



Legislation and Regulation Committee

Kenneth Schell, PharmD, Chair
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member
Shirley Wheat, Public Member
Tappan Zee, Public Member

PART 2: LEGISLATION REPORT AND ACTION

Including a report of the meeting held July 14, 2010

a. Board Sponsored Legislation

ATTACHMENT 1

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

Background

Last Amendment: June 17, 2010

Current Status: Assembly Appropriations

On January 20, 2010, the board voted to support the inclusion of several amendments in the Senate Business Professions and Economic Development Committee's Omnibus measure for 2010. SB 1489 was introduced on March 11, 2010 and included the board's requested proposals. This bill has been amended three times, most recently on June 17, 2010. The provisions affecting Pharmacy Law that are contained in SB 1489 are listed below, and a copy of the bill is provided in Attachment 1.

General Omnibus Provisions

§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 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).

§4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4 time 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 been corrected to restore the provision to law without a sunset date.

§4101 – Veterinary Food-Animal Drug Retailer

Provisions to Update References to the Department of Public Health (reflecting its new name):

§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

Provision to Correctly Reference 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

Provisions to Correct 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

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

Request

Chair Schell suggests that the board may wish to discuss from a policy perspective the amendment to Business and Professions Code section 4013 as reflected in the June 17, 2010, version of the bill.

Committee Discussion / Action

Chair Schell advised that the June 17, 2010 version of the bill includes a modification to Business and Professions Code section 4013. The amendment has been incorporated at the request of industry, which had concerns about the implementation of the e-mail notification requirement that took effect July 1, 2010. He advised that board staff provided some technical input on the drafting of the language to ensure that the intent of the section was not altered as a result of the proposed change, which was accepted by staff of the Business, Professions and Economic Development Committee and subsequently amended into the bill. He stated that the board has not discussed this from a policy perspective and may wish to do so.

Recent Updates

SB 1489 has been scheduled for hearing in Assembly Appropriations on August 4, 2010.

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

ATTACHMENT 2

1. Board of Pharmacy

AB 2104 (Hayashi) – California State Board of Pharmacy

Background

This bill would authorize the Board of Pharmacy, with the approval of the Department of Consumer Affairs, to appoint the Executive Officer of the Board. A copy of the June 24, 2010, version is provided in Attachment 2.

The previous version of the bill would have authorized the Governor to appoint the executive officer and would have required the board to receive DCA approval before sponsoring or taking positions on legislation; the bill also would have defined ex parte communications and establish reporting requirements for board members that engage in such communications.

Last Amendment: June 24, 2010

Current Status: Referred to Senate Appropriations (6/29/10).
As of July 21, the bill has not yet been scheduled for hearing.

Committee Discussion / Action

Chair Schell provided that this bill has been recently amended to authorize the Board of Pharmacy, with the approval of the Department of Consumer Affairs, to appoint the Executive Officer of the Board. He stated that in April 2010, the board established a position to Oppose AB 2104 (April 8 version).

Chair Schell stated that the bill passed out of the Senate Business, Professions and Economic Development Committee on June 28, and was referred to Senate Appropriations. He stated this bill specifically targets the Board of Pharmacy, adding that the bill should be applicable to all healing arts boards. DCA does not have a position on the current version of the bill.

Committee Recommendation: Maintain position of Oppose on AB 2104

SB 1390 (Corbett) – Prescription Container Labels

Background

Previous versions of the 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. Copies of the June 15 and April 26 versions of the bill are provided in Attachment 2.

Last Amendment: June 15, 2010

Current Status: Failed passage in Assembly Business Professions and Consumer Protection (6/29/10)

Committee Discussion / Action

Chair Schell advised the committee that SB 1390 as amended June 15 established statutory requirements for patient-centered prescription drug container labels, and that the bill failed passage in the Assembly Committee on Business Professions and Consumer Protection.

The committee did not take action on this bill.

2. Sunset Review and Legislative Oversight Proposals

AB 1659 (Huber) – State Government, Agency Repeals

Background

This bill creates a new Joint 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. A copy of the July 15 amendment is provided in Attachment 2.

Last Amendment: July 15, 2010

Current Status: Hearing in Senate Appropriations scheduled for August 2, 2010

Committee Discussion / Action

Chair Schell advised the committee that the bill passed out of the Senate Committee on Business, Professions and Economic Development. He added that the board has no position on the bill.

Committee Recommendation: Recommendation to the board to not establish a position on AB 1659.

Recent Updates

The July 15, 2010, amendment specifies that the Senate Committee on Rules (not the President pro Tempore of the Senate) appoint five of the 10 members of the committee.

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

Background

AB 2130 is a related bill to 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. A copy of the June 22 version of the bill is provided in Attachment 2.

Last Amendment: June 22, 2010

Current Status: Hearing in Senate Appropriations scheduled for August 2, 2010

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.

Committee Discussion / Action

Chair Schell summarized the scope bill and added that the board does not have a position on the bill. He stated that the bill passed out of the Senate Committee on Business, Professions and Economic Development (6/29/10), and was referred to the Senate Committee on Rules.

Committee Recommendation: Recommendation to the board to not establish a position on AB 2130.

3. Regulation of Dangerous Drugs and Devices

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

Background

This bill, sponsored by the Hemophilia Council of California, establishes the “Standards of Service for Providers of Blood Clotting Products for Home Use Act.” 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. A copy of the June 23 version of the bill is provided in Attachment 2.

Last Amendment: June 23, 2010

Current Status: Scheduled for hearing in Assembly Appropriations August 4, 2010

Committee Discussion / Action

Chair Schell advised that the board currently regulates pharmacies that provide blood clotting products for home use. He added that the board has not taken a position on this bill.

A representative from the Department of Consumer Affairs stated the department has taken an Oppose position on SB 971. He added that DCA does not believe the bill is necessary or that an existing problem has been identified.

Committee Recommendation: Recommendation to the board to not establish a position on SB 971.

SB 1071 (DeSaulnier) – CURES

Background

SB 1071 creates a fund to support the Controlled Substance Utilization Review and Evaluation System (CURES) and imposes a tax on every manufacturer, importer, or other person that makes the first sale of a controlled substance classified as Schedule II, III or IV at the rate of \$0.0025 for each pill sold. A copy of the June 16 version of the bill is provided in Attachment 2.

Last Amendment: June 16, 2010

Current Status: In Senate Health Committee. Hearing canceled at the request of the author (6/16/10).

Committee Discussion / Action

Chair Schell advised the committee of the current status of the bill, adding that the board has not taken a position on this bill. The committee did not take any action on this bill.

SB 1106 (Yee) – Prescribers – Dispensing of Samples

Background

SB 1106 would require a prescriber, dispensing a drug sample or starter kit, to 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.

At the April 2010 Board Meeting, the board established a Support if Amended position, if amended to clarify that the drug informational material required to be provided to patients by a practitioner dispensing a drug sample or starter kit is the same that a pharmacy must provide to patients when dispensing a drug. (Discussions during hearings and with the author indicated that this is the intent of the bill.)

This bill was passed to the Assembly on April 22. It passed out of Assembly Business, Professions and Consumer Protection on June 29 and was re-referred to Assembly Appropriations. A copy of the April 5th amendment is provided in Attachment 2.

Last Amendment: April 5, 2010

Current Status: Hearing in Assembly Appropriations Scheduled for August 4, 2010.

Committee Discussion / Action

The committee discussed the intent of the bill with regard to the specific information required to accompany a drug dispensed by a physician. It was stated that the board's mission is consistent with the intent of the bill as it relates to consumers properly taking their medications.

Public comment included a recommendation that the bill be amended to apply to all physician dispensing, not just drug samples or starter kits.

Committee Recommendation: Recommendation to the board to maintain its current position of Support if Amended on SB 1106.

4. Pharmacy Licensing Issues

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Background

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.

As amended on June 23, 2010, AB 2077 requires bar coding, allows for anticipatory unit dose packaging to ensure continuity of care, and also specifies that a hospital pharmacy utilizing the centralized packaging must notify the board in writing and in advance of utilizing a centralized packaging pharmacy and upon the closure or discontinued use of a facility. A copy of the June 23 version of the bill is provided in Attachment 2.

Last Amendment: June 23, 2010

Current Status: Referred to Senate Appropriations. As of July 21, no hearing has been scheduled.

Committee Discussion / Action

Chair Schell advised the committee that AB 2077 passed out of the Senate Committee on Business, Professions and Economic Development and was referred to Senate Appropriations. He stated that the board supported key provisions now incorporated in the bill (those which were formerly contained in Solorio's AB 1370).

Committee Recommendation: Recommendation to the board to establish a position of Support on AB 2077

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

Background

As amended on April 26, 2010, AB 2551 establishes the California Pharmacy Technician Scholarship and Loan Repayment Program within the Health Professions Education Foundation. This program will be administered by the Office of Statewide Health Planning and Development for the purpose of providing scholarships to pay for educational expenses of pharmacy technician school students and to repay qualifying educational loans to pharmacy technicians who agree to participate in medically underserved areas. The bill allows the Health Professions Education Foundation to solicit and receive funds from business, industry, foundations and other private and public sources.

The bill passed the Senate Committee on Health (6/21/10) and was re-referred to Senate Appropriations. A copy of the April 26th version of the bill is provided in Attachment 2.

Last Amendment: April 26, 2010

Current Status: In Senate Committee on Appropriations.
Hearing scheduled for August 2, 2010

Committee Discussion / Action

Chair Schell stated that the board has no established position on this bill. Ms. Sodergren indicated that this bill establishes independent funding sources instead of requiring licensee contributions, as required by other bills that have been before the board.

Committee Recommendation: Recommendation to the board to not establish a position on
AB 2551

5. Distribution of Needles and Syringes

AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Background

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. A copy of the introduced version of AB 1701 is provided in Attachment 2.

The bill passed out of the Senate Committee on Health on June 23, as amended. However, as of July 21, amendments are not yet in print. The bill was referred to Senate Appropriations.

Current Version (in print): April 26, 2010 (Introduced)

Current Status: In Senate Committee on Appropriations.
Hearing scheduled for August 2, 2010

Committee Discussion / Action

Chair Schell advised that at the April 2010 Board Meeting, the board established a position of Support on AB 1701. He indicated that as amended, the bill would extend the sunset date of the Disease Prevention Demonstration Project for eight years – not repeal it. However, the amendments are not yet in print.

Committee Recommendation: Recommendation to the board to maintain a position of Support on
AB 1701

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

Background

AB 1858 allows the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease through the sharing of unclean hypodermic needles and syringes. As amended July 15, 2010, the bill requires an entity to submit an application to CDPH prior to implementing its program, and also requires that a 45-day public comment period lapse prior to approval of any program. Further, the bill specifies that a participant in a clean needle & syringe exchange program shall not be subject to criminal prosecution for possession of needles and syringes acquired under an approved program.

A copy of the June 10 and July 15 amendments are provided in Attachment 2.

Last Amendment: July 15, 2010

Current Status: In Senate Committee on Appropriations.
Hearing scheduled for August 2, 2010

Committee Discussion / Action

The committee discussed the content of the June 10th version of the bill and provided the recommendation below.

Committee Recommendation: Recommendation to the board to maintain no position on AB 1858, as amended June 10, 2010.

Recent Updates

The bill was amended on July 15, 2010, to require that in order to be authorized by the California Department of Public Health (CDPH) to conduct a clean needle and syringe exchange program, that the entity be required to submit an application to CDPH, and that the application shall demonstrate the entities compliance with minimum standards, as defined in the bill. A 45-day public comment period would be required prior to approval by CDPH. The bill would also specify that participants in a clean needle and syringe exchange program as approved by CDPH would not be subject to criminal prosecution for possession of needles and syringes acquired under the program.

SB 1029 (Yee) – Hypodermic Needles and Syringes

Background

SB 1029 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 30 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; and requires pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment. A copy of the June 23 version of the bill is provided in Attachment 2.

Last Amendment: June 23, 2010

Current Status: In Assembly Committee on Appropriations.
Hearing scheduled for August 4, 2010

Committee Discussion / Action

Chair Schell provided the committee with a summary of the bill's scope and current status. He added that the board does not have a position on this bill.

Committee Recommendation: Recommendation to the board to maintain no position on SB 1029

6. General / Other

SB 1172 (Negrete McLeod) – Diversion Programs

Background

This bill requires specified healing arts boards (including the Board of Pharmacy) to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the Licensees probation or diversion program. This bill also allows a healing arts board to adopt regulations authorizing the board to order a licensee (on probation or in a diversion program) to cease practice for (1) major violations or (2) when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to uniform and specific standards, as specified.

Committee Discussion / Action

Chair Schell summarized the bill and indicated that the board has not established a position on the bill. Ms. Herold stated that participants in the Pharmacists Recovery Program (PRP) who test positive for any prohibited substance currently are removed from work pending the receipt of two negative tests. She stated that pharmacy technicians are not included in the PRP.

Ms. Sodergren added that a cease practice for a positive test is typically called for in the terms and conditions of a licensee's probation. She provided an overview on the 16 standards established by the Substance Abuse Coordination Committee as required by SB 1441. Ms. Sodergren added that the board has not formally vetted those standards. She further advised that the Board of Registered Nursing has been amended out of SB 1172, so its provisions will not affect nurses who test positive. A representative from the Department of Consumer Affairs indicated that DCA does not have a position on the bill.

Committee Recommendation: Recommend to the board to maintain no position on SB 1172.

7. Other Legislation Impacting the Board's Jurisdiction

ATTACHMENT 1

AMENDED IN ASSEMBLY JUNE 17, 2010

AMENDED IN SENATE APRIL 26, 2010

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, 2516, 2530.2, 2539.1, 2570.19, 3025.1, 3046, 3057.5, 3147, 3147.6, 3147.7, 3365.5, 4013, 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. 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

1 licensee shall, prior to fitting or selling a hearing aid to any
2 individual, suggest to that individual in writing that his best
3 interests would be served if he would consult a licensed physician
4 specializing in diseases of the ear or if no such licensed physician
5 is available in the community then to a duly licensed physician:

- 6 (1) Visible congenital or traumatic deformity of the ear.
- 7 (2) History of, or active drainage from the ear within the
8 previous 90 days.
- 9 (3) History of sudden or rapidly progressive hearing loss within
10 the previous 90 days.
- 11 (4) Acute or chronic dizziness.
- 12 (5) Unilateral hearing loss of sudden or recent onset within the
13 previous 90 days.
- 14 (6) Significant air-bone gap (when generally acceptable
15 standards have been established).
- 16 (7) *Visible evidence of significant cerumen accumulation or a*
17 *foreign body in the ear canal.*
- 18 (8) *Pain or discomfort in the ear.*

19 No ~~such~~ referral for medical opinion need be made by any
20 licensee in the instance of replacement only of a hearing aid ~~which~~
21 *that* has been lost or damaged beyond repair within one year of
22 the date of purchase. A copy of the written recommendation shall
23 be retained by the licensee for the period provided for in Section
24 3366. A person receiving the written recommendation who elects
25 to purchase a hearing aid shall sign a receipt for the same, and the
26 receipt shall be kept with the other papers retained by the licensee
27 for the period provided for in Section 3366. Nothing in this section
28 required to be performed by a licensee shall mean that the licensee
29 is engaged in the diagnosis of illness or the practice of medicine
30 or any other activity prohibited by the provisions of this code.

31 *SEC. 19. Section 4013 of the Business and Professions Code*
32 *is amended to read:*

33 4013. (a) Any facility licensed by the board shall join the
34 board's e-mail notification list within 60 days of obtaining a license
35 or at the time of license renewal.

36 (b) Any facility licensed by the board shall update its e-mail
37 address with the board's e-mail notification list within 30 days of
38 a change in the facility's e-mail address.

39 (c) *An owner of two or more facilities licensed by the board*
40 *may comply with subdivisions (a) and (b) by subscribing a single*

1 *e-mail address to the board’s e-mail notification list, where the*
2 *owner maintains an electronic notification system within all of its*
3 *licensed facilities that, upon receipt of an e-mail notification from*
4 *the board, immediately transmits electronic notice of the same*
5 *notification to all of its licensed facilities. If an owner chooses to*
6 *comply with this section by using such an electronic notice system,*
7 *the owner shall register the electronic notification system with the*
8 *board by July 1, 2011, or within 60 days of initial licensure,*
9 *whichever is later, informing the board of the single e-mail address*
10 *to be utilized by the owner, describing the electronic notification*
11 *system, and listing all facilities to which immediate electronic*
12 *notification will be provided.*

13 (e)

14 (d) This section shall become operative on July 1, 2010.

15 ~~SEC. 16.~~

16 *SEC. 20.* Section 4017 of the Business and Professions Code
17 is amended to read:

18 4017. “Authorized officers of the law” means inspectors of the
19 California State Board of Pharmacy, inspectors of the Food and
20 Drug Branch of the State Department of Public Health, and
21 investigators of the department’s Division of Investigation or peace
22 officers engaged in official investigations.

23 ~~SEC. 17.~~

24 *SEC. 21.* Section 4028 of the Business and Professions Code
25 is amended to read:

26 4028. “Licensed hospital” means an institution, place, building,
27 or agency that maintains and operates organized facilities for one
28 or more persons for the diagnosis, care, and treatment of human
29 illnesses to which persons may be admitted for overnight stay, and
30 includes any institution classified under regulations issued by the
31 State Department of Public Health as a general or specialized
32 hospital, as a maternity hospital, or as a tuberculosis hospital, but
33 does not include a sanitarium, rest home, a nursing or convalescent
34 home, a maternity home, or an institution for treating alcoholics.

35 ~~SEC. 18.~~

36 *SEC. 22.* Section 4037 of the Business and Professions Code
37 is amended to read:

38 4037. (a) “Pharmacy” means an area, place, or premises
39 licensed by the board in which the profession of pharmacy is
40 practiced and where prescriptions are compounded. “Pharmacy”

1 includes, but is not limited to, any area, place, or premises
2 described in a license issued by the board wherein controlled
3 substances, dangerous drugs, or dangerous devices are stored,
4 possessed, prepared, manufactured, derived, compounded, or
5 repackaged, and from which the controlled substances, dangerous
6 drugs, or dangerous devices are furnished, sold, or dispensed at
7 retail.

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

15 ~~SEC. 19.~~

16 *SEC. 23.* Section 4052.3 of the Business and Professions Code
17 is amended to read:

18 4052.3. (a) Notwithstanding any other provision of law, a
19 pharmacist may furnish emergency contraception drug therapy in
20 accordance with either of the following:

21 (1) Standardized procedures or protocols developed by the
22 pharmacist and an authorized prescriber who is acting within his
23 or her scope of practice.

24 (2) Standardized procedures or protocols developed and
25 approved by both the board and the Medical Board of California
26 in consultation with the American College of Obstetricians and
27 Gynecologists, the California Pharmacist Association, and other
28 appropriate entities. Both the board and the Medical Board of
29 California shall have authority to ensure compliance with this
30 clause, and both boards are specifically charged with the
31 enforcement of this provision with respect to their respective
32 licensees. Nothing in this clause shall be construed to expand the
33 authority of a pharmacist to prescribe any prescription medication.

34 (b) Prior to performing a procedure authorized under this
35 paragraph, a pharmacist shall complete a training program on
36 emergency contraception that consists of at least one hour of
37 approved continuing education on emergency contraception drug
38 therapy.

39 (c) A pharmacist, pharmacist’s employer, or pharmacist’s agent
40 may not directly charge a patient a separate consultation fee for

1 emergency contraception drug therapy services initiated pursuant
2 to this paragraph, but may charge an administrative fee not to
3 exceed ten dollars (\$10) above the retail cost of the drug. Upon an
4 oral, telephonic, electronic, or written request from a patient or
5 customer, a pharmacist or pharmacist's employee shall disclose
6 the total retail price that a consumer would pay for emergency
7 contraception drug therapy. As used in this subparagraph, total
8 retail price includes providing the consumer with specific
9 information regarding the price of the emergency contraception
10 drugs and the price of the administrative fee charged. This
11 limitation is not intended to interfere with other contractually
12 agreed-upon terms between a pharmacist, a pharmacist's employer,
13 or a pharmacist's agent, and a health care service plan or insurer.
14 Patients who are insured or covered and receive a pharmacy benefit
15 that covers the cost of emergency contraception shall not be
16 required to pay an administrative fee. These patients shall be
17 required to pay copayments pursuant to the terms and conditions
18 of their coverage. The provisions of this subparagraph shall cease
19 to be operative for dedicated emergency contraception drugs when
20 these drugs are reclassified as over-the-counter products by the
21 federal Food and Drug Administration.

22 (d) A pharmacist may not require a patient to provide
23 individually identifiable medical information that is not specified
24 in Section 1707.1 of Title 16 of the California Code of Regulations
25 before initiating emergency contraception drug therapy pursuant
26 to this section.

27 (e) For each emergency contraception drug therapy initiated
28 pursuant to this section, the pharmacist shall provide the recipient
29 of the emergency contraception drugs with a standardized factsheet
30 that includes, but is not limited to, the indications for use of the
31 drug, the appropriate method for using the drug, the need for
32 medical followup, and other appropriate information. The board
33 shall develop this form in consultation with the State Department
34 of Public Health, the American College of Obstetricians and
35 Gynecologists, the California Pharmacists Association, and other
36 health care organizations. The provisions of this section do not
37 preclude the use of existing publications developed by nationally
38 recognized medical organizations.

1 ~~SEC. 20.~~

2 *SEC. 24.* Section 4059 of the Business and Professions Code
3 is amended to read:

4 4059. (a) A person may not furnish any dangerous drug, except
5 upon the prescription of a physician, dentist, podiatrist, optometrist,
6 veterinarian, or naturopathic doctor pursuant to Section 3640.7. A
7 person may not furnish any dangerous device, except upon the
8 prescription of a physician, dentist, podiatrist, optometrist,
9 veterinarian, or naturopathic doctor pursuant to Section 3640.7.

10 (b) This section does not apply to the furnishing of any
11 dangerous drug or dangerous device by a manufacturer, wholesaler,
12 or pharmacy to each other or to a physician, dentist, podiatrist,
13 optometrist, veterinarian, or naturopathic doctor pursuant to Section
14 3640.7, or to a laboratory under sales and purchase records that
15 correctly give the date, the names and addresses of the supplier
16 and the buyer, the drug or device, and its quantity. This section
17 does not apply to the furnishing of any dangerous device by a
18 manufacturer, wholesaler, or pharmacy to a physical therapist
19 acting within the scope of his or her license under sales and
20 purchase records that correctly provide the date the device is
21 provided, the names and addresses of the supplier and the buyer,
22 a description of the device, and the quantity supplied.

23 (c) A pharmacist, or a person exempted pursuant to Section
24 4054, may distribute dangerous drugs and dangerous devices
25 directly to dialysis patients pursuant to regulations adopted by the
26 board. The board shall adopt any regulations as are necessary to
27 ensure the safe distribution of these drugs and devices to dialysis
28 patients without interruption thereof. A person who violates a
29 regulation adopted pursuant to this subdivision shall be liable upon
30 order of the board to surrender his or her personal license. These
31 penalties shall be in addition to penalties that may be imposed
32 pursuant to Section 4301. If the board finds any dialysis drugs or
33 devices distributed pursuant to this subdivision to be ineffective
34 or unsafe for the intended use, the board may institute immediate
35 recall of any or all of the drugs or devices distributed to individual
36 patients.

37 (d) Home dialysis patients who receive any drugs or devices
38 pursuant to subdivision (c) shall have completed a full course of
39 home training given by a dialysis center licensed by the State
40 Department of Public Health. The physician prescribing the dialysis

1 products shall submit proof satisfactory to the manufacturer or
2 wholesaler that the patient has completed the program.

3 (e) A pharmacist may furnish a dangerous drug authorized for
4 use pursuant to Section 2620.3 to a physical therapist. A record
5 containing the date, name and address of the buyer, and name and
6 quantity of the drug shall be maintained. This subdivision shall
7 not be construed to authorize the furnishing of a controlled
8 substance.

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

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

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

24 ~~SEC. 21.~~

25 *SEC. 25.* Section 4072 of the Business and Professions Code
26 is amended to read:

27 4072. (a) Notwithstanding any other provision of law, a
28 pharmacist, registered nurse, licensed vocational nurse, licensed
29 psychiatric technician, or other healing arts licentiate, if so
30 authorized by administrative regulation, who is employed by or
31 serves as a consultant for a licensed skilled nursing, intermediate
32 care, or other health care facility, may orally or electronically
33 transmit to the furnisher a prescription lawfully ordered by a person
34 authorized to prescribe drugs or devices pursuant to Sections 4040
35 and 4070. The furnisher shall take appropriate steps to determine
36 that the person who transmits the prescription is authorized to do
37 so and shall record the name of the person who transmits the order.
38 This section shall not apply to orders for Schedule II controlled
39 substances.

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

6 ~~SEC. 22.~~

7 *SEC. 26.* Section 4101 of the Business and Professions Code
8 is amended to read:

9 4101. (a) A pharmacist may take charge of and act as the
10 pharmacist-in-charge of a pharmacy upon application by the
11 pharmacy and approval by the board. Any pharmacist-in-charge
12 who ceases to act as the pharmacist-in-charge of the pharmacy
13 shall notify the board in writing within 30 days of the date of that
14 change in status.

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

23 ~~SEC. 23.~~

24 *SEC. 27.* Section 4119 of the Business and Professions Code
25 is amended to read:

26 4119. (a) Notwithstanding any other provision of law, a
27 pharmacy may furnish a dangerous drug or dangerous device to a
28 licensed health care facility for storage in a secured emergency
29 pharmaceutical supplies container maintained within the facility
30 in accordance with facility regulations of the State Department of
31 Public Health set forth in Title 22 of the California Code of
32 Regulations and the requirements set forth in Section 1261.5 of
33 the Health and Safety Code. These emergency supplies shall be
34 approved by the facility's patient care policy committee or
35 pharmaceutical service committee and shall be readily available
36 to each nursing station. Section 1261.5 of the Health and Safety
37 Code limits the number of oral dosage form or suppository form
38 drugs in these emergency supplies to 24.

39 (b) Notwithstanding any other provision of law, a pharmacy
40 may furnish a dangerous drug or a dangerous device to an approved

1 service provider within an emergency medical services system for
2 storage in a secured emergency pharmaceutical supplies container,
3 in accordance with the policies and procedures of the local
4 emergency medical services agency, if all of the following are
5 met:

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

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

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

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

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

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

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

34 ~~SEC. 24.~~

35 *SEC. 28.* Section 4127.1 of the Business and Professions Code
36 is amended to read:

37 4127.1. (a) A pharmacy shall not compound injectable sterile
38 drug products in this state unless the pharmacy has obtained a
39 license from the board pursuant to this section. The license shall
40 be renewed annually and is not transferable.

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

9 (c) A license to compound injectable sterile drug products may
 10 not be renewed until the location has been inspected by the board
 11 and found to be in compliance with this article and regulations
 12 adopted by the board.

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

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

- 21 (1) The sterile powder was obtained from a manufacturer.
- 22 (2) The drug is reconstituted for administration to patients by
 23 a health care professional licensed to administer drugs by injection
 24 pursuant to this division.

25 ~~SEC. 25.~~

26 *SEC. 29.* Section 4169 of the Business and Professions Code
 27 is amended to read:

28 4169. (a) A person or entity may not do any of the following:

- 29 (1) Purchase, trade, sell, or transfer dangerous drugs or
 30 dangerous devices at wholesale with a person or entity that is not
 31 licensed with the board as a wholesaler or pharmacy.
- 32 (2) Purchase, trade, sell, or transfer dangerous drugs that the
 33 person knew or reasonably should have known were adulterated,
 34 as set forth in Article 2 (commencing with Section 111250) of
 35 Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
- 36 (3) Purchase, trade, sell, or transfer dangerous drugs that the
 37 person knew or reasonably should have known were misbranded,
 38 as defined in Section 111335 of the Health and Safety Code.
- 39 (4) Purchase, trade, sell, or transfer dangerous drugs or
 40 dangerous devices after the beyond use date on the label.

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

3 (b) Notwithstanding any other provision of law, a violation of
4 this section or of subdivision (c) or (d) of Section 4163 may subject
5 the person or entity that has committed the violation to a fine not
6 to exceed the amount specified in Section 125.9 for each
7 occurrence, pursuant to a citation issued by the board.

8 (c) Amounts due from any person under this section shall be
9 offset as provided under Section 12419.5 of the Government Code.
10 Amounts received by the board under this section shall be deposited
11 into the Pharmacy Board Contingent Fund.

12 (d) This section shall not apply to a pharmaceutical manufacturer
13 licensed by the Food and Drug Administration or by the State
14 Department of Public Health.

15 ~~SEC. 26.~~

16 *SEC. 30.* Section 4181 of the Business and Professions Code
17 is amended to read:

18 4181. (a) Prior to the issuance of a clinic license authorized
19 under Section 4180, the clinic shall comply with all applicable
20 laws and regulations of the State Department of Public Health
21 relating to the drug distribution service to ensure that inventories,
22 security procedures, training, protocol development, recordkeeping,
23 packaging, labeling, dispensing, and patient consultation occur in
24 a manner that is consistent with the promotion and protection of
25 the health and safety of the public. The policies and procedures to
26 implement the laws and regulations shall be developed and
27 approved by the consulting pharmacist, the professional director,
28 and the clinic administrator.

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

33 ~~SEC. 27.~~

34 *SEC. 31.* Section 4191 of the Business and Professions Code
35 is amended to read:

36 4191. (a) Prior to the issuance of a clinic license authorized
37 under this article, the clinic shall comply with all applicable laws
38 and regulations of the State Department of Public Health and the
39 board relating to drug distribution to ensure that inventories,
40 security procedures, training, protocol development, recordkeeping,

1 packaging, labeling, dispensing, and patient consultation are carried
2 out in a manner that is consistent with the promotion and protection
3 of the health and safety of the public. The policies and procedures
4 to implement the laws and regulations shall be developed and
5 approved by the consulting pharmacist, the professional director,
6 and the clinic administrator.

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

11 ~~SEC. 28.~~

12 *SEC. 32.* Section 4196 of the Business and Professions Code
13 is amended to read:

14 4196. (a) No person shall conduct a veterinary food-animal
15 drug retailer in the State of California unless he or she has obtained
16 a license from the board. A license shall be required for each
17 veterinary food-animal drug retailer owned or operated by a
18 specific person. A separate license shall be required for each of
19 the premises of any person operating a veterinary food-animal
20 drug retailer in more than one location. The license shall be
21 renewed annually and shall not be transferable.

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

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

38 (d) Every veterinary food-animal drug retailer shall be
39 supervised or managed by a designated representative-in-charge.
40 The designated representative-in-charge shall be responsible for

1 the veterinary food-animal drug retailer’s compliance with state
2 and federal laws governing veterinary food-animal drug retailers.
3 As part of its initial application for a license, and for each renewal,
4 each veterinary food-animal drug retailer shall, on a form designed
5 by the board, provide identifying information and the California
6 license number for a designated representative or pharmacist
7 proposed to serve as the designated representative-in-charge. The
8 proposed designated representative-in-charge shall be subject to
9 approval by the board. The board shall not issue or renew a
10 veterinary food-animal drug retailer license without identification
11 of an approved designated representative-in-charge for the
12 veterinary food-animal drug retailer.

13 (e) Every veterinary food-animal drug retailer shall notify the
14 board in writing, on a form designed by the board, within 30 days
15 of the date when a designated representative-in-charge who ceases
16 to act as the designated representative-in-charge, and shall on the
17 same form propose another designated representative or pharmacist
18 to take over as the designated representative-in-charge. The
19 proposed replacement designated representative-in-charge shall
20 be subject to approval by the board. If disapproved, the veterinary
21 food-animal drug retailer shall propose another replacement within
22 15 days of the date of disapproval, and shall continue to name
23 proposed replacements until a designated representative-in-charge
24 is approved by the board.

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

29 ~~SEC. 29.~~

30 *SEC. 33.* Section 4200.1 is added to the Business and
31 Professions Code, to read:

32 4200.1. (a) Notwithstanding Section 135, an applicant may
33 take the North American Pharmacist Licensure Examination four
34 times, and may take the California Practice Standards and
35 Jurisprudence Examination for Pharmacists four times.

36 (b) Notwithstanding Section 135, an applicant may take the
37 North American Pharmacist Licensure Examination and the
38 California Practice Standards and Jurisprudence Examination for
39 Pharmacists four additional times each if he or she successfully

1 completes, at a minimum, 16 additional semester units of education
2 in pharmacy as approved by the board.

3 (c) The applicant shall comply with the requirements of Section
4 4200 for each application for reexamination made pursuant to
5 subdivision (b).

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

10 (e) For purposes of this section, the board shall treat each failing
11 score on the pharmacist licensure examination administered by
12 the board prior to January 1, 2004, as a failing score on both the
13 North American Pharmacist Licensure Examination and the
14 California Practice Standards and Jurisprudence Examination for
15 Pharmacists.

16 ~~SEC. 30.~~

17 *SEC. 34.* Section 4425 of the Business and Professions Code
18 is amended to read:

19 4425. (a) As a condition for the participation of a pharmacy
20 in the Medi-Cal program pursuant to Chapter 7 (commencing with
21 Section 14000) of Division 9 of the Welfare and Institutions Code,
22 the pharmacy, upon presentation of a valid prescription for the
23 patient and the patient's Medicare card, shall charge Medicare
24 beneficiaries a price that does not exceed the Medi-Cal
25 reimbursement rate for prescription medicines, and an amount, as
26 set by the State Department of Health Care Services to cover
27 electronic transmission charges. However, Medicare beneficiaries
28 shall not be allowed to use the Medi-Cal reimbursement rate for
29 over-the-counter medications or compounded prescriptions.

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

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

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

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

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

11 (e) If prescription drugs are added to the scope of benefits
12 available under the federal Medicare program, the Senate Office
13 of Research shall report that fact to the appropriate committees of
14 the Legislature. It is the intent of the Legislature to evaluate the
15 need to continue the implementation of this article under those
16 circumstances.

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

19 ~~SEC. 31.~~

20 *SEC. 35.* Section 4426 of the Business and Professions Code
21 is amended to read:

22 4426. The State Department of Health Care Services shall
23 conduct a study of the adequacy of Medi-Cal pharmacy
24 reimbursement rates including the cost of providing prescription
25 drugs and services.

26 ~~SEC. 32.~~

27 *SEC. 36.* Section 4980.07 of the Business and Professions Code
28 is repealed.

29 ~~SEC. 33.~~

30 *SEC. 37.* Section 4980.40.5 of the Business and Professions
31 Code is amended to read:

32 4980.40.5. (a) A doctoral or master's degree in marriage,
33 family, and child counseling, marital and family therapy,
34 psychology, clinical psychology, counseling psychology, or
35 counseling with an emphasis in either marriage, family, and child
36 counseling, or marriage and family therapy, obtained from a school,
37 college, or university approved by the Bureau for Private
38 Postsecondary and Vocational Education as of June 30, 2007, shall
39 be considered by the board to meet the requirements necessary for
40 licensure as a marriage and family therapist and for registration

ATTACHMENT 2

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 2104

VERSION: As Amended June 24, 2010

AUTHOR: Hayashi

SPONSOR: Author Sponsored

BOARD POSITION: Oppose

SUBJECT: California State Board of Pharmacy

Affected Sections: Amend Business and Professions Code Section 4003

Current Status: Senate Appropriation (hearing date not set)

EXISTING LAW:

Authorizes the board to appoint an executive officer who shall exercise powers and perform duties delegated by the board.

THIS BILL WOULD:

Authorize the board, with the approval of the Department of Consumer Affairs, to appoint an executive officer.

AUTHOR'S INTENT:

According to the author, the author wishes to ensure that the Board is assured of choosing the best possible management of its functions, responsibilities, programs and board governance. Allowing both the Board and Director of the Department to choose an Executive Officer will ensure that the best qualified individual will be chosen to serve the Board.

FISCAL IMPACT:

We do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS:

This bill has been amended three times. As originally introduced, this bill would have required the governor to appoint the executive officer, required the board to report ex

parte communications as defined and specified as well as required the board to receive approval from the department for all legislation it sought to sponsor as well as require approval for all legislation the board wanted to take a position on. On May 28, 2010, the bill was amended to remove the ex parte reporting requirements. The proposal was heard in committee on June 21, 2010, but failed by a vote of 0-3. Reconsideration was granted, and the proposal was amended. The most recent amendments replaced the provisions requiring that the governor appoint the executive officer as well as the provisions regarding legislative approvals. In its current form, this proposal allows the board to appoint an executive officer after approval by the department.

The board voted to oppose this bill (as amended April 8, 2010) during its April 2010 Board Meeting. Since that time, board staff met with legislative staff and testified in committee hearings when appropriate, sent letters to legislators and developed a fact sheet.

There are currently five programs within the department that have a similar provision for approval in their statute. They include:

1. Acupuncture Board
2. Athletic Commission
3. Board of Barbering and Cosmetology
4. Contractors' State Licensing Board
5. Dental Board of California

It is important to note that in several of the above noted agencies, the authority for the director to approve the appointment of the executive officer was instituted when the board was sunsetted or had serious issues securing public protection issues.

SUPPORT and OPPOSITION:

SUPPORT

None on file (As of June 24, 2010)

OPPOSITION

Board of Pharmacy

HISTORY:

Date Action

June 29	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 0.) (June 28.)
June 24	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. On B., P. & E.D.
June 10	Referred to Com. on B., P. & E.D.
June 3	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 44. Noes 29. Page 5519.)
June 1	Read second time. To third reading.
May 28	From committee: Amend, and do pass as amended. (Ayes 11. Noes 6.) (May 28.) Read second time and amended. Ordered returned to second reading.
May 5	In committee: Set, first hearing. Referred to APPR. Suspense file.
Apr. 21	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 4.) (April 20.)

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 SENATE JUNE 24, 2010

AMENDED IN ASSEMBLY MAY 28, 2010

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 Section 4008.1 to, the Business and Professions Code, relating to pharmacy.~~ *An act to amend Section 4003 of 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. The department is under the control of the Director of Consumer Affairs.~~ 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~~ *board* 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 *with the approval of the director*.

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~~ *board, with the approval of the*
- 4 *director*, may appoint a person exempt from civil service who shall
- 5 be designated as an executive officer and who shall exercise the
- 6 powers and perform the duties delegated by the board and vested
- 7 in him or her by this chapter. The executive officer may or may
- 8 not be a member of the board as the ~~Governor~~ *board* may
- 9 determine.
- 10 (b) The executive officer shall receive the compensation as
- 11 established by the board with the approval of the Director of
- 12 Finance. The executive officer shall also be entitled to travel and
- 13 other expenses necessary in the performance of his or her duties.
- 14 (c) The executive officer shall maintain and update in a timely
- 15 fashion records containing the names, titles, qualifications, and
- 16 places of business of all persons subject to this chapter.
- 17 (d) The executive officer shall give receipts for all money
- 18 received by him or her and pay it to the ~~Department of Consumer~~
- 19 ~~Affairs~~ *department*, taking its receipt therefor. Besides the duties
- 20 required by this chapter, the executive officer shall perform other
- 21 duties pertaining to the office as may be required of him or her by
- 22 the board.
- 23 (e) In accordance with Sections 101.1 and 473.1, this section
- 24 shall remain in effect only until January 1, 2013, and as of that
- 25 date is repealed, unless a later enacted statute, that is enacted before
- 26 January 1, 2013, deletes or extends that date.

1 ~~SEC. 2. Section 4008.1 is added to the Business and Professions~~
2 ~~Code, to read:~~
3 ~~4008.1. The board shall submit to the department and receive~~
4 ~~prior approval for every piece of state legislation the board seeks~~
5 ~~to sponsor, support, or oppose. The board shall resubmit and~~
6 ~~receive subsequent approval from the department on the same~~
7 ~~legislation after any substantive amendments.~~

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1390

VERSION: As Amended June 15, 2010

AUTHOR: Corbett

SPONSOR: California Pan-Ethnic Health Network

BOARD POSITION: None

SUBJECT: Patient-Centered Prescription Labels

Affected Sections: Repeal and Add Business and Professions Code Section 4076.5
Add Business and Professions Code Sections 4076.7 & 4076.9

Current Status: Failed Passage in Assembly Business, Professions and Consumer Protection Committee

EXISTING LAW:

1. Defines the requirements for the prescription label.
2. Requires the board to promulgate regulations to create a patient-centered prescription label by January 1, 2011.

THIS BILL WOULD:

1. Repeal the patient-centered regulation provisions currently contained in B&PC 4076.5.
2. Require the board to develop, collect and publish on its web site the following:
 - a. Translations for the directions for use as specified, in a minimum of 14 languages.
 - b. Include all non-English languages identified by the Medi-Cal Managed Care Division within the Department of Health Care Services for the translations of vital documents.
 - c. Translations for any other primary languages for groups of 10,000 or more to facilitate use of those directions by pharmacies.
3. Specifies 16 standardized directions for use.
4. Requires the board to provide examples of conforming label designs to aid pharmacies.
5. Specifies that on or after January 1, 2012, all prescription labels dispensed to California patients shall conform to the following:
 - Clustering of specified elements - - patient name, drug name and strength, directions for use and purpose.

- Clustered elements must comprise at least 50% of the label.
 - Clustered elements must be printed in at least a 12-point sans serifs typeface.
 - Label shall include highlight in bold typeface or color, or use of blank space to set off items.
6. Established 16 standard directions for use and specifies that the phrases are to be used when appropriate.
 - Defines “appropriate dosage form” as the prescribed form of the prescription medication and includes pill, caplet, capsule and tablet. (The term appropriate dosage form is used in the standardized directions referenced in item 6.)
 7. Defines “limited-English proficient” or “LEP” as a person who does not speak English as his or her primary language, and who has a limited ability to read, write, speak or understand English but who can understand a language other than English.
 8. Requires on or after January 1, 2012, a pharmacy to provide oral interpretative services when the pharmacy is open.
 9. Requires on or after January 1, 2012, a pharmacy to develop policies and procedures to assist LEP patients orally understand information on the drug label.
 10. Requires on or after January 1, 2013, a pharmacy shall also provide an LEP patient with other written information relevant to the prescription drug label.

AUTHOR’S INTENT:

According to the author, this bill establishes patient-centered prescription labeling in California, which will protect consumers from medication errors. The author cites a report from the Institute of Medicine of the National Academies that states that medication errors are the most common medical errors, harming at least 1.5 million people each year. The author states that this bill will minimize medication errors by ensuring that seniors and individuals with LEP receive readable and adequate information about their prescription drugs.

FISCAL IMPACT:

The board could incur significant fiscal impact in obtaining the translations required by this bill. In the regulation adopted by the board, the board committed to provide translations for the directions for use in five languages. These translations were to be provided after development by experts in medical translations as well as field tested by national experts.

COMMENTS:

Since April of 2008, the board has focused significant resources into developing regulations that establish a patient-centered prescription label. The board convened special public meetings throughout the state, publically discussed the proposal and underlying statutory requirements at board meetings in 2008, 2009 and 2010, including convening three special board meetings to specifically discuss the regulation. The board worked with experts in the field of label design, developed a consumer survey that was distributed at consumer fairs as well as published on the web site for one-line submissions and worked with stakeholders to ensure dissemination of the survey. Based on the results of the survey, in 2009, the board sponsored legislation to require the inclusion of the purpose for which a drug is prescribed on the prescription label if indicated on the prescription document.

Further, upon initiating the rulemaking process, the board has considered public comment at no less than three public meetings as well as reviewed about 1200 written comments received.

Below is a brief comparison of the bill requirements and the regulation adopted by the board.

	<u>Bill</u>	<u>Regulation</u>
Font Size	12 point sans serif	10 point sans serif, unless otherwise request by the consumer
Translations	Min. 14 languages	5 languages
Effective Date	January 1, 2012 (most provisions)	January 1, 2011

SUPPORT and OPPOSITION:

Support

California Pan-Ethnic Health Network (sponsor)
 California Alliance for Retired Americans
 Consumer's Union

Opposition

The California Retailers Association
 The Civil Justice Association
 Medco Health Solutions, Inc.
 National Association of Chain Drug Stores

HISTORY:

Date Action

June 29 Set, first hearing. Failed passage in committee.

June 23 From committee: Do pass, but first be re-referred to Com. on B.,P. & C.P. (Ayes 10. Noes 6.)
Re-referred to Com. on B.,P. & C.P. (Heard in committee on June 22.)

June 15 From committee with author's amendments. Read second time. Amended. Re-referred to
Com. on HEALTH.

June 3 To Coms. on HEALTH and B.,P. & C.P.

May 24 In Assembly. Read first time. Held at Desk.

May 24 Read third time. Passed. (Ayes 32. Noes 0. Page 3586.) To Assembly.

May 18 Read second time. To third reading.

May 17 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.

Apr. 26 Read second time. Amended. Re-referred to Com. on APPR.

Apr. 22 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes
7. Noes 0. Page 3293.)

Apr. 15 From committee: Do pass, but first be re-referred to Com. on B.,P. & E.D. (Ayes 9. Noes 0.
Page 3211.) Re-referred to Com. On B., P. & E.D. Set for hearing April 19.

Apr. 5 From committee with author's amendments. Read second time. Amended. Re-referred to
Com. on HEALTH. (April 5 amended version corrected April 15.)

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 ASSEMBLY JUNE 15, 2010

AMENDED IN SENATE APRIL 26, 2010

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL

No. 1390

Introduced by Senator Corbett

February 19, 2010

An act to ~~amend~~ *add Sections 4076.7 and 4076.9 to, and to repeal and add 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. *A knowing violation of the Pharmacy Law is a crime.*

~~This bill would authorize the board to exempt from these regulatory requirements certain prescriptions dispensed to patients in a health facility, as defined.~~ *repeal that provision and would instead, on and after January 1, 2012, require prescription drug labels on all prescription drugs dispensed to patients in California to conform to a specified standardized, patient-centered format including that certain elements of the label be printed in a specified typeface and that, when applicable, directions for use utilize certain phrases and be translated into non-English languages, as specified. The bill would exempt from*

these requirements certain prescription drugs dispensed to patients in a health facility, as defined.

The bill would require the board, by January 1, 2012, to develop, collect, and publish on its Internet Web site (1) translations of the directions for use into certain languages and (2) examples of labels meeting the standardized, patient-centered format requirements.

The bill would require a pharmacy, by January 1, 2012, during its hours of operation, to provide interpreter services, as specified, to non-English-speaking patients at no charge to help the patient understand the information on his or her prescription drug label. The bill would also, by January 1, 2013, require a pharmacy to provide these non-English patients with any other written information relevant to the prescription drug in the patient's language. The bill would require these pharmacies to develop written policies and procedures by certain specified dates in order to carry out these requirements.

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

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

- 1 SECTION 1. *The Legislature hereby finds and declares all of*
- 2 *the following:*
- 3 (a) *Health care costs and spending in the United States are*
- 4 *rising dramatically and are expected to continue to rise. Overall,*
- 5 *national health care spending grew an estimated 5.7 percent in*
- 6 *2009, reaching \$2.5 trillion and accounting for 17.3 percent of*
- 7 *the nation's gross domestic product.*
- 8 (b) *In 2009, spending on prescription drugs in the United States*
- 9 *totaled over \$300 billion dollars, a 5-percent increase from the*
- 10 *previous year.*

1 (c) *The cost of prescription drugs continues to be among the*
2 *most significant cost factors in California’s overall spending on*
3 *health care.*

4 (d) *According to the Institute of Medicine of the National*
5 *Academies, medication errors are among the most common medical*
6 *errors, harming at least 1.5 million people every year.*

7 (e) *Up to one-half of all medications are taken incorrectly or*
8 *mixed with other medications that cause dangerous reactions that*
9 *can lead to injury and death.*

10 (f) *Approximately 46 percent of American adults cannot*
11 *understand the label on their prescription drugs.*

12 (g) *Ninety percent of Medicare patients take medications for*
13 *chronic conditions and nearly one-half of them take five or more*
14 *different medications each day.*

15 (h) *Nearly six out of 10 adults in the United States have taken*
16 *prescription medications incorrectly.*

17 (i) *According to the 2006 American Community Survey of the*
18 *United States Census Bureau, over 42 percent of Californians*
19 *speak a language other than English at home, which is significantly*
20 *above the national figure of 19.7 percent. Of these, 47 percent*
21 *could be considered limited-English proficient and represents just*
22 *over 20 percent of all Californians.*

23 (j) *Numerous articles and studies, including a study by the*
24 *Institute of Medicine entitled *Unequal Treatment: Confronting**
25 *Racial and Ethnic Disparities in Health* (2002), *highlight the*
26 *language barriers faced by patients who do not speak English and*
27 *show that providing adequate language services improves health*
28 *outcomes and patient satisfaction, comports with existing federal*
29 *and state requirements, and achieves long-term cost savings.*

30 (k) *Title VI of the Federal Civil Rights Act of 1964 (42 U.S.C.*
31 *Sec. 1981 et seq.) prohibits recipients of federal financial*
32 *assistance from discriminating against persons based on race,*
33 *color, or national origin. This has been interpreted to mean that*
34 *a limited-English proficient (LEP) individual is entitled to*
35 *meaningful access and participation in federally funded programs*
36 *through the provision of language assistance services. Any*
37 *recipient of federal funding, including a pharmacy operating in*
38 *California that participates in the Medi-Cal, Healthy Families, or*
39 *Medicare programs, is subject to the Title VI requirements.*

1 (l) According to the Policy Guidance on the Prohibition Against
 2 National Origin Discrimination as it Affects Persons with Limited
 3 English Proficiency published by the Office for Civil Rights within
 4 the United States Department of Health and Human Services on
 5 August 8, 2003 (68 Fed. Reg. 47311-23), providers of health care
 6 and social services that receive federal financial assistance,
 7 including pharmacies, must take adequate steps to ensure that
 8 LEP persons receive language assistance free of charge necessary
 9 to afford them meaningful access to the provider’s services.

10 (m) Current regulations of the California State Board of
 11 Pharmacy (16 Cal Code Regs. 1707.2), require pharmacists to
 12 provide oral consultation to all patients in all care settings where
 13 the patient is present in the pharmacy for a new prescription and
 14 a prescription of the same dosage, form, strength, or with the same
 15 directions has not been previously dispensed to the patient.

16 (n) The people of the State of California recognize the
 17 importance of reducing medication-related errors and increasing
 18 health care literacy regarding prescription drugs and prescription
 19 container labeling, which can increase consumer protection and
 20 improve the health, safety, and well-being of consumers.

21 (o) The Legislature affirms the importance of identifying
 22 deficiencies in, and opportunities for improving, patient
 23 prescription drug safety systems in order to identify and encourage
 24 the adoption of structural safeguards related to prescription drug
 25 container labels.

26 SEC. 2. Section 4076.5 of the Business and Professions Code
 27 is repealed.

28 ~~4076.5. (a) The board shall promulgate regulations that require,~~
 29 ~~on or before January 1, 2011, a standardized, patient-centered,~~
 30 ~~prescription drug label on all prescription medicine dispensed to~~
 31 ~~patients in California.~~

32 ~~(b) To ensure maximum public comment, the board shall hold~~
 33 ~~public meetings statewide that are separate from its normally~~
 34 ~~scheduled hearings in order to seek information from groups~~
 35 ~~representing consumers, seniors, pharmacists or the practice of~~
 36 ~~pharmacy, other health care professionals, and other interested~~
 37 ~~parties.~~

38 ~~(c) When developing the requirements for prescription drug~~
 39 ~~labels, the board shall consider all of the following factors:~~

- 1 ~~(1) Medical literacy research that points to increased~~
- 2 ~~understandability of labels.~~
- 3 ~~(2) Improved directions for use.~~
- 4 ~~(3) Improved font types and sizes.~~
- 5 ~~(4) Placement of information that is patient-centered.~~
- 6 ~~(5) The needs of patients with limited English proficiency.~~
- 7 ~~(6) The needs of senior citizens.~~
- 8 ~~(7) Technology requirements necessary to implement the~~
- 9 ~~standards.~~

10 ~~(d) (1) On or before January 1, 2010, the board shall report to~~
11 ~~the Legislature on its progress under this section as of the time of~~
12 ~~the report.~~

13 ~~(2) On or before January 1, 2013, the board shall report to the~~
14 ~~Legislature the status of implementation of the prescription drug~~
15 ~~label requirements adopted pursuant to this section.~~

16 *SEC. 3. Section 4076.5 is added to the Business and Professions*
17 *Code, to read:*

18 *4076.5. (a) The board shall promulgate any regulations*
19 *necessary to clarify the provisions in this section and in Sections*
20 *4076.7 and 4076.9.*

21 *(b) On or before January 1, 2012, the board shall develop,*
22 *collect, and publish on its Internet Web site the following:*

23 *(1) Translations for the directions for use described in*
24 *subparagraphs (A) to (P), inclusive, in a minimum of 14 languages,*
25 *to include all of the non-English languages identified by the*
26 *Medi-Cal Managed Care Division within the State Department of*
27 *Health Care Services for translation in vital documents, as well*
28 *as any other primary languages for groups of 10,000 or more with*
29 *limited-English-proficient persons in California, to facilitate the*
30 *use of those directions for use by pharmacies in California.*

31 *(A) Take 1 [insert appropriate dosage form] at bedtime.*

32 *(B) Take 2 [insert appropriate dosage form] at bedtime.*

33 *(C) Take 3 [insert appropriate dosage form] at bedtime.*

34 *(D) Take 1 [insert appropriate dosage form] in the morning.*

35 *(E) Take 2 [insert appropriate dosage form] in the morning.*

36 *(F) Take 3 [insert appropriate dosage form] in the morning.*

37 *(G) Take 1 [insert appropriate dosage form] in the morning,*
38 *and 1 [insert appropriate dosage form] at bedtime.*

39 *(H) Take 2 [insert appropriate dosage form] in the morning,*
40 *and 2 [insert appropriate dosage form] at bedtime.*

1 (I) Take 3 [insert appropriate dosage form] in the morning, and
2 3 [insert appropriate dosage form] at bedtime.

3 (J) Take 1 [insert appropriate dosage form] in the morning, 1
4 [insert appropriate dosage form] at noon, and 1 [insert appropriate
5 dosage form] in the evening.

6 (K) Take 2 [insert appropriate dosage form] in the morning, 2
7 [insert appropriate dosage form] at noon, and 2 [insert appropriate
8 dosage form] in the evening.

9 (L) Take 3 [insert appropriate dosage form] in the morning, 3
10 [insert appropriate dosage form] at noon, and 3 [insert appropriate
11 dosage form] in the evening.

12 (M) Take 1 [insert appropriate dosage form] in the morning, 1
13 [insert appropriate dosage form] at noon, 1 [insert appropriate
14 dosage form] in the evening, and 1 [insert appropriate dosage
15 form] at bedtime.

16 (N) Take 2 [insert appropriate dosage form] in the morning, 2
17 [insert appropriate dosage form] at noon, 2 [insert appropriate
18 dosage form] in the evening, and 2 [insert appropriate dosage
19 form] at bedtime.

20 (O) Take 3 [insert appropriate dosage form] in the morning, 3
21 [insert appropriate dosage form] at noon, 3 [insert appropriate
22 dosage form] in the evening, and 3 [insert appropriate dosage
23 form] at bedtime.

24 (P) If you have pain, take [insert appropriate dosage form] at
25 a time. Wait at least ___ hours before taking again. Do not take
26 more than [appropriate dosage form] in one day.

27 (2) Examples of labels conforming to the requirements described
28 in Section 4076.7 to aid pharmacies in label design and
29 compliance.

30 SEC. 4. Section 4076.7 is added to the Business and Professions
31 Code, to read:

32 4076.7. (a) On and after January 1, 2012, all prescription
33 drug labels on all prescription drugs dispensed to patients in
34 California shall conform to the following standardized,
35 patient-centered format:

36 (1) Each of the following elements shall be clustered into one
37 area of the label that comprises at least 50 percent of the label.
38 Each item shall be printed in at least a 12-point sans serif typeface,
39 and listed in the following order:

40 (A) Name of the patient.

- 1 (B) Name of the drug and strength of the drug. For the purposes
2 of this section, “name of the drug” means the generic name of the
3 drug and, if applicable, the manufacturer’s trade name.
- 4 (C) Directions for use.
- 5 (D) Purpose or condition, if entered on the prescription by the
6 prescriber or otherwise known to the pharmacy.
- 7 (2) For added emphasis, the label shall also highlight in bold
8 typeface or color, or use a blank space to set off, the items listed
9 in paragraph (1).
- 10 (3) The remaining elements required for the label as described
11 in Section 4076, as well as any other items of information
12 appearing on the label or the container, shall be printed so as not
13 to interfere with the legibility or emphasis of the primary elements
14 specified in paragraph (1). These remaining elements may appear
15 in any style, font, and size typeface.
- 16 (4) When applicable, directions for use shall utilize one of the
17 following phrases and, when appropriate shall be in the language
18 of the patient as translated pursuant to Section 4076.5:
- 19 (A) Take 1 [insert appropriate dosage form] at bedtime.
- 20 (B) Take 2 [insert appropriate dosage form] at bedtime.
- 21 (C) Take 3 [insert appropriate dosage form] at bedtime.
- 22 (D) Take 1 [insert appropriate dosage form] in the morning.
- 23 (E) Take 2 [insert appropriate dosage form] in the morning.
- 24 (F) Take 3 [insert appropriate dosage form] in the morning.
- 25 (G) Take 1 [insert appropriate dosage form] in the morning,
26 and 1 [insert appropriate dosage form] at bedtime.
- 27 (H) Take 2 [insert appropriate dosage form] in the morning,
28 and 2 [insert appropriate dosage form] at bedtime.
- 29 (I) Take 3 [insert appropriate dosage form] in the morning, and
30 3 [insert appropriate dosage form] at bedtime.
- 31 (J) Take 1 [insert appropriate dosage form] in the morning, 1
32 [insert appropriate dosage form] at noon, and 1 [insert appropriate
33 dosage form] in the evening.
- 34 (K) Take 2 [insert appropriate dosage form] in the morning, 2
35 [insert appropriate dosage form] at noon, and 2 [insert appropriate
36 dosage form] in the evening.
- 37 (L) Take 3 [insert appropriate dosage form] in the morning, 3
38 [insert appropriate dosage form] at noon, and 3 [insert appropriate
39 dosage form] in the evening.

1 (M) Take 1 [insert appropriate dosage form] in the morning, 1
2 [insert appropriate dosage form] at noon, 1 [insert appropriate
3 dosage form] in the evening, and 1 [insert appropriate dosage
4 form] at bedtime.

5 (N) Take 2 [insert appropriate dosage form] in the morning, 2
6 [insert appropriate dosage form] at noon, 2 [insert appropriate
7 dosage form] in the evening, and 2 [insert appropriate dosage
8 form] at bedtime.

9 (O) Take 3 [insert appropriate dosage form] in the morning, 3
10 [insert appropriate dosage form] at noon, 3 [insert appropriate
11 dosage form] in the evening, and 3 [insert appropriate dosage
12 form] at bedtime.

13 (P) If you have pain, take [insert appropriate dosage form] at
14 a time. Wait at least ____ hours before taking again. Do not take
15 more than [insert appropriate dosage form] in one day.

16 (b) As used in this section, “appropriate dosage form” means
17 the prescribed form of the prescription medication and includes
18 a pill, caplet, capsule, or tablet.

19 (c) This section shall not apply to prescriptions dispensed to a
20 patient in a health facility, as defined in Section 1250 of the Health
21 and Safety Code, if the prescriptions are administered by a licensed
22 health care professional. Prescriptions dispensed to a patient in
23 a health facility that will not be administered by a licensed health
24 care professional or that are provided to the patient upon discharge
25 from the facility shall be subject to the requirements of this section.
26 Nothing in this subdivision shall alter or diminish existing statutory
27 and regulatory informed consent, patients’ rights, or
28 pharmaceutical labeling and storage requirements, including, but
29 not limited to, the requirements of Section 1418.9 of the Health
30 and Safety Code or Section 72357, 72527, or 72528 of Title 22 of
31 the California Code of Regulations.

32 SEC. 5. Section 4076.9 is added to the Business and Professions
33 Code, to read:

34 4076.9. (a) For the purposes of this section, “limited-English
35 proficient” or “LEP,” means a person who does not speak English
36 as his or her primary language, and who has a limited ability to
37 read, write, speak, or understand English and who can read, speak,
38 or understand a language other than English.

39 (b) (1) On and after January 1, 2012, a pharmacy shall provide,
40 during all hours when the pharmacy is open, competent interpreter

1 services to each LEP patient in the LEP patient’s language at no
2 charge in order to help an LEP understand the information on his
3 or her prescription drug label. The interpreter services may be
4 provided in person by pharmacy staff, in person by a third-party
5 interpreter service, or by telephone or video conference using a
6 third-party interpreter service.

7 (2) On or before January 1, 2012, each pharmacy shall develop
8 written policies and procedures to help an LEP patient orally
9 understand the information on his or her prescription drug label,
10 including the directions for use, as described in Section 4076.7.
11 The policies and procedures shall include, at a minimum, the means
12 to (A) identify and record the patient’s oral and written language,
13 (B) provide language assistance services, including interpreter
14 services pursuant to paragraph (1) and translation services, (c)
15 train pharmacy staff on these policies and procedures, (d) provide
16 clear and prominent notice to LEP patients about the availability
17 of free language assistance services, and (e) monitor and update
18 the relevant policies and procedures.

19 (C) (1) On and after January 1, 2013, in addition to providing
20 the required information on the prescription drug label in the
21 language of an LEP patient a pharmacy shall provide an LEP
22 patient with any other written information relevant to the
23 prescription drug in the language of the LEP patient.

24 (2) On or before January 1, 2013, each pharmacy shall develop
25 written policies and procedures to carry out the requirement in
26 paragraph (1).

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

36 SECTION 1. ~~Section 4076.5 of the Business and Professions~~
37 ~~Code is amended to read:~~

38 ~~4076.5. (a) The board shall promulgate regulations that require,~~
39 ~~on or before January 1, 2011, a standardized, patient-centered,~~

1 prescription drug label on all prescription medicine dispensed to
2 patients in California.

3 ~~(b) To ensure maximum public comment, the board shall hold~~
4 ~~public meetings statewide that are separate from its normally~~
5 ~~scheduled hearings in order to seek information from groups~~
6 ~~representing consumers, seniors, pharmacists or the practice of~~
7 ~~pharmacy, other health care professionals, and other interested~~
8 ~~parties.~~

9 ~~(c) When developing the requirements for prescription drug~~
10 ~~labels, the board shall consider all of the following factors:~~

11 ~~(1) Medical literacy research that points to increased~~
12 ~~understandability of labels.~~

13 ~~(2) Improved directions for use.~~

14 ~~(3) Improved font types and sizes.~~

15 ~~(4) Placement of information that is patient-centered.~~

16 ~~(5) The needs of patients with limited English proficiency.~~

17 ~~(6) The needs of senior citizens.~~

18 ~~(7) Technology requirements necessary to implement the~~
19 ~~standards.~~

20 ~~(d) The board may exempt from the requirements of regulations~~
21 ~~promulgated pursuant to subdivision (a) prescriptions dispensed~~
22 ~~to a patient in a health facility, as defined in Section 1250 of the~~
23 ~~Health and Safety Code, if the prescriptions are administered by~~
24 ~~a licensed health care professional. Prescriptions dispensed to a~~
25 ~~patient in a health facility that will not be administered by a~~
26 ~~licensed health care professional or that are provided to the patient~~
27 ~~upon discharge from the facility shall be subject to the requirements~~
28 ~~of this section and the associated regulations. Nothing in this~~
29 ~~subdivision shall alter or diminish existing statutory and regulatory~~
30 ~~informed consent, patients' rights, or pharmaceutical labeling and~~
31 ~~storage requirements, including, but not limited to, the requirements~~
32 ~~of Section 1418.9 of the Health and Safety Code or Section 72357,~~
33 ~~72527, or 72528 of Title 22 of the California Code of Regulations.~~

34 ~~(e) (1) On or before January 1, 2010, the board shall report to~~
35 ~~the Legislature on its progress under this section as of the time of~~
36 ~~the report.~~

1 ~~(2) On or before January 1, 2013, the board shall report to the~~
2 ~~Legislature the status of implementation of the prescription drug~~
3 ~~label requirements adopted pursuant to this section.~~

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1659

VERSION: As Amended June 2, 2010

AUTHOR: Huber

SPONSOR: Author Sponsored

BOARD POSITION: None

SUBJECT: Joint Sunset Review Committee

Affected Sections: Add Article 7.5 (commencing with §9147.7) to the Government Code

Current Status: Re-referred to Senate Rule Committee

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. Add Article 7.5. Sunset Review to the Government Code to
 - a. Establish the Joint Sunset Review Committee to identify and eliminate waste, duplication and inefficiencies in government agencies;
 - b. Require that defined eligible entities (excluded agencies that are constitutionally created as well as an agency related to post secondary education) to submit to the committee no later than December 1, prior to the year the agency is set to repeal, 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 unless it is exempt from this article.
- e. Allow for a one-year extension of a sunset date to allow the committee more time to evaluate the agency.
- f. Specifies that the committee shall have 10 members and 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.

COMMENTS:

The board is already subject to review by the Joint Committee on Boards, Commissions and Consumer Protection (previously referred to as the Joint Legislative Sunset Review Committee). The board is scheduled to initiate the review process next year, with staff completing a report to be submitted next fall. In 2002, the board submitted its previous Sunset Review report and made several recommendations to improve both our licensing and enforcement activities. Many of these recommendations resulted in statutory changes, including changing the licensing requirements for pharmacists to include passage of both a national exam and state specific

examination as well as extending the establishment of CURES (controlled substances utilization reports) and the elimination of the triplicate prescription for schedule II prescriptions. A copy of the full report is provided on the board's Web site using the following link:
<http://www.pharmacy.ca.gov/publications/sunset02.pdf>

HISTORY:

Date Action

June 22 From committee: Do pass, and re-refer to Com. on RLS. Re-referred. (Ayes 6. Noes 0.) (June 21.)
June 10 Referred to Coms. on B., P. & E.D. and RLS.
June 7 In Senate. Read first time. To Com. on RLS. for assignment.
June 3 Assembly Rule 69(d) suspended. (Page 5549.) Read third time, passed, and to Senate. (Ayes 73. Noes 3. Page 5551.)
June 2 Read third time, amended, and returned to third reading. (Page 5447.)
May 28 From committee: Do pass. (Ayes 17. Noes 0.) (May 28.) Read second time. To third reading.
May 5 In committee: Set, second hearing. Referred to APPR. Suspense file.
Apr. 29 Re-referred to Com. on APPR.
Apr. 28 From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
Apr. 21 In committee: Set, first hearing. Hearing canceled at the request of author.
Apr. 8 Re-referred to Com. on APPR.
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.) (April 6.)
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 SENATE JULY 15, 2010
AMENDED IN ASSEMBLY JUNE 2, 2010
AMENDED IN ASSEMBLY APRIL 28, 2010
AMENDED IN ASSEMBLY APRIL 7, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 1659

Introduced by Assembly Member Huber
(Coauthor: Assembly Member Niello)
(Coauthor: Senator DeSaulnier)

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 and to conduct a comprehensive analysis of every "eligible

agency,” as defined, to determine if the agency is still necessary and cost effective. The bill would define an “eligible agency” as an entity of state government, however denominated, for which a date for repeal has been established by statute on or after January 1, 2011. The bill would require each eligible 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 eligible agency prior to the date the agency is scheduled to be repealed, and would require that an eligible agency be eliminated unless the Legislature enacts a law 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 *Committee on Rules* and the Speaker of the Assembly, and certain aspects of its operating procedure.

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 7.5 (commencing with Section 9147.7)
 2 is added to Chapter 1.5 of Part 1 of Division 2 of Title 2 of the
 3 Government Code, to read:

4
 5 Article 7.5. Sunset Review
 6

7 9147.7. (a) For the purpose of this section, “eligible agency”
 8 means any agency, authority, board, bureau, commission,
 9 conservancy, council, department, division, or office of state
 10 government, however denominated, excluding an agency that is
 11 constitutionally created or an agency related to postsecondary
 12 education, for which a date for repeal has been established by
 13 statute on or after January 1, 2011.

14 (b) The Joint Sunset Review Committee is hereby created to
 15 identify and eliminate waste, duplication, and inefficiency in
 16 government agencies. The purpose of the committee is to conduct
 17 a comprehensive analysis over 15 years, and on a periodic basis
 18 thereafter, of every eligible agency to determine if the agency is
 19 still necessary and cost effective.

20 (c) Each eligible agency scheduled for repeal shall submit to
 21 the committee, on or before December 1 prior to the year it is set

1 to be repealed, a complete agency report covering the entire period
2 since last reviewed, including, but not limited to, the following:

- 3 (1) The purpose and necessity of the agency.
- 4 (2) A description of the agency budget, priorities, and job
5 descriptions of employees of the agency.
- 6 (3) Any programs and projects under the direction of the agency.
- 7 (4) Measures of the success or failures of the agency and
8 justifications for the metrics used to evaluate successes and failures.
- 9 (5) Any recommendations of the agency for changes or
10 reorganization in order to better fulfill its purpose.

11 (d) The committee shall take public testimony and evaluate the
12 eligible agency prior to the date the agency is scheduled to be
13 repealed. An eligible agency shall be eliminated unless the
14 Legislature enacts a law to extend, consolidate, or reorganize the
15 eligible agency. No eligible agency shall be extended in perpetuity
16 unless specifically exempted from the provisions of this section.
17 The committee may recommend that the Legislature extend the
18 statutory sunset date for no more than one year to allow the
19 committee more time to evaluate the eligible agency.

20 (e) The committee shall be comprised of 10 members of the
21 Legislature. ~~The President pro Tempore of the Senate~~ *Senate*
22 *Committee on Rules* shall appoint five members of the Senate to
23 the committee, not more than three of whom shall be members of
24 the same political party. The Speaker of the Assembly shall appoint
25 five members of the Assembly to the committee, not more than
26 three of whom shall be members of the same political party.
27 Members shall be appointed within 15 days after the
28 commencement of the regular session. Each member of the
29 committee who is appointed by the ~~President pro Tempore of the~~
30 ~~Senate~~ *Senate Committee on Rules* or the Speaker of the Assembly
31 shall serve during that committee member's term of office or until
32 that committee member no longer is a Member of the Senate or
33 the Assembly, whichever is applicable. A vacancy on the
34 committee shall be filled in the same manner as the original
35 appointment. Three Assembly Members and three Senators who
36 are members of the committee shall constitute a quorum for the
37 conduct of committee business. Members of the committee shall
38 receive no compensation for their work with the committee.

39 (f) The committee shall meet not later than 30 days after the
40 first day of the regular session to choose a chairperson and to

1 establish the schedule for eligible agency review provided for in
2 the statutes governing the eligible agencies. The chairperson of
3 the committee shall alternate every two years between a Member
4 of the Senate and a Member of the Assembly, and the vice
5 chairperson of the committee shall be a member of the opposite
6 house as the chairperson.

7 (g) This section shall not be construed to change the existing
8 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 Amended June 22, 2010

AUTHOR: Huber

SPONSOR: Author Sponsored

BOARD POSITION: None

SUBJECT: Sunset Review Act Implementation

Affected Sections: Amend Business and Professions Code Section 4001

CURRENT STATUS: Referred to the Senate Committee on Appropriations

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. Abolish the authority granted to the Joint Committee in January of 2004, to review all existing state boards and other entities every four years and replace it with the Joint Sunset Review Committee (JSRC).
2. Make all "eligible agencies," as defined, subject to review by the new JSRC which would be established pursuant to AB 1659.
3. Specify that the following four agencies would be subject to review by the JSRC in its first year of operation and would have sunset dates of January 1, 2013:
 - a) The State Race Track Leasing Commission.
 - b) The Capitol Area Committee.
 - c) The Continuing Care Advisory Committee.
 - d) The California Recreational Trails Committee.
4. Provide that the JSRC shall make a report available to the public and the Legislature on whether an agency should be terminated, or continued, or whether its functions should be revised or consolidated with those of another agency, and include any

other recommendations as necessary to improve the effectiveness and efficiency of the agency.

5. Provide that if the JSRC deems it advisable, the report may include proposed bill to carry out its recommendations.
6. Specify that the provisions of this measure would not become operative unless AB 1659 is enacted and establishes the JSRC.

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. Any minor impact could be absorbed within existing resources.

SUPPORT and OPPOSITION:

Support

None on file as of June 21, 2010

Oppose

None on file as of June 21, 2010

HISTORY:

Date	Action
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June 30	Withdrawn from committee. Re-referred to Com. on APPR.
June 29	From committee: Do pass, and re-refer to Com. on RLS. Re-referred. (Ayes 7. Noes 0.) (June 28.)
June 22	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. On B., P. & E.D.
June 16	In committee: Set, first hearing. Hearing canceled at the request of author.
June 10	Referred to Coms. on B., P. & E.D. and RLS.
June 7	In Senate. Read first time. To Com. on RLS. for assignment.
June 3	Assembly Rule 69(d) suspended. (Page 5549.) Read third time, passed, and to Senate. (Ayes 74. Noes 3. Page 5552.)
June 2	Read third time, amended, and returned to third reading. (Page 5447.)
May 28	From committee: Do pass. (Ayes 17. Noes 0.) (May 28). Read second time. To third reading.
Apr. 21	In committee: Set, first hearing. Referred to APPR. Suspense file.
Apr. 6	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 11. Noes 0.) (April 6.)
Mar. 11	Referred to Com. on B. & P.
Feb. 19	From printer. May be heard in committee March 21.
Feb. 18	Read first time. To print.

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

AMENDED IN SENATE JUNE 22, 2010

AMENDED IN ASSEMBLY JUNE 2, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 2130

Introduced by Assembly Member Huber
(Coauthor: Assembly Member Niello)
(Coauthor: Senator DeSaulnier)

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.~~
An act to amend Section 22 of, to repeal Section 101.1 of, and to repeal Division 1.2 (commencing with Section 473) of, the Business and Professions Code, to amend Section 4351 of, and to repeal Chapter 9 (commencing with Section 4351) of Part 3 of Division 3 of, the Food and Agricultural Code, to amend Sections 9148.51 and 9148.52 of, and to amend and repeal Sections 8164.1, 8164.2, and 8164.3 of, the Government Code, to amend and repeal Sections 1777, 1777.2, and 1777.4 of the Health and Safety Code, to amend and repeal Sections 5073.5, 5073.7, and 5074 of the Public Resources Code, relating to professions and vocations.

LEGISLATIVE COUNSEL’S DIGEST

AB 2130, as amended, 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 *and make other conforming changes*. ~~The bill would instead make specified boards and regulatory programs subject to review by the Joint Sunset Review Committee. The~~

Existing law provides that the Joint Committee on Boards, Commissions, and Consumer Protection review all state boards, except as specified, every four years.

This bill would instead require the Joint Sunset Review Committee to review all eligible agencies, as specified. The bill would require the committee to make a report pursuant to an evaluation which shall be available to the public and the Legislature, as specified. The bill would impose a sunset date of January 1, 2013, on the State Race Track Leasing Commission, the Capitol Area Committee, the Continuing Care Advisory Committee, and the California Recreational Trails Committee.

The bill would provide that its provisions would not become operative unless AB 1659 of the 2009–10 Regular Session 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,”

1 “commission,” “committee,” “department,” “division,” “examining
2 committee,” “program,” and “agency.”

3 ~~(b) Whenever the regulatory program of a board that is subject
4 to review by the Joint Sunset Review Committee, as provided for
5 in Article 7.5 (commencing with Section 9147.7) of Chapter 1.5
6 of Part 1 of Division 2 of Title 2 of the Government Code, is taken
7 over by the department, that program shall be designated as a
8 “bureau.”~~

9 ~~SEC. 2. Section 101.1 of the Business and Professions Code
10 is amended to read:~~

11 ~~101.1. (a) It is the intent of the Legislature that all existing
12 and proposed consumer-related boards or categories of licensed
13 professionals be subject to a review every four years to evaluate
14 and determine whether each board has demonstrated a public need
15 for the continued existence of that board in accordance with
16 enumerated factors and standards as set forth in Article 7.5
17 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of
18 Division 2 of Title 2 of the Government Code.~~

19 ~~(b) (1) If any board, as defined in Section 22, becomes
20 inoperative or is repealed in accordance with the act that added
21 this section, or by subsequent acts, the Department of Consumer
22 Affairs shall succeed to and is vested with all the duties, powers,
23 purposes, responsibilities and jurisdiction not otherwise repealed
24 or made inoperative of that board and its executive officer.~~

25 ~~(2) Any provision of existing law that provides for the
26 appointment of board members and specifies the qualifications
27 and tenure of board members shall not be implemented and shall
28 have no force or effect while that board is inoperative or repealed.
29 Every reference to the inoperative or repealed board, as defined
30 in Section 22, shall be deemed to be a reference to the department.~~

31 ~~(3) Notwithstanding Section 107, any provision of law
32 authorizing the appointment of an executive officer by a board
33 subject to the review described in Article 7.5 (commencing with
34 Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2
35 of the Government Code, or prescribing his or her duties, shall not
36 be implemented and shall have no force or effect while the
37 applicable board is inoperative or repealed. Any reference to the
38 executive officer of an inoperative or repealed board shall be
39 deemed to be a reference to the director or his or her designee.~~

1 ~~(e) It is the intent of the Legislature that subsequent legislation~~
 2 ~~to extend or repeal the inoperative date for any board shall be a~~
 3 ~~separate bill for that purpose.~~

4 ~~SEC. 2. Section 101.1 of the Business and Professions Code~~
 5 ~~is repealed.~~

6 ~~101.1. (a) It is the intent of the Legislature that all existing~~
 7 ~~and proposed consumer-related boards or categories of licensed~~
 8 ~~professionals be subject to a review every four years to evaluate~~
 9 ~~and determine whether each board has demonstrated a public need~~
 10 ~~for the continued existence of that board in accordance with~~
 11 ~~enumerated factors and standards as set forth in Division 1.2~~
 12 ~~(commencing with Section 473).~~

13 ~~(b) (1) In the event that any board, as defined in Section 477,~~
 14 ~~becomes inoperative or is repealed in accordance with the act that~~
 15 ~~added this section, or by subsequent acts, the Department of~~
 16 ~~Consumer Affairs shall succeed to and is vested with all the duties,~~
 17 ~~powers, purposes, responsibilities and jurisdiction not otherwise~~
 18 ~~repealed or made inoperative of that board and its executive officer.~~

19 ~~(2) Any provision of existing law that provides for the~~
 20 ~~appointment of board members and specifies the qualifications~~
 21 ~~and tenure of board members shall not be implemented and shall~~
 22 ~~have no force or effect while that board is inoperative or repealed.~~
 23 ~~Every reference to the inoperative or repealed board, as defined~~
 24 ~~in Section 477, shall be deemed to be a reference to the department.~~

25 ~~(3) Notwithstanding Section 107, any provision of law~~
 26 ~~authorizing the appointment of an executive officer by a board~~
 27 ~~subject to the review described in Division 1.2 (commencing with~~
 28 ~~Section 473), or prescribing his or her duties, shall not be~~
 29 ~~implemented and shall have no force or effect while the applicable~~
 30 ~~board is inoperative or repealed. Any reference to the executive~~
 31 ~~officer of an inoperative or repealed board shall be deemed to be~~
 32 ~~a reference to the director or his or her designee.~~

33 ~~(e) It is the intent of the Legislature that subsequent legislation~~
 34 ~~to extend or repeal the inoperative date for any board shall be a~~
 35 ~~separate bill for that purpose.~~

36 ~~SEC. 3. Division 1.2 (commencing with Section 473) of the~~
 37 ~~Business and Professions Code is repealed.~~

38 ~~SEC. 4. Section 1601.1 of the Business and Professions Code,~~
 39 ~~as added by Section 1 of Chapter 35 of the Statutes of 2008, is~~
 40 ~~amended to read:~~

1 ~~1601.1.— (a) There shall be in the Department of Consumer~~
2 ~~Affairs the Dental Board of California in which the administration~~
3 ~~of this chapter is vested. The board shall consist of eight practicing~~
4 ~~dentists, one registered dental hygienist, one registered dental~~
5 ~~assistant, and four public members. Of the eight practicing dentists,~~
6 ~~one shall be a member of a faculty of any California dental college,~~
7 ~~and one shall be a dentist practicing in a nonprofit community~~
8 ~~clinic. The appointing powers, described in Section 1603, may~~
9 ~~appoint to the board a person who was a member of the prior board.~~
10 ~~The board shall be organized into standing committees dealing~~
11 ~~with examinations, enforcement, and other subjects as the board~~
12 ~~deems appropriate.~~

13 ~~(b) For purposes of this chapter, any reference in this chapter~~
14 ~~to the Board of Dental Examiners shall be deemed to refer to the~~
15 ~~Dental Board of California.~~

16 ~~(c) The board shall have all authority previously vested in the~~
17 ~~existing board under this chapter. The board may enforce all~~
18 ~~disciplinary actions undertaken by the previous board.~~

19 ~~(d) This section shall remain in effect only until January 1, 2012,~~
20 ~~and as of that date is repealed, unless a later enacted statute, that~~
21 ~~is enacted before January 1, 2012, deletes or extends that date. The~~
22 ~~repeal of this section renders the board subject to the review~~
23 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
24 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
25 ~~Code.~~

26 ~~SEC. 5.— Section 1601.1 of the Business and Professions Code,~~
27 ~~as added by Section 3 of Chapter 31 of the Statutes of 2008, is~~
28 ~~repealed.~~

29 ~~SEC. 6.— Section 1917.2 of the Business and Professions Code~~
30 ~~is amended to read:~~

31 ~~1917.2.— (a) The committee shall license as a registered dental~~
32 ~~hygienist a third- or fourth-year dental student who is in good~~
33 ~~standing at an accredited California dental school and who satisfies~~
34 ~~the following requirements:~~

35 ~~(1) Satisfactorily performs on a clinical examination and an~~
36 ~~examination in California law and ethics as prescribed by the~~
37 ~~committee.~~

38 ~~(2) Satisfactorily completes a national written dental hygiene~~
39 ~~examination approved by the committee.~~

1 ~~(b) A dental student who is granted a registered dental hygienist~~
2 ~~license pursuant to this section may only practice in a dental~~
3 ~~practice that serves patients who are insured under Denti-Cal, the~~
4 ~~Healthy Families Program, or other government programs, or a~~
5 ~~dental practice that has a sliding scale fee system based on income.~~

6 ~~(c) Upon receipt of a license to practice dentistry pursuant to~~
7 ~~Section 1634, a registered dental hygienist license issued pursuant~~
8 ~~to this section is automatically revoked.~~

9 ~~(d) The dental hygienist license is granted for two years upon~~
10 ~~passage of the dental hygiene examination, without the ability for~~
11 ~~renewal.~~

12 ~~(e) Notwithstanding subdivision (d), if a dental student fails to~~
13 ~~remain in good standing at an accredited California dental school,~~
14 ~~or fails to graduate from the dental program, a registered dental~~
15 ~~hygienist license issued pursuant to this section shall be revoked.~~
16 ~~The student shall be responsible for submitting appropriate~~
17 ~~verifying documentation to the committee.~~

18 ~~(f) The provisions of this section shall be reviewed pursuant to~~
19 ~~Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of~~
20 ~~Part 1 of Division 2 of Title 2 of the Government Code. However,~~
21 ~~the review shall be limited to the fiscal feasibility and impact on~~
22 ~~the committee.~~

23 ~~(g) This section shall become inoperative on January 1, 2012.~~

24 ~~SEC. 7. Section 2001 of the Business and Professions Code is~~
25 ~~amended to read:~~

26 ~~2001. (a) There is in the Department of Consumer Affairs a~~
27 ~~Medical Board of California that consists of 15 members, seven~~
28 ~~of whom shall be public members.~~

29 ~~(b) The Governor shall appoint 13 members to the board, subject~~
30 ~~to confirmation by the Senate, five of whom shall be public~~
31 ~~members. The Senate Committee on Rules and the Speaker of the~~
32 ~~Assembly shall each appoint a public member.~~

33 ~~(c) Notwithstanding any other provision of law, to reduce the~~
34 ~~membership of the board to 15, the following shall occur:~~

35 ~~(1) Two positions on the board that are public members having~~
36 ~~a term that expires on June 1, 2010, shall terminate instead on~~
37 ~~January 1, 2008.~~

38 ~~(2) Two positions on the board that are not public members~~
39 ~~having a term that expires on June 1, 2008, shall terminate instead~~
40 ~~on August 1, 2008.~~

1 ~~(3) Two positions on the board that are not public members~~
2 ~~having a term that expires on June 1, 2011, shall terminate instead~~
3 ~~on January 1, 2008.~~

4 ~~(d) This section shall remain in effect only until January 1, 2013,~~
5 ~~and as of that date is repealed, unless a later enacted statute, that~~
6 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
7 ~~repeal of this section renders the board subject to the review~~
8 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
9 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
10 ~~Code.~~

11 ~~SEC. 8. Section 2450.3 of the Business and Professions Code~~
12 ~~is amended to read:~~

13 ~~2450.3. There is within the jurisdiction of the Osteopathic~~
14 ~~Medical Board of California a Naturopathic Medicine Committee~~
15 ~~authorized under the Naturopathic Doctors Act (Chapter 8.2~~
16 ~~(commencing with Section 3610)). This section shall become~~
17 ~~inoperative on January 1, 2013, and, as of that date is repealed,~~
18 ~~unless a later enacted statute that is enacted before January 1, 2013,~~
19 ~~deletes or extends that date. The repeal of this section renders the~~
20 ~~Naturopathic Medicine Committee subject to the review required~~
21 ~~by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5~~
22 ~~of Part 1 of Division 2 of Title 2 of the Government Code.~~

23 ~~SEC. 9. Section 2460 of the Business and Professions Code is~~
24 ~~amended to read:~~

25 ~~2460. (a) There is created within the jurisdiction of the Medical~~
26 ~~Board of California the California Board of Podiatric Medicine.~~

27 ~~(b) This section shall remain in effect only until January 1, 2013,~~
28 ~~and as of that date is repealed, unless a later enacted statute, that~~
29 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
30 ~~repeal of this section renders the California Board of Podiatric~~
31 ~~Medicine subject to the review required by Article 7.5~~
32 ~~(commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
33 ~~Division 2 of Title 2 of the Government Code.~~

34 ~~SEC. 10. Section 2531 of the Business and Professions Code~~
35 ~~is amended to read:~~

36 ~~2531. (a) There is in the Department of Consumer Affairs a~~
37 ~~Speech-Language Pathology and Audiology and Hearing Aid~~
38 ~~Dispensers Board in which the enforcement and administration of~~
39 ~~this chapter are vested. The Speech-Language Pathology and~~

1 Audiology and Hearing Aid Dispensers Board shall consist of nine
2 members, three of whom shall be public members.

3 ~~(b) This section shall remain in effect only until January 1, 2012,~~
4 ~~and as of that date is repealed, unless a later enacted statute, that~~
5 ~~is enacted before January 1, 2012, deletes or extends that date. The~~
6 ~~repeal of this section renders the board subject to the review~~
7 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
8 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
9 ~~Code.~~

10 SEC. 11. Section 2569 of the Business and Professions Code
11 is amended to read:

12 2569. The powers and duties of the board, as set forth in this
13 chapter, shall be subject to the review required by Article 7.5
14 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of
15 Division 2 of Title 2 of the Government Code.

16 SEC. 12. Section 2570.19 of the Business and Professions
17 Code is amended to read:

18 2570.19. (a) There is hereby created a California Board of
19 Occupational Therapy, hereafter referred to as the board. The board
20 shall enforce and administer this chapter.

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

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

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

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

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

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

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

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

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

26 ~~(h) Notice of each meeting of the board shall be given in~~
27 ~~accordance with the Bagley-Keene Open Meeting Act (Article 9~~
28 ~~(commencing with Section 11120) of Chapter 1 of Part 1 of~~
29 ~~Division 3 of Title 2 of the Government Code).~~

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

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

38 ~~(k) A loan is hereby authorized from the General Fund to the~~
39 ~~Occupational Therapy Fund on or after July 1, 2000, in an amount~~
40 ~~of up to one million dollars (\$1,000,000) to fund operating,~~

1 personnel, and other startup costs of the board. Six hundred ten
2 thousand dollars (\$610,000) of this loan amount is hereby
3 appropriated to the board to use in the 2000-01 fiscal year for the
4 purposes described in this subdivision. In subsequent years, funds
5 from the Occupational Therapy Fund shall be available to the board
6 upon appropriation by the Legislature in the annual Budget Act.
7 The loan shall be repaid to the General Fund over a period of up
8 to five years, and the amount paid shall also include interest at the
9 rate accruing to moneys in the Pooled Money Investment Account.
10 The loan amount and repayment period shall be minimized to the
11 extent possible based upon actual board financing requirements
12 as determined by the Department of Finance.

13 *(f)* This section shall become inoperative on July 1, 2013, and,
14 as of January 1, 2014, is repealed, unless a later enacted statute
15 that is enacted before January 1, 2014, deletes or extends the dates
16 on which it becomes inoperative and is repealed. The repeal of
17 this section renders the board subject to the review required by
18 Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of
19 Part 1 of Division 2 of Title 2 of the Government Code.

20 SEC. 13.— Section 2602 of the Business and Professions Code
21 is amended to read:

22 2602.— The Physical Therapy Board of California, hereafter
23 referred to as the board, shall enforce and administer this chapter.
24 This section shall become inoperative on July 1, 2013, and, as of
25 January 1, 2014, is repealed, unless a later enacted statute, which
26 becomes effective on or before January 1, 2014, deletes or extends
27 the dates on which it becomes inoperative and is repealed.

28 The repeal of this section renders the board subject to the review
29 required by Article 7.5 (commencing with Section 9147.7) of
30 Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
31 Code.

32 SEC. 14.— Section 2607.5 of the Business and Professions Code
33 is amended to read:

34 2607.5.— The board may appoint a person exempt from civil
35 service who shall be designated as an executive officer and who
36 shall exercise the powers and perform the duties delegated by the
37 board and vested in him or her by this chapter.

38 This section shall become inoperative on July 1, 2013, and, as
39 of January 1, 2014, is repealed, unless a later enacted statute, which

1 becomes effective on or before January 1, 2014, deletes or extends
2 the dates on which it becomes inoperative and is repealed.

3 ~~SEC. 15. Section 2701 of the Business and Professions Code~~
4 ~~is amended to read:~~

5 ~~2701. (a) There is in the Department of Consumer Affairs the~~
6 ~~Board of Registered Nursing consisting of nine members.~~

7 ~~(b) Within the meaning of this chapter, board, or the board,~~
8 ~~refers to the Board of Registered Nursing. Any reference in state~~
9 ~~law to the Board of Nurse Examiners of the State of California or~~
10 ~~California Board of Nursing Education and Nurse Registration~~
11 ~~shall be construed to refer to the Board of Registered Nursing.~~

12 ~~(c) This section shall remain in effect only until January 1, 2013,~~
13 ~~and as of that date is repealed, unless a later enacted statute, that~~
14 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
15 ~~repeal of this section renders the board subject to the review~~
16 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
17 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
18 ~~Code.~~

19 ~~SEC. 16. Section 2841 of the Business and Professions Code~~
20 ~~is amended to read:~~

21 ~~2841. (a) There is in the Department of Consumer Affairs a~~
22 ~~Board of Vocational Nursing and Psychiatric Technicians of the~~
23 ~~State of California, consisting of 11 members.~~

24 ~~(b) Within the meaning of this chapter, "board," or "the board,"~~
25 ~~refers to the Board of Vocational Nursing and Psychiatric~~
26 ~~Technicians of the State of California.~~

27 ~~(c) This section shall remain in effect only until January 1, 2012,~~
28 ~~and as of that date is repealed, unless a later enacted statute, that~~
29 ~~is enacted before January 1, 2012, deletes or extends that date. The~~
30 ~~repeal of this section renders the board subject to the review~~
31 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
32 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
33 ~~Code.~~

34 ~~SEC. 17. Section 3010.5 of the Business and Professions Code~~
35 ~~is amended to read:~~

36 ~~3010.5. (a) There is in the Department of Consumer Affairs~~
37 ~~a State Board of Optometry in which the enforcement of this~~
38 ~~chapter is vested. The board consists of 11 members, five of whom~~
39 ~~shall be public members.~~

40 ~~Six members of the board shall constitute a quorum.~~

1 ~~(b) The board shall, with respect to conducting investigations,~~
2 ~~inquiries, and disciplinary actions and proceedings, have the~~
3 ~~authority previously vested in the board as created pursuant to~~
4 ~~Section 3010. The board may enforce any disciplinary actions~~
5 ~~undertaken by that board.~~

6 ~~(c) This section shall remain in effect only until January 1, 2013,~~
7 ~~and as of that date is repealed, unless a later enacted statute, that~~
8 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
9 ~~repeal of this section renders the board subject to the review~~
10 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
11 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
12 ~~Code.~~

13 ~~SEC. 18. Section 3502.1 of the Business and Professions Code~~
14 ~~is amended to read:~~

15 ~~3502.1. (a) In addition to the services authorized in the~~
16 ~~regulations adopted by the board, and except as prohibited by~~
17 ~~Section 3502, while under the supervision of a licensed physician~~
18 ~~and surgeon or physicians and surgeons authorized by law to~~
19 ~~supervise a physician assistant, a physician assistant may~~
20 ~~administer or provide medication to a patient, or transmit orally,~~
21 ~~or in writing on a patient's record or in a drug order, an order to a~~
22 ~~person who may lawfully furnish the medication or medical device~~
23 ~~pursuant to subdivisions (c) and (d).~~

24 ~~(1) A supervising physician and surgeon who delegates authority~~
25 ~~to issue a drug order to a physician assistant may limit this authority~~
26 ~~by specifying the manner in which the physician assistant may~~
27 ~~issue delegated prescriptions.~~

28 ~~(2) Each supervising physician and surgeon who delegates the~~
29 ~~authority to issue a drug order to a physician assistant shall first~~
30 ~~prepare and adopt, or adopt, a written, practice specific, formulary~~
31 ~~and protocols that specify all criteria for the use of a particular~~
32 ~~drug or device, and any contraindications for the selection.~~
33 ~~Protocols for Schedule II controlled substances shall address the~~
34 ~~diagnosis of illness, injury, or condition for which the Schedule II~~
35 ~~controlled substance is being administered, provided, or issued.~~
36 ~~The drugs listed in the protocols shall constitute the formulary and~~
37 ~~shall include only drugs that are appropriate for use in the type of~~
38 ~~practice engaged in by the supervising physician and surgeon.~~
39 ~~When issuing a drug order, the physician assistant is acting on~~
40 ~~behalf of and as an agent for a supervising physician and surgeon.~~

1 ~~(b) “Drug order” for purposes of this section means an order~~
2 ~~for medication that is dispensed to or for a patient, issued and~~
3 ~~signed by a physician assistant acting as an individual practitioner~~
4 ~~within the meaning of Section 1306.02 of Title 21 of the Code of~~
5 ~~Federal Regulations. Notwithstanding any other provision of law,~~
6 ~~(1) a drug order issued pursuant to this section shall be treated in~~
7 ~~the same manner as a prescription or order of the supervising~~
8 ~~physician, (2) all references to “prescription” in this code and the~~
9 ~~Health and Safety Code shall include drug orders issued by~~
10 ~~physician assistants pursuant to authority granted by their~~
11 ~~supervising physicians and surgeons, and (3) the signature of a~~
12 ~~physician assistant on a drug order shall be deemed to be the~~
13 ~~signature of a prescriber for purposes of this code and the Health~~
14 ~~and Safety Code.~~

15 ~~(c) A drug order for any patient cared for by the physician~~
16 ~~assistant that is issued by the physician assistant shall either be~~
17 ~~based on the protocols described in subdivision (a) or shall be~~
18 ~~approved by the supervising physician and surgeon before it is~~
19 ~~filled or carried out.~~

20 ~~(1) A physician assistant shall not administer or provide a drug~~
21 ~~or issue a drug order for a drug other than for a drug listed in the~~
22 ~~formulary without advance approval from a supervising physician~~
23 ~~and surgeon for the particular patient. At the direction and under~~
24 ~~the supervision of a physician and surgeon, a physician assistant~~
25 ~~may hand to a patient of the supervising physician and surgeon a~~
26 ~~properly labeled prescription drug prepackaged by a physician and~~
27 ~~surgeon, manufacturer as defined in the Pharmacy Law, or a~~
28 ~~pharmacist.~~

29 ~~(2) A physician assistant may not administer, provide, or issue~~
30 ~~a drug order to a patient for Schedule II through Schedule V~~
31 ~~controlled substances without advance approval by a supervising~~
32 ~~physician and surgeon for that particular patient unless the~~
33 ~~physician assistant has completed an education course that covers~~
34 ~~controlled substances and that meets standards, including~~
35 ~~pharmacological content, approved by the committee. The~~
36 ~~education course shall be provided either by an accredited~~
37 ~~continuing education provider or by an approved physician assistant~~
38 ~~training program. If the physician assistant will administer, provide,~~
39 ~~or issue a drug order for Schedule II controlled substances, the~~
40 ~~course shall contain a minimum of three hours exclusively on~~

1 Schedule II controlled substances. Completion of the requirements
2 set forth in this paragraph shall be verified and documented in the
3 manner established by the committee prior to the physician
4 assistant's use of a registration number issued by the United States
5 Drug Enforcement Administration to the physician assistant to
6 administer, provide, or issue a drug order to a patient for a
7 controlled substance without advance approval by a supervising
8 physician and surgeon for that particular patient.

9 (3) Any drug order issued by a physician assistant shall be
10 subject to a reasonable quantitative limitation consistent with
11 customary medical practice in the supervising physician and
12 surgeon's practice.

13 (d) A written drug order issued pursuant to subdivision (a),
14 except a written drug order in a patient's medical record in a health
15 facility or medical practice, shall contain the printed name, address,
16 and phone number of the supervising physician and surgeon, the
17 printed or stamped name and license number of the physician
18 assistant, and the signature of the physician assistant. Further, a
19 written drug order for a controlled substance, except a written drug
20 order in a patient's medical record in a health facility or a medical
21 practice, shall include the federal controlled substances registration
22 number of the physician assistant and shall otherwise comply with
23 the provisions of Section 11162.1 of the Health and Safety Code.
24 Except as otherwise required for written drug orders for controlled
25 substances under Section 11162.1 of the Health and Safety Code,
26 the requirements of this subdivision may be met through stamping
27 or otherwise imprinting on the supervising physician and surgeon's
28 prescription blank to show the name, license number, and if
29 applicable, the federal controlled substances number of the
30 physician assistant, and shall be signed by the physician assistant.
31 When using a drug order, the physician assistant is acting on behalf
32 of and as the agent of a supervising physician and surgeon.

33 (e) The medical record of any patient cared for by a physician
34 assistant for whom the physician assistant's Schedule II drug order
35 has been issued or carried out shall be reviewed and countersigned
36 and dated by a supervising physician and surgeon within seven
37 days.

38 (f) All physician assistants who are authorized by their
39 supervising physicians to issue drug orders for controlled

1 substances shall register with the United States Drug Enforcement
2 Administration (DEA):

3 ~~(g) The committee shall consult with the Medical Board of~~
4 ~~California and report during its sunset review required by Article~~
5 ~~7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
6 ~~Division 2 of Title 2 of the Government Code the impacts of~~
7 ~~exempting Schedule III and Schedule IV drug orders from the~~
8 ~~requirement for a physician and surgeon to review and countersign~~
9 ~~the affected medical record of a patient.~~

10 SEC. 19. Section 3504 of the Business and Professions Code
11 is amended to read:

12 3504. ~~There is established a Physician Assistant Committee~~
13 ~~of the Medical Board of California. The committee consists of~~
14 ~~nine members. This section shall become inoperative on July 1,~~
15 ~~2011, and, as of January 1, 2012, is repealed, unless a later enacted~~
16 ~~statute, which becomes effective on or before January 1, 2012,~~
17 ~~deletes or extends the dates on which it becomes inoperative and~~
18 ~~is repealed. The repeal of this section renders the committee subject~~
19 ~~to the review required by Article 7.5 (commencing with Section~~
20 ~~9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the~~
21 ~~Government Code.~~

22 SEC. 20. Section 3685 of the Business and Professions Code
23 is amended to read:

24 3685. ~~The repeal of this chapter renders the committee subject~~
25 ~~to the review required by Article 7.5 (commencing with Section~~
26 ~~9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the~~
27 ~~Government Code.~~

28 SEC. 21. Section 3710 of the Business and Professions Code
29 is amended to read:

30 3710. ~~(a) The Respiratory Care Board of California, hereafter~~
31 ~~referred to as the board, shall enforce and administer this chapter.~~

32 ~~(b) This section shall remain in effect only until January 1, 2013,~~
33 ~~and as of that date is repealed, unless a later enacted statute, that~~
34 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
35 ~~repeal of this section renders the board subject to the review~~
36 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
37 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
38 ~~Code.~~

39 SEC. 22. Section 4001 of the Business and Professions Code
40 is amended to read:

1 4001. ~~(a) There is in the Department of Consumer Affairs a~~
2 ~~California State Board of Pharmacy in which the administration~~
3 ~~and enforcement of this chapter is vested. The board consists of~~
4 ~~13 members.~~

5 ~~(b) The Governor shall appoint seven competent pharmacists~~
6 ~~who reside in different parts of the state to serve as members of~~
7 ~~the board. The Governor shall appoint four public members, and~~
8 ~~the Senate Committee on Rules and the Speaker of the Assembly~~
9 ~~shall each appoint a public member who shall not be a licensee of~~
10 ~~the board, any other board under this division, or any board referred~~
11 ~~to in Section 1000 or 3600.~~

12 ~~(c) At least five of the seven pharmacist appointees to the board~~
13 ~~shall be pharmacists who are actively engaged in the practice of~~
14 ~~pharmacy. Additionally, the membership of the board shall include~~
15 ~~at least one pharmacist representative from each of the following~~
16 ~~practice settings: an acute care hospital, an independent community~~
17 ~~pharmacy, a chain community pharmacy, and a long-term health~~
18 ~~care or skilled nursing facility. The pharmacist appointees shall~~
19 ~~also include a pharmacist who is a member of a labor union that~~
20 ~~represents pharmacists. For the purposes of this subdivision, a~~
21 ~~“chain community pharmacy” means a chain of 75 or more stores~~
22 ~~in California under the same ownership, and an “independent~~
23 ~~community pharmacy” means a pharmacy owned by a person or~~
24 ~~entity who owns no more than four pharmacies in California.~~

25 ~~(d) Members of the board shall be appointed for a term of four~~
26 ~~years. No person shall serve as a member of the board for more~~
27 ~~than two consecutive terms. Each member shall hold office until~~
28 ~~the appointment and qualification of his or her successor or until~~
29 ~~one year shall have elapsed since the expiration of the term for~~
30 ~~which the member was appointed, whichever first occurs.~~
31 ~~Vacancies occurring shall be filled by appointment for the~~
32 ~~unexpired term.~~

33 ~~(e) Each member of the board shall receive a per diem and~~
34 ~~expenses as provided in Section 103.~~

35 ~~(f) This section shall remain in effect only until January 1, 2013,~~
36 ~~and as of that date is repealed, unless a later enacted statute, that~~
37 ~~is enacted before January 1, 2013, deletes or extends that date. The~~
38 ~~repeal of this section renders the board subject to the review~~
39 ~~required by Article 7.5 (commencing with Section 9147.7) of~~

1 Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
2 Code.

3 ~~SEC. 23. Section 4615 of the Business and Professions Code~~
4 ~~is amended to read:~~

5 ~~4615. This chapter shall be subject to the review required by~~
6 ~~Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of~~
7 ~~Part 1 of Division 2 of Title 2 of the Government Code.~~

8 ~~SEC. 24. Section 4800 of the Business and Professions Code~~
9 ~~is amended to read:~~

10 ~~4800. There is in the Department of Consumer Affairs a~~
11 ~~Veterinary Medical Board in which the administration of this~~
12 ~~chapter is vested. The board consists of seven members, three of~~
13 ~~whom shall be public members.~~

14 ~~This section shall become inoperative on July 1, 2011, and, as~~
15 ~~of January 1, 2012, is repealed, unless a later enacted statute, which~~
16 ~~becomes effective on or before January 1, 2012, deletes or extends~~
17 ~~the dates on which it becomes inoperative and is repealed.~~

18 ~~The repeal of this section renders the board subject to the review~~
19 ~~provided for by Article 7.5 (commencing with Section 9147.7) of~~
20 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
21 ~~Code.~~

22 ~~SEC. 25. Section 4809.8 of the Business and Professions Code~~
23 ~~is amended to read:~~

24 ~~4809.8. (a) The board shall appoint a voluntary, advisory~~
25 ~~multidisciplinary committee to assist, advise, and make~~
26 ~~recommendations for the implementation of rules and regulations~~
27 ~~necessary to ensure proper administration and enforcement of this~~
28 ~~chapter. Members of the committee shall be appointed from lists~~
29 ~~of nominees solicited by the board. The committee shall consist~~
30 ~~of no more than nine members.~~

31 ~~(b) The committee shall be subject to the requirements of Article~~
32 ~~9 (commencing with Section 11120) of Chapter 1 of Part 1 of~~
33 ~~Division 3 of Title 2 of the Government Code.~~

34 ~~(c) Committee members shall receive a per diem as provided~~
35 ~~in Section 103 and shall be compensated for their actual travel~~
36 ~~expenses in accordance with the rules and regulations adopted by~~
37 ~~the Department of Personnel Administration.~~

38 ~~(d) This section shall become inoperative on July 1, 2011, and~~
39 ~~as of January 1, 2012, is repealed, unless a later enacted statute,~~
40 ~~that becomes operative on or before January 1, 2012, deletes or~~

1 extends the dates on which it becomes inoperative and is repealed.
2 The repeal of this section renders the committee subject to the
3 review required by Article 7.5 (commencing with Section 9147.7)
4 of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
5 Code.

6 ~~SEC. 26.— Section 4989 of the Business and Professions Code~~
7 ~~is amended to read:~~

8 ~~4989.— The powers and duties of the board, as set forth in this~~
9 ~~chapter, shall be subject to the review required by Article 7.5~~
10 ~~(commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
11 ~~Division 2 of Title 2 of the Government Code.~~

12 ~~SEC. 27.— Section 4990.24 of the Business and Professions~~
13 ~~Code is amended to read:~~

14 ~~4990.24.— The powers and duties of the board, as set forth in~~
15 ~~this chapter, shall be subject to the review required by Article 7.5~~
16 ~~(commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
17 ~~Division 2 of Title 2 of the Government Code.~~

18 ~~SEC. 28.— Section 5000 of the Business and Professions Code~~
19 ~~is amended to read:~~

20 ~~5000.— There is in the Department of Consumer Affairs the~~
21 ~~California Board of Accountancy, which consists of 15 members,~~
22 ~~seven of whom shall be licensees, and eight of whom shall be~~
23 ~~public members who shall not be licentiates of the board or~~
24 ~~registered by the board. The board has the powers and duties~~
25 ~~conferred by this chapter.~~

26 ~~The Governor shall appoint four of the public members, and the~~
27 ~~seven licensee members as provided in this section. The Senate~~
28 ~~Rules Committee and the Speaker of the Assembly shall each~~
29 ~~appoint two public members. In appointing the seven licensee~~
30 ~~members, the Governor shall appoint members representing a cross~~
31 ~~section of the accounting profession with at least two members~~
32 ~~representing a small public accounting firm. For the purposes of~~
33 ~~this chapter, a small public accounting firm shall be defined as a~~
34 ~~professional firm that employs a total of no more than four~~
35 ~~licensees as partners, owners, or full-time employees in the practice~~
36 ~~of public accountancy within the State of California.~~

37 ~~This section shall become inoperative on July 1, 2011, and as~~
38 ~~of January 1, 2012, is repealed, unless a later enacted statute, that~~
39 ~~becomes effective on or before January 1, 2012, deletes or extends~~
40 ~~the dates on which this section becomes inoperative and is repealed.~~

1 The repeal of this section renders the board subject to the review
2 required by Article 7.5 (commencing with Section 9147.7) of
3 Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
4 Code. However, the review of the board shall be limited to reports
5 or studies specified in this chapter and those issues identified by
6 the Joint Sunset Review Committee and the board regarding the
7 implementation of new licensing requirements.

8 SEC. 29.— Section 5510 of the Business and Professions Code
9 is amended to read:

10 5510.— There is in the Department of Consumer Affairs a
11 California Architects Board which consists of 10 members:

12 Any reference in law to the California Board of Architectural
13 Examiners shall mean the California Architects Board.

14 This section shall become inoperative on July 1, 2011, and, as
15 of January 1, 2012, is repealed, unless a later enacted statute, which
16 becomes effective on or before January 1, 2012, deletes or extends
17 the dates on which it becomes inoperative and is repealed. The
18 repeal of this section renders the board subject to the review
19 required by Article 7.5 (commencing with Section 9147.7) of
20 Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government
21 Code.

22 SEC. 30.— Section 5810 of the Business and Professions Code
23 is amended to read:

24 5810.—(a) This chapter shall be subject to the review required
25 by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5
26 of Part 1 of Division 2 of Title 2 of the Government Code.

27 (b) This chapter shall remain in effect only until January 1,
28 2013, and as of that date is repealed, unless a later enacted statute,
29 that is enacted before January 1, 2013, deletes or extends that date.

30 SEC. 31.— Section 6510 of the Business and Professions Code
31 is amended to read:

32 6510.—(a) There is within the jurisdiction of the department
33 the Professional Fiduciaries Bureau. The bureau is under the
34 supervision and control of the director. The duty of enforcing and
35 administering this chapter is vested in the chief of the bureau, who
36 is responsible to the director. Every power granted or duty imposed
37 upon the director under this chapter may be exercised or performed
38 in the name of the director by a deputy director or by the chief,
39 subject to conditions and limitations as the director may prescribe.

1 ~~(b) The Governor shall appoint, subject to confirmation by the~~
2 ~~Senate, the chief of the bureau, at a salary to be fixed and~~
3 ~~determined by the director with the approval of the Director of~~
4 ~~Finance. The chief shall serve under the direction and supervision~~
5 ~~of the director and at the pleasure of the Governor.~~

6 ~~(e) This section shall become inoperative on July 1, 2011, and,~~
7 ~~as of January 1, 2012, is repealed, unless a later enacted statute,~~
8 ~~that becomes operative on or before January 1, 2012, deletes or~~
9 ~~extends the dates on which it becomes inoperative and is repealed.~~
10 ~~The repeal of this section renders the bureau subject to the review~~
11 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
12 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
13 ~~Code.~~

14 ~~Notwithstanding any other provision of law, upon the repeal of~~
15 ~~this section, the responsibilities and jurisdiction of the bureau shall~~
16 ~~be transferred to the Professional Fiduciaries Advisory Committee,~~
17 ~~as provided by Section 6511.~~

18 ~~SEC. 32.— Section 6710 of the Business and Professions Code~~
19 ~~is amended to read:~~

20 ~~6710. (a) There is in the Department of Consumer Affairs a~~
21 ~~Board for Professional Engineers and Land Surveyors, which~~
22 ~~consists of 13 members.~~

23 ~~(b) Any reference in any law or regulation to the Board of~~
24 ~~Registration for Professional Engineers and Land Surveyors is~~
25 ~~deemed to refer to the Board for Professional Engineers and Land~~
26 ~~Surveyors.~~

27 ~~(e) This section shall become inoperative on July 1, 2011, and,~~
28 ~~as of January 1, 2012, is repealed, unless a later enacted statute,~~
29 ~~that becomes effective on or before January 1, 2012, deletes or~~
30 ~~extends the dates on which it becomes inoperative and is repealed.~~
31 ~~The repeal of this section renders the board subject to the review~~
32 ~~required by Article 7.5 (commencing with Section 9147.7) of~~
33 ~~Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
34 ~~Code.~~

35 ~~SEC. 33.— Section 7200.2 is added to the Business and~~
36 ~~Professions Code, to read:~~

37 ~~7200.2.— The board shall be subject to the review required by~~
38 ~~Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of~~
39 ~~Part 1 of Division 2 of Title 2 of the Government Code.~~

1 ~~SEC. 34.— Section 7304 of the Business and Professions Code~~
2 ~~is amended to read:~~

3 ~~7304. The board shall be subject to review pursuant to Article~~
4 ~~7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
5 ~~Division 2 of Title 2 of the Government Code.~~

6 ~~SEC. 35.— Section 7501 of the Business and Professions Code~~
7 ~~is amended to read:~~

8 ~~7501. (a) There is in the Department of Consumer Affairs a~~
9 ~~Bureau of Security and Investigative Services. The bureau is under~~
10 ~~the supervision and control of the director. The director shall~~
11 ~~administer and enforce the provisions of this chapter.~~

12 ~~(b) The bureau shall be subject to the review required by Article~~
13 ~~7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of~~
14 ~~Division 2 of Title 2 of the Government Code.~~

15 ~~SEC. 36.— Section 7611 is added to the Business and Professions~~
16 ~~Code, to read:~~

17 ~~7611. The bureau shall be subject to the review required by~~
18 ~~Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of~~
19 ~~Part 1 of Division 2 of Title 2 of the Government Code.~~

20 ~~SEC. 37.— Section 8710 of the Business and Professions Code~~
21 ~~is amended to read:~~

22 ~~8710. (a) The Board for Professional Engineers and Land~~
23 ~~Surveyors is vested with power to administer the provisions and~~
24 ~~requirements of this chapter, and may make and enforce rules and~~
25 ~~regulations that are reasonably necessary to carry out its provisions.~~

26 ~~(b) The board may adopt rules and regulations of professional~~
27 ~~conduct that are not inconsistent with state and federal law. The~~
28 ~~rules and regulations may include definitions of incompetence and~~
29 ~~negligence. Every person who holds a license or certificate issued~~
30 ~~by the board pursuant to this chapter, or a license or certificate~~
31 ~~issued to a civil engineer pursuant to Chapter 7 (commencing with~~
32 ~~Section 6700), shall be governed by these rules and regulations.~~

33 ~~(c) This section shall become inoperative on July 1, 2011, and,~~
34 ~~as of January 1, 2012, is repealed, unless a later enacted statute,~~
35 ~~which becomes effective on or before January 1, 2012, deletes or~~
36 ~~extends the dates on which it becomes inoperative and is repealed.~~
37 ~~The repeal of this section shall render the board subject to the~~
38 ~~review required by Article 7.5 (commencing with Section 9147.7)~~
39 ~~of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government~~
40 ~~Code.~~

1 SEC. 38.—Section 9815 is added to the Business and Professions
2 Code, to read:

3 9815.—The bureau shall be subject to the review required by
4 Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of
5 Part 1 of Division 2 of Title 2 of the Government Code.

6 SEC. 39.—Section 9882 of the Business and Professions Code
7 is amended to read:

8 9882.—(a) There is in the Department of Consumer Affairs a
9 Bureau of Automotive Repair under the supervision and control
10 of the director. The duty of enforcing and administering this chapter
11 is vested in the chief who is responsible to the director. The director
12 may adopt and enforce those rules and regulations that he or she
13 determines are reasonably necessary to carry out the purposes of
14 this chapter and declaring the policy of the bureau, including a
15 system for the issuance of citations for violations of this chapter
16 as specified in Section 125.9. These rules and regulations shall be
17 adopted pursuant to Chapter 3.5 (commencing with Section 11340)
18 of Part 1 of Division 3 of Title 2 of the Government Code.

19 (b) In 2003 and every four years thereafter, the Joint Sunset
20 Review Committee shall hold a public hearing to receive testimony
21 from the Director of Consumer Affairs and the bureau. In those
22 hearings, the bureau shall have the burden of demonstrating a
23 compelling public need for the continued existence of the bureau
24 and its regulatory program, and that its function is the least
25 restrictive regulation consistent with the public health, safety, and
26 welfare. The committee shall evaluate and review the effectiveness
27 and efficiency of the bureau and shall report its findings and
28 recommendations to the Legislature as specified in Article 7.5
29 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of
30 Division 2 of Title 2 of the Government Code. The bureau shall
31 prepare an analysis and submit a report to the committee as
32 specified in subdivision (c) of Section 9147.7 of the Government
33 Code.

34 SEC. 40.—Section 11506 of the Business and Professions Code
35 is amended to read:

36 11506.—This part shall be subject to the review required by
37 Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of
38 Part 1 of Division 2 of Title 2 of the Government Code. This part
39 shall remain in effect only until January 1, 2012, and as of that

1 ~~date is repealed, unless a later enacted statute, that is enacted before~~
2 ~~January 1, 2012, deletes or extends that date.~~

3 ~~SEC. 41. Section 22259 of the Business and Professions Code~~
4 ~~is amended to read:~~

5 ~~22259. This chapter shall be subject to the review required by~~
6 ~~Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of~~
7 ~~Part 1 of Division 2 of Title 2 of the Government Code.~~

8 ~~This chapter shall remain in effect only until January 1, 2012,~~
9 ~~and as of that date is repealed, unless a later enacted statute, that~~
10 ~~is enacted before January 1, 2012, deletes or extends that date.~~

11 ~~SEC. 4. Section 4351 of the Food and Agricultural Code is~~
12 ~~amended to read:~~

13 4351. (a) There is hereby created the State Race Track Leasing
14 Commission which shall be composed of the Director of Food and
15 Agriculture, the Director of Finance, and the Director of General
16 Services and three individuals, appointed by the Governor, who
17 are members of the Board of Directors of the 22nd District
18 Agricultural Association. The Director of Finance shall serve as
19 chairperson of the commission. All meetings of the commission
20 shall be open and public.

21 (b) *This chapter shall remain in effect only until January 1,*
22 *2013, and as of that date is repealed, unless a later enacted statute,*
23 *that is enacted before January 1, 2013, deletes or extends that*
24 *date.*

25 ~~SEC. 5. Section 8164.1 of the Government Code is amended~~
26 ~~to read:~~

27 8164.1. There is in state government a Capitol Area Committee
28 consisting of nine members who shall be appointed in the following
29 manner:

30 (a) Four members of the committee shall be appointed by the
31 Governor of which at least one member shall be appointed from
32 a list of three candidates submitted by the City of Sacramento and
33 at least one member shall be appointed from a list of three
34 candidates submitted by the County of Sacramento. Two members
35 shall be appointed for a term expiring December 31, 1979, and
36 two for a term expiring December 31, 1981.

37 (b) Two members shall be appointed by the Speaker of the
38 Assembly, one of whom may be a Member of the Assembly, and
39 two members shall be appointed by the Senate Rules Committee,
40 one of whom may be a Member of the Senate. Legislative members

1 of the committee shall meet and, except as otherwise provided by
2 the Constitution, advise the department to the extent that the
3 advisory participation is not incompatible with their respective
4 positions as Members of the Legislature. Of the four appointments
5 by the Legislature, two shall be appointed for a term expiring
6 December 31, 1979, and two for a term expiring December 31,
7 1981.

8 (c) One shall be appointed by and serve at the pleasure of the
9 director.

10 Subsequent appointments pursuant to subdivisions (a) and (b)
11 shall be for terms of four years, ending on December 31st of the
12 fourth year after the end of the prior term, except that appointments
13 to fill vacancies occurring for any reason other than the expiration
14 of the term shall be for the unexpired portion of the term in which
15 they occur. The members of the board shall hold office until their
16 successors are appointed and qualify.

17 The members of the committee shall not receive compensation
18 from the state for their services under this article but, when called
19 to attend a meeting of the committee, shall be reimbursed for their
20 actual and necessary expenses incurred in connection with the
21 meeting in accordance with the rules of the Department of
22 Personnel Administration.

23 (d) *This section shall remain in effect only until January 1, 2013,*
24 *and as of that date is repealed, unless a later enacted statute, that*
25 *is enacted before January 1, 2013, deletes or extends that date.*

26 SEC. 6. *Section 8164.2 of the Government Code is amended*
27 *to read:*

28 8164.2. (a) The committee shall elect a chairperson. The
29 committee shall meet at least quarterly or upon the call of the
30 chairperson or the written request of any three members.

31 (b) *This section shall remain in effect only until January 1, 2013,*
32 *and as of that date is repealed, unless a later enacted statute, that*
33 *is enacted before January 1, 2013, deletes or extends that date.*

34 SEC. 7. *Section 8164.3 of the Government Code is amended*
35 *to read:*

36 8164.3. (a) It is the purpose of the committee to independently
37 review the reports of the department to the Legislature and counsel
38 and advise the department in the carrying out of its responsibilities
39 related to the Capitol Area Plan. The committee may submit
40 separate comments on the departmental reports on the Capitol Area

1 Plan to the Legislature. The committee shall involve a broad cross
2 section of interested citizens in the form of an advisory body. The
3 advisory body shall serve without compensation.

4 *(b) This section shall remain in effect only until January 1, 2013,*
5 *and as of that date is repealed, unless a later enacted statute, that*
6 *is enacted before January 1, 2013, deletes or extends that date.*

7 ~~SEC. 42.~~

8 SEC. 8. Section 9148.51 of the Government Code is amended
9 to read:

10 9148.51. (a) It is the intent of the Legislature that all existing
11 and proposed ~~state boards~~ *eligible agencies, as defined in*
12 *subdivision (a) of Section 9147.7*, be subject to review ~~every four~~
13 ~~years~~ to evaluate and determine whether each has demonstrated a
14 public need for its continued existence in accordance with
15 enumerated factors and standards as set forth in Article 7.5
16 (commencing with Section 9147.7).

17 (b) If any state board becomes inoperative or is repealed in
18 accordance with the act that added this section, any provision of
19 existing law that provides for the appointment of board members
20 and specifies the qualifications and tenure of board members shall
21 not be implemented and shall have no force or effect while that
22 state board is inoperative or repealed.

23 (c) Any provision of law authorizing the appointment of an
24 executive officer by a state board subject to the review described
25 in Article 7.5 (commencing with Section 9147.7), or prescribing
26 his or her duties, shall not be implemented and shall have no force
27 or effect while the applicable state board is inoperative or repealed.

28 ~~(d) It is the intent of the Legislature that subsequent legislation~~
29 ~~to extend or repeal the inoperative date for any state board shall~~
30 ~~be a separate bill for that purpose.~~

31 ~~SEC. 43.~~

32 SEC. 9. Section 9148.52 of the Government Code is amended
33 to read:

34 9148.52. (a) The Joint Sunset Review Committee established
35 pursuant to Section 9147.7 shall review all ~~state boards, as defined~~
36 ~~in Section 9148.2, every four years~~ *eligible agencies*.

37 (b) The committee shall evaluate and make determinations
38 pursuant to Article 7.5 (commencing with Section 9147.7).

39 (c) *Pursuant to an evaluation made as specified in this section,*
40 *the committee shall make a report which shall be available to the*

1 *public and the Legislature on whether an agency should be*
2 *terminated, or continued, or whether its functions should be revised*
3 *or consolidated with those of another agency, and include any*
4 *other recommendations as necessary to improve the effectiveness*
5 *and efficiency of the agency. If the committee deems it advisable,*
6 *the report may include proposed legislative proposals that would*
7 *carry out its recommendations.*

8 *SEC. 10. Section 1777 of the Health and Safety Code is*
9 *amended to read:*

10 1777. (a) The Continuing Care Advisory Committee of the
11 department shall act in an advisory capacity to the department on
12 matters relating to continuing care contracts.

13 (b) The members of the committee shall include:

14 (1) Three representatives of nonprofit continuing care providers
15 pursuant to this chapter, each of whom shall have offered
16 continuing care services for at least five years prior to appointment.
17 One member shall represent a multifacility provider and shall be
18 appointed by the Governor in even years. One member shall be
19 appointed by the Senate Committee on Rules in odd years. One
20 member shall be appointed by the Speaker of the Assembly in odd
21 years.

22 (2) Three senior citizens who are not eligible for appointment
23 pursuant to paragraphs (1) and (4) who shall represent consumers
24 of continuing care services, all of whom shall be residents of
25 continuing care retirement communities but not residents of the
26 same provider. One senior citizen member shall be appointed by
27 the Governor in even years. One senior citizen member shall be
28 appointed by the Senate Committee on Rules in odd years. One
29 senior citizen member shall be appointed by the Speaker of the
30 Assembly in odd years.

31 (3) A certified public accountant with experience in the
32 continuing care industry, who is not a provider of continuing care
33 services. This member shall be appointed by the Governor in even
34 years.

35 (4) A representative of a for-profit provider of continuing care
36 contracts pursuant to this chapter. This member shall be appointed
37 by the Governor in even years.

38 (5) An actuary. This member shall be appointed by the
39 Governor in even years.

1 (6) One representative of residents of continuing care retirement
2 communities appointed by the senior citizen representatives on
3 the committee.

4 (7) One representative of either nonprofit or for-profit providers
5 appointed by the representatives of nonprofit and for-provider
6 providers on the committee.

7 (c) Commencing January 1, 1997, all members shall serve
8 two-year terms and be appointed based on their interest and
9 expertise in the subject area. The Governor shall designate the
10 chairperson for the committee with the advice and consent of the
11 Senate. A member may be reappointed at the pleasure of the
12 appointing power. The appointing power shall fill all vacancies
13 on the committee within 60 days. All members shall continue to
14 serve until their successors are appointed and qualified.

15 (d) The members of the committee shall serve without
16 compensation, except that each member shall be paid from the
17 Continuing Care Provider Fee Fund a per diem of twenty-five
18 dollars (\$25) for each day's attendance at a meeting of the
19 committee not to exceed six days in any month. The members of
20 the committee shall also receive their actual and necessary travel
21 expenses incurred in the course of their duties. Reimbursement of
22 travel expenses shall be at rates not to exceed those applicable to
23 comparable state employees under Department of Personnel
24 Administration regulations.

25 (e) Prior to commencement of service, each member shall file
26 with the department a statement of economic interest and a
27 statement of conflict of interest pursuant to Article 3 (commencing
28 with Section 87300) of the Government Code.

29 (f) If, during the period of appointment, any member no longer
30 meets the qualifications of subdivision (b), that member shall
31 submit his or her resignation to their appointing power and a
32 qualified new member shall be appointed by the same power to
33 fulfill the remainder of the term.

34 (g) *This section shall remain in effect only until January 1, 2013,*
35 *and as of that date is repealed, unless a later enacted statute, that*
36 *is enacted before January 1, 2013, deletes or extends that date.*

37 *SEC. 11. Section 1777.2 of the Health and Safety Code is*
38 *amended to read:*

39 1777.2. (a) The Continuing Care Advisory Committee shall:

1 (1) Review the financial and managerial condition of continuing
2 care retirement communities operating under a certificate of
3 authority.

4 (2) Review the financial condition of any continuing care
5 retirement community that the committee determines is indicating
6 signs of financial difficulty and may be in need of close
7 supervision.

8 (3) Monitor the condition of those continuing care retirement
9 communities that the department or the chair of the committee
10 may request.

11 (4) Make available consumer information on the selection of
12 continuing care contracts and necessary contract protections in the
13 purchase of continuing care contracts.

14 (5) Review new applications regarding financial, actuarial, and
15 marketing feasibility as requested by the department.

16 (b) The committee shall make recommendations to the
17 department regarding needed changes in its rules and regulations
18 and upon request provide advice regarding the feasibility of new
19 continuing care retirement communities and the correction of
20 problems relating to the management or operation of any
21 continuing care retirement community. The committee shall also
22 perform any other advisory functions necessary to improve the
23 management and operation of continuing care retirement
24 communities.

25 (c) The committee may report on its recommendations directly
26 to the director of the department.

27 (d) The committee may hold meetings, as deemed necessary
28 to the performance of its duties.

29 (e) *This section shall remain in effect only until January 1, 2013,*
30 *and as of that date is repealed, unless a later enacted statute, that*
31 *is enacted before January 1, 2013, deletes or extends that date.*

32 *SEC. 12. Section 1777.4 of the Health and Safety Code is*
33 *amended to read:*

34 1777.4. (a) Any member of the Continuing Care Advisory
35 Committee is immune from civil liability based on acts performed
36 in his or her official capacity. Costs of defending civil actions
37 brought against a member for acts performed in his or her official
38 capacity shall be borne by the complainant. However, nothing in
39 this section immunizes any member for acts or omissions
40 performed with malice or in bad faith.

1 (b) *This section shall remain in effect only until January 1, 2013,*
2 *and as of that date is repealed, unless a later enacted statute, that*
3 *is enacted before January 1, 2013, deletes or extends that date.*

4 SEC. 13. *Section 5073.5 of the Public Resources Code is*
5 *amended to read:*

6 5073.5. (a) The Governor shall establish a California
7 Recreational Trails Committee to advise the director in the
8 development and coordination of the system. The committee shall
9 consist of seven members appointed by the Governor. Two
10 members shall be selected from the northern, two members from
11 the southern, and two members from the central portions of the
12 state, and one member shall be selected at large. Members shall
13 be selected from lists submitted by private organizations which
14 have a demonstrated interest in the establishment of recreation
15 trails. The chairman of the committee shall be elected by the
16 members from their membership.

17 (b) *This section shall remain in effect only until January 1, 2013,*
18 *and as of that date is repealed, unless a later enacted statute, that*
19 *is enacted before January 1, 2013, deletes or extends that date.*

20 SEC. 14. *Section 5073.7 of the Public Resources Code is*
21 *amended to read:*

22 5073.7. (a) The terms of the members of the committee shall
23 be four years, except that such members first appointed to the
24 committee shall classify themselves by lot so that the term of three
25 members shall expire January 15, 1976, the term of two members
26 shall expire January 15, 1977, and the term of two members shall
27 expire January 15, 1978.

28 Members of the committee shall serve without compensation,
29 but shall be reimbursed for actual and necessary expenses,
30 including traveling expenses, incurred in the performance of their
31 duties.

32 (b) *This section shall remain in effect only until January 1, 2013,*
33 *and as of that date is repealed, unless a later enacted statute, that*
34 *is enacted before January 1, 2013, deletes or extends that date.*

35 SEC. 15. *Section 5074 of the Public Resources Code is*
36 *amended to read:*

37 5074. The committee shall have the following powers and
38 duties:

39 (a) Coordinate trail planning and development among cities,
40 counties, and districts. In carrying out this responsibility, the

1 committee shall review records of easements and other interests
2 in lands which are available for recreational trail usage, including
3 public lands, utility easements, other rights-of-way, gifts, or surplus
4 public lands which may be adaptable for such use, and shall advise
5 the director in the development of standards for trail construction
6 so that uniform construction standards may be available to cities,
7 counties, and districts.

8 (b) Advise the director in the preparation and maintenance of
9 the plan.

10 (c) Study the problems and opportunities presented by the use
11 of private property for recreational trail use and advise the director
12 on measures to mitigate undesirable aspects of such usage.

13 (d) *This section shall remain in effect only until January 1, 2013,*
14 *and as of that date is repealed, unless a later enacted statute, that*
15 *is enacted before January 1, 2013, deletes or extends that date.*

16 ~~SEC. 44.~~

17 *SEC. 16.* The provisions of this act shall not become operative
18 unless Assembly Bill 1659 of the 2009–10 Regular Session is also
19 enacted and becomes operative on or before January 1, 2011, and
20 adds Article 7.5 (commencing with Section 9147.7) to Chapter
21 1.5 of Part 1 of Division 2 of Title 2 of the Government Code to
22 establish the Joint Sunset Review Committee.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 971

VERSION: Amended June 23, 2010

AUTHOR: Pavely

SPONSOR: Hemophilia Council of California

BOARD POSITION: None

SUBJECT: Bleeding disorders: blood clotting products

Affected Sections: Amend Business and Professions Code Section 4003

Current Status: Senate Appropriation (hearing date not set)

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 "assay," "ancillary infusion equipment and supplies," "bleeding disorder," "blood clotting product," "emergency," "hemophilia," "hemophilia treatment center," "home nursing services," "home use," "patient," and "provider of blood clotting products for home use."
4. Specify that that each provider of blood clotting products shall have the following:

- a. Have sufficient knowledge and understanding of bleeding disorders to accurately follow prescriber directions.
 - b. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to ensure appropriate supply of clotting factor.
 - c. Have access to knowledgeable pharmacy staffing on call 24 hours a day to initiate emergency requests for clotting factors.
 - d. Have the ability to obtain all brands of FDA blood clotting products in multiple assays and vial sizes as specified.
 - e. Supply all necessary ancillary infusion equipment and supplies.
 - f. Store and ship, or otherwise deliver, all blood clotting products as required by law and product package inserts.
 - g. Provide services in a nursing home either directly or via a third party.
 - h. Provide supplies in a nonemergency within two business days or less.
 - i. Provide product within 12 hours in an emergency situation or as otherwise specified.
 - j. Maintain 24 hour on call service seven days a week.
 - k. Provide contact information for reporting problems with delivery as specified.
 - l. Provide patients with recall notifications.
 - m. Provide language interpretative services.
 - n. Have a detailed plan for meeting these requirements.
 - o. Provide sharps containers and instructions on how to dispose of medical waste.
 - p. Provide appropriate record keeping requirements.
5. Require the Board of Pharmacy to administer and enforce these requirements.
 6. Exempts hospitals and health systems pharmacies that dispense blood clotting products due to an emergency from the provision of this article as specified.

AUTHOR'S INTENT:

According to the author's office, "The intent of the bill is to place standards in state law regarding the proper storage and delivery of blood clotting factor, a prescribed biologic that is infused several times per week by people with Hemophilia and other bleeding disorders. The bill would set standards in place for the delivery of clotting factor and other related equipment and supplies for home usage."

"In previous years, some pharmacies have mishandled clotting factor through improper storage and delivery - posing a health risk to patients. This bill would ensure that pharmacies have proper safeguards in place to ensure the safety and well-being of patients."

COMMENTS:

This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received.

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 its 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:

Support

Hemophilia Council of California (sponsor)
California Medical Association
CSL Behring
Federal Hemophilia Treatment Centers/Region IX
Grifols Inc.
Herndon Healthcare, Inc.
National Hemophilia Foundation
Plasma Protein Therapeutics Association

Oppose

Department of Consumer Affairs

HISTORY:

June 30 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 11. Noes 0.) Re-referred to Com. on APPR. (Heard in committee on June 29.)

June 23 From committee: Do pass, but first be re-referred to Com. on B.,P. & C.P. (Ayes 19. Noes 0.) Re-referred to Com. on B.,P. & C.P. (Heard in committee on June 22.) From committee with author's amendments. Read second time. Amended. Re-referred to Com. On B.,P. & C.P.

June 15 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.

June 10 To Coms. on HEALTH and B.,P. & C.P.

June 2 In Assembly. Read first time. Held at Desk.

June 2 Read third time. Passed. (Ayes 34. Noes 0. Page 3732.) To Assembly.

June 1 Read second time. To third reading.

May 28 Read third time. Amended. To second reading. (May 28 amended measure version corrected June 2.)

May 18 Read second time. To third reading.

May 17 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.

May 12 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on APPR.

May 7 Set for hearing May 17.

May 6 Set, first hearing. Hearing canceled at the request of author.

May 4 Set for hearing May 10.

May 3 Hearing postponed by committee. From committee with author's amendments. Read second time. Amended. Re-referred to Com. On APPR.

Apr. 23 Set for hearing May 3.

Apr. 21 Read second time. Amended. Re-referred to Com. on APPR.

Apr. 20 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 8. Noes 0. Page 3293.)

Apr. 15 From committee: Do pass, but first be re-referred to Com. on B., P. & E.D. (Ayes 9. Noes 0. Page 3210.) Re-referred to Com. On B., P. & E.D. Set for hearing April 19.

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.

AMENDED IN ASSEMBLY JUNE 23, 2010

AMENDED IN ASSEMBLY JUNE 15, 2010

AMENDED IN SENATE MAY 28, 2010

AMENDED IN SENATE MAY 12, 2010

AMENDED IN SENATE MAY 3, 2010

AMENDED IN SENATE APRIL 21, 2010

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, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require

the California State Board of Pharmacy to administer and enforce these provisions.

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:

4
5 Article 5. Standards of Service for Providers of Blood Clotting
6 Products for Home Use Act
7

8 125286.1. This article shall be known, and may be cited, as
9 the Standards of Service for Providers of Blood Clotting Products
10 for Home Use Act.

11 125286.2. The Legislature hereby finds and declares all of the
12 following:

13 (a) Hemophilia is a rare, hereditary, bleeding disorder affecting
14 at least 4,000 persons in California and is a chronic, lifelong, and
15 incurable, but treatable, disease.

16 (b) Von Willebrand disease is a human bleeding disorder caused
17 by a hereditary deficiency or abnormality of the von Willebrand
18 Factor in human blood, which is a protein that helps clot blood.
19 Von Willebrand disease is a chronic, lifelong, incurable, but
20 treatable, disease affecting at least 360,000 Californians.

21 (c) Until the 1970s, people with severe hemophilia suffered
22 from uncontrollable internal bleeding, crippling orthopedic
23 deformities, and a shortened lifespan. More recently, the production
24 of highly purified blood clotting factors have provided people with
25 hemophilia and other bleeding disorders with the opportunity to
26 lead normal lives, free of pain and crippling arthritis.

27 (d) The preferred method of treatment of hemophilia today is
28 intravenous injection, or infusion, of prescription blood clotting
29 products several times per week, along with case management and
30 specialized medical care at a federally designated regional
31 hemophilia treatment center.

1 (e) Pharmacies and other entities specializing in the delivery of
2 blood clotting products and related equipment, supplies, and
3 services for home use form a growing enterprise in California.

4 (f) Timely access to federally designated regional hemophilia
5 centers and appropriate products and services in the home,
6 including infusion of blood clotting products and related
7 equipment, and supplies and services for persons with hemophilia
8 and other bleeding disorders, reduces mortality and bleeding-related
9 hospitalizations, and is extremely cost effective, according to the
10 federal Centers for Disease Control and Prevention and the Medical
11 and Scientific Advisory Council of the National Hemophilia
12 Foundation.

13 (g) Eligible persons with hemophilia or other bleeding disorders
14 may receive treatment through the Genetically Handicapped
15 Persons Program, the California Children’s Services Program, and
16 the Medi-Cal program. Access to quality blood clotting products
17 for home use and related equipment, supplies, and services for
18 people with hemophilia or other bleeding disorders promotes cost
19 containment in each of these publicly funded programs as well as
20 in the health insurance and health care industries more generally.

21 (h) For the benefit of persons with hemophilia or other bleeding
22 disorders, as well as for cost containment in health care, the
23 purposes of this article are to do the following:

24 (1) Establish standards of service for entities that deliver blood
25 clotting products and related equipment, supplies, and services for
26 home use.

27 (2) Promote access to a full range of essential, cost effective,
28 lifesaving, blood clotting products and related equipment, supplies,
29 and high-quality services for home use for persons with hemophilia
30 and other bleeding disorders.

31 125286.3. Unless the context otherwise requires, the following
32 definitions shall apply for purposes of this article:

33 (a) “Assay” means the amount of a particular constituent of a
34 mixture or of the biological or pharmacological potency of a drug.

35 (b) “Ancillary infusion equipment and supplies” means the
36 equipment and supplies required to infuse a blood clotting product
37 into a human vein, including, but not limited to, syringes, needles,
38 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
39 tourniquets, medical tape, sharps or equivalent biohazard waste
40 containers, and cold compression packs.

1 (c) “Bleeding disorder” means a medical condition characterized
2 by a deficiency or absence of one or more essential blood clotting
3 proteins in the human blood, often called “factors,” including all
4 forms of hemophilia and other bleeding disorders that result in
5 uncontrollable bleeding or abnormal blood clotting without
6 treatment.

7 (d) “Blood clotting product” means an intravenously
8 administered medicine manufactured from human plasma or
9 recombinant biotechnology techniques, approved for distribution
10 by the federal Food and Drug Administration, that is used for the
11 treatment and prevention of symptoms associated with bleeding
12 disorders. Blood clotting products include, but are not limited to,
13 Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von
14 Willebrand Factor products, bypass products for patients with
15 inhibitors, and activated prothrombin complex concentrates.

16 (e) “Emergency” means care as defined in Section 1317.1.

17 (f) “Hemophilia” means a human bleeding disorder caused by
18 a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII,
19 or XIII blood clotting protein in human blood.

20 (g) “Hemophilia treatment center” means a facility for the
21 treatment of bleeding disorders, including, but not limited to,
22 hemophilia, that receives funding specifically for the treatment of
23 patients with bleeding disorders from federal government sources,
24 including, but not limited to, the federal Centers for Disease
25 Control and Prevention and the federal Health Resources and
26 Services Administration (HRSA) of the United States Department
27 of Health and Human Services.

28 (h) “Home nursing services” means specialized nursing care
29 provided in the home setting to assist a patient in the reconstitution
30 and administration of blood clotting products.

31 (i) “Home use” means infusion or other use of a blood clotting
32 product in a place other than a state-recognized hemophilia
33 treatment center or other clinical setting. Places where home use
34 occurs include, without limitation, a home or other nonclinical
35 setting.

36 (j) “Patient” means a person needing a blood clotting product
37 for home use.

38 (k) (1) “Provider of blood clotting products for home use”
39 means all the following pharmacies, except as described in Section
40 125286.6, that dispense blood clotting factors for home use:

- 1 (A) Hospital pharmacies.
- 2 (B) Health system pharmacies.
- 3 (C) Pharmacies affiliated with hemophilia treatment centers.
- 4 (D) Specialty home care pharmacies.
- 5 (E) Retail pharmacies.
- 6 (2) The providers described in this subdivision may also provide
- 7 home nursing services for persons with bleeding disorders.
- 8 (3) The providers described in this subdivision shall include a
- 9 health care service plan and all its affiliated providers if the health
- 10 care service plan exclusively contracts with a single medical group
- 11 in a specified geographic area to provide professional services to
- 12 its enrollees.
- 13 125286.4. Each provider of blood clotting products for home
- 14 use shall meet all of the following requirements:
- 15 (a) Have sufficient knowledge and understanding of bleeding
- 16 disorders to accurately follow the instructions of the prescribing
- 17 physician and ensure high-quality service for the patient and the
- 18 medical and psychosocial management thereof, including, but not
- 19 limited to, home therapy.
- 20 (b) Have access to a provider with sufficient clinical experience
- 21 providing services to persons with bleeding disorders that enables
- 22 the provider to know when patients have an appropriate supply of
- 23 clotting factor on hand and about proper storage and refrigeration
- 24 of clotting factors.
- 25 (c) Have access to knowledgeable pharmacy staffing on call 24
- 26 hours a day, to initiate emergency requests for clotting factors.
- 27 (d) Have the ability to obtain all brands of blood clotting
- 28 products approved by the federal Food and Drug Administration
- 29 in multiple assay ranges (low, medium, and high, as applicable)
- 30 and vial sizes, including products manufactured from human
- 31 plasma and those manufactured with recombinant biotechnology
- 32 techniques, provided manufacturer supply exists and payer
- 33 authorization is obtained.
- 34 (e) Supply all necessary ancillary infusion equipment and
- 35 supplies with each prescription, as needed.
- 36 (f) Store and ship, or otherwise deliver, all blood clotting
- 37 products in conformity with all state and federally mandated
- 38 standards, including, but not limited to, the standards set forth in
- 39 the product's approved package insert (PI).

1 (g) When home nursing services are necessary, as determined
2 by the treating physician, provide these services either directly or
3 through a qualified third party with experience in treating bleeding
4 disorders and coordinate pharmacy services with the third party
5 when one is used to provide home nursing services.

6 (h) Upon receiving approved authorization for a nonemergency
7 prescription, provided manufacturer supply exists, ship the
8 prescribed blood clotting products and ancillary infusion equipment
9 and supplies to the patient within two business days or less for
10 established and new patients.

11 (i) Upon receiving approved authorization to dispense a
12 prescription for an emergency situation, provided manufacturer
13 supply exists, deliver prescribed blood products, ancillary infusion
14 equipment and supplies, medications, and home nursing services
15 to the patient within 12 hours for patients living within 100 miles
16 of a major metropolitan airport, and within one day for patients
17 living more than 100 miles from a major metropolitan airport.

18 (j) Maintain 24-hour on call service seven days a week for every
19 day of the year, adequately screen phone calls for emergencies,
20 and acknowledge all phone calls within one hour or less.

21 (k) Provide patients who have ordered their products with a
22 designated contact phone number for reporting problems with a
23 delivery and respond to these calls within a reasonable time period.

24 (l) Provide patients with notification of Class 1 and Class 2
25 recalls and withdrawals of blood clotting products and ancillary
26 infusion equipment within 24 hours of the provider of blood
27 clotting products for home use receiving notification and participate
28 in the National Patient Notification System for blood clotting
29 product recalls.

30 (m) Provide language interpretive services over the phone or in
31 person, as needed by the patient.

32 (n) Have a detailed plan for meeting the requirements of this
33 article in the event of a natural or manmade disaster or other
34 disruption of normal business operations.

35 ~~(o) Provide for proper collection, removal, and disposal of~~
36 ~~medical waste pursuant to the Medical Waste Management Act~~
37 ~~(Part 14 (commencing with Section 117600) of Division 104).~~

38 *(o) Provide the patient with a sharps container and instructions*
39 *on how to dispose of medical waste sharps. However, the provider*
40 *of blood clotting products shall not be liable for any acts or*

1 *omissions of the patient in the handling and disposal of medical*
2 *waste.*

3 (p) Provide appropriate and necessary recordkeeping and
4 documentation as required by state and federal law and retain
5 copies of the patient's prescriptions.

6 (q) Comply with the privacy and confidentiality requirements
7 of the Health Insurance Portability and Accountability Act of 1996
8 (HIPAA).

9 125286.5. The California State Board of Pharmacy shall
10 administer and enforce this article.

11 125286.6. Nothing in this article shall apply to either hospital
12 pharmacies or health system pharmacies that dispense blood
13 clotting products due only to emergency, urgent care, or inpatient
14 encounters, or if an inpatient is discharged with a supply of blood
15 clotting products for home use.

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1071

VERSION: Amended 3/24/2010

AUTHOR: DeSaulnier

SPONSOR: Troy and Alana Pack Foundation

SUBJECT: Controlled Substances Utilization and Evaluation System (CURES)

Affected Sections: Amend Health and Safety Code §11165
Add Health and Safety Code §11165.05
Add Revenue and Tax Code §17054.8
Add Division 2 of the Revenue and Tax Code beginning with §70001

Current Status: Senate Health. Hearing cancelled at the request of the author.

EXISTING LAW:

1. 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 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 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 all persons that manufacture controlled substances (schedules II-IV) to register with the Department of Justice, who will provide the information to the Board of Equalization.
2. Require registrants to submit an annual report to the DOJ as specified.
3. Require registrants to submit quarterly reports to include the following:
 - a. Number of schedule II-IV pills sold, imported, transferred or otherwise furnished during the reporting period.
 - b. Any other relevant information necessary for administration of this section.

4. Require the California Department of Justice, to report, on a quarterly basis as specified, to the BOE, registrant information for those required to pay tax pursuant to this section.
5. Established a tax rate of \$0.0025 per pill.
6. Creates a sunset date of January 1, 2016.
7. Creates the Controlled Substances Tax Law and defines the following:
 - a. "CURES program" as the Controlled Substance Utilization Review and Evaluation System.
 - b. "Importer" as a person that imports schedule II-IV into California for sale or distribution.
 - c. "Manufacturer" as every person who prepares, derives, produces, compounds or repackages schedule II-IV except a pharmacy as specified.
 - d. "Quarterly report" as a report that a registrant is required to file with the DOJ.
 - e. "Registrant" as a manufacturer or importer of controlled substances as defined.
8. Create 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 and is authorized to adopt and enforce regulations and/or emergency regulations governing the collection and implementation of the prescribed fees. [§11165.05(c)(d)]
9. Specifies that the CURES Fund may reimburse the DOJ for the following expenses: [§11165.05(b)]
 - 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.
10. Make Legislative findings and declarations regarding the CURES program as an investigative, preventive, and educational tool for law enforcement, regulatory boards, educational researchers and the health care community. [Section 1]

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:

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. The author further states that the bill will provide the revenue necessary to investigate patients who "doctor shop" as well as those

physicians who sell or divert prescriptions to drug dealers or addicts, and those pharmacists who falsely record employees who steal narcotics and prescriptions.

RELATED LEGISLATION:

Also, AB 2548 (Block) establishes 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. This bill was held under submission in the Assembly Appropriations Committee.

FISCAL IMPACT:

The board currently pays about \$92,000 to help fund the CURES system. This money would no longer be expended.

SUPPORT and OPPOSITION

Support

California Statewide Law Enforcement Association
Peace Officers Research Association of California (previous version of the bill)
Consumer Attorneys
Multiple Individuals
California Narcotics Officers Assn
California Peace Officers Assn
California Police Chiefs Assn
California State Sheriffs' Assn
Troy and Alana Pack Foundation
Six Individuals (previous version of the bill)

Oppose

Genentech (previous version of the bill)
BioCom (previous version of the bill)
Healthcare Distribution Management Association (previous version of the bill)
California Healthcare Institute, Inc.
California Taxpayers' Association (previous version of the bill)
California Retailers Association (Oppose Unless Amended)
Pharmaceutical Research and Manufacturers of America

HISTORY:

Date Action

2010

June 16 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH. Set, second hearing. Hearing canceled at the request of author.

June 2 Set for hearing June 16. (For vote only.)

May 5 Set, first hearing. Failed passage in committee. (Ayes 4. Noes 5. Page 3466.) Reconsideration granted.

Apr. 28 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.

Apr. 27 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.

Apr. 16 Set for hearing May 5.

Apr. 15 Withdrawn from committee. Re-referred to Coms. on HEALTH and REV. & TAX.

Apr. 12 Hearing postponed by committee.

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.

AMENDED IN SENATE JUNE 16, 2010
AMENDED IN SENATE APRIL 28, 2010
AMENDED IN SENATE APRIL 27, 2010
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 to add and repeal Section 11165.05 of, the Health and Safety Code, and to add and repeal Section 17054.8 of, and to add and repeal Part 33 (commencing with Section 70001) of Division 2 of, the Revenue and Taxation Code, relating to taxation, to take effect immediately, tax levy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1071, as amended, DeSaulnier. Personal income tax: credit: prescription drugs: controlled substances tax: CURES.

The Personal Income Tax Law authorizes various credits against the tax imposed by that law.

This bill would, on and after January 1, 2011, and before January 1, 2016, authorize a credit against that tax for a person who is 55 years of age or older in an amount equal to the amount paid or incurred for that taxpayer's own medicines or drugs, as described, that is not reimbursable or payable by public or private health insurance plans or by any 3rd party.

Existing law imposes various taxes, including taxes on the privilege of engaging in certain activities. The Fee Collection Procedures Law, the violation of which is a crime, provides procedures for the collection of certain fees and surcharges. Existing law also requires the Department

of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

This bill would, on and after January 1, 2011, and before January 1, 2016, impose a tax ~~at the rate of \$0.0025 per pill included in Schedule II, III, or IV upon every manufacturer and importer of controlled substances classified as Schedule II, III, or IV, or other person that makes the first sale in this state of a Schedule II, III, or IV controlled substance~~ *upon every manufacturer and importer of a controlled substance classified as Schedule II, III, or IV upon the first sale of that substance at the rate of \$0.0025 for each pill sold.* The tax would be administered by the State Board of Equalization and would be collected pursuant to the procedures set forth in the Fee Collection Procedures Law.

The bill would require the board to deposit all taxes, penalties, and interest collected, less refunds and administrative costs, in the CURES Fund, which this bill would create. This bill would require moneys in the fund, upon appropriation by the Legislature, to be allocated to the Department of Justice for the cost of administration of the CURES program, as specified.

This bill would also require a person that manufactures controlled substances classified in Schedule II, III, or IV in this state, or that imports controlled substances classified in Schedule II, III, or IV into this state, to register with the Department of Justice to enable the department to report specified information to the board for purposes of collecting a tax on those persons. Those provisions would remain in effect until January 1, 2016.

Because this bill would expand the application of the Fee Collection Procedures Law, the violation of which is 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.

This bill would take effect immediately as a tax levy.

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 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 60,000
7 requests from practitioners and pharmacists to (1) help identify
8 and deter drug abuse and diversion through accurate and rapid
9 tracking of Schedule II, III, and IV controlled substances, (2) help
10 practitioners make better prescribing decisions, and (3) cut down
11 on the misuse, abuse, and trafficking of prescription drugs in
12 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 death.
17 The tax that is imposed by this bill on manufacturers and importers
18 of Schedules II, III, and IV controlled substances seeks to mitigate
19 these effects of the drugs by supporting the operation of the
20 CURES program, which has proved a cost-effective tool to help
21 to reduce the misuse, abuse, and trafficking of those drugs.

22 (d) It is the nature of these Schedule II, III, and IV controlled
23 substances that their addictive qualities and the ever present market
24 for their misuse and abuse pose inherent risks to public health that
25 must be systematically addressed, as by the CURES program.
26 Once these products are present in California, ad hoc enforcement
27 of conditions on distribution and criminal and civil sanctions on
28 downstream actors in the distribution system are extraordinarily
29 costly, ineffective, and inefficient means to attempt to control the
30 misuse, abuse, and trafficking of these substances. It is therefore
31 appropriate for manufacturers and importers, which benefit from
32 the commercial markets for these inherently dangerous products
33 with knowledge of their potential for misuse and abuse absent
34 systematic tracking and monitoring, to pay for the cost-effective
35 CURES program.

36 SEC. 2. Section 11165 of the Health and Safety Code is
37 amended to read:

1 11165. (a) To assist law enforcement and regulatory agencies
2 in their efforts to control the diversion and resultant abuse of
3 Schedule II, Schedule III, and Schedule IV controlled substances,
4 and for statistical analysis, education, and research, the Department
5 of Justice shall, contingent upon the availability of adequate funds
6 from the CURES Fund and from the Contingent Fund of the
7 Medical Board of California, the Pharmacy Board Contingent
8 Fund, the State Dentistry Fund, the Board of Registered Nursing
9 Fund, and the Osteopathic Medical Board of California Contingent
10 Fund, maintain the Controlled Substance Utilization Review and
11 Evaluation System (CURES) for the electronic monitoring of the
12 prescribing and dispensing of Schedule II, Schedule III, and
13 Schedule IV controlled substances by all practitioners authorized
14 to prescribe or dispense these controlled substances.

15 (b) The reporting of Schedule III and Schedule IV controlled
16 substance prescriptions to CURES shall be contingent upon the
17 availability of adequate funds from the Department of Justice. The
18 Department of Justice may seek and use grant funds to pay the
19 costs incurred from the reporting of controlled substance
20 prescriptions to CURES. Funds shall not be appropriated from the
21 Contingent Fund of the Medical Board of California, the Pharmacy
22 Board Contingent Fund, the State Dentistry Fund, the Board of
23 Registered Nursing Fund, the Naturopathic Doctor's Fund, or the
24 Osteopathic Medical Board of California Contingent Fund to pay
25 the costs of reporting Schedule III and Schedule IV controlled
26 substance prescriptions to CURES.

27 (c) CURES shall operate under existing provisions of law to
28 safeguard the privacy and confidentiality of patients. Data obtained
29 from CURES shall only be provided to appropriate state, local,
30 and federal persons or public agencies for disciplinary, civil, or
31 criminal purposes and to other agencies or entities, as determined
32 by the Department of Justice, for the purpose of educating
33 practitioners and others in lieu of disciplinary, civil, or criminal
34 actions. Data may be provided to public or private entities, as
35 approved by the Department of Justice, for educational, peer
36 review, statistical, or research purposes, provided that patient
37 information, including any information that may identify the
38 patient, is not compromised. Further, data disclosed to any
39 individual or agency as described in this subdivision shall not be
40 disclosed, sold, or transferred to any third party.

1 (d) For each prescription for a Schedule II, Schedule III, or
2 Schedule IV controlled substance, the dispensing pharmacy or
3 clinic shall provide the following information to the Department
4 of Justice on a weekly basis and in a format specified by the
5 Department of Justice:

6 (1) The full name, address, and telephone number of the ultimate
7 user or research subject, or contact information as determined by
8 the Secretary of the United States Department of Health and Human
9 Services, and the gender and date of birth of the ultimate user.

10 (2) The prescriber's category of licensure and license number;
11 federal controlled substance registration number; and the state
12 medical license number of any prescriber using the federal
13 controlled substance registration number of a government-exempt
14 facility.

15 (3) Pharmacy prescription number, license number, and federal
16 controlled substance registration number.

17 (4) NDC (National Drug Code) number of the controlled
18 substance dispensed.

19 (5) Quantity of the controlled substance dispensed.

20 (6) ICD-9 (diagnosis code), if available.

21 (7) Number of refills ordered.

22 (8) Whether the drug was dispensed as a refill of a prescription
23 or as a first-time request.

24 (9) Date of origin of the prescription.

25 (10) Date of dispensing of the prescription.

26 SEC. 3. Section 11165.05 is added to the Health and Safety
27 Code, to read:

28 11165.05. (a) A person that manufactures controlled substances
29 classified in Schedule II, III, or IV in this state, or that imports
30 controlled substances classified in Schedule II, III, or IV into this
31 state, shall register with the Department of Justice to enable the
32 department to report to the State Board of Equalization the persons
33 subject to the tax imposed pursuant to Part 33 (commencing with
34 Section 70001) of Division 2 of the Revenue and Taxation Code.

35 (b) A person required to register with the department shall file
36 an annual report with the department. The annual report shall be
37 due on or before January 1, 2011, and on or before January 1 each
38 year thereafter, and shall provide the name, address, and telephone
39 number of the person required to register.

1 (c) A person required to register with the department shall also
2 file a quarterly report with the department. The quarterly report
3 shall be due on the last day of the month following each quarterly
4 period and shall provide all of the following information:

5 (1) The number of Schedule II, III, or IV pills the registrant has
6 sold in this state during that quarterly reporting period.

7 (2) The number of Schedule II, III, or IV pills the registrant has
8 imported into this state during that quarterly reporting period.

9 (3) The number of Schedule II, III, or IV pills the registrant has
10 sold, transferred, or otherwise furnished to other persons in this
11 state during that quarterly reporting period.

12 (4) Any other information the department deems necessary for
13 the purpose of administering this section.

14 (d) Each registrant that is required to provide the information
15 required by this section may be subject to audit by the department.

16 (e) On the last day of each month following the due date for
17 filing a quarterly report pursuant to subdivision (d), the department
18 shall send to the State Board of Equalization a report containing
19 all of the following information:

20 (1) The name, address, and telephone number of each person
21 required to register with the department pursuant to this section,
22 and the necessary information regarding who owes the tax imposed
23 pursuant to Part 33 (commencing with Section 70001) of Division
24 2 of the Revenue and Taxation Code on each Schedule II, III, or
25 IV pill sold in this state in the amount of \$0.0025 per pill for the
26 previous quarterly period.

27 (2) The number of Schedule II, III, or IV pills each registrant
28 manufactured in this state or imported into this state.

29 (f) This section shall remain in effect until January 1, 2016, and
30 as of that date is repealed.

31 SEC. 4. Section 17054.8 is added to the Revenue and Taxation
32 Code, to read:

33 17054.8. (a) For each taxable year beginning on or after
34 January 1, 2011, and before January 1, 2016, there shall be allowed
35 to a taxpayer who is 55 years of age or older as a credit against
36 the "net tax," as defined in Section 17039, an amount equal to that
37 amount paid or incurred by the taxpayer during the taxable year
38 for that taxpayer's own medicine or drugs, as described in Section
39 213(b) of the Internal Revenue Code, that was not reimbursable

1 or payable by public or private health insurance plans or by any
2 third party.

3 (b) The taxpayer shall claim the credit on a timely filed original
4 return.

5 (c) The Franchise Tax Board may prescribe rules, guidelines,
6 or procedures necessary or appropriate to carry out the purposes
7 of this section. Chapter 3.5 (commencing with Section 11340) of
8 Part 1 of Division 3 of Title 2 of the Government Code shall not
9 apply to any rule, guideline, or procedure prescribed by the
10 Franchise Tax Board pursuant to this section.

11 (d) In the case where the credit allowed by this section exceeds
12 the “net tax,” the excess may be carried over to reduce the “net
13 tax” for the following year, and the succeeding seven years, until
14 the credit is exhausted.

15 (e) (1) The total amount of credits that may be allowed pursuant
16 to this section shall not exceed the total amount of taxes collected
17 pursuant to Part 33 (commencing with Section 70001) of Division
18 2 for any taxable year.

19 (2) The intent of paragraph (1) is to ensure that the act adding
20 this section does not produce a net revenue gain in state taxes, and
21 the board and the Franchise Tax Board shall cooperate in
22 exchanging information for this purpose.

23 (f) This section shall remain in effect only until December 1,
24 2016, and as of that date is repealed.

25 SEC. 5. Part 33 (commencing with Section 70001) is added to
26 Division 2 of the Revenue and Taxation Code, to read:

27

28 PART 33. CONTROLLED SUBSTANCES TAX LAW

29

30 70001. This part shall be known and may be cited as the
31 Controlled Substances Tax Law.

32 70002. For purposes of this part:

33 (a) “CURES program” means the Controlled Substance
34 Utilization Review and Evaluation System program described in
35 Section 11165 of the Health and Safety Code.

36 (b) “Importer” means a person that imports *into this state*
37 controlled substances classified in Schedule II, III, or IV ~~into this~~
38 *state pursuant to Chapter 2 (commencing with Section 11053) of*
39 *Division 10 of the Health and Safety Code*, for sale or distribution

1 in this state, including, but not limited to, a distributor, retailer,
2 or wholesaler.

3 ~~(e) “Manufacturer” means a person that manufactures controlled~~
4 ~~substances classified in Schedule II, III, or IV sold in this state,~~
5 ~~either directly or indirectly.~~

6 (c) (1) “Manufacturer” means and includes every person who
7 prepares, derives, produces, compounds, or repackages controlled
8 substances classified in Schedule II, III, or IV pursuant to Chapter
9 2 (commencing with Section 11053) of Division 10 of the Health
10 and Safety Code, except a pharmacy that manufactures on the
11 immediate premises where the controlled substance is sold to the
12 ultimate consumer.

13 (2) Notwithstanding paragraph (1), “manufacturer” shall not
14 mean the following:

15 (A) A pharmacy compounding a drug for parental therapy,
16 pursuant to a prescription, for delivery to another pharmacy for
17 the purpose of delivering or administering the drug to the patient
18 or patients named in the prescription, provided that neither the
19 components for the drug nor the drug are compounded, fabricated,
20 packaged, or otherwise prepared prior to receipt of the
21 prescription.

22 (B) A pharmacy that, at a patient’s request, repackages a drug
23 previously dispensed to a patient, or to the patient’s agent,
24 pursuant to a prescription.

25 (d) “Quarterly report” means the report that a registrant is
26 required to file with the Department of Justice pursuant to Section
27 11165.05 of the Health and Safety Code.

28 (e) “Registrant” means a manufacturer or importer of controlled
29 substances classified in Schedule II, III, or IV that is required to
30 annually register and report certain information to the Department
31 of Justice pursuant to Section 11165.05 of the Health and Safety
32 Code.

33 ~~70003. On and after January 1, 2011, a tax is hereby imposed~~
34 ~~at the rate of \$0.0025 per pill included in Schedule II, III, or IV~~
35 ~~upon every manufacturer and importer of controlled substances~~
36 ~~classified as Schedule II, III, or IV, or other person that makes the~~
37 ~~first sale in this state of a Schedule II, III, or IV controlled~~
38 ~~substance. The tax imposed by this part is for the purpose of~~
39 ~~reimbursing the Department of Justice for the cost of administering~~
40 ~~the CURES program, which provides for the electronic monitoring~~

1 of the prescribing and dispensing of controlled substances classified
2 in Schedule II, III, or IV.

3 70003. (a) *On and after January 1, 2011, every manufacturer*
4 *and every importer shall pay a tax upon the first sale in this state*
5 *of controlled substances classified as Schedule II, III, or IV*
6 *pursuant to Chapter 2 (commencing with Section 11053) of*
7 *Division 10 of the Health and Safety Code at the rate of*
8 *one-quarter of one cent (\$0.0025) for each pill sold.*

9 (b) *The purpose of the tax imposed by this part is to reimburse*
10 *the Department of Justice for the cost of administering the CURES*
11 *program, which provides for the electronic monitoring of the*
12 *prescribing and dispensing of controlled substances classified in*
13 *Schedule II, III, or IV.*

14 70004. The board shall administer and collect the tax imposed
15 by this part pursuant to the Fee Collection Procedures Law (Part
16 30 (commencing with Section 55001)). For purposes of this part,
17 the references in the Fee Collection Procedures Law to “fee” shall
18 include the tax imposed by this part and references to “feepayer”
19 shall include a person required to pay the tax imposed by this part.

20 70005. Each person required to pay the tax shall prepare and
21 file with the board a return in the form prescribed by the board
22 containing information as the board deems necessary or appropriate
23 for the proper administration of this part. The return shall be filed
24 on or before the last day of the calendar month following the
25 calendar quarter to which it relates, together with a remittance
26 payable to the board for the amount of tax due for that period.

27 70006. The board may prescribe those forms and reporting
28 requirements as are necessary to implement the tax, including, but
29 not limited to, information regarding the total amount of tax due.

30 70007. (a) (1) The CURES Fund is hereby created in the State
31 Treasury. The CURES Fund shall consist of all taxes, interest,
32 penalties, and other amounts collected pursuant to this part, less
33 refunds and reimbursement to the board for expenses incurred in
34 the administration and collection of the tax.

35 (2) Money in the CURES Fund shall, upon appropriation by the
36 Legislature, be used to reimburse the Franchise Tax Board for
37 administrative costs related to Section 17054.8.

38 (b) All moneys in the CURES Fund less refunds and
39 reimbursement pursuant to subdivision (a), shall, upon
40 appropriation by the Legislature, be allocated to the Department

1 of Justice for the following, *with particular priority given to*
2 *paragraph (3)*:

3 (1) The cost of the administration of the CURES program as
4 required by this section and Section 11165.05 of the Health and
5 Safety Code.

6 (2) The cost of the maintenance of, and any improvements to,
7 the CURES program.

8 (3) The cost of education and outreach relating to the CURES
9 program *and increasing the real-time access to the Prescription*
10 *Drug Monitoring Program (PDMP) system within the CURES*
11 *program*.

12 (4) The cost of the investigation of abuses of the CURES
13 program.

14 70008. This part shall remain in effect only until January 1,
15 2016, and as of that date is repealed.

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

25 SEC. 7. This act provides for a tax levy within the meaning of
26 Article IV of the Constitution and shall go into immediate effect.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1106

VERSION: As amended April 5, 2010

AUTHOR: Yee

SPONSOR: Author

RECOMMENDED POSITION: Support, if amended.

SUBJECT: Prescribers Dispensing of Samples

Affected Sections: Amend Section 4171 of the Business and Professions Code

CURRENT STATUS: Assembly Appropriations

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.

Comments:

During the April 2010 board meeting, the board established a support if amended position - to clarify the drug information materials that would be provided to patients by a practitioner dispensing samples is the same that a pharmacy must currently provide to patients when dispensing drugs. (Discussions during hearings and with the author indicated that that is the intent of the bill.)

SUPPORT/OPPOSITION:

Support

California Alliance for Retired Americans
Consumer Attorneys of California
CALPIRG

Oppose

California Medical Association

HISTORY:

June 30 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 6. Noes 4.) Re-referred to Com. on APPR. (Heard in committee on June 29.)
June 23 From committee: Do pass, but first be re-referred to Com. on B.,P. & C.P. (Ayes 11. Noes 6.) Re-referred to Com. on B.,P. & C.P. (Heard in committee on June 22.)
June 15 Hearing postponed by committee.
May 13 To Coms. on HEALTH and B.,P. & C.P.
Apr. 22 In Assembly. Read first time. Held at Desk.
Apr. 22 Read third time. Passed. (Ayes 25. Noes 6. Page 3275.) To Assembly.
Apr. 13 Read second time. To third reading.
Apr. 12 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
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:

1 SECTION 1. Section 4171 of the Business and Professions
 2 Code is amended to read:

3 4171. (a) Section 4170 shall not prohibit the furnishing of a
 4 limited quantity of samples by a prescriber, if the prescriber
 5 dispenses the samples to the patient in the package provided by
 6 the manufacturer, no charge is made to the patient therefor, and
 7 an appropriate record is entered in the patient’s chart.

8 (b) Section 4170 shall not apply to clinics, as defined in
 9 subdivision (a) of Section 1204 or subdivision (b) or (c) of Section
 10 1206 of the Health and Safety Code, to programs licensed pursuant
 11 to Sections 11876, 11877, and 11877.5 of the Health and Safety
 12 Code, or to a prescriber dispensing parenteral chemotherapeutic
 13 agents, biologicals, or delivery systems used in the treatment of
 14 cancer.

15 ~~(c) No prescriber dispensing drugs pursuant to Section 4170~~
 16 ~~shall dispense a drug sample or a starter kit unless the appropriate~~
 17 ~~manufacturer’s warning pamphlet is physically attached to the~~
 18 ~~package containing the drug sample or starter kit or the~~

19 (c) *A prescriber dispensing a drug sample or starter kit pursuant*
 20 *to subdivision (a) or Section 4170 shall either (1) provide the*
 21 *patient with a copy of the FDA-approved package insert for the*
 22 *drug sample or starter kit or (2) ensure that the manufacturer’s*
 23 *warnings are affixed to the package containing the drug sample*
 24 *or starter kit.*

25 SEC. 2. No reimbursement is required by this act pursuant to
 26 Section 6 of Article XIII B of the California Constitution because
 27 the only costs that may be incurred by a local agency or school
 28 district will be incurred because this act creates a new crime or
 29 infraction, eliminates a crime or infraction, or changes the penalty
 30 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 June 23, 2010

AUTHOR: Solorio

**SPONSOR: California Hospital Association &
California Society of Health-
Systems Pharmacists**

BOARD POSITION: None

SUBJECT: Centralized Hospital Packaging Pharmacies

Affected Sections: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Senate Committee on Appropriations

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. A centralized pharmacy allows hospitals to take advantage of technology and affords better regulatory control via the pharmacist-in-charge,

- e. 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. Allow for unit-dose packaging from a centralized location for hospitals under common ownership that is bar coded down to the patient level.
4. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
5. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital as specified.
6. Require a pharmacy perform such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:

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

FISCAL IMPACT:

Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

During the October 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 (Solario). During the January 2010 Board Meeting, the board voted to support the measure.

During the April 2010 Board Meeting, the board was advised that the then 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. The board was also advised that as amended, the 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.

The bar coding provision was amended back into the bill on June 23, 2010. This version also allows for anticipatory unit dose packaging to ensure continuity of care. This bill also specifies that a hospital pharmacy utilizing the centralized packaging must notify the board in writing.

SUPPORT/OPPOSITION

Support

California Hospital Association (Co-Sponsor)
California Society of Health-System Pharmacists (Co-Sponsor)
Catholic Healthcare West
Numerous Health System Pharmacists

Oppose

None on file as of June 21, 2010

HISTORY:

Date	Action
June 29	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 0.) (June 28.)
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
May 27	Referred to Com. on B., P. & E.D.
May 13	In Senate. Read first time. To Com. on RLS. for assignment.
May 13	Read third time, passed, and to Senate. (Ayes 68. Noes 5. Page 5150.)
May 11	Read second time. To third reading.
May 10	Read second time and amended. Ordered returned to second reading.
May 6	From committee: Amend, and do pass as amended. (Ayes 16. Noes 0.) (May 5.)
Apr. 26	Re-referred to Com. on APPR.
Apr. 22	Read second time and amended.
Apr. 21	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 1.) (April 20).
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 SENATE JUNE 23, 2010

AMENDED IN ASSEMBLY MAY 10, 2010

AMENDED IN ASSEMBLY APRIL 22, 2010

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

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, *and makes a knowing violation of that law a crime*. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a

drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located 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, *but would require that any unit-dose medication produced by a pharmacy under common ownership be barcoded to be readable at the patient’s bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances.* The bill would also provide that a “manufacturer” does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. *The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill’s requirements would be a crime, the bill would impose a state-mandated local program.*

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

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

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

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

- 1 SECTION 1. The Legislature makes the following findings
- 2 and declarations:
- 3 (a) Hospitals have been encouraged to move toward the use of
- 4 automation and bedside barcode checking to improve the safety

1 and efficiency of drug distribution and administration to patients.
2 For many hospitals, the technology to enable them to achieve this
3 patient-safety goal is cost prohibitive.

4 (b) Many drugs received from manufacturers are not in the
5 proper unit dose for immediate administration to patients, and are
6 not barcoded. As a result, individual hospitals must locally prepare
7 and package these drugs or contract with a packager, that is not
8 licensed by either the California State Board of Pharmacy or
9 managed by a pharmacist-in-charge who is licensed by the
10 California State Board of Pharmacy, to do so.

11 (c) The Business and Professions Code definition of drug
12 “manufacturer” allows one hospital pharmacy to compound and
13 package medications for another hospital only for specific patients,
14 without being licensed as a manufacturer. This restriction does not
15 support the most current hospital drug distribution processes, nor
16 does it accommodate innovations that will improve patient safety.

17 ~~(d) The federal Food and Drug Administration (FDA) has~~
18 ~~amended its position to allow hospitals under common control and~~
19 ~~operating within a state to consolidate resources at a single location~~
20 ~~for timely, economic repackaging and distribution with greater,~~
21 ~~more dedicated expertise, without becoming federally registered~~
22 ~~manufacturers for those products. This FDA action is in recognition~~
23 ~~that the compounding and repackaging activity is not truly drug~~
24 ~~manufacturing.~~

25 (e)

26 (d) Centralization of the packaging operations as a licensed
27 pharmacy under the license of a hospital, rather than as a
28 “manufacturer,” ensures the patient-safety oversight of the
29 California State Board of Pharmacy and other hospital regulatory
30 and accreditation bodies, and adherence to the new stronger
31 pharmacy compounding regulations.

32 SEC. 2. Section 4029 of the Business and Professions Code is
33 amended to read:

34 4029. (a) “Hospital pharmacy” means and includes a pharmacy,
35 licensed by the board, located within any licensed hospital,
36 institution, or establishment that maintains and operates organized
37 facilities for the diagnosis, care, and treatment of human illnesses
38 to which persons may be admitted for overnight stay and that meets
39 all of the requirements of this chapter and the rules and regulations
40 of the board.

1 (b) A hospital pharmacy also includes a pharmacy, licensed by
2 the board, that may be located outside of the hospital, in another
3 physical plant on the same premises or on a separate premises that
4 is regulated under a hospital’s license. Nothing in this subdivision
5 shall be construed to restrict or expand the services that a hospital
6 pharmacy may provide.

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

10 (d) *A hospital pharmacy may prepare and store a limited*
11 *quantity of unit-dose medications in advance of receipt of a*
12 *patient-specific prescription in a quantity as is necessary to ensure*
13 *continuity of care for an identified population of patients of the*
14 *hospital based on a documented history of prescriptions for that*
15 *patient population.*

16 (e) *Nothing in this section shall obviate the obligation of a*
17 *hospital pharmacy, hospital, or pharmacist to comply with all*
18 *applicable federal and state laws.*

19 SEC. 3. Section 4033 of the Business and Professions Code is
20 amended to read:

21 4033. (a) (1) “Manufacturer” means and includes every person
22 who prepares, derives, produces, compounds, or repackages any
23 drug or device except a pharmacy that manufactures on the
24 immediate premises where the drug or device is sold to the ultimate
25 consumer.

26 (2) Notwithstanding paragraph (1), “manufacturer” shall not
27 mean a pharmacy compounding or repackaging a drug for
28 parenteral therapy or oral therapy in a hospital for delivery to
29 another pharmacy or hospital under common ownership for the
30 purpose of dispensing or administering the drug, pursuant to a
31 prescription or order, to the patient or patients named in the
32 prescription or order. *A pharmacy compounding or repackaging*
33 *a drug as described in this paragraph shall notify the board in*
34 *writing of the location where the compounding or repackaging is*
35 *being performed within 30 days of initiating the compounding or*
36 *repackaging. The pharmacy shall report any change in that*
37 *information to the board in writing within 30 days of the change.*

38 (3) Notwithstanding paragraph (1), “manufacturer” shall not
39 mean a pharmacy that, at a patient’s request, repackages a drug

1 previously dispensed to the patient, or to the patient’s agent,
2 pursuant to a prescription.

3 (b) Notwithstanding subdivision (a), as used in Sections 4034,
4 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
5 means a person who prepares, derives, manufactures, produces,
6 or repackages a dangerous drug, as defined in Section 4022, device,
7 or cosmetic. Manufacturer also means the holder or holders of a
8 New Drug Application (NDA), an Abbreviated New Drug
9 Application (ANDA), or a Biologics License Application (BLA),
10 provided that such application has been approved; a manufacturer’s
11 third-party logistics provider; a private label distributor (including
12 colicensed partners) for whom the private label distributor’s
13 prescription drugs are originally manufactured and labeled for the
14 distributor and have not been repackaged; or the distributor agent
15 for the manufacturer, contract manufacturer, or private label
16 distributor, whether the establishment is a member of the
17 manufacturer’s affiliated group (regardless of whether the member
18 takes title to the drug) or is a contract distributor site.

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

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 2551

VERSION: As Amended April 26, 2010

AUTHOR: Hernandez

SPONSOR: Author Sponsored

BOARD POSITION: None

SUBJECT: Pharmacy Technician: Scholarship and Loan Repayment Program

Affected Sections: Amend Section 128345 of the Health and Safety Code
Add Article 6 (commencing with Section 128560, of Chapter 5 of
Part 3 of Division 107 of the Health and Safety Code)

CURRENT STATUS: Senate Appropriations

EXISTING LAW:

1. Defines the requirements for licensure as a pharmacy technician including one of the following qualifying methods:
 - a. Completion of a technician training program as specified
 - b. Eligibility to take the pharmacist licensure exam
 - c. Associates degree in pharmacy technology
 - d. Certification from the Pharmacy Technician Certification Board
2. Establishes the California Pharmacist Scholarship and Loan Repayment Program, administered by the Office of Statewide Health Planning and Development (OSHDP), to provide for the educational expenses of pharmacy students and to repay qualifying educational loans of pharmacists who agree to serve in areas of the state where unmet priority needs exist.
3. Establishes the California Pharmacist Scholarship and Loan Repayment Program Fund in the State Treasury, which is funded by voluntary contributions made by pharmacies or pharmacists upon renewal of their license, and requires that the moneys in the fund be available for the purpose of implementing the above program, upon appropriation by the Legislature.
4. Authorizes the Health Professions Education Foundation (HPEF) to implement various loan repayment programs for nurses, mental health service providers, and physicians.

THIS BILL WOULD:

1. Establish the California Pharmacy Technician Scholarship and Loan Repayment Program (Program) to provide scholarships to pay for educational expenses of pharmacy technician school students and to repay qualifying educational loans to pharmacy technicians who agree to participate in medically underserved areas.
2. Specify that the Program will be administered through the Health Professions Education Foundation.
3. Specify that funds may be obtained from businesses, industry, foundations, and other public and private sources.
4. State that funds will only be allocated after the Program determines that sufficient funds are available and the funds are appropriated by the legislature.

AUTHOR'S INTENT:

According to the author's office, pharmacy technicians are the second largest field within Allied Health. Yet, there is no comprehensive statewide public or private financial aid program to meet the needs of pharmacy technicians. Post-secondary education tuition ranges from (approximately) \$1,664 in fees at a community college (\$23,306 total cost) to over \$23,000 at a career or vocational college (not including supplies or cost of living). Unfortunately, very few community colleges in California provide training to become a pharmacy technician, so most students rely on private, costly education to become licensed.

FISCAL IMPACT:

The board does not anticipate any fiscal impact to board operations as the administration of this Program resides with another agency.

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 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 as part of a licensees renewal. 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:

July 1 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 2.) (June 30.)

June 22 From committee: Do pass, and re-refer to Com. on HEALTH. Re-referred. (Ayes 5. Noes 1.) (June 21.)

June 10 Referred to Coms. on B., P. & E.D. and HEALTH.

June 1 In Senate. Read first time. To Com. on RLS. for assignment.

June 1 Read third time, passed, and to Senate. (Ayes 50. Noes 27. Page 5392.)

May 20 Read second time. To third reading.

May 19 From committee: Do pass. (Ayes 11. Noes 5.) (May 19.)

May 4 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. Ayes 7 Noes 4. (May 4.)

Apr. 27 Re-referred to Com. on B.,P. & C.P.

Apr. 26 From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.

Apr. 8 Referred to Com. on B.,P. & C.P.

Feb. 22 Read first time.

Feb. 21 From printer. May be heard in committee March 23.

Feb. 19 Introduced. To print.

AMENDED IN ASSEMBLY APRIL 26, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 2551

Introduced by Assembly Member Hernandez

February 19, 2010

~~An act relating to public health.~~ *An act to amend Section 128345 of, and to add Article 6 (commencing with Section 128560) to Chapter 5 of Part 3 of Division 107 of, the Health and Safety Code, relating to pharmacy technicians.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2551, as amended, Hernandez. ~~Health professions development: loan repayment.~~ *Pharmacy technicians: scholarship and loan repayment program.*

Existing law establishes the California Pharmacist Scholarship and Loan Repayment Program, administered by the Office of Statewide Health Planning and Development, to provide for the educational expenses of pharmacy students and to repay qualifying educational loans of pharmacists who agree to serve in areas of the state where unmet priority needs exist, as specified. Existing law establishes the California Pharmacist Scholarship and Loan Repayment Program Fund in the State Treasury, which is funded by voluntary contributions made by pharmacies or pharmacists upon renewal of their license, and requires that the moneys in the fund be available for the purpose of implementing the above program, upon appropriation by the Legislature.

Existing law also authorizes the Health Professions Education Foundation to implement various loan repayment programs for nurses, mental health service providers, and physicians.

This bill would establish the California Pharmacy Technician Scholarship and Loan Repayment Program, to be administered by the Health Professions Education Foundation, to pay for educational expenses of pharmacy technician students and to repay qualifying educational loans of pharmacy technicians who agree to serve in areas of the state where unmet priority needs exist, as specified. This bill would authorize the foundation to solicit and receive funds from specified sources for the purpose of providing financial assistance through the California Pharmacy Technician Scholarship and Loan Repayment Program. This bill would require that private or public funds made available for purposes of the program to be deposited in the California Pharmacy Technician Scholarship and Loan Repayment Fund established by the bill.

The bill would require, upon accumulation of sufficient moneys in the fund to implement the program, as determined by the foundation, and upon appropriation by the Legislature, that the moneys in the fund be available for the purpose of implementing the program.

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

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

- 1 SECTION 1. Section 128345 of the Health and Safety Code is
- 2 amended to read:
- 3 128345. The Health Professions Education Foundation may
- 4 do any of the following:
- 5 (a) Solicit and receive funds from business, industry,
- 6 foundations, and other private or public sources for the purpose
- 7 of providing financial assistance in the form of scholarships or
- 8 loans to ~~African-American~~ African American students, Native
- 9 American students, ~~Hispanic-American~~ Hispanic American
- 10 students, and other students from underrepresented groups. These

1 funds shall be expended by the office after transfer to the Health
2 Professions Education Fund, created pursuant to Section 128355.

3 (b) Recommend to the director the disbursement of private
4 sector moneys deposited in the Health Professions Education Fund
5 to students from underrepresented groups accepted to or enrolled
6 in schools of medicine, dentistry, nursing, or other health
7 professions in the form of loans or scholarships.

8 (c) Recommend to the director a standard contractual agreement
9 to be signed by the director and any participating student, that
10 would require a period of obligated professional service in the
11 areas in California designated by the commission as deficient in
12 primary care services. The agreement shall include a clause
13 entitling the state to recover the funds awarded plus the maximum
14 allowable interest for failure to begin or complete the service
15 obligation.

16 (d) Develop criteria for evaluating the likelihood that applicants
17 for scholarships or loans would remain to practice their profession
18 in designated areas deficient in primary care services.

19 (e) Develop application forms, which shall be disseminated to
20 students from underrepresented groups interested in applying for
21 scholarships or loans.

22 (f) Encourage private sector institutions, including hospitals,
23 community clinics, and other health agencies to identify and
24 provide educational experiences to students from underrepresented
25 groups who are potential applicants to schools of medicine,
26 dentistry, nursing, or other health professions.

27 (g) Prepare and submit an annual report to the office
28 documenting the amount of money solicited from the private sector,
29 the number of scholarships and loans awarded, the enrollment
30 levels of students from underrepresented groups in schools of
31 medicine, dentistry, nursing, and other health professions, and the
32 projected need for scholarships and loans in the future.

33 (h) Recommend to the director that a portion of the funds
34 solicited from the private sector be used for the administrative
35 requirements of the foundation.

36 (i) Implement the Steven M. Thompson Physician Corps Loan
37 Repayment Program and the Volunteer Physician Program, as
38 provided under Article 5 (commencing with Section 128550).

39 (j) *Solicit and receive funds from business, industry, foundations,*
40 *and other private and public sources for the purpose of providing*

1 *financial assistance in the form of scholarships and loans through*
2 *the California Pharmacy Technician Scholarship and Loan*
3 *Repayment Program, pursuant to Article 6 (commencing with*
4 *Section 128560).*

5 *(k) Administer the California Pharmacy Technician Scholarship*
6 *and Loan Repayment Program, pursuant to Article 6 (commencing*
7 *with Section 128560).*

8 *SEC. 2. Article 6 (commencing with Section 128560) is added*
9 *to Chapter 5 of Part 3 of Division 107 of the Health and Safety*
10 *Code, to read:*

11
12 *Article 6. California Pharmacy Technician Scholarship and*
13 *Loan Repayment Program*
14

15 *128560. (a) (1) There is hereby established within the Health*
16 *Professions Education Foundation the California Pharmacy*
17 *Technician Scholarship and Loan Repayment Program.*

18 *(2) The program shall provide scholarships to pay for the*
19 *educational expenses of pharmacy technician school students and*
20 *to repay qualifying educational loans of pharmacy technicians*
21 *who agree to participate in designated medically underserved*
22 *areas as provided in this section.*

23 *(b) The Health Professions Education Foundation shall*
24 *administer the California Pharmacy Technician Scholarship and*
25 *Loan Repayment Program utilizing the same general guidelines*
26 *applicable to the federal National Health Service Corps*
27 *Scholarship Program established pursuant to Section 254 l of Title*
28 *42 of the United States Code and the National Health Service*
29 *Corps Loan Repayment Program established pursuant to Section*
30 *254 l-1 of Title 42 of the United States Code, except as follows:*

31 *(1) A pharmacy technician or pharmacy technician student shall*
32 *be eligible to participate in the program if he or she agrees to*
33 *provide pharmacy technician services in a practice site located in*
34 *an area of the state where unmet priority needs for primary care*
35 *family physicians exist as determined by the Health Workforce*
36 *Policy Commission.*

37 *(2) No matching funds shall be required from any entity in the*
38 *practice site area.*

39 *(c) This section shall be implemented only to the extent that*
40 *sufficient moneys are available in the California Pharmacy*

1 *Technician Scholarship and Loan Repayment Program Fund to*
2 *administer the program.*

3 *128561. The California Pharmacy Technician Scholarship and*
4 *Loan Repayment Program Fund is hereby established in the State*
5 *Treasury. Any private or public funds made available for purposes*
6 *of the California Pharmacy Technician Scholarship and Loan*
7 *Repayment Program shall be deposited into the fund. Upon*
8 *accumulation of sufficient moneys in the fund to implement the*
9 *program, as determined by the foundation, and upon appropriation*
10 *by the Legislature, moneys in the fund shall be available for*
11 *expenditure by the Health Professions Education Foundation for*
12 *purposes of implementing the California Pharmacy Technician*
13 *Scholarship and Loan Repayment Program pursuant to this article.*
14 *The Health Professions Education Foundation shall be under no*
15 *obligation to administer a program under this article until*
16 *sufficient moneys have been accumulated in the fund and*
17 *appropriated to the foundation by the Legislature.*

18 ~~SECTION 1. It is the intent of the Legislature to enact~~
19 ~~legislation that would establish a new fee structure for loan~~
20 ~~repayment of various health professions development programs,~~
21 ~~including, but not limited to, all of the following:~~

22 ~~(a) The Song-Brown Health Care Workforce Training Act~~
23 ~~(Article 1 (commencing with Section 128200) of Chapter 4 of Part~~
24 ~~3 of Division 107 of the Health and Safety Code).~~

25 ~~(b) The Health Professions Education Foundation Programs~~
26 ~~established pursuant to (Chapter 5 (commencing with Section~~
27 ~~128330) of Part 3 of Division 107 of the Health and Safety Code).~~

28 ~~(c) The Steven M. Thompson Physician Corps Loan Repayment~~
29 ~~Program, as set forth in Article 5 (commencing with Section~~
30 ~~128550) of Chapter 5 (commencing with Section 128330) of Part~~
31 ~~3 of Division 107 of the Health and Safety Code.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1701

VERSION: As Introduced

AUTHOR: Chesbro

**SPONSOR: Health Officers Association of
California**

BOARD POSITION: Support

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) 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 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.

Related Bills

AB 1858 (Blumenfield) allows the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes.

SB 1029 (Yee) 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 30 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; and requires pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

SUPPORT and OPPOSITION:

Support

Health Officers Association of California

AIDS Project Los Angeles

Alameda County Board of Supervisors

California Association of Alcohol and Drug Program Executives, Inc.

California Medical Association
California Opioid Maintenance Providers
California Primary Care Association
California State Association of Counties
City of West Hollywood
City and County of San Francisco
Contra Costa County Board of Supervisors
County Alcohol and drug Program Administrators Association of California
County Health Executives Association of California
County of Yolo Health Department
Planned Parenthood Affiliates of California, Inc.
San Luis Obispo County Health Officer
San Mateo County Health System
Santa Clara County Health Officer
Santa Clara County Board of Supervisors
Santa Cruz County Health Services Agency

Oppose

None on file (June 23, 2010)

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)

1 of Section 11054, specified in paragraph (14), (15), or (20) of
2 subdivision (d) of Section 11054, specified in subdivision (b) or
3 (c) of Section 11055, or specified in paragraph (2) of subdivision
4 (d) of Section 11055, or (2) a controlled substance which is a
5 narcotic drug classified in Schedule III, IV, or V.

6 (b) This section shall not apply to hypodermic needles or
7 syringes that have been containerized for safe disposal in a
8 container that meets state and federal standards for disposal of
9 sharps waste.

10 (c) Pursuant to authorization by a county, with respect to all of
11 the territory within the county, or a city, with respect to the territory
12 within in the city, ~~for the period commencing January 1, 2005, and~~
13 ~~ending December 31, 2010~~, subdivision (a) shall not apply to the
14 possession solely for personal use of 10 or fewer hypodermic
15 needles or syringes if acquired from an authorized source.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1858

VERSION: As Amended June 10, 2010

AUTHOR: Blumenfield

SPONSOR: Drug Policy Alliance

BOARD POSITION: None

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Health and Safety Code
Amend Sections 121349 - 121349.3

CURRENT STATUS: Failed Passage in the Senate Committee on Appropriations.
Reconsideration granted.

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, 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 DPH to authorize NEPs under this bill as recommended by the U.S. 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. Require 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. The author claims that most counties in California do not have safe, legal access to sterile syringes, even in areas with high rates of HIV and hepatitis. The provision of sterile syringes through exchange programs is considered a vital component of a comprehensive HIV and hepatitis control strategy, and is endorsed by every major state, national, and international health and medical association, including the US Centers for Disease Control and Prevention, U.S. Public Health Service, National Institutes of Health, and the World Health Organization, among others.

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 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.

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.

Related Bills

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. (Recent amendments, not yet in print, would extend the sunset date to December 31, 2018, rather than eliminate it.)

SB 1029 (Yee), 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 30 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; and requires pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

SUPPORT and OPPOSITION:

Support

Drug Policy Alliance (sponsor)
AIDS Project Los Angeles
American Civil Liberties Union
Asian Pacific AIDS Intervention Team
California Association of Alcohol and Drug Program Executives, Inc.
California Hepatitis Alliance
California Medical Association
Community Health Empowerment/Exchange Works
County Alcohol and Drug Program Administrators Association of California
Drug Policy Alliance
Friends Committee of Legislation of California
Harm Reduction Coalition
HIV Education and Prevention Project of Alameda County
Homeless Health Care Los Angeles
Planned Parenthood Affiliates of California
Health Officers Association of California
Solid Waste Association of North American (If amended)

Oppose

California Narcotic Officers' Association
League of California Cities

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 SENATE JULY 15, 2010

AMENDED IN SENATE JUNE 10, 2010

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
(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 *or her* 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 infection spread through the sharing of used hypodermic needles and syringes. *The bill would require the entities to submit an application to the department, would require a 45 day public comment period, would specify that participants shall not be subject to criminal prosecution for possession of needles and syringes acquired under the program, and would make conforming changes.*

The bill would also require the department to ~~allow local entities to apply for authorization~~ 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 bloodborne infections, the State
- 23 Department of Public Health may, notwithstanding any other

1 provision of law, authorize entities that *provide services set forth*
2 *in paragraph (1) of subdivision (d)*, apply for authorization ~~and~~
3 ~~that~~ *under this chapter*, and have sufficient staff and capacity to
4 provide services as described in Section 121349.1, as determined
5 by the department, to provide hypodermic needle and syringe
6 exchange services consistent with state and federal standards,
7 including those of the United States Public Health Service, in any
8 location where the department determines that the conditions exist
9 for the rapid spread of HIV, viral hepatitis, or any other potentially
10 deadly or disabling infection spread through the sharing of used
11 hypodermic needles and syringes.

12 *(d) In order for an entity to be authorized to conduct a project*
13 *pursuant to this chapter by the State Department of Public Health,*
14 *its application to the department shall demonstrate that the entity*
15 *complies with all of the following minimum standards:*

16 *(1) The entity provides, directly or through referral, any of the*
17 *following services:*

18 *(A) Drug abuse treatment services.*

19 *(B) HIV or hepatitis C screening.*

20 *(C) Hepatitis A and hepatitis B vaccination.*

21 *(D) Screening for sexually transmitted infections.*

22 *(E) Housing services for the homeless, for victims of domestic*
23 *violence, or other similar housing services.*

24 *(F) Services related to provision of education and materials for*
25 *the reduction of sexual risk behaviors, including, but not limited*
26 *to, the distribution of condoms.*

27 *(2) The entity has the capacity to commence needle and syringe*
28 *exchange services within three months of authorization.*

29 *(3) The entity has adequate funding to do all of the following*
30 *at reasonably projected program participation levels:*

31 *(A) Provide needles and syringe exchange services for all of its*
32 *participants.*

33 *(B) Provide HIV and viral hepatitis prevention education*
34 *services for all of its participants.*

35 *(C) Provide for the safe recovery and disposal of used syringes*
36 *and sharps waste from all of its participants.*

37 *(4) The entity has the capacity, and an established plan, to*
38 *collect evaluative data in order to assess program impact,*
39 *including, but not limited to, all of the following:*

40 *(A) The total number of persons served.*

1 (B) *The total number of syringes and needles distributed,*
2 *recovered, and disposed of.*

3 (C) *The total numbers and types of referrals to drug treatment*
4 *and other services.*

5 (5) *If the application is provisionally deemed appropriate by*
6 *the State Department of Public Health the department shall, at*
7 *least 45 days prior to approval of the application, provide for a*
8 *period of public comment as follows:*

9 (A) *Post on the department’s Internet Web site the name of the*
10 *applicant, the nature of the services, and the location where the*
11 *applying entity will provide the services.*

12 (B) *Send a written and an electronic mail notice to the local*
13 *public health officer of the affected jurisdiction.*

14 ~~(d)~~

15 (e) *The State Department of Public Health shall establish and*
16 *maintain on its Internet Web site the address and contact*
17 *information of programs providing hypodermic needle and syringe*
18 *exchange services pursuant to subdivision (c).*

19 ~~(e)~~

20 (f) *The authorization provided under this section shall only be*
21 *for a clean needle and syringe exchange project as described in*
22 *Section 121349.1.*

23 SEC. 2. Section 121349.1 of the Health and Safety Code is
24 amended to read:

25 121349.1. The State Department of Public Health, or a city
26 and county, or a county, or a city with or without a health
27 department, in consultation with the State Department of Public
28 Health, that acts to authorize a clean needle and syringe exchange
29 project pursuant to this chapter shall authorize the exchange of
30 clean hypodermic needles and syringes, as recommended by the
31 United States Public Health Service, subject to the availability of
32 funding, as part of a network of comprehensive services, including
33 treatment services, to combat the spread of HIV and bloodborne
34 hepatitis infection among injection drug users. Staff and volunteers
35 participating in an exchange project authorized by the state, county,
36 city, or city and county pursuant to this chapter shall not be subject
37 to criminal prosecution for violation of any law related to the
38 possession, furnishing, or transfer of hypodermic needles or
39 syringes during participation in an exchange project. ~~Program~~
40 ~~participants shall be allowed to possess syringes consistent with~~

1 ~~Section 11364.~~ *Program participants shall not be subject to*
2 *criminal prosecution for possession of needles or syringes acquired*
3 *from an authorized needle and syringe exchange project entity.*

4 SEC. 3. Section 121349.2 of the Health and Safety Code is
5 amended to read:

6 121349.2. Local government, local public health officials, and
7 law enforcement shall be given the opportunity to comment on
8 clean needle and syringe exchange programs on a biennial basis.
9 The public shall be given the opportunity to provide input to local
10 leaders to ensure that any potential adverse impacts on the public
11 welfare of clean needle and syringe exchange programs are
12 addressed and mitigated.

13 SEC. 4. Section 121349.3 of the Health and Safety Code is
14 amended to read:

15 121349.3. The health officer of the participating jurisdiction
16 shall present biennially at an open meeting of the board of
17 supervisors or city council a report detailing the status of clean
18 needle and syringe exchange programs, including, but not limited
19 to, relevant statistics on bloodborne infections associated with
20 needle sharing activity and the use of public funds for these
21 programs. Law enforcement, administrators of alcohol and drug
22 treatment programs, other stakeholders, and the public shall be
23 afforded ample opportunity to comment at this annual meeting.
24 The notice to the public shall be sufficient to ensure adequate
25 participation in the meeting by the public. This meeting shall be
26 noticed in accordance with all state and local open meeting laws
27 and ordinances, and as local officials deem appropriate. For
28 hypodermic needle and syringe exchange services authorized by
29 the State Department of Public Health, a biennial report shall be
30 provided by the department to the local health officer based on the
31 reports to the department from service providers within the
32 jurisdiction of the local health officer.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1029

VERSION: As Amended June 23, 2010

AUTHOR: Yee

**SPONSOR: Drug Policy Alliance and
The San Francisco Aids Foundation**

BOARD POSITION: None

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Business and Professions Code
Amend Sections 4145 and 4148
Repeal Section 4140
Health and Safety Code
Amend Sections 11364, 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 furnish 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 could likely utilize existing resources to comply with the posting requirements.

PREVIOUS/CURRENT LEGISLATION:

SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 - Furnishing Hypodermic Needles and Syringes Without Prescription authorized until December 31, 2010, a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription

hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required. The board had a support position on this bill.

SB 774 (Vasconcellos, 2005) would have authorized a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription as specified. The board supported this bill; however it was vetoed by the governor.

SB 1305 (Figueroa) Chapter 64, Statutes of 2006, prohibited a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

AB 110 (Laird), Chapter 707, Statutes of 2007, permits a public entity that receives General Fund money from the Department of Health Services (now DPH) for HIV prevention and education to use that money to support needle exchange programs. The board had a support position on this bill.

Related Bills

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. (Recent amendments, not yet in print, would extend the sunset date to December 31, 2018, rather than eliminate it.)

AB 1858 (Blumenfeld) allows the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes.

SUPPORT and OPPOSITION:

Support

San Francisco Aids Foundation (Co-sponsor)
AIDS Project Los Angeles
Alameda County Board of Supervisors
American Civil Liberties Union
California Association of Alcohol and Drug Program Executives, Inc
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
 City of West Hollywood
 County Alcohol & Drug Program Administrators Association of California
 Drug Policy Alliance
 Equality California
 Friends Committee on Legislation of California
 Health Officers Association of California
 Osteopathic Physicians and Surgeons of California
 Planned Parenthood Action Fund of San Diego and Riverside Counties
 Planned Parenthood Advocacy Project of Los Angeles County
 Planned Parenthood Affiliates of California
 Republican Liberty Caucus
 Rite Aid
 San Francisco Mayor's Hepatitis C Task Force
 Walgreens

Oppose

None on file

HISTORY:

Date Action

June 30 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 6. Noes 2.)
 Re-referred to Com. on APPR. (Heard in committee on June 29.)
 June 23 From committee: Do pass, but first be re-referred to Com. on B.,P. & C.P. (Ayes 12. Noes 6.)
 Re-referred to Com. on B.,P. & C.P. (Heard in committee on June 22.) From committee with
 author's amendments. Read second time. Amended. Re-referred to Com. on B.,P. & C.P.
 June 10 To Coms. on HEALTH and B.,P. & C.P.
 May 28 In Assembly. Read first time. Held at Desk.
 May 28 Read third time. Passed. (Ayes 21. Noes 6. Page 3652.) To Assembly. Motion to reconsider
 made by Senator Yee. Reconsideration granted. (Ayes 30. Noes 0. Page 3654.) Read third
 time. Passed. (Ayes 21. Noes 8. Page 3655.) To Assembly.
 May 12 Read second time. To third reading.
 May 11 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
 Apr. 30 Set for hearing May 10.
 Apr. 22 Set for hearing April 22. (For vote only.) From committee: Do pass, but first be re-referred to
 Com. on APPR.(Ayes 5. Noes 1. Page 3294.) Re-referred to Com. on APPR.
 Apr. 19 Set, second hearing. Testimony taken. Further hearing to be set.
 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 ASSEMBLY JUNE 23, 2010

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

1 legitimate medical need requiring a hypodermic needle or syringe
2 to administer a medicine or treatment.

3 (b) Notwithstanding any other provision of law, for the period
4 beginning January 1, 2011, and ending December 31, 2018, as a
5 public health measure intended to prevent the transmission of HIV,
6 viral hepatitis, and other bloodborne diseases among persons who
7 use syringes and hypodermic needles, and to prevent subsequent
8 infection of sexual partners, newborn children, or other persons,
9 a physician or pharmacist may, without a prescription or a permit,
10 furnish 30 or fewer hypodermic needles and syringes for human
11 use to a person 18 years of age or older, and a person 18 years of
12 age or older may, without a prescription or license, obtain 30 or
13 fewer hypodermic needles and syringes solely for personal use
14 from a physician or pharmacist.

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

24 (d) Pharmacies *that furnish nonprescription hypodermic needles*
25 *and syringes* shall store hypodermic needles and syringes in a
26 manner that ensures that they are available only to authorized
27 personnel, and are not accessible to other persons.

28 (e) In order to provide for the safe disposal of hypodermic
29 needles and syringes, pharmacies that furnish nonprescription
30 hypodermic needles and syringes shall provide consumers with
31 one or more of the following disposal options:

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

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

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

1 (f) Pharmacies that furnish nonprescription syringes shall
2 provide written information or verbal counseling to consumers at
3 the time of furnishing or sale of nonprescription hypodermic
4 needles or syringes on how to do the following:

- 5 (1) Access drug treatment.
- 6 (2) Access testing and treatment for HIV and hepatitis C.
- 7 (3) Safely dispose of sharps waste.

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

10 4148. All stocks of hypodermic needles or syringes shall be
11 confiscated if found outside the licensed premises of any person
12 holding a permit under Section 4141 and found not in the
13 possession or under the control of a person entitled to an exemption
14 under Section 4143, 4144, or 4145, or under Section 11364,
15 121349, or 121349.1 of the Health and Safety Code.

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

18 11364. (a) It is unlawful to possess an opium pipe or any
19 device, contrivance, instrument, or paraphernalia used for
20 unlawfully injecting or smoking (1) a controlled substance specified
21 in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f)
22 of Section 11054, specified in paragraph (14), (15), or (20) of
23 subdivision (d) of Section 11054, specified in subdivision (b) or
24 (c) of Section 11055, or specified in paragraph (2) of subdivision
25 (d) of Section 11055, or (2) a controlled substance which is a
26 narcotic drug classified in Schedule III, IV, or V.

27 (b) This section shall not apply to hypodermic needles or
28 syringes that have been containerized for safe disposal in a
29 container that meets state and federal standards for disposal of
30 sharps waste.

31 (c) For the period beginning January 1, 2011, and ending
32 December 31, 2018, as a public health measure intended to prevent
33 the transmission of HIV, viral hepatitis, and other bloodborne
34 diseases among persons who use syringes and hypodermic needles,
35 and to prevent subsequent infection of sexual partners, newborn
36 children, or other persons, this section shall not apply to the
37 possession solely for personal use of 30 or fewer hypodermic
38 needles or syringes if acquired from a physician, pharmacist,
39 hypodermic needle and syringe exchange program, or any other

1 source that is authorized by law to provide sterile syringes or
2 hypodermic needles without a prescription.

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

5 121281. In order to assist pharmacists and pharmacy personnel
6 in the education of consumers who are at risk of bloodborne
7 infections regarding methods and opportunities for improving and
8 protecting the consumer's health, and thereby protect the public
9 health, the Office of AIDS shall develop and maintain all of the
10 following information, on its Internet Web site, and the California
11 State Board of Pharmacy shall also post, or maintain a link to, the
12 information on its Internet Web site:

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

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

17 (c) How consumers can access drug treatment.

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

20 SEC. 8. No reimbursement is required by this act pursuant to
21 Section 6 of Article XIII B of the California Constitution because
22 the only costs that may be incurred by a local agency or school
23 district will be incurred because this act creates a new crime or
24 infraction, eliminates a crime or infraction, or changes the penalty
25 for a crime or infraction, within the meaning of Section 17556 of
26 the Government Code, or changes the definition of a crime within
27 the meaning of Section 6 of Article XIII B of the California
28 Constitution.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1172

VERSION: As Amended June 22, 2010

AUTHOR: Negrete McLeod

SPONSOR: Department of Consumer Affairs

BOARD POSITION: None

SUBJECT: Regulatory boards: Diversion Programs

Affected Sections: Amend Section 156.1 and add Sections 315.2 and 315.4 of the Business and Professions Code.

CURRENT STATUS: Assembly Appropriations

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 a board to order a licensee to cease practice if a licensee tests positive for any prohibited substance as specified. (The Board of Registered Nursing is exempt from this requirement.)
2. Authorizes the board to adopt regulations authorizing 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. (The Board of Registered Nursing is exempt from this requirement.)
3. Specify that a cease practice order does not constitute disciplinary action.

AUTHOR'S INTENT:

According to the author's office, "Pursuant to SB 1441 (Ridley-Thomas), Chapter 548, Statutes of 2008, DCA was required to adopt uniform guidelines on 16 specific standards that would apply to substance abusing health care licensees, regardless of whether a board has a diversion program.

"Although most of the adopted guidelines do not need additional statutes for implementation, there are a few changes that must be statutorily adopted to fully implement these standards.

"This bill seeks to provide the statutory authority to allow boards to order a licensee 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, if a major violation is committed and while undergoing clinical diagnostic evaluation."

FISCAL IMPACT:

As amended, the board does not anticipate any ongoing significant fiscal impact. Any minor impact 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, 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.

Board staff worked with counsel and evaluated the requirements of the Uniform Standards adopted by the committee. The majority of the standards require statutory or regulatory changes. This bill will facilitate implementation of some of these standards.

SUPPORT/OPPOSITION

None on file.

HISTORY:

Date	Action
June 30	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 11. Noes 0.) Re-referred to Com. on APPR. (Heard in committee on June 29.)
June 22	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B.,P. & C.P.
June 10	To Com. on B.,P. & C.P.
May 28	In Assembly. Read first time. Held at Desk.
May 28	Read third time. Passed. (Ayes 27. Noes 0. Page 3655.) To Assembly.
May 18	Read second time. To third reading.
May 17	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
May 12	Set for hearing May 17.
May 11	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on APPR.
May 10	Set, first hearing. Hearing canceled at the request of author.

May 4 Set for hearing May 10.
May 3 Hearing postponed by committee.
Apr. 27 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on APPR.
Apr. 22 Set for hearing May 3.
Apr. 20 From committee: Do pass, but first be re-referred to Com. on APPR.
(Ayes 7. Noes 1. Page 3293.) Re-referred to Com. on APPR.
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 ASSEMBLY JUNE 22, 2010

AMENDED IN SENATE MAY 11, 2010

AMENDED IN SENATE APRIL 27, 2010

AMENDED IN SENATE APRIL 12, 2010

SENATE BILL

No. 1172

Introduced by Senator Negrete McLeod

February 18, 2010

An act to amend Section 156.1 of, and to add Sections ~~315.2, 315.4, and 315.6~~ 315.2 and 315.4 to, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

SB 1172, as amended, Negrete McLeod. Regulatory boards: diversion programs.

(1) Existing law provides for the regulation of specified professions and vocations by various boards, as defined, within the Department of Consumer Affairs. 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 specify that those records and documents shall be kept for 3 years and kept confidential and are not subject to discovery or subpoena unless otherwise expressly provided by law.

(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.

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.~~ *The bill would provide that these provisions do not affect the Board of Registered Nursing.*

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 156.1 of the Business and Professions
 2 Code is amended to read:
 3 156.1. (a) Notwithstanding any other provision of law,
 4 individuals or entities contracting with the department or any board
 5 within the department for the provision of services relating to the
 6 treatment and rehabilitation of licentiates impaired by alcohol or
 7 dangerous drugs shall retain all records and documents pertaining
 8 to those services until such time as these records and documents
 9 have been reviewed for audit by the department. These records
 10 and documents shall be retained for three years from the date of
 11 the last treatment or service rendered to that licentiate, after which
 12 time the records and documents may be purged and destroyed by
 13 the contract vendor. This provision shall supersede any other

1 provision of law relating to the purging or destruction of records
2 pertaining to those treatment and rehabilitation programs.

3 (b) Unless otherwise expressly provided by statute or regulation,
4 all records and documents pertaining to services for the treatment
5 and rehabilitation of licentiates impaired by alcohol or dangerous
6 drugs provided by any contract vendor to the department or to any
7 board within the department shall be kept confidential and are not
8 subject to discovery or subpoena.

9 (c) With respect to all other contracts for services with the
10 department or any board within the department other than those
11 set forth in subdivision (a), the director or chief deputy director
12 may request an examination and audit by the department's internal
13 auditor of all performance under the contract. For this purpose, all
14 documents and records of the contract vendor in connection with
15 such performance shall be retained by such vendor for a period of
16 three years after final payment under the contract. Nothing in this
17 section shall affect the authority of the State Auditor to conduct
18 any examination or audit under the terms of Section 8546.7 of the
19 Government Code.

20 SEC. 2. Section 315.2 is added to the Business and Professions
21 Code, to read:

22 315.2. (a) A board, as described in Section 315, shall order a
23 licensee of the board to cease practice if the licensee tests positive
24 for any substance that is prohibited under the terms of the licensee's
25 probation or diversion program.

26 (b) An order to cease practice under this section shall not be
27 governed by the provisions of Chapter 5 (commencing with Section
28 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

29 (c) A cease practice order under this section shall not constitute
30 disciplinary action.

31 (d) *This section shall have no effect on the Board of Registered*
32 *Nursing pursuant to Article 3.1 (commencing with Section 2770)*
33 *of Chapter 6 of Division 2.*

34 SEC. 3. Section 315.4 is added to the Business and Professions
35 Code, to read:

36 315.4. (a) A board, as described in Section 315, may adopt
37 regulations authorizing the board to order a licensee on probation
38 or in a diversion program to cease practice for major violations
39 and when the board orders a licensee to undergo a clinical

1 diagnostic evaluation pursuant to the uniform and specific standards
2 adopted and authorized under Section 315.

3 (b) An order to cease practice under this section shall not be
4 governed by the provisions of Chapter 5 (commencing with Section
5 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

6 (c) A cease practice order under this section shall not constitute
7 disciplinary action.

8 ~~SEC. 4. Section 315.6 is added to the Business and Professions
9 Code, to read:~~

10 ~~315.6. Unless otherwise authorized by statute or regulation, a
11 board, as described in Section 315, shall not disclose to the public
12 that a licensee is participating in a board diversion program unless
13 participation was ordered as a term of probation. However, a board
14 shall disclose to the public any restrictions that are placed on a
15 licensee's practice as a result of the licensee's participation in a
16 board diversion program provided that the disclosure does not
17 contain information linking the restriction to the licensee's
18 participation in the board's diversion program.~~

19 *(d) This section shall have no effect on the Board of Registered
20 Nursing pursuant to Article 3.1 (commencing with Section 2770)
21 of Chapter 6 of Division 2.*