (1) help*
8 *identify and deter drug abuse and diversion through accurate and*
9 *rapid tracking of Schedule II, III, and IV controlled substances,*
10 *(2) help practitioners make better prescribing decisions, and (3)*
11 *cut down on the misuse, abuse, and trafficking of prescription*
12 *drugs in California.*
13 *(c) The manufacture and importation of Schedules II, III, and*
14 *IV controlled substances have had deleterious effects on private*
15 *and public interests, including the misuse, abuse, and trafficking*
16 *in dangerous prescription medications resulting in injury and*
17 *death. The fee that is imposed by this bill on manufacturers and*
18 *importers of Schedules II, III, and IV controlled substances is to*
19 *be limited in amount and seeks to mitigate these effects of the drugs*
20 *by supporting the operation of the CURES program, which has*
21 *proved a cost-effective tool to help to reduce the misuse, abuse,*
22 *and trafficking of those drugs. There is a sufficient nexus between*
23 *the fee this bill imposes on manufacturers and importers of*
24 *Schedule II, III, and IV controlled substances and the deleterious*
25 *effects the bill would ameliorate through its funding of the CURES*
26 *program.*
27 *(d) It is the nature of these Schedule II, III, and IV controlled*
28 *substances that their addictive qualities and the ever present*
29 *market for their misuse and abuse pose inherent risks to public*
30 *health that must be systematically addressed, as by the CURES*
31 *program. Once these products are present in California, ad hoc*
32 *enforcement of conditions on distribution and criminal and civil*
33 *sanctions on downstream actors in the distribution system is an*
34 *extraordinarily costly, ineffective, and inefficient means to attempt*
35 *to control the misuse, abuse, and trafficking of these substances.*
36 *It is therefore appropriate for manufacturers and importers, which*
37 *benefit from the commercial markets for these inherently dangerous*
38 *products with knowledge of their potential for misuse and abuse*

absent systematic tracking and monitoring, to pay for the cost-effective CURES program.

(e) The Legislature declares that the imposition of a fee upon the manufacturers and importers of Schedule II, III and IV controlled substances by this act would not result in the imposition of a tax within the meaning of Article XIII of the California Constitution, because the amount and nature of the fee has a fair and reasonable relationship to the adverse impact and burden imposed by the manufacture and importation of Schedule II, III, and IV controlled substances.

~~SECTION 1.~~

SEC. 2. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds *from the CURES Fund and* from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, 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.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) The full name, address, and telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

SEC. 3. Section 11165.05 is added to the Health and Safety Code, to read:

11165.05. (a) The Department of Justice shall, beginning January 1, 2011, and annually thereafter, impose a fee on manufacturers and importers of controlled substances classified in Schedule II, III, or IV in order to reimburse the department for costs related to the CURES program which provides for the electronic monitoring of the prescribing and dispensing of controlled substances classified in Schedule II, III, or IV.

(b) The department shall impose a fee on manufacturers and importers of controlled substances classified in Schedule II, III, or IV that the department determines to be sufficient for, and limited to, reimbursement of the department for the following expenses:

(1) The cost of the administration of the CURES program as required by this section and Sections 11165 and 11165.1.

(2) The cost of the maintenance of, and any improvements to, the CURES program.

(3) The cost of education and outreach relating to the CURES program.

(4) The cost of the investigation of abuses of the CURES program.

(c) The State Board of Equalization shall administer and collect the fee imposed by the department in compliance with the following:

(1) The board may prescribe, adopt, and enforce regulations relating to the administration and enforcement of this section, including, but not limited to, regulations governing collections, reports, refunds, and appeals relating to the fee imposed by this section.

(2) The board may prescribe, adopt, and enforce emergency regulations as necessary to implement the fee imposed by this section.

(3) The imposed fee shall be due and payable from the manufacturer or importer to the board on a quarterly basis, on or before the last day of the second month following each calendar quarter.

(4) Each manufacturer or importer of controlled substances classified in Schedule II, III, or IV shall, on or before the last day of the second month following each calendar quarter, pay the

imposed fee and file a return for the preceding quarterly period with the board using electronic media, as prescribed by the board. Returns shall be authenticated in a form or pursuant to methods as may be prescribed by the board.

(5) The board may, to facilitate administration of the fee, require that the payment of the fee and filing of the returns be made for periods other than quarterly periods.

(d) The CURES Fund is hereby established in the State Treasury. All fees imposed under this section, and any interest or penalties imposed by the department or board with respect to those fees, shall be paid to the board in the form of remittances payable to the board. The board shall transmit any payment to the Treasurer for deposit in the CURES Fund.

(e) Except for payments required to reimburse the board for its administrative costs in collecting the fee imposed by this section, all moneys deposited in the CURES Fund shall, upon appropriation by the Legislature, be expended only for the purposes specified in subdivision (b).

(f) Any fee imposed pursuant to this section shall be consistent with all applicable legal requirements for imposing fees, including the requirements set forth in Sinclair Paint Co. v. State Bd. of Equalization (1997) 15 Cal.4th 866.

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AMENDED IN SENATE MARCH 24, 2010

SENATE BILL No. 1071

Introduced by Senator DeSaulnier

February 17, 2010

An act to amend Section 11165 of, *and add Section 11165.05 to,* the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1071, as amended, DeSaulnier. Controlled Substance Utilization Review and Evaluation System.

Existing law provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would *require the Department of Justice, beginning January 1, 2011, and annually thereafter, to determine and impose a fee on manufacturers and importers of controlled substances classified in Schedules II, III, and IV, as specified. The bill would require the State Board of Equalization to administer and collect the fee, as specified, and to deposit the fee in the CURES Fund established by the bill. The moneys in the CURES Fund would be available for expenditure, upon appropriation by the Legislature, only for reimbursement of the department for specified costs related to the CURES program. The bill would require that the fee imposed shall be consistent with all applicable legal requirements for imposing fees, as specified. The bill would* make technical, nonsubstantive changes to ~~these~~ *specified* provisions *relating to the CURES program.*

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. The Legislatures finds and declares all of the*
2 *following:*
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4 *and educational tool for law enforcement, regulatory boards,*
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6 *(b) Each year the CURES program responds to more than*
7 *60,000 requests from practitioners and pharmacists to (1) help*
8 *identify and deter drug abuse and diversion through accurate and*
9 *rapid tracking of Schedule II, III, and IV controlled substances,*
10 *(2) help practitioners make better prescribing decisions, and (3)*
11 *cut down on the misuse, abuse, and trafficking of prescription*
12 *drugs in California.*
13 *(c) The manufacture and importation of Schedules II, III, and*
14 *IV controlled substances have had deleterious effects on private*
15 *and public interests, including the misuse, abuse, and trafficking*
16 *in dangerous prescription medications resulting in injury and*
17 *death. The fee that is imposed by this bill on manufacturers and*
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31 *program. Once these products are present in California, ad hoc*
32 *enforcement of conditions on distribution and criminal and civil*
33 *sanctions on downstream actors in the distribution system is an*
34 *extraordinarily costly, ineffective, and inefficient means to attempt*
35 *to control the misuse, abuse, and trafficking of these substances.*
36 *It is therefore appropriate for manufacturers and importers, which*
37 *benefit from the commercial markets for these inherently dangerous*
38 *products with knowledge of their potential for misuse and abuse*

absent systematic tracking and monitoring, to pay for the cost-effective CURES program.

(e) The Legislature declares that the imposition of a fee upon the manufacturers and importers of Schedule II, III and IV controlled substances by this act would not result in the imposition of a tax within the meaning of Article XIII of the California Constitution, because the amount and nature of the fee has a fair and reasonable relationship to the adverse impact and burden imposed by the manufacture and importation of Schedule II, III, and IV controlled substances.

~~SECTION 1.~~

SEC. 2. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds *from the CURES Fund and* from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, 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.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) The full name, address, and telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

SEC. 3. Section 11165.05 is added to the Health and Safety Code, to read:

11165.05. (a) The Department of Justice shall, beginning January 1, 2011, and annually thereafter, impose a fee on manufacturers and importers of controlled substances classified in Schedule II, III, or IV in order to reimburse the department for costs related to the CURES program which provides for the electronic monitoring of the prescribing and dispensing of controlled substances classified in Schedule II, III, or IV.

(b) The department shall impose a fee on manufacturers and importers of controlled substances classified in Schedule II, III, or IV that the department determines to be sufficient for, and limited to, reimbursement of the department for the following expenses:

(1) The cost of the administration of the CURES program as required by this section and Sections 11165 and 11165.1.

(2) The cost of the maintenance of, and any improvements to, the CURES program.

(3) The cost of education and outreach relating to the CURES program.

(4) The cost of the investigation of abuses of the CURES program.

(c) The State Board of Equalization shall administer and collect the fee imposed by the department in compliance with the following:

(1) The board may prescribe, adopt, and enforce regulations relating to the administration and enforcement of this section, including, but not limited to, regulations governing collections, reports, refunds, and appeals relating to the fee imposed by this section.

(2) The board may prescribe, adopt, and enforce emergency regulations as necessary to implement the fee imposed by this section.

(3) The imposed fee shall be due and payable from the manufacturer or importer to the board on a quarterly basis, on or before the last day of the second month following each calendar quarter.

(4) Each manufacturer or importer of controlled substances classified in Schedule II, III, or IV shall, on or before the last day of the second month following each calendar quarter, pay the

imposed fee and file a return for the preceding quarterly period with the board using electronic media, as prescribed by the board. Returns shall be authenticated in a form or pursuant to methods as may be prescribed by the board.

(5) The board may, to facilitate administration of the fee, require that the payment of the fee and filing of the returns be made for periods other than quarterly periods.

(d) The CURES Fund is hereby established in the State Treasury. All fees imposed under this section, and any interest or penalties imposed by the department or board with respect to those fees, shall be paid to the board in the form of remittances payable to the board. The board shall transmit any payment to the Treasurer for deposit in the CURES Fund.

(e) Except for payments required to reimburse the board for its administrative costs in collecting the fee imposed by this section, all moneys deposited in the CURES Fund shall, upon appropriation by the Legislature, be expended only for the purposes specified in subdivision (b).

(f) Any fee imposed pursuant to this section shall be consistent with all applicable legal requirements for imposing fees, including the requirements set forth in Sinclair Paint Co. v. State Bd. of Equalization (1997) 15 Cal.4th 866.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1106 **VERSION: As amended April 5, 2010**

AUTHOR: Yee **SPONSOR: Author**

RECOMMENDED POSITION:

SUBJECT: Prescribers Dispensing of Samples

Affected Sections: Amend Section 4171 of the Business and Professions Code

EXISTING LAW:

Allows for the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, at no charge to the patient, and an appropriate record is maintained.

THIS BILL WOULD:

Require a prescriber, dispensing a drug sample or starter kit, to either provide the patient with a copy of the FDA-approved package insert or insure that the manufacturers warnings are affixed to the package.

AUTHOR'S INTENT:

According to the Author, although sample prescription drugs have an important role to play in our health care delivery system, patients need to be armed with the same information that they are provided from the pharmacy. There are no requirements in current law that pertinent information be given to patients who receive sample drugs.

FISCAL IMPACT:

It is unlikely that the board would have any fiscal impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Support
Consumer Attorneys of California

HISTORY:

Apr. 5	Read second time. Amended. Re-referred to Com. on APPR.
Mar. 25	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 2986.)
Mar. 9	Set for hearing March 22.
Feb. 25	To Com. on B., P. & E.D.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL No. 1106

Introduced by Senator Yee

February 17, 2010

An act to amend Section 4171 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1106, as amended, Yee. Prescribers: dispensing of samples.

Existing law, the Pharmacy Law, ~~the knowing violation of which is a crime,~~ regulates prescribers, as defined, and the dispensing of drugs. Existing law prohibits a prescriber from dispensing drugs or dangerous devices to patients in his or her office unless certain requirements are met. Existing law also authorizes prescribers to furnish a limited quantity of samples if (1) the samples are dispensed in the manufacturer's package, (2) there is no charge to the patient, and (3) an appropriate record is entered in the patient's chart. *A knowing violation of the Pharmacy Law is a crime.*

This bill would ~~prohibit~~ *require* a prescriber ~~from~~ dispensing a drug sample or a starter kit ~~unless the appropriate manufacturer's warning pamphlet is physically attached to the package~~ *to either (1) provide the patient with a copy of the FDA-approved package insert for the drug sample or starter kit* or ~~the~~ *(2) ensure that the* manufacturer's warnings are affixed to the package containing the drug sample or starter kit.

Because this bill would impose a new requirement under the Pharmacy Law, the knowing violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 4171 of the Business and Professions Code is amended to read:

4171. (a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

~~(c) No prescriber dispensing drugs pursuant to Section 4170 shall dispense a drug sample or a starter kit unless the appropriate manufacturer's warning pamphlet is physically attached to the package containing the drug sample or starter kit or the~~

(c) A prescriber dispensing a drug sample or starter kit pursuant to subdivision (a) or Section 4170 shall either (1) provide the patient with a copy of the FDA-approved package insert for the drug sample or starter kit or (2) ensure that the manufacturer's warnings are affixed to the package containing the drug sample or starter kit.

SEC. 2. 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

1 the Government Code, or changes the definition of a crime within
2 the meaning of Section 6 of Article XIII B of the California
3 Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2077 **VERSION: As Amended April 13, 2010**

AUTHOR: Solorio **SPONSOR: California Hospital Association**
California Society of Health-Systems Pharmacists

BOARD POSITION:

SUBJECT: Centralized Hospital Packaging Pharmacies

Affected Sections: Amend Sections 4029 and 4033 ~~Add Sections 4128 – 4128.7~~ of the Business and Professions Code

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. Makes several findings and declarations including:
    a. Hospitals have been encouraged to move toward the use of automation and bedside barcoding to improve patient safety,
    b. Many drugs received by a manufacturer are not in unit dose packaging for immediate administration,
    c. Current restriction in the definition of manufacturing does not support current hospital drug distribution,
    d. The federal FDA recently changed its position to allow a hospital under common control to consolidate resources at a single location as specified, in recognition that compounding and repackaging are not truly manufacturing,

   e. A centralized pharmacy allows hospitals to take advantage of technology and affords better regulatory control via the pharmacist-in-charge,
   f. Centralizing the packaging functions assures better patient-safety and oversight by the board and others as specified.
2. Would specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license.
3. Exempt 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.

~~1. Create a centralized hospital packaging pharmacy to allow for the preparation of medication for administration to patients within a hospital under common ownership within California, that are located within a 100 mile radius of the centralized pharmacy.~~
~~2. Allow for the centralized pharmacy to complete the following:~~
   ~~a. Prepare unit dose packaging for single administration as specified if the unit dose is barcoded.~~
   ~~b. Prepare compounded unit dose drugs of parenteral therapy as well as other compounded unit dose drugs as specified if the unit dose is barcoded.~~
~~3. Defines centralized hospital packaging pharmacy as a pharmacy within a general acute care hospital.~~
~~4. Requires a specialty license by the board to perform authorized functions.~~
~~5. Establishes the application and requirements as well as the fees.~~
~~6. Requires the board to inspect the pharmacy prior to issuing or renewing a specialty license.~~
~~7. Allows for a limited supply of prepackaged unit dose drugs that are not patient specific to ensure continuity of care and requires the expiration date to be consistent with established compendium standards.~~
~~8. Requires the barcode to, at a minimum, include the expiration date, lot number and national drug code directory number.~~
~~9. Requires that the unit dose medication label contain the expiration date, drug name, quantity of the active ingredient and the name of the packaging pharmacy.~~
~~10. Specifies that the specialty pharmacy must comply with all pharmacy laws and regulations including compounding and sterile injectable compounding.~~
~~11. Specifies that the specialty pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality and labeled strength of any unit dose prepared at the centralized hospital packaging pharmacy.~~

AUTHOR'S INTENT:

As amended 4/13/10, AB 2077 would allow a hospital pharmacy to be located on a consolidated hospital license or another location regulated under a hospital's license. It would also allow a pharmacy to prepare or compound unit dose medications for parenteral oral therapy without being a manufacturer.

FISCAL IMPACT:

None expected.

COMMENTS:

During the October 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.

The provisions contained in this bill as introduced, were previously in AB 1370 (Solorio). During the January 2010 Board Meeting, the board voted to support the measure.

However, the current version of the bill no longer requires bar coding for pharmacies that do repackaging under the manufacturing exception, nor is there a limit of the repackaging duties limited to those hospital pharmacies under common ownership.

As amended, this bill removes the specialty license requirement, the common ownership provision as well as the requirement for barcoding. It appears that the bill, in its current form, would not require a hospital to have a pharmacy located on the premises, and rather would allow for a hospital to contract out for pharmacy services.

SUPPORT/OPPOSITION

None of file.

HISTORY:

Date	Action
Apr. 14	Re-referred to Com. on B.,P. & C.P.
Apr. 13	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
Apr. 5	Re-referred to Com. on B. & P. by unanimous consent.
Mar. 29	In committee: Set, second hearing. Hearing canceled at the request of author.
Mar. 23	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 4	Referred to Coms. on HEALTH and B. & P.
Feb. 21	From printer. May be heard in committee March 23.
Feb. 18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 13, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 2077

Introduced by Assembly Member Solorio

February 18, 2010

~~An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.~~ *An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, as amended, Solorio. ~~Centralized hospital packaging pharmacies.~~ *Pharmacy.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy. 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. ~~A knowing violation of the Pharmacy Law is a crime.~~

~~This bill would authorize a centralized hospital packaging pharmacy, as defined, to prepare medications, by performing specified functions, for administration only to patients within its own general acute care hospital and one or more general other acute care hospitals if the hospitals are under common ownership, in California, and within a 100 mile radius of the pharmacy. The bill would prohibit a person from conducting a centralized hospital packaging pharmacy without a specialty license from the board and would require applicants to apply annually to the board on forms developed by the board. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.~~

~~The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that drugs prepared in advance of receipt of a patient specific prescription shall meet specified standards, that medications be barcoded to be readable at the patient's bedside, and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions 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.~~

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located in another physical plant on the same premises or on a separate premises 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. 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 in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order.

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

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

1 *SECTION 1. The Legislature makes the following findings and*
2 *declarations:*
3 *(a) Hospitals have been encouraged to move toward the use of*
4 *automation and bedside barcode checking to improve the safety*
5 *and efficiency of drug distribution and administration to patients.*
6 *For many hospitals, the technology to enable them to achieve this*
7 *patient-safety goal is cost prohibitive.*
8 *(b) Many drugs received from manufacturers are not in the*
9 *proper unit dose for immediate administration to patients, and are*
10 *not barcoded. As a result, individual hospitals must locally prepare*
11 *and package these drugs or contract with a packager, that is not*
12 *licensed by either the California State Board of Pharmacy or*
13 *managed by a pharmacist-in-charge who is licensed by the*
14 *California State Board of Pharmacy, to do so.*
15 *(c) The Business and Professions Code definition of drug*
16 *"manufacturer" allows one hospital pharmacy to compound and*
17 *package medications for another hospital only for specific patients,*
18 *without being licensed as a manufacturer. This restriction does*
19 *not support the most current hospital drug distribution processes,*
20 *nor does it accommodate innovations that will improve patient*
21 *safety.*
22 *(d) The federal Food and Drug Administration (FDA) has*
23 *amended its position to allow hospitals under common control*
24 *and operating within a state to consolidate resources at a single*
25 *location for timely, economic repackaging and distribution with*
26 *greater, more dedicated expertise, without becoming federally*
27 *registered manufacturers for those products. This FDA action is*

in recognition that the compounding and repackaging activity is not truly drug manufacturing.

(e) A centralized pharmacy compounding and packaging operations approach allows hospitals to take advantage of high-speed automated equipment, economies of scale, space efficiencies, and more consistent standardized quality control systems. Likewise, a centralized licensed pharmacy approach allows for greater regulatory control via the pharmacist-in-charge and greater assurance of safety by concentrating the professional expertise among a centralized management, staff, and quality assurance program.

(f) Centralization of the packaging operations as a licensed pharmacy under the license of a hospital, rather than as a "manufacturer," assures the patient-safety oversight of the California State Board of Pharmacy and other hospital regulatory and accreditation bodies, and adherence to the new stronger pharmacy compounding regulations.

SEC. 2. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy, *licensed by the board,* that may be located outside of the hospital, in another physical plant *on the same premises or on a separate premises* that is regulated under a hospital's ~~consolidated~~ license ~~issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant~~. Nothing in this ~~paragraph~~ *subdivision* shall be construed to restrict or expand the services that a hospital pharmacy may provide.

SEC. 3. Section 4033 of the Business and Professions Code is amended to read:

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

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding *and repackaging* a drug for parenteral therapy~~, pursuant to a prescription,~~ *or oral therapy in a hospital* for delivery to another pharmacy *or hospital* for the purpose of ~~delivering~~ *dispensing* or administering the drug, *pursuant to a prescription or order,* to the patient or patients named in the prescription~~, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription~~ *or order*.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

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

~~SECTION 1. Section 4029 of the Business and Professions Code is amended to read:~~

~~4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital,~~

~~institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.~~

~~(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.~~

~~SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:~~

~~Article 7.6. Centralized Hospital Packaging Pharmacies~~

~~4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to patients within its own general acute care hospital and one or more other general acute care hospitals if the hospitals are (1) under common ownership, (2) in California, and (3) located within a 100-mile radius of the centralized hospital packaging pharmacy.~~

~~(1) Preparing unit dose packages for single administration to patients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.~~

~~(2) Preparing compounded unit dose drugs for parenteral therapy for administration to patients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.~~

~~(3) Preparing compounded unit dose drugs for administration to patients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.~~

~~(b) For the purposes of this article, a "centralized hospital packaging pharmacy" means a licensed hospital pharmacy located within a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.~~

~~4128.1. (a) No person shall conduct a centralized hospital packaging pharmacy unless it has obtained a specialty license from the board.~~

~~(b) A licensed hospital pharmacy serving only its own patients shall not be required to obtain a specialty license as described in subdivision (a).~~

~~4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.~~

~~(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.~~

~~(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.~~

~~(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.~~

~~(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.~~

~~(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.~~

~~(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.~~

~~(h) The fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).~~

~~4128.3. A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient specific prescription~~

~~in a quantity as is necessary to ensure continuity of care for an identified population of patients of the general acute care hospital based on a documented history of prescriptions for that patient population. The expiration date for these drugs shall meet established compendium standards as stated in the United States Pharmacopica and other widely accepted references.~~

~~4128.4. Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the patient's bedside. The bar code shall contain at least the following information:~~

~~(a) Expiration date.~~

~~(b) Lot number or control number.~~

~~(c) National Drug Code Directory number.~~

~~4128.5. The label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain all of the following information:~~

~~(a) Expiration date.~~

~~(b) Established name of the drug.~~

~~(c) Quantity of the active ingredient.~~

~~(d) Special storage or handling requirements.~~

~~(e) Name of the packaging pharmacy.~~

~~4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable regulations, including, but not limited to, regulations regarding compounding and when appropriate, sterile injectable compounding.~~

~~4128.7. A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.~~

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB 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~~

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 2292 **VERSION: As Introduced February 18, 2010**

AUTHOR: Lowenthal **SPONSOR: Long Beach Endoscopy Center**

BOARD POSITION:

SUBJECT: Pharmacy: Clinics

Affected Sections: Amend Section 4190 of the Business and Professions Code.

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.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may not purchase drugs at wholesale or maintain a commingled drug stock unless licensed by the California State Board of Pharmacy.
3. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:

Modify the licensing requirements for a board-issued clinic license for surgical clinic 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 (This board issued license would allow the clinic to purchase drugs at wholesale for administration or dispensing as well as commingle medications.)

AUTHOR'S INTENT:

This bill will expand the conditions under which the board can issue a clinic license.

PRIOR HISTORY/RELATED BILLS:

AB 1574 (Plescia) of 2008 contained similar provisions to those proposed in this bill 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 there after. 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 has 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.

FISCAL IMPACT:

The sponsor believes that 1100 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications should all eligible facilities choose to pursue licensure with the board. In addition, board staff recommend an additional inspector to complete initial and annual inspections of those surgical license specified.

COMMENTS:

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However, there is no requirement that a surgical center must be licensed by the DPH to operate.

About three years ago, the California Department of Public Health was involved in a lawsuit regarding the regulation of a physician-owned ambulatory surgical clinic. In deciding that lawsuit, 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 foregoing, the California State Board of Pharmacy cannot issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

SUPPORT/OPPOSITION:

Support

California Ambulatory Surgery Association
Coast Surgery Center
Folsom Surgery Center
Kings Eye Center Medical Group
North State Surgery Centers
Oasis Surgery Center
Pacific Endo Surgical Center
Peninsula Eye Surgery Center
Presidio Surgery Center
Riverside Surgery Center, Inc.
Roseville Surgery Center
Salinas Surgery Center
San Gabriel Valley Surgical Center

Santa Maria Digestive Diagnostic Center
Scripps Encinitas Surgery Center
St. Joseph's Surgery Center
Surgecenter of Palo Alto
Sutter Fairfield Surgery Center
Sylvan Surgery Center, Inc.
United Surgical Partners International
University Ambulatory Surgery Center

Opposition
None on file.

HISTORY:

Mar. 24	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 19. Noes 0.) (March 23).
Mar. 11	Referred to Com. on HEALTH.
Feb. 21	From printer. May be heard in committee March 23.
Feb. 18	Read first time. To print.

ASSEMBLY BILL No. 2292

Introduced by Assembly Member Bonnie Lowenthal

February 18, 2010

An act to amend Section 4190 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 2292, 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 a knowing violation of this law is 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, to patients registered for care at the clinic. Existing law requires these clinics to obtain a license from the board and to comply with various regulatory requirements. Existing law also authorizes the board to inspect a clinic at any time in order to determine whether a surgical clinic is, or is not, operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting and an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing under those same circumstances and subject to the same licensing, regulatory, and inspection requirements.

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 *(b)* Notwithstanding any provision of this chapter, a ~~surgical~~
18 ~~clinic, as defined in paragraph (1) of subdivision (b) of Section~~
19 ~~1204 of the Health and Safety Code~~ *clinic* may purchase drugs at
20 wholesale for administration or dispensing, under the direction of
21 a physician *and surgeon*, to patients registered for care at the clinic,
22 as provided in subdivision ~~(b)~~ *(c)*. The clinic shall keep records of
23 the kind and amounts of drugs purchased, administered, and
24 dispensed, and the records shall be available and maintained for
25 a minimum of three years for inspection by all properly authorized
26 personnel.
27 ~~(b)~~
28 *(c)* The drug distribution service of a ~~surgical~~ clinic shall be
29 limited to the use of drugs for administration to the patients of the
30 ~~surgical~~ clinic and to the dispensing of drugs for the control of

pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

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

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

~~(d)~~

(e) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) The board shall conduct inspections of these clinics in accordance with Section 4195.

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

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ASSEMBLY BILL No. 2292

Introduced by Assembly Member Bonnie Lowenthal

February 18, 2010

An act to amend Section 4190 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 2292, 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 a knowing violation of this law is 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, to patients registered for care at the clinic. Existing law requires these clinics to obtain a license from the board and to comply with various regulatory requirements. Existing law also authorizes the board to inspect a clinic at any time in order to determine whether a surgical clinic is, or is not, operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting and an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing under those same circumstances and subject to the same licensing, regulatory, and inspection requirements.

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:

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

Article 14. ~~Surgical~~ Clinics

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

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

(b) Notwithstanding any provision of this chapter, ~~a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code~~ *clinic* may purchase drugs at wholesale for administration or dispensing, under the direction of a physician *and surgeon*, to patients registered for care at the clinic, as provided in subdivision ~~(b)~~ *(c)*. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

~~(b)~~

(c) The drug distribution service of a ~~surgical~~ clinic shall be limited to the use of drugs for administration to the patients of the ~~surgical~~ clinic and to the dispensing of drugs for the control of

pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

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

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

~~(d)~~

(e) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) The board shall conduct inspections of these clinics in accordance with Section 4195.

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2551 **VERSION: As introduced February 19, 2010**

AUTHOR: Hernandez **SPONSOR:**

BOARD POSITION:

SUBJECT: **Pharmacy Technician: Scholarship and Loan Repayment Program**

Affected Sections: The bill is currently intent language only.

EXISTING LAW:

Defines the requirements for licensure as a pharmacy technician.

THIS BILL WOULD:

State that it is the intent of the legislature to establish a new fee structure for loan repayment of various health professions development programs.

AUTHOR'S INTENT:

According to the author's office, the bill will be amended to create a scholarship fund for pharmacy technicians.

FISCAL IMPACT:

The cost associated with the development and implementation of this fund could include modifications to existing cashiering programs, forms and procedures for deposits into separate funds. However, these costs would be covered by the board's prorata to the Department.

COMMENTS:

In 2002, a bill was passed that established a scholarship and loan repayment fund for pharmacists. To date, no funds have been distributed from this fund, as the minimum account balance of $200,000 annually has not yet been obtained.

In 2007 the board considered a similar bill that would have established a scholarship fund to assist in the repayment of loans associated with pharmacy technician training

programs. The board opposed this legislation because contributions to a scholarship fund were mandatory. At that time the board believed that contributions should be voluntary and was concerned that the mandatory contribution could create a financial hardship for pharmacy technicians.

SUPPORT/OPPOSITION

None on file.

HISTORY:

Feb. 22 Read first time.
Feb. 21 From printer. May be heard in committee March 23.
Feb. 19 Introduced. To print.

ASSEMBLY BILL No. 2551

Introduced by Assembly Member Hernandez

February 19, 2010

An act relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2551, as introduced, Hernandez. Health professions development: loan repayment.

Existing law establishes various health professions development programs, including, but not limited to, the Song-Brown Health Care Workforce Training Act, the Health Professions Education Foundation Programs, and the Steven M. Thompson Physician Corps Loan Repayment Program.

This bill would declare the intent of the Legislature to enact legislation that would establish a new fee structure for loan repayment of health professions development programs.

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 establish a new fee structure for loan
3 repayment of various health professions development programs,
4 including, but not limited to, all of the following:
5 (a) The Song-Brown Health Care Workforce Training Act
6 (Article 1 (commencing with Section 128200) of Chapter 4 of Part
7 3 of Division 107 of the Health and Safety Code).

1 (b) The Health Professions Education Foundation Programs
2 established pursuant to (Chapter 5 (commencing with Section
3 128330) of Part 3 of Division 107 of the Health and Safety Code).
4 (c) The Steven M. Thompson Physician Corps Loan Repayment
5 Program, as set forth in Article 5 (commencing with Section
6 128550) of Chapter 5 (commencing with Section 128330) of Part
7 3 of Division 107 of the Health and Safety Code.

O

ASSEMBLY BILL No. 2551

Introduced by Assembly Member Hernandez

February 19, 2010

An act relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2551, as introduced, Hernandez. Health professions development: loan repayment.

Existing law establishes various health professions development programs, including, but not limited to, the Song-Brown Health Care Workforce Training Act, the Health Professions Education Foundation Programs, and the Steven M. Thompson Physician Corps Loan Repayment Program.

This bill would declare the intent of the Legislature to enact legislation that would establish a new fee structure for loan repayment of health professions development programs.

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 establish a new fee structure for loan
3 repayment of various health professions development programs,
4 including, but not limited to, all of the following:
5 (a) The Song-Brown Health Care Workforce Training Act
6 (Article 1 (commencing with Section 128200) of Chapter 4 of Part
7 3 of Division 107 of the Health and Safety Code).

1 (b) The Health Professions Education Foundation Programs
2 established pursuant to (Chapter 5 (commencing with Section
3 128330) of Part 3 of Division 107 of the Health and Safety Code).
4 (c) The Steven M. Thompson Physician Corps Loan Repayment
5 Program, as set forth in Article 5 (commencing with Section
6 128550) of Chapter 5 (commencing with Section 128330) of Part
7 3 of Division 107 of the Health and Safety Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1701 **VERSION: As Introduced**

AUTHOR: Chesbro **SPONSOR: Health Officers Association of California**

BOARD POSITION:

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Business and Professions Code Section 4145
Health and Safety Code Section 11364

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 as December 31, 2010 sunset date for this provisions.

THIS BILL WOULD:

Eliminate the sunset date and make the provisions in law permanent.

AUTHOR'S INTENT:
According to the author, in response to the growing epidemic of AIDS and other infection related diseases in 2004 California launched a new pilot program, the Disease Prevention Demonstration Project (DPDP), which has allowed over 650 pharmacies the ability to provide the opportunity of syringe sale while providing injection drug users with health materials, important information, and links to care. The author states that the implementation of the program was successful. Participants remain positive and enthusiastic and research has shown that there is no evidence of negative effects such as increased syringe litter.

FISCAL IMPACT:

We do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

PRIOR HISTORY/RELATED BILLS:

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 authorize a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy as specified. The board supported this bill; however it was vetoed by the governor.

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.

SUPPORT and OPPOSITION:

Support
Health Officers Association of California
AIDS Project Los Angeles
California Psychiatric Association
County Health Executives Association of California
Drug Policy Alliance
San Luis Obispo County Health Officer
Santa Clara County Health Officer
Santa Clara County Board of Supervisors
Santa Cruz County Health Services Agency

Oppose
California Correctional Supervisors Organization
California Narcotic Officers Association

HISTORY:

Date	Action
Apr. 5	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 5	Read third time, passed, and to Senate. (Ayes 49. Noes 27.)
Mar. 25	Read second time. To third reading.
Mar. 24	From committee: Do pass. (Ayes 14. Noes 4.) (March 23).
Feb. 11	Referred to Com. on HEALTH.
Feb. 2	From printer. May be heard in committee March 4.
Feb. 1	Read first time. To print.

ASSEMBLY BILL No. 1701

Introduced by Assembly Member Chesbro

February 1, 2010

An act to amend Section 4145 of the Business and Professions Code, and to amend Section 11364 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1701, as introduced, Chesbro. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

Existing law, until December 31, 2010, authorizes a city or county to authorize a licensed 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. Existing law prohibits the possession and sale of drug paraphernalia, but until December 31, 2010, allows a person, if authorized by a city or county, to possess 10 or fewer hypodermic needles or syringes if acquired through an authorized source.

This bill would delete the December 31, 2010, end dates for these authorizations and would thereby reestablish these authorizations indefinitely.

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 4145 of the Business and Professions
2 Code is amended to read:
3 4145. (a) Notwithstanding any other provision of law, a
4 pharmacist or physician may, without a prescription or a permit,
5 furnish hypodermic needles and syringes for human use, and a
6 person may, without a prescription or license, obtain hypodermic
7 needles and syringes from a pharmacist or physician for human
8 use, if one of the following requirements is met:
9 (1) The person is known to the furnisher and the furnisher has
10 previously been provided a prescription or other proof of a
11 legitimate medical need requiring a hypodermic needle or syringe
12 to administer a medicine or treatment.
13 (2) Pursuant to authorization by a county, with respect to all of
14 the territory within the county, or a city, with respect to the territory
15 within the city, ~~for the period commencing January 1, 2005, and~~
16 ~~ending December 31, 2010,~~ a pharmacist may furnish or sell 10
17 or fewer hypodermic needles or syringes at any one time to a
18 person 18 years of age or older if the pharmacist works for a
19 pharmacy that is registered for the Disease Prevention
20 Demonstration Project pursuant to Chapter 13.5 (commencing
21 with Section 121285) of Part 4 of Division 105 of the Health and
22 Safety Code and the pharmacy complies with the provisions of
23 that chapter.
24 (b) Notwithstanding any other provision of law, a pharmacist,
25 veterinarian, or person licensed pursuant to Section 4141 may,
26 without a prescription or license, furnish hypodermic needles and
27 syringes for use on animals, and a person may, without a
28 prescription or license, obtain hypodermic needles and syringes
29 from a pharmacist, veterinarian, or person licensed pursuant to
30 Section 4141 for use on animals, providing that no needle or
31 syringe shall be furnished to a person who is unknown to the
32 furnisher and unable to properly establish his or her identity.
33 SEC. 2. Section 11364 of the Health and Safety Code is
34 amended to read:
35 11364. (a) It is unlawful to possess an opium pipe or any
36 device, contrivance, instrument, or paraphernalia used for
37 unlawfully injecting or smoking (1) a controlled substance specified
38 in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)

of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, ~~for the period commencing January 1, 2005, and ending December 31, 2010,~~ subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

O

ASSEMBLY BILL No. 1701

Introduced by Assembly Member Chesbro

February 1, 2010

An act to amend Section 4145 of the Business and Professions Code, and to amend Section 11364 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1701, as introduced, Chesbro. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

Existing law, until December 31, 2010, authorizes a city or county to authorize a licensed 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. Existing law prohibits the possession and sale of drug paraphernalia, but until December 31, 2010, allows a person, if authorized by a city or county, to possess 10 or fewer hypodermic needles or syringes if acquired through an authorized source.

This bill would delete the December 31, 2010, end dates for these authorizations and would thereby reestablish these authorizations indefinitely.

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

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

SECTION 1. Section 4145 of the Business and Professions Code is amended to read:

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

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

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, ~~for the period commencing January 1, 2005, and ending December 31, 2010,~~ a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

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

SEC. 2. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)

of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, ~~for the period commencing January 1, 2005, and ending December 31, 2010,~~ subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1858 **VERSION: As Amended April 13, 2010**

AUTHOR: Blumenfield **SPONSOR: Drug Policy Alliance**

BOARD POSITION:

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Business and Professions Code
~~Amend Section 4148~~
~~Repeal Section 4140~~
Health and Safety Code
Amend Sections 11364, 121349 - 121349.3
Add Section 121349.4

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 as December 31, 2010 sunset date for this provisions.
3. Allows for a person to possess, for personal use, 10 or fewer hypodermic needles and syringes if acquired from an authorized source.
4. 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. Allow the Department of Public Health (CDPH) to authorize and register clinics ~~health organizations, community-based organizations and other entities to provide NEPs as specified~~. that have sufficient staff to provide the services authorized, or other entities that that apply for authorization to provide NEPs consistent with the U.S. Public Health Service.
2. ~~Require CDPH to allow local entities to apply for such authorization~~
3. Requires DPH to authorize NEPs under this bill as recommended by the U.S. ~~Secretary of Health and Human Services~~ Public Health Service, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, as specified.

4. Require CDPH to establish and maintain a Web site with contact information of programs providing NEPs.
5. Allows local governments, local health officers, and law enforcement, the opportunity to comment on NEPs on a biennial basis (currently annually.)
6. For those programs authorized by CDPH, requires CDPH to provide local health officers to provide biennial status reports, as specified.
7. Requires local health officers with county- and city-authorized NEPs to report on the program's status biennially, as specified

AUTHOR'S INTENT:

To expand the provisions of these sections to allow California Department of Public Health to authorize needle exchange programs in addition to those currently authorized by counties and cities.

FISCAL IMPACT:

We do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS:

According to the author's office, this bill is to compliment the efforts of SB 1029, information below.

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 authorize a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy as specified. The board supported this bill; however it was vetoed by the governor.

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), makes permanent, the Disease Prevention Demonstration Project (DPDP), 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.

SB 1029 (Yee), currently in the Senate Business, Professions and Economic Development Committee, eliminates most provisions of the DPDP, including requirement that LHDs register pharmacies and provide pharmacies with educational material for distribution, and instead allow pharmacists statewide the discretion to sell 30 or fewer syringes to an adult without the requirement of a local authorization vote and eliminates other elements of the demonstration project including state requirements regarding advisory board and evaluation. SB 1029 also deletes the prohibition against possession of hypodermic needles and syringes, and permits adults to possess 30 or fewer syringes solely for personal use. SB 1029 would also require the Office of AIDS to develop and maintain information on its Web site to educate consumers at risk of blood-borne infections of opportunities to improve and protect the consumer's health, and to protect the public health. SB 1029 would require pharmacies that provide non-prescription syringes to promote safe syringe disposal, and to store syringes securely.

SUPPORT and OPPOSITION:

Support
Drug Policy Alliance (sponsor)
AIDS Project Los Angeles
American Civil Liberties Union
California Association of Alcohol and Drug Program Executives, Inc.
California Hepatitis Alliance
California Opioid Maintenance Providers
Common Ground - The Westside HIV Community Center
Homeless Health Care Los Angeles

Oppose
California Narcotic Officers' Association
California Peace Officers' Association
California Police Chiefs Association

HISTORY:

Date	Action
Apr. 12	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 11. Noes 5.) (April 6).
Mar. 25	Re-referred to Com. on HEALTH.
Mar. 24	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 25	Referred to Com. on HEALTH.
Feb. 16	From printer. May be heard in committee March 18.
Feb. 12	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 13, 2010

AMENDED IN ASSEMBLY MARCH 24, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1858

Introduced by Assembly Member Blumenfield
~~(Coauthor: Assembly Member Monning)~~
(Coauthors: Assembly Members Ammiano, Monning, and Skinner)

February 12, 2010

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 1858, as amended, Blumenfield. Hypodermic needles and syringes: exchange services.

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 control any hypodermic needle or syringe, except in accordance with those regulatory provisions.

Existing law authorizes a clean needle and syringe exchange project in any city and county, county, or city, as specified.

This bill would permit the State Department of Public Health to authorize *certain* entities, *that meet prescribed conditions,* 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~~ *infection* spread through the sharing of used hypodermic needles and syringes.

The bill would also require the department to allow local entities to apply for authorization to provide hypodermic needle and syringe exchange services and to establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services. The bill would change related hearing requirements from annually to biennially.

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 121349 of the Health and Safety Code
2 is 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 reduce the spread of HIV infection and
12 bloodborne hepatitis among the intravenous drug user population
13 within California, the Legislature hereby authorizes a clean needle
14 and syringe exchange project pursuant to this chapter in any city
15 and county, county, or city upon the action of a county board of
16 supervisors and the local health officer or health commission of
17 that county, or upon the action of the city council, the mayor, and
18 the local health officer of a city with a health department, or upon
19 the action of the city council and the mayor of a city without a
20 health department.
21 (c) In order to reduce the spread of HIV infection, viral hepatitis,
22 and other potentially deadly ~~blood-borne~~ *bloodborne* infections,
23 the State Department of Public Health may, notwithstanding any
24 provision of law, authorize ~~clinics, health services organizations,~~
25 ~~community-based organizations,~~ *clinics that apply for authorization*
26 *and that have sufficient staff and capacity to provide services as*
27 *described in Section 121349.1, as determined by the department,*

or other entities *that apply for authorization,* to provide hypodermic needle and syringe exchange services *consistent with state and federal standards, including those of the United States Public Health Service,* 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~~ *infection* spread through the sharing of used hypodermic needles and syringes.

~~(d) The State Department of Public Health shall, in addition to activity authorized pursuant to subdivision (c), allow local entities to apply for authorization to provide hypodermic needle and syringe exchange services.~~

~~(e)~~

(d) The State Department of Public Health shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to subdivision (c).

~~(f)~~

(e) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

SEC. 2. Section 121349.1 of the Health and Safety Code is amended to read:

121349.1. The State Department of Public Health, or a city and county, or a county, or a city with or without a health department, in consultation with the State Department of Public Health, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States ~~Secretary of Health and Human Services~~ *Public Health Service*, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to 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. Program participants shall be allowed to possess syringes consistent with Section 11364.

SEC. 3. Section 121349.2 of the Health and Safety Code is amended to read:

121349.2. Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on ~~an~~ *a* biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

SEC. 4. Section 121349.3 of the Health and Safety Code is amended to read:

121349.3. The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ~~assure~~ *ensure* adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local ~~public~~ health officer based on the reports to the department from service providers within the jurisdiction of the local ~~public~~ health officer.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2139 **VERSION: As Amended April 6, 2010**

AUTHOR: Chesbro **SPONSOR:**

BOARD POSITION:

SUBJECT: Solid Waste: Product Stewardship

Affected Sections: Add Chapter 5 (Commencing with Section 48800) of the Public Resources Code

EXISTING LAW:

1. Defines "home-generated sharps waste" to mean hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household. (Health and Safety Code Section 117671)

2. Prohibits the disposal of home-generated sharps waste in the solid waste or recycling streams.

3. Requires a pharmaceutical manufacturer that sells or distributes a medication that is self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle to submit to the California Department of Resources Recycling and Recovery (CalRecycle) a plan that describes how the manufacturer supports the safe collection and destruction of home-generated sharps waste.

THIS BILL WOULD:

1. Establish the Product Stewardship Program within the Department of Resources Recycling and Recovery.
2. Make several findings and declarations including that Product stewardship is a mechanism to place responsibility for end-of-life management issues for products on those involved in the product chain in an equitable manner.
3. Establishes three types of covered products to be included in the ERP program including home generated medical sharps, including hypodermic needles, pen needles , intravenous needles, and lancets.

4. Defines various terms used throughout the Chapter, including covered products. "Covered product 1" means home-generated sharps waste, including, but not limited to, hypodermic needles, pen needles, intravenous needles, lancets, and other devices, that are used to penetrate the skin for the delivery of medications derived from a household, including from a multifamily residence or household.
5. Would require on or before September 30, 2011, a producer or a product stewardship organization that is created by one or more producers of a covered product shall submit a product stewardship plan to the department. Specifies that a product stewardship organization created pursuant to this section shall be open for participation by all producers of a covered product.
6. Beginning July 1, 2012, prohibits the sale of a covered product unless the producer is in compliance with the Act.
7. Requires, after June 20, 2013, the submission of an annual report to CalRecycle, including specified elements.
8. Establishes the Extended Producer Responsibility Account (Account) and the Extended Producer Responsibility Penalty Subaccount (Subaccount) in the Integrated Waste Management Fund.

AUTHOR'S INTENT:

According to the author, "AB 2139 proposes an Extended Producer Responsibility (EPR) Framework, which would establish one law to address a wide range of toxic products, including medical waste such has hypodermic needles, household pesticides, small propane tanks and other hazardous waste found around the home. Consumers deserve convenient, affordable options for disposing of products and leftover pesticides."

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 would likely utilize existing resources and incorporate into its inspection program any compliance with the provisions of this measure, if enacted.

PRIOR HISTORY/RELATED BILLS:

AB 501 (Swanson, 2008) Require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide upon request of a consumer, a postage prepaid mail-back sharps container for safe disposal of the used device or a sharps container for storage and transport to a sharps consolidation location. The board had a support position on this bill that was vetoed by the Governor.

There are several bills pending this year also addressing product stewardship including:

- AB 1343 (Huffman). Creates an architectural paint recovery program,
- AB 2176 (Blumenfield). Enacts the California Lighting Toxics Reduction and Jobs in Recycling Act (Act),
- AB 2398 (J. Perez). Requires, by September 30, 2011, a producer or the product stewardship organization created by one or more producers of carpet to submit a carpet stewardship plan,
- SB 1100 (Corbett). Creates a product stewardship program for household batteries

SUPPORT and OPPOSITION:

Support
CA Resource Recovery Association
California Product Stewardship Council
Californians Against Waste
Central Contra Costa Solid Waste Authority
City of San Francisco
Del Norte County Solid Waste Management Authority
Humboldt County Waste Management Authority
League of California Cities
Marin Sanitary Services
Napa County

Oppose
BayBio
BIOCOM
The California Healthcare Institute
The Pharmaceutical Researchers and Manufacturers Association
AdvaMed
Consumer Specialty Products Association
Soap and Detergent Association
American Chemistry Council
California Chamber of Commerce
California Grocers Association
California Manufacturers and Technology Association
Grocery Manufacturers Association
Monsanto
Responsible Industry for a Sound Environment

HISTORY:

Date	Action
Apr. 5	In Senate. Read first time. To Com. on RLS. for assignment.

Apr. 5	Read third time, passed, and to Senate. (Ayes 49. Noes 27.)
Mar. 25	Read second time. To third reading.
Mar. 24	From committee: Do pass. (Ayes 14. Noes 4.) (March 23).
Feb. 11	Referred to Com. on HEALTH.
Feb. 2	From printer. May be heard in committee March 4.
Feb. 1	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 6, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 2139

Introduced by Assembly Member Chesbro

February 18, 2010

An act to add Chapter 5 (commencing with Section 48800) to Part 7 of Division 30 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 2139, as amended, Chesbro. Solid waste: product stewardship.

The California Integrated Waste Management Act of 1989, administered by the Department of Resources Recycling and Recovery, requires a pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit a plan to the department that describes how the manufacturer supports the safe collection and proper disposal of the waste devices.

This bill would create the California Product Stewardship Act and would define the term "covered product" as including *ome-generated* medical sharps, ~~containers used to contain~~ pesticides intended for residential use, ~~small personal use propane tanks, personal butane lighters, and single-use food packaging that the department determines is a significant source of ocean and beach contamination. The bill would require the department by July 1, 2011, to establish a baseline collection rate for the amount of those products that is discarded and subsequently collected. The bill would provide a procedure for determining the collection rate applicable commencing January 1, 2014~~ *and nonrefillable propane cylinders, as defined.*

The bill would require, by September 30, 2011, a producer or the product stewardship organization created by one or more producers of a covered product to submit a product stewardship plan to the department, which would be required to include specified elements, including performance goals, *a collection rate,* and product goals. On or before January 1, 2012, the department would be required to review and either approve or disapprove the product stewardship plan submitted to the department.

The bill would prohibit the producer of a covered product, on and after July 1, 2012, from selling a covered product unless the producer or product stewardship organization of the covered product has submitted a plan to the department that is approved by the department. *T e bill would require t e department, on July 1, 2012, and on January 1 and July 1 annually t ereafter, to post on its Internet Web site t e covered products t at are not in compliance and t e bill would require a w olesaler or retailer t at distributes or sells covered products to monitor t e department's Internet Web site to determine if a covered product is in compliance.* The act would require a producer of a covered product to collect the covered product pursuant to the product stewardship plan and to meet the performance goals included in the product stewardship plan.

Each producer or product stewardship organization implementing a product stewardship plan would be required to prepare and submit to the department an annual report describing the activities carried out pursuant to the product stewardship plan.

A producer or product stewardship organization submitting a product stewardship plan would be required to pay the department a fee of ~~$10,000~~ *an unspecified amount* when submitting the plan for review and approval and to pay an annual administrative fee of ~~$1,000~~ *an unspecified amount*. The bill would provide for the imposition of administrative civil penalties upon a producer who does not comply with the act's requirements. The bill would create in the existing Integrated Waste Management Fund the Product Stewardship Account and would require that the administrative fees be deposited into that account and that the penalties be deposited into the Product Stewardship Penalty Subaccount that the bill would create in that account. The bill would authorize the fees and penalties to be expended, upon appropriation by the Legislature, to cover the board's program implementation costs and as incentives to enhance recyclability and

redesign efforts and to reduce environmental and safety impacts of covered products.

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

T e people of t e State of California do enact as follows:

1 SECTION 1. Chapter 5 (commencing with Section 48800) is
2 added to Part 7 of Division 30 of the Public Resources Code, to
3 read:
4
5 CHAPTER 5. CALIFORNIA PRODUCT STEWARDSHIP PROGRAM
6
7 Article 1. Findings and Declarations
8
9 48800. The Legislature finds and declares all of the following:
10 (a) This chapter requires the Department of Resources Recycling
11 and Recovery to develop, implement, and administer the Product
12 Stewardship Program.
13 (b) Product stewardship is a mechanism to place responsibility
14 for end-of-life management issues for products on those involved
15 in the product chain in an equitable manner.
16 (c) The program established by this chapter will test the efficacy
17 of a consistent framework approach for managing products that
18 have significant end-of-life waste management impacts as well as
19 impacts on the environment and public health. This framework
20 approach provides a consistent process that includes goals and
21 oversight so that a level playing field exists among all producers,
22 while maintaining flexibility for specific products and for producers
23 to design their product stewardship programs.
24 (d) End-of-life management of solid waste has historically been
25 the responsibility of state and local governments with the primary
26 physical management and financial burden placed on local
27 government and ratepayers, who have no ability to influence the
28 design of the products or packaging to reduce waste management
29 costs.
30 (e) Prior to this program, the state addressed products with
31 end-of-life management issues through a patchwork of product
32 and material specific programs.

(f) Implementing product stewardship programs that are funded and managed by the producers of products with significant end-of-life impacts reduces the role of, and cost to, state and local government and ratepayers.

(g) The Product Stewardship Program established by this chapter will explore the feasibility and potential environmental, economic, and social benefits of instituting a permanent product stewardship program for an extended number of products while still providing producers with the flexibility to customize individual product stewardship plans toward the most effective and efficient approach for a particular product or product category.

(h) The Product Stewardship Program established by this chapter will test the applicability of extended producer responsibility and may be used as a template for including additional products in these programs.

Article 2. General Provisions

48800.1. This chapter shall be known and may be cited as the California Product Stewardship Act.

Article 3. Definitions

48800.2. For purposes of this chapter, and unless the context otherwise requires, the definitions in this article govern the construction of this chapter.

48800.3. "Brand" means a name, symbol, word, or mark that identifies a product, rather than its components, and attributes the product to the owner or licensee of the brand as the producer.

48800.4. "Collection rate" means a quantitative measure ~~established by the department pursuant to Section 48811 or determined pursuant to Section 48812, as applicable, that~~ *t at* establishes the amount of a covered product required to be collected pursuant to a product stewardship plan.

48800.5. "Consumer product" means a product that is sold in this state in a transaction that is a retail sale or in a transaction to which a use tax applies pursuant to Part 1 (commencing with Section 6001) of Division 2 of the Revenue and Taxation Code.

48800.6. "Covered product" means all of the following consumer products that are used or discarded in this state, as defined by the department:

(a) "Covered product 1" means ~~medical sharps, including hypodermic needles, hypodermic needles with syringes, blades, and needles, that are not subject to Article 3.3 (commencing with Section 47115) or Chapter 1 of Part 7.~~ *ome-generated s arps waste, including, but not limited to, ypodermic needles, pen needles, intravenous needles, lancets, and ot er devices, t at are used to penetrate t e skin for t e delivery of medications derived from a ouse old, including from a multifamily residence or ouse old.*

(b) *(1)* "Covered product 2" means ~~containers used to contain pesticides intended for residential use.~~ *pesticides, as defined in Section 12753 of t e Food and Agricultural Code, t at are intended for residential use, including any of t e following:*

(A) A spray adjuvant.

(B) A substance or mixture of substances t at is intended to be used for defoliating plants, regulating plant growt , or for preventing, destroying, repelling, or mitigating a pest, as defined in Section 12754.5 of t e Food and Agricultural Code, t at may infest or be detrimental to vegetation, uman, animal, or ouse old, or be present in a agricultural or nonagricultural environment w atsoever.

(2) For purposes of t is c apter, pesticides intended for residential use s all be limited to t ose defined as a consumer product, pursuant to Section 48800.5, but s all exclude t ose consumer products t at are intended primarily for residential cleaning and disinfecting.

(c) "Covered product 3" means ~~small personal use propane tanks.~~

~~(d) "Covered product 4" means personal butane lighters.~~

~~(e) "Covered product 5" means single-use food packaging that the department determines is a significant source of ocean and beach contamination.~~ *nonrefillable propane cylinders, as defined in Section 178.65 of Title 49 of t e Code of Federal Regulations.*

48800.7. "Department" means the Department of Resources Recycling and Recovery.

48800.8. "Performance goal" means the collection rate of a covered product, and may include, but is not limited to, the reuse

and recycling rate established by the product stewardship plan for that covered product.

48800.9. "Producer" shall be determined, with regard to a covered product that is sold, offered for sale, or distributed in the state, as meaning one of the following:

(a) A person who manufactures the covered product and who sells, offers for sale, or distributes that covered product in the state under that person's own name or brand.

(b) If there is no person who sells, offers for sale, or distributes the covered product in the state under the person's own name or brand, the producer of the covered product is the owner or licensee of a trademark or brand under which the covered product is sold or distributed in the state, whether or not the trademark is registered.

(c) If there is no person who is a producer of the covered product for purposes of subdivisions (a) and (b), the producer of that covered product is the person who imports the product into the state for sale or distribution.

48800.10. "Product goal" means those qualitative or quantitative goals determined by the producer to measure improvements that reduce the life cycle impacts of a covered product.

48800.11. "Product stewardship" means requiring the producer of a covered product, and all other entities involved in the product chain, to share in the responsibility of reducing the life cycle impact of the covered product and its packaging, including requiring the producer who makes design and marketing decisions for the covered product to bear the primary responsibility for this reduction.

48800.12. "Product stewardship organization" means an organization appointed by one or more producers to act as an agent on behalf of the producer to design, submit, and administer a product stewardship plan pursuant to this chapter.

48800.13. "Product stewardship plan" or "plan" means a plan written by an individual producer or a product stewardship organization, on behalf of one or more producers, that includes all of the information required by Section 48813.

48800.14. "Recycling rate" means a quantitative measure that establishes the amount of a collected covered product that is recycled as compared to the total amount of the covered product

that is collected, including the amount of the covered product that is discarded for reuse, energy recovery, or safe disposal.

48800.15. "Reporting period" means the period commencing January 1 and ending on December 31 of the same calendar year.

48800.16. "Reuse rate" means a quantitative measure that establishes the amount of a collected covered product that is reused as compared to the total amount of the covered product that is collected, including the amount of the covered product that is discarded by recycling, energy recovery, or safe disposal.

48800.17. "Sell" or "sales" means any transfer of title of a covered product for consideration, including a remote sale conducted through a sale outlet, catalog, or Internet Web site or similar electronic means, but does not include a lease.

Article 4. Product Stewardship Program

48810. This chapter does not limit, supersede, duplicate, or otherwise conflict with the authority of the Department of Toxic Substances Control under Section 25257.1 of the Health and Safety Code to fully implement Article 14 (commencing with Section 25251) of Chapter 6.5 of Division 20 of the Health and Safety Code, including the authority of the Department of Toxic Substances Control to include products in its product registry.

~~48811. (a) On or before July 1, 2011, the department shall establish a baseline collection rate for the amount of each covered product that is discarded and subsequently collected, based on existing collection data.~~

~~(b) On and after July 1, 2011, and for the calendar years commencing January 1, 2012, and January 1, 2013, the collection rate shall be the collection rate established pursuant to this section.~~

~~48812. (a) On and after January 1, 2014, the collection rate for a covered product shall be determined in the following manner:~~

~~(1) For the calendar year commencing January 1, 2014, the collection rate shall be 5 percent more than the baseline collection rate determined pursuant to Section 48811.~~

~~(2) On and after January 1, 2015, the collection rate for each covered product shall increase by no less than 5 percent annually until a 95 percent collection rate is reached.~~

~~(b) A producer may petition the department for an adjustment to the collection rate. The department may grant an adjustment to~~

~~the collection rate only if the department determines there are documented exigent circumstances that are beyond the control of the producer or product stewardship organization.~~

48813. (a) On or before September 30, 2011, a producer or a product stewardship organization that is created by one or more producers of a covered product shall submit a product stewardship plan to the department. A product stewardship organization created pursuant to this section shall be open for participation by all producers of a covered product.

~~(b) A producer, group of producers, or product stewardship organization shall consult with stakeholders during the development of the product stewardship plan, including soliciting stakeholder comments and responding to stakeholder comments prior to submitting the product stewardship plan.~~

~~(c)~~

(b) Each product stewardship plan for a covered product shall address the environmental impacts of the covered product over the entire life cycle of that product, including the product design, manufacture, and distribution of the covered product, and the collection, transportation, reuse, recycling, and final disposition of the discarded covered product, in accordance with this chapter. The plan shall include, at a minimum, all of the following elements:

(1) Contact information for all participating producers.

(2) A description of the covered product and associated brands covered by the plan.

(3) Performance goals, including a detailed description of how the performance goals will be achieved and how results will be measured, and including ~~both~~ *all* of the following:

(A) ~~The collection rate~~ *A collection rate, w ic* shall be included as a performance goal for the covered product.

(B) A reuse rate and a recycling rate for the covered product shall be included in the performance goals.

(C) If t e covered product is pro ibited from being disposed of at a solid waste disposal facility, t e performance goal s all include a sc edule to accomplis a 100 percent collection rate.

(4) ~~An overview of the~~ *T e* roles and responsibilities of key players along the product chain.

(5) Financing methods for the product stewardship plan.

(6) Strategies for managing and reducing the life cycle impacts of the covered product, steps that will be taken to ensure

environmentally sound management, and how impacts will be tracked over time to show continual improvement.

(7) Education and outreach activities.

~~(8) A description of the consultation process used to consult with affected stakeholders regarding the product stewardship plan.~~

~~(9)~~

(8) Product goals, including, but not limited to, product designing and materials content, manufacturing, packaging, distribution, and end-of-life management goals. The product goals shall address the use of virgin material in the manufacture of the covered product, the impact upon, or use of, water or energy by the covered product, the use of, or generation of hazardous substances by, the covered product, the carbon footprint of the covered product, the covered product's longevity, the recycled content of the covered product, and the covered product's recyclability, where applicable.

48814. (a) On or before January 1, 2012, the department shall review the product stewardship plan submitted to the department and either approve or disapprove the plan. If the department does not approve the plan, the department shall notify the producer or organization that submitted the plan and the producer or organization shall revise and resubmit the disapproved product stewardship plan within 30 days after receiving the notification.

(b) All product stewardship plans submitted to the department shall be available to the public on the department's Internet Web site.

(c) A producer shall notify the department 30 days before instituting a significant or material change to a product stewardship plan.

48815. *(a)* On and after July 1, 2012, a producer shall not offer a covered product for sale in this state or offer a covered product for promotional purposes in this state unless the producer or a product stewardship organization consisting of producers of the covered product has submitted a product stewardship plan to the department pursuant to Section ~~48816~~ *48813* and the product stewardship plan is approved by the department pursuant to Section ~~48817~~ *48814*.

(b) On July 1, 2012, and on January 1 and July 1 annually t ereafter, t e department s all post on its Internet Web site covered products t at are not in compliance wit t is section.

(c) A w olesaler or retailer t at distributes or sells covered products s all monitor t e department's Internet Web site to determine if t e sale of a covered product is in compliance wit t is section.

48816. A producer of a covered product shall do all of the following when implementing this chapter, including an approved product stewardship plan:

(a) Collect the individual covered product to be reused or recycled pursuant to the product stewardship plan for the covered product submitted by the producer or product stewardship organization pursuant to Section 48813 and approved by the department pursuant to Section 48814.

(b) Meet the performance goals included in the product stewardship plan~~, including achieving the collection rate established pursuant to Section 48812~~.

(c) Provide collection services, in accordance with Section 48817, for the covered product, that do not charge a fee at the time when the covered product is collected for either recycling or disposal.

(d) Pay ~~all administrative and operational~~ costs associated with the product stewardship plan, including the costs of collection, transportation, and recycling or disposal, or both, of the covered product.

(e) Submit the annual report required by Section 48818.

48817. A covered product shall be handled and recycled, or if not feasible to be recycled, disposed of, in accordance with all state and federal laws and regulations and local ordinances and regulations, including, but not limited to, any law, regulation, or ordinance that regulates hazardous waste.

Article 5. Reporting

48818. (a) Beginning one year after a product stewardship plan is approved or no later than January 1, 2013, whichever date is earlier, and every subsequent year thereafter, each producer or stewardship organization implementing a product stewardship plan shall prepare and submit to the department an annual report describing the activities carried out pursuant to the product stewardship plan during the previous reporting period, including, but not limited to, all of the following:

(1) Whether the producer or product stewardship organization, in implementing the plan, attained the performance goals for the covered product, and if the performance goals were not met, what actions the producer or product stewardship organization will take during the next reporting period to attain those performance goals.

(2) Whether the producer or product stewardship organization, in implementing the plan, attained the product goals for the covered product, and if the product goals were not met, what actions the producer or stewardship organization will take during the next reporting period to achieve those product goals.

(b) The department shall review a report submitted pursuant to this section and shall approve the report if the department determines the report contains the information required by this section.

(c) The department shall make all reports submitted to the department pursuant to this section available to the public on the department's Internet Web site.

Article 6. Financial Provisions

48819. (a) The producer or product stewardship organization submitting a product stewardship plan shall pay the department an administrative fee in the amount of ~~ten thousand dollars ($10,000)~~ ____ when the plan is submitted for review and approval and thereafter pay an annual administrative fee of ~~one thousand dollars ($1,000)~~ ____.

(b) The total amount of annual fees collected pursuant to this section shall not exceed the amount necessary to recover costs incurred by the department in connection with the administration and enforcement of the requirements of this chapter.

48820. (a) The Product Stewardship Account and the Product Stewardship Penalty Subaccount are hereby established in the Integrated Waste Management Fund.

(b) All fees collected pursuant to this chapter shall be deposited in the Product Stewardship Account and may be expended by the department, upon appropriation by the Legislature, to cover the department's costs to implement this chapter.

(c) All penalties collected pursuant to this chapter shall be deposited in the Product Stewardship Penalty Subaccount and may be expended by the department, upon appropriation by the

Legislature, to cover the department's costs to implement this chapter.

(d) All funds collected may be expended as incentives to enhance reuse, recyclability, and redesign efforts and to reduce environmental and safety impacts of covered products.

Article 7. Enforcement

48821. (a) If, after holding a public hearing, the department finds that a producer has failed to make a good faith effort to comply with this chapter, the department shall issue a compliance order with a schedule for achieving compliance.

(b) If, after issuing an order and schedule for compliance pursuant to subdivision (a), the department finds that the producer has failed to make a good faith effort to comply with this chapter, the department may impose an administrative civil penalty of ~~ten thousand dollars ($10,000)~~ ____ per day until the producer achieves compliance.

(c) For purposes of this section, "good faith effort" means all reasonable and feasible efforts by a producer towards implementing the requirements of this chapter, including, but not limited to, meeting the performance goals specified in the plan.

48822. (a) The department, or its designee, may inspect, audit, or require and review third-party audits of producers, product stewardship organizations, and service providers, including collectors and recyclers, that are utilized to fulfill the requirements of a product stewardship plan.

(b) For purposes of this section, a "service provider" means any person who is authorized to perform an action to implement the product stewardship plan with regard to the collection, recycling, reuse, or disposal of a covered product, but does not include the consumer of the covered product.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1029 **VERSION: As Amended April 7, 2010**

AUTHOR: Yee **SPONSOR: Drug Policy Alliance and The San Francisco Aids Foundation**

BOARD POSITION:

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, 121281
Repeal Chapter 13.5 (commencing with Section 121285)

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, 2010 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.
4. Allows for a person to possess, for personal use, 10 or fewer hypodermic needles and syringes if acquired from an authorized source.
5. 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. Allow a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older.
2. Specifies that pharmacies shall store such products in a manner to ensure that they are only available to authorized personnel.
3. Shall provide consumers with disposal options including an onsite collection program or make available mail-back sharps containers or personal medical sharps disposal containers.
4. 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.
5. Removes the requirement for local authorization through a vote of a Board of Supervisors or City Council.
6. Requires 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; requires the Board to either post or maintain a link to the same information on its website.

AUTHOR'S INTENT:

According to the Author, "This bill is needed because California is suffering an unnecessarily high rate of HIV and viral hepatitis due to syringe scarcity. While many states allow an unlimited number of syringes to be sold to an adult, this bill is an incremental move away from complete prohibition of sale and possession of syringes, allowing an adult to purchase and possess 30 or fewer syringes for personal use."

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 would likely utilize existing resources and incorporate into its inspection program any compliance with the provisions of this measure, if enacted.

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), makes permanent, the Disease Prevention Demonstration Project (DPDP), 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.

SB 1029 (Yee), currently in the Senate Business, Professions and Economic Development Committee, eliminates most provisions of the DPDP, including requirement that LHDs register pharmacies and provide pharmacies with educational material for distribution, and instead allow pharmacists statewide the discretion to sell 30 or fewer syringes to an adult without the requirement of a local authorization vote and eliminates other elements of the demonstration project including state requirements regarding advisory board and evaluation. SB 1029 also deletes the prohibition against possession of hypodermic needles and syringes, and permits adults to possess 30 or fewer syringes solely for personal use. SB 1029 would also require the Office of AIDS to develop and maintain information on its Web site to educate consumers at risk of blood-borne infections of opportunities to improve and protect the consumer's health, and to protect the public health. SB 1029 would require pharmacies that provide non-prescription syringes to promote safe syringe disposal, and to store syringes securely.

SUPPORT and OPPOSITION:

Support
San Francisco Aids Foundation (Co-sponsor)
AIDS Project Los Angeles

American Civil Liberties Union
California Communities United Institute
California Hepatitis Alliance (CalHEP)
California Nurses Association/National Nurses Organizing Committee
California Medical Association
California Opioid Maintenance Providers
California Pharmacists Association
California Psychiatric Association
California Retailers Association
California Society of Addiction Medicine
City and County of San Francisco
County Alcohol & Drug Program Administrators Association of California
County of Alameda
Equality California
Planned Parenthood
Project Inform
Rite Aid
San Francisco Mayor's Hepatitis C Task Force
Walgreens

Oppose
California Narcotic Officers' Association
California Peace Officers' Association
California Police Chiefs Association

HISTORY:

Date	Action
Apr. 14	Set for hearing April 19.
Apr. 12	Set, first hearing. Hearing canceled at the request of author.
Apr. 7	Read second time. Amended. Re-referred to Com. on B., P. & E.D.
Apr. 6	From committee: Do pass as amended, but first amend, and re-refer to Com. on B., P. & E.D. (Ayes 6. Noes 3. Page 3038.)
Mar. 26	Set for hearing April 12 in B., P. & E.D. pending receipt.
Mar. 17	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
Mar. 16	Set for hearing March 24.
Mar. 15	Set, first hearing. Hearing canceled at the request of author.
Mar. 12	Set for hearing April 14.
Feb. 25	To Coms. on HEALTH and B., P. & E.D.
Feb. 16	From print. May be acted upon on or after March 15.
Feb. 12	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 7, 2010

AMENDED IN SENATE MARCH 17, 2010

SENATE BILL **No. 1029**

Introduced by Senator Yee
(Principal coauthor: Senator Leno)
(Coauthors: Assembly Members Monning and Swanson)

February 12, 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 1029, as amended, 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, until December 31, 2010, 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, *for the period beginning January 1, 2011, and ending December 31, 2018,* 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, until December 31, 2010, 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, 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 *for the period beginning January 1, 2011, and ending December 31, 2018,* 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 the consumer's 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 SEC. 3. Section 4145 of the Business and Professions Code is
11 amended to read:
12 4145. (a) Notwithstanding any other provision of law, a
13 pharmacist or physician may, without a prescription or a permit,
14 furnish hypodermic needles and syringes for human use, and a
15 person may, without a prescription or license, obtain hypodermic
16 needles and syringes from a pharmacist or physician for human
17 use, if the person is known to the furnisher and the furnisher has
18 previously been provided a prescription or other proof of a
19 legitimate medical need requiring a hypodermic needle or syringe
20 to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, *for the period beginning January 1, 2011, and ending December 31, 2018,* as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

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

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

(e) In order to provide for the safe disposal of hypodermic needles and syringes, pharmacies that furnish nonprescription hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

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

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

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

(f) Pharmacies that furnish nonprescription syringes shall provide written information or verbal counseling to consumers at

the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

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

(3) Safely dispose of sharps waste.

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

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

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

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

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) ~~As~~ *For the period beginning January 1, 2011, and ending December 31, 2018, as* a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of 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.

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

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

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

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

(c) How consumers can access drug treatment.

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

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

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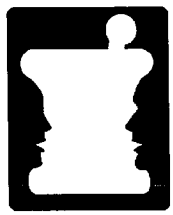
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: **AB 2112** **VERSION: Amended April 7, 2010**

AUTHOR: **Monning** **SPONSOR: Author Sponsored**

BOARD POSITION:

SUBJECT: **Prescription Record Privacy Act**

Affected Sections of Law:
Division 1 of the Civil Code - Add Part 2.7 (commencing with Section 60)
Amend Section 130202 of the Health and Safety Code

EXISTING LAW:

1. Establishes the Confidentiality of Medical Information Act (Civil Code section 56-56.07) which prohibits the disclosure of medical information without authorization or as otherwise authorized by law.

2. Authorizes the Office of Health Information Integrity within the California Health and Human Services Agency to assess an administrative fine against any person or provider of health care who violates the Confidentiality of Medical Information Act, as specified.

THIS BILL WOULD:

1. Establish the Prescription Record Privacy Act (PRP Act) within Division 1 of the Civil Code and states the Legislature's intent to further the state's interest in
   - improving the quality and lowering the cost of health care;
   - restrain undue influence exerted by pharmaceutical industry marketing representatives over prescribing decisions;
   - combat vexatious and harassing sales practices;
   - safeguard the confidentiality of physician prescribing data;
   - protect the integrity of the doctor patient relationship; and
   - maintain the integrity and public trust of the medical profession.
2. Provide definitions of terms, such as:
   - "Licensee" as a person described in Section 4036 or 4037 of the Business and Professions Code (i.e., Pharmacist or Pharmacist-in-Charge);
   - "Marketing" activities as it relates to the PRP Act;

- "Physician" as a person described in Section 2041 of the Business and Professions Code; and other terms used throughout the section.

3. Precludes a person or entity from selling or releasing to a third party, or exchange for remuneration, any prescribing data for marketing purposes, unless specified or as otherwise lawful.
4. Authorize the adoption of regulations as necessary to implement this measure.
5. Specify administrative penalties, minimum statutory penalty, and violations for persons who knowingly fail to comply with the provisions of the Act.
6. Additionally authorize the Office of Health Information Integrity to assess an administrative fine against any person or provider of health care, whether licensed or unlicensed, for any violation of the Confidentiality of Medical Information Act.

COMMENTS:

The author's office stated that the bill has been pulled from committee and that they do not have plans to move this bill forward.

HISTORY:

2010

Apr. 8 Re-referred to Com. on HEALTH.

Apr. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Apr. 6 In committee: Set, first hearing. Hearing canceled at the request of author.

Mar. 25 Re-referred to Com. on HEALTH.

Mar. 24 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Mar. 11 Referred to Coms. on HEALTH and JUD.

Feb. 19 From printer. May be heard in committee March 21.

Feb. 18 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 7, 2010

AMENDED IN ASSEMBLY MARCH 24, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 2112

Introduced by Assembly Member Monning

February 18, 2010

An act to add Part 2.7 (commencing with Section 60) to Division 1 of the Civil Code, and to amend Section 130202 of the Health and Safety Code, relating to privacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2112, as amended, Monning. Prescription Record Privacy Act.

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies.

This bill would enact the Prescription Record Privacy Act, prohibiting a person *or entity, including a pharmacist,* from ~~knowingly disclosing or using regulated records that include prescription information containing individual identifying information for marketing a prescribed product, as provided, except when information may be transferred to another entity, as provided, and in accordance with other state and federal laws. The act would not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if the data is aggregated, does not contain individual identifying information, and cannot reasonably be used to obtain individual~~

~~identifying information~~ *selling or releasing to a 3rd party any physician prescribing data for marketing purposes, as defined, except when the data is necessary for any local, state, or federal governmental or oversight activity, as provided, or is necessary for the processing of a health care claim. The bill also would permit the release of physician prescribing data to a licensed health care professional, service plan, contractor, or facility, as provided, a health insurer or disability insurer, or an authorized operator of a program related to the treatment of chronic and seriously debilitating or life-threatening conditions. The bill would also permit the release of data for clinical trials or established research projects, as provided.* This bill would also require that any person that knowingly fails to comply with these provisions be subject to an administrative penalty of at least $10,000 and not more than $50,000 per violation.

This bill would authorize the Secretary of California Health and Human Services to adopt regulations to implement these provisions. This bill would require the office of the Attorney General to enforce payment of penalties for violations of these provisions, as provided. This bill would also authorize the Office of Health Information Integrity, upon receipt of a complaint of a violation of these provisions, to conduct an administrative hearing, in accordance with the administrative adjudication provisions set forth in the Administrative Procedure Act, and to assess an administrative fine against a person or entity found to have committed a violation of these provisions.

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. Part 2.7 (commencing with Section 60) is added
2 to Division 1 of the Civil Code, to read:
3
4 PART 2.7. PRESCRIPTION RECORD PRIVACY ACT
5
6 60. This part may be cited as the Prescription Record Privacy
7 Act.
8 60.5. It is the intent of the Legislature to *further the state's*
9 *interest in improving the quality and lowering the cost of health*
10 *care, restrain undue influence exerted by pharmaceutical industry*
11 *marketing representatives over prescribing decisions, combat*

vexatious and harassing sales practices, safeguard the confidentiality of ~~prescribing information~~ *physician prescribing data*, protect the integrity of the doctor-patient relationship, *and* maintain the integrity and public trust of the medical profession~~, combat vexatious and harassing sales practices, restrain undue influence exerted by pharmaceutical industry marketing representatives over prescribing decisions, and further the state's interest in improving the quality and lowering the cost of health care~~. The Legislature intends to regulate ~~the monitoring of prescribing practices~~ *physician prescribing data* only for commercial marketing purposes by companies selling prescribed products. The intent is not to regulate ~~monitoring for~~ other uses, such as quality control, research unrelated to marketing, or use by governments or other entities not in the business of selling health care products.

61. For purposes of this part:

~~(a) "Bona fide clinical trial" means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome, has received approval from an appropriate institutional review board, and has been registered at http://ClinicalTrials.gov prior to commencement.~~

~~(b) "Individual identifying information" means information that directly or indirectly identifies a prescriber or a patient in this state, indicates where the information is derived from, or relates to a prescription for any prescribed product.~~

(a) "Licensee" means a person described in Section 4036 or 4037 of the Business and Professions Code.

~~(c)~~

(b) "Marketing" means any activity by a company making or selling prescribed products, or by that company's agent, intended to influence prescribing or purchasing choices of its products, including, but not limited to:

(1) Advertising, publicizing, promoting, or sharing information about a product.

(2) Identifying individuals to receive a message promoting use of a particular product, including, but not limited to, an advertisement, brochure, or contact by a sales representative.

(3) Planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document.

(4) Evaluating or compensating sales representatives.

(5) Identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation, or employment of value.

(6) Advertising or promoting prescribed products directly to patients.

~~(d) "Person" means a business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.~~

~~(e) "Pharmacy" means any individual or entity licensed under state law to dispense prescribed products.~~

(c) "Physician" means a person described in Section 2041 of the Business and Professions Code.

(d) "Physician prescribing data" means information that sets forth a prescription written on or after the operative date of this part by a physician in combination with any data that individually identifies the physician, including a unique number identifier assigned for tracking purposes, telephone number, e-mail address, medical identification number, business or home address, or any other information that can reasonably be used to identify the physician or track the prescribing habits of the physician.

~~(f)~~

(e) "Prescribed product" includes a biological product as defined in Section 262 of Title 42 of the United States Code and a device or a drug as defined in Section 321 of Title 21 of the United States Code.

~~(g) "Regulated record" means information or documentation from a prescription written by a prescriber doing business in this state or a prescription dispensed in this state.~~

~~62. (a) No person shall knowingly disclose or use regulated records that include prescription information containing individual identifying information for marketing a prescribed product.~~

~~(b) A regulated record containing individual identifying information may be transferred to another entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient will safeguard the records from being disclosed or used for a marketing purpose prohibited~~

~~under this section and only if the transfer is in accordance with other state and federal laws.~~

~~(c) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for nonmarketing purposes only in accordance with other state and federal laws.~~

~~(d) This section does not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if:~~

~~(1) The data is aggregated.~~

~~(2) The data does not contain individual identifying information.~~

~~(3) There is no reasonable basis to believe that the data can be used to obtain individual identifying information.~~

~~(e) This section shall not prevent any person from disclosing regulated records to the identified individual as long as the information does not include protected information pertaining to any other person.~~

(f) "Release to a third party" or "release" does not include communication or use of physician prescribing data among covered entities that participate in an organized health care arrangement, as defined in Section 160.103 of Title 45 of the Code of Federal Regulations.

62. A person or entity, including a licensee, shall not sell or release to a third party, or exchange for remuneration, any physician prescribing data for marketing purposes.

63. Nothing in this part may be construed to limit or restrict the release of physician prescribing data that is necessary for any local, state, or federal governmental oversight or regulatory activity, including, but not limited to, the release of physician prescribing data to a local, state, or federal law enforcement or public health authority in furtherance of its regulatory activity.

64. Nothing in this part may be construed to limit or restrict the release of physician prescribing data that is necessary for the processing of a health care claim.

65. Nothing in this part is intended to limit or restrict the otherwise lawful activities of a licensee.

66. Nothing in this part is intended to prohibit or limit an individual patient of a physician from releasing any identifiable information relating to a prescription that the patient received, or

that the physician wrote, that is not otherwise restricted or prohibited by law.

67. Nothing in this part may be construed to limit or restrict the release of physician prescribing data to any of the following:

(a) A licensed health care professional, if the release is directly related to providing health care to a patient.

(b) A health insurer or disability insurer, health care service plan, pharmacy benefit manager, employee-sponsored health benefit plan, or their contractors, if the data is directly related to administrating or monitoring the use of a health care benefit.

(c) An authorized operator of a program related to the treatment of chronic and seriously debilitating or life-threatening conditions, as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code.

(d) An employee benefit plan or any other person or private entity responsible for paying for health care services rendered to the patient, if the physician prescribing data is reasonably necessary to complete or verify a health care transaction related to the prescription information sought to be disclosed.

(e) Any health care service plan, contractor, or other health care professional or facility exclusively for purposes of diagnosis or treatment of a patient.

(f) Use by a health care service plan or health insurer or disability insurer as permitted or required by Sections 1367.01 or 1370 of the Health and Safety Code or Sections 10123.135 or subdivision (d) of Section 10133 of the Insurance Code.

68. Nothing in this part may be construed to prohibit the release of aggregate prescription data to any individual or entity, provided that data does not include identifiable physician prescribing data as described in this part.

69. (a) Nothing in this part may be construed to prohibit the release of physician prescribing data if it is solely intended to be used for clinical trials or established research projects conducted in accordance with protocols, guidelines, or standards recognized by the federal Health and Human Services Agency, the federal Food and Drug Administration, the National Institutes of Health, the National Cancer Institute, or the Centers for Disease Control and Prevention.

(b) Any entity receiving physician prescribing data pursuant to this section may not use the data for any other purpose.

70. Nothing in this part may be construed to limit or restrict the release of physician prescribing data for the purposes of providing the physician with information regarding action by the state or by the federal Food and Drug Administration limiting or disallowing the sale or use of a specific drug, or to provide the physician with information regarding adverse events related to a specific drug or medical device.

71. Nothing in this part shall prohibit the otherwise lawful use or release of physician prescribing data for litigation purposes.

~~63.~~

72. The Secretary of California Health and Human Services may adopt regulations as necessary to implement this part.

~~64.~~

73. Any person that knowingly fails to comply with the requirements of this part or regulations adopted pursuant to this part by using or disclosing regulated records in a manner not authorized by this part or its regulations, shall be subject to an administrative penalty of at least ten thousand dollars ($10,000) per violation and not more than fifty thousand dollars ($50,000) per violation, as assessed by the California Health and Human Services Agency. Each disclosure of a regulated record shall constitute a violation. The office of the Attorney General shall take necessary action to enforce payment of penalties assessed under this section. Minimum statutory penalties shall be set at ten thousand dollars ($10,000) per violation, notwithstanding Section 125.9 of the Business and Professions Code.

~~64.5.~~

74. In addition to any other remedy provided by law, a violation of this chapter shall be an unfair or deceptive act in trade or commerce and an unfair method of competition and may be enforced as an unfair business practice pursuant to Chapter 5 of Part 2 of Division 7 of the Business and Professions Code.

~~65. (a) The intent of this section is to ensure the confidentiality of data held by a state agency or its agent, which could be used to directly or indirectly identify a patient or a health care professional licensed to prescribe drugs, biological products, or medical devices.~~

~~(b) For the purposes of this section:~~

~~(1) "Individual identifying information" shall have the same meaning as in Section 61.~~

~~(2) "Prescribed product" includes a biological product as defined in Section 262 of Title 42 of the United States Code and a device or a drug as defined in Section 321 of Title 21 of the United States Code.~~

~~(3) "State health care program" means a program for which the state purchases prescribed products, including, but not limited to, a state pharmaceutical assistance program, or a program for state employees and their dependents, individuals under the supervision of corrections, or state retirees and their dependents with the exception of the state medical assistance program (Medi-Cal).~~

~~(c) Records held by an agency administering a state health care program that include prescription information containing individual identifying information shall only be disclosed for the purposes allowed in Section 62.~~

~~(d) Any person who knowingly fails to comply with the requirements of this chapter or rules adopted pursuant to this part by using or disclosing regulated records in a manner not authorized by this part or its rules shall be subject to an administrative penalty of at least ten thousand dollars ($10,000) per violation and not more than fifty thousand dollars ($50,000) per violation, as assessed by the California Health and Human Services Agency. Each disclosure of a regulated record shall constitute a violation. The office of the Attorney General shall take necessary action to enforce payment of penalties assessed under this section.~~

~~65.5. (a) The intent of this part is to ensure compliance with federal Medicaid law and regulations prohibiting the disclosure and use of Medicaid data, except to administer the Medicaid program, and to ensure that data held by the state agency or its agents that could directly or indirectly identify patients or health care professionals licensed to prescribe products be kept confidential.~~

~~(b) The State Department of Health Care Services, which administers the state medical assistance program (Medi-Cal) under subchapter C of Chapter 4 of Title 42 of the Code of Federal Regulations (Medicaid) or a Medicaid waiver approved by the Centers for Medicare and Medicaid Services, shall disclose records that include prescription information only as provided for under Section 431 of Title 42 of the Code of Federal Regulations and the federal Privacy Act of 1974. The department shall ensure that any agent or contractors with the department are informed of the~~

~~limitations on redisclosure or use of the data provided for under applicable federal regulations and shall have policies and procedures for ensuring compliance with this statute and federal regulations.~~

~~(c) Any person that knowingly fails to comply with the requirements of this part or rules adopted pursuant to this part by using or disclosing regulated records in a manner not authorized by this part or its rules shall be subject to an administrative penalty of at least ten thousand dollars ($10,000) per violation and not more than fifty thousand dollars ($50,000) per violation, as assessed by the California Health and Human Services Agency. Each disclosure of a regulated record shall constitute a violation. The office of the Attorney General shall take necessary action to enforce payment of penalties assessed under this section.~~

~~66.~~

75. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

~~67.~~

76. Nothing in this act shall be interpreted to regulate conduct that takes place entirely outside of the state.

~~67.5.~~

77. Nothing in this act shall be interpreted to regulate the content, time, place, or manner of any discussion between a prescriber and his or her patient, or a prescriber and any person representing a prescription drug manufacturer.

SEC. 2. Section 130202 of the Health and Safety Code is amended to read:

130202. (a) (1) Upon receipt of a referral from the State Department of Public Health, the office may assess an administrative fine against any person or any provider of health care, whether licensed or unlicensed, for any violation of this division in an amount as provided in Section 56.36 of the Civil Code. Proceedings against any person or entity for a violation of this section shall be held in accordance with the administrative adjudication provisions of Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(2) Paragraph (1) shall not apply to a clinic, health facility, agency, or hospice licensed pursuant to Section 1204, 1250, 1725, or 1745 if Senate Bill 541 of the 2007–08 Regular Session is enacted and becomes effective on or before January 1, 2009.

(3) Nothing in paragraph (1) shall be construed as authorizing the office to assess the administrative penalties described in Section 1280.15 of the Health and Safety Code.

(b) Upon receipt of a complaint under Part 2.7 (commencing with Section 60) of Division 1 of the Civil Code, the office may assess an administrative fine against any person or any provider of health care, whether licensed or unlicensed, for any violation of that part. Proceedings against any person or entity for a violation of Part 2.7 (commencing with Section 60) of Division 1 of the Civil Code shall be held in accordance with the administrative adjudication provisions of Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c) The office shall adopt, amend, or repeal, in accordance with the provisions of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, such rules and regulations as may be reasonable and proper to carry out the purposes and intent of this division, and to enable the authority to exercise the powers and perform the duties conferred upon it by this division not inconsistent with any other provision of law.

(d) Paragraph (3) of subdivision (a) shall only become operative if Senate Bill 541 of the 2007–08 Regular Session is enacted and becomes effective on or before January 1, 2009.

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Attachment C

Third Quarterly Report on Legislation/Regulation Committee Goals for 2009/10

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	1. Secure extension of board's sunset date. *1st Qtr 06/07:* *Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.* *4th Qtr 06/07:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process.* *1st Qtr 08/09:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.* *Governor signs SB 963 (Chapter 385, Statutes of 2008)* *1st Qtr 09/10:* *Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.* *2nd Qtr 09/10:* *Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.* *3rd Qtr 09/10:* *Sunset bills introduced* *AB 1659 (Huber) – State Government, Agency Repeals* *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection* *SB 954 (Harmon) – Legislative Procedure, Committee Referrals* *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations*

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: *SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions*

Oct. 2007: *Board sponsors omnibus provisions for 2008. Four types of changes are discussed.*

(1) Changes specific to the PIC and DRC requirements

- *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*
- *Section 4036.5 – Pharmacist-in-Charge*
- *Section 4161 – Nonresident wholesaler*
- *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*
- *Section 4329 – Nonpharmacists; Prohibited Acts*
- *Section 4330 – Proprietors; Prohibited Acts*

(2) Changes to allow for the use of mobile pharmacies

- *Section 4062 – Furnishing Dangerous Drugs During an Emergency.*
- *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.*

(3) General changes

- *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.*
- *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*
- *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*
- *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*
- *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.*

(4) Changes based on recodification of Business and Professions Code section 4052

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

	Jan. 2008: *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.* *Board approved language for omnibus bill.* *April 2008:* *Some provisions of omnibus bill removed:* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *Oct. 2008:* *Governor vetoes SB 1779* *1st Qtr 08/09:* *Board seeks to pursue omnibus provisions (formerly contained in SB 1779).* *Four areas of change:* *(1) Changes specific to the PIC and DRC requirements* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *(2) Changes to allow for the use of mobile pharmacies* • *Section 4062 – Furnishing Dangerous Drugs During an Emergency.* • *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.* *(3) General changes* • *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.* • *Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory* • *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.* • *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.* *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.*

	(4) Changes based on recodification of Business and Professions Code section 4052 • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription* ***1st Qtr 08/09:*** *Board seeks to introduce additional changes:* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *New Provisions* • *4200.1 – Pharmacist Examination; Remedial Education* • *4112 – Non-resident Pharmacy: Registration Required* • *4146 – Return and Disposal of Sharps* • *4013 – Subscriber Alert* ***2nd Qtr 08/09:*** *Provisions contained in SB 821:* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* ***New Provisions*** • *4112 – Non-resident Pharmacy: Registration Required* • *4146 – Return and Disposal of Sharps* • *4013 – Subscriber Alert*

	3rd Qtr 08/09: *Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.* *Jan. 2010:* *Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.* ***Omnibus Proposal #1:*** *(1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)* • *§650.1 – Lease Prohibition – Hospitals or Prescribers* • *§652 – Violation of Unprofessional Conduct* • *§4017 – Authorized Officers of the Law* • *§4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *§4028 – Definition of Licensed Hospital* • *§4037 – Definition of Pharmacy* • *§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations* • *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions.* • *§4072 – Oral or Electronic Transmission of Prescription – Health Care Facility* • *§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies* • *§4127.1 – License to Compound Injectable Sterile Drug Products Required* • *§4169 – Prohibited Acts (also, strike operative date of 2008)* • *§4181 – License Requirements; Policies and Procedures; Who May Dispense* • *§4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs* *(2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)* • *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions* *(3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)* • *§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring* • *§4426 – Department of Health Care Services to Study Reimbursement Rates* ***Omnibus Proposal #2*** *(1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge* *(2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)* *(3) Add §4362 – Pharmacists Recovery Program* *3rd Qtr 09/10:* *Provisions contained in SB 1489 (Senate Business, Professions, and Economic Development Committee)*

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: *Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.*

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: *Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

Aug. 2008: *Regulatory effort initiated. (See Objective 3.2, Task 12)*

Oct. 2009: *Board approves regulatory language for Initial Notice.*

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*

Sept. 2008: *Governor signs SB 1307 which delays implementation of e-pedigree.*

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

Oct. 2007: *Governor signs the following:*

AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.

SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.

SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.

Governor vetoes the following:

AB 249 (Eng) Healing Arts: Settlement Agreements.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.

AB 1025 (Bass) Professions and Vocations: Denial of Licensure.

SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.

Oct. 2008: *Governor signs the following:*

AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks

SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review

Governor vetoes the following:

AB 501 (Swanson) Pharmaceutical Devices

AB 865 (Davis) State Agencies

AB1574 (Plescia) Surgical Clinics: Licensure

Jan. 2009: *Legislation introduced affecting Pharmacy law:*

(New Session) *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.*

SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.

	4th Qtr 08/09:	*AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements* *AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License* *AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012* *AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid* *AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice* *AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container* *AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)* *AB 1370 (Solorio) "Best Before" Date on a Prescription Label* *AB 1458 (Davis) Drugs: Adverse Effects Reporting* *SB 26 (Simitian) Home-Generated Pharmaceutical Waste* *SB 43 (Alquist) Cultural and Linguistic Competency* *SB 238 (Calderon) Medical Information* *SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs* *SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus* *SB 484 (Wright) Ephedrine Products to Schedule V* *SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews* *SB 762 (Aanestad) Professions and Vocations; Healing Arts* *AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012* *AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid* *AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container* *AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)* *SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus* *SB 484 (Wright) Ephedrine Products to Schedule V* *SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews* *SB 762 (Aanestad) Professions and Vocations; Healing Arts*
	1st Qtr 09/10:	*Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts*
	2nd Qtr 09/10:	*Governor signs SB 819 (Omnibus)* *Governor signs SB 821 (Omnibus)* *Governor signs SB 470 (Corbett) - "Purpose"* *Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset* *Governor signs AB 931 (Fletcher) - Emergency Supplies Container* *Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia*

	3rd Qtr 09/10: *Board considers new legislation* *1. Board of Pharmacy* • *AB 2104 (Hayashi) – California State Board of Pharmacy* • *SB 1390 (Corbett) – Prescription Container Labels* *2. Pharmacy Practice* • *AB 1869 (Anderson) – Pharmacy (spot bill)* • *AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors* *3. Sunset Review and Legislative Oversight Proposals* • *AB 1659 (Huber) – State Government, Agency Repeals* • *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection* • *SB 954 (Harmon) – Legislative Procedure, Committee Referrals* • *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations* • *SB 1172 (Negrete McLeod) – Sunset of Diversion Program* *4. Regulation of Dangerous Drugs and Devices* • *AB 1455 (Hill) -- Pseudoephredrine* • *AB 2548 (Block) – CURES – Prescription Drug Monitoring Program* • *SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products* • *SB 1071 (DeSaulnier) – CURES* • *SB 1106 (Yee) – Prescribers – Dispensing of Samples* *5. Pharmacy Licensing Issues* • *AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies* • *AB 2292 (Lowenthal) – Pharmacy: Clinics* • *AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program* *6. Distribution of Needles and Syringes* • *AB 1701 (Chesbro) – Hypodermic Needles and Syringes* • *AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services* • *AB 2139 (Chesbro) – Solid Waste: Product Stewardship* • *SB 1029 (Yee) -- Hypodermic Needles and Syringes* *7. General / Other* • *AB 2112 (Monning) – Prescription Record Privacy Act*

	7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol. *March 2007:* *Licensing Committee considers and approves concept. More work is required.* *June 2007:* *Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.* *Sept. 2007:* *Licensing Committee forwards to full board legislative proposal.* *Oct. 2007:* *Board approved draft legislation.* *Nov. 2007:* *Staff meeting with stakeholders to elicit support for the proposal.* *Dec. 2007:* *Staff develop fact sheets and work with experts in immunizations.* *Feb. 2009:* *Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.* *April 2009:* *Bill amended to allow pharmacists to initiate and administer pneumonoccocal and influenza vaccines.* *May 2009:* *Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)* *Jan. 2010:* *Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.* *Jan. 2010:* *AB 977 passes out of Assembly Health Committee*

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

Oct. 2007: *Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*

Apr. 2008: *First public forum held in Fremont.*

May 2008: *Staff develop survey form to distribute to consumers to solicit input*
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.

June 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

July 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

Oct. 2008: *Staff continues to attend community events, interview attendees about prescription label and distribute surveys.*
Public Education Committee updated on the status of survey results.

Feb. 2009: *Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.*

May 2009: *Bill passes out of the Senate*

Oct. 2009: *Governor signs SB 470 (Chapter 590, Statutes of 2009).*

Oct. 2009: *Board approves regulatory language for notice.*

Nov. 2009: *Regulatory effort initiated (See Objective 3.2, Task 16)*

9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.

Dec. 2008: *Board receives findings of independent fee audit.*

Jan. 2009: *Board votes to pursue fee increase.*

Feb. 2009: *Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.*

June 2009: *Bill passes out of the Assembly.*

Sept. 2009: *Bill is enrolled and sent to the Governor.*

Sept. 2009: *Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.*

Oct. 2009: *Governor signs AB 1071 (Chapter 270, Statutes of 2009)*

Jan. 2010: *Statutory fee schedule implemented (supersedes 16 CCR 1749)*

10. Advocate legislation to enhance the board's enforcement activities.

Jan. 2010: *Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):*
Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory,
Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). *Jan. 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). *Jan. 2007:* *Regulation takes effect following approval by the Office of Administrative Law.* 3. Make technical changes in pharmacy regulations to keep the code updated. *April 2007:* *Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.* *June 2007:* *Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.* 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). *March 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 5. Revise and update Disciplinary Guidelines revision and update (section 1760). *Oct. 2007:* *Board approves Disciplinary Guidelines for 45-day comment period.* *May 2009:* *Regulation approved and takes effect.* 6. Self-assessment of a wholesaler by the designated representative (section 1784). *April 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 7. Exempt the address of records of interns from display on the board's Website (section 1727.1). *Sept. 2006:* *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.*
	8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. *July 2006:* *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.* *June 2007:* *Board staff submit rulemaking file to the California Building Standards Commission.* 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). *Feb. 2007:* *Board notices regulation for 45 days comment period.* *Nov. 2007:* *Regulation changes takes effect.* *Jul. 2008:* *Board mails updated Notice to Consumers to all pharmacies in California.*

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

Dec. 2007: *Office of Administrative Law approves Section 100 Changes.*
Amend the following:
1707 – Waiver of requirements for off-site storage of records
1709.1 – Designation of pharmacist-in-charge
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge
1717 – Pharmacy practice
1746 – Emergency contraception
1780.1 – Minimum standards for veterinary food-animal drug retailers
1781 – Exemption certificate
1787 – Authorization to distribute dialysis drugs and devices
1790 – Assembling and packaging
1793.8 – Technician check technician
Repeal section 1786 – Exemptions

March 2009: *Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*

11. Increase fees to keep the board's contingency fund solvent and maintain operations.

Nov. 2007: *Office of Administrative Law approves rulemaking.*
Nov. 2007: *Staff complete necessary programming changes and begin advising licensees of the change.*
Jan. 1, 2008: *New fees take effect.*
Oct. 2009: *Governor signs AB 1071, new fee schedule.*
Jan. 2010: *Statutory fee schedule becomes effective (supersedes 16 CCR §1749)*

12. Secure regulatory standards for pharmacies that compound.

Nov. 2007: *Board releases language for the 45-day comment period.*
Jan. 2010: *Office of Administrative Law approves regulation.*

13. Establish an ethics course.

Sep. 2008: *Board notices regulation for 45-day comment period.*
Sep. 2009: *Regulation takes effect.*

14. Pharmacist Renewal Requirements

Dec. 2009: *Board notices regulation for 45-day comment period.*
Feb. 2010: *Board adopts regulation.*
Rulemaking submitted to department.

15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions

Oct. 2009: *Board notices regulation for 45-day comment period.*
Jan. 2010: *Board adoption of regulation as noticed.*
March 2010: *Rulemaking submitted to department.*

16. Standardized, Patient-Centered Prescription Labels

Oct. 2009: *Board approves language to initiate rulemaking.*
Nov. 2009: *Board notices regulation for 45-day comment period.*
Jan. 2010: *Regulation hearing scheduled.*
Feb. 2010: *Board considers comments and votes to pursue 15 day comment period.*

17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Jan. 2010: *Board to consider approval of draft regulation to correct a typographical error in the Emergency Contraception Protocol regulation (16 CCR §1746(b)(11)).*

	18. Board Issued Continuing Education (CE) Credit ***Feb. 2010:*** *Board votes to amend section 1732.2 defining board issued CE.*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	1. Initiate review of the pharmacist-in-charge requirement. *Aug. 2007:* *Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.* *Oct. 2007:* *Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.* *Jan. 2008:* *Board approves omnibus language recommended by Legislation and Regulation Committee.* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *April 2008:* *The following provisions are not incorporated into omnibus bill.* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* *Sept. 2008:* *Governor vetoes SB 1779.* *Jan. 2009:* *Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821.* *Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.* *Sept. 2009:* *SB 819 and SB 821 enrolled and sent to the Governor.* *Oct. 2009:* *Governor signs SB 819 and SB 821. Provisions go into effect January 2010.*