



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Legislation and Regulation Committee

Andrea Zinder, Public Member, Chair
Ryan Brooks, Public Member
Jim Burgard, Public Member
Robert Swart, PharmD
Shirley Wheat, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

Part 2. Legislative Report: Discussion and Action on Pending Legislation

A. Board Sponsored Legislation

1. SB 819 (Senate Business, Professions and Economic Development Committee) – Omnibus Provisions formerly contained in the enrolled version of SB 1779 [2008], vetoed).

Attachment A-1

At the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

These omnibus provisions were categorized into four types of changes:

- a. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.
- b. General omnibus provisions.
- c. Use of mobile pharmacies.
- d. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.

Below is a summary of the changes by category and section.

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

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

Section 733 – Dispensing Prescription Drugs and Devices
Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

Section 4040 – Prescription; Content Requirements
Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
Section 4060 – Controlled Substance – Prescription Required, Exceptions
Section 4076 – Prescription Container – Requirements for Labeling
Section 4111 – Restrictions on Prescriber Ownership
Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
H&SC 11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Provisions

In addition to the changes listed above, all of the following proposals were also approved as omnibus provisions for 2008:

Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.

A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

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

This section requires amendment to replace the term “representative-in-charge” with “designated representative-in-charge.”

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

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

This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

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

This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency

This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership

This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

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

Consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a

result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs. These changes were approved by the board and many were incorporated in SB 1779 as omnibus provisions. This bill was vetoed by the Governor. Board staff recommends that the board again consider including these changes as omnibus provisions in 2009.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed changes. The proposed language is following this memo.

Section 4022.5 – Designated Representative; Designated Representative-in-Charge

This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge

A new section is needed to define the term “pharmacist-in-charge” as well as the responsibilities of a pharmacist serving as such.

Section 4161 – Non-Resident Wholesaler; Requirements

This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043.

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

This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

While board staff does not anticipate any opposition to these provisions, should it occur, board members will be advised.

2. SB 820 (Senate Business, Professions and Economic Development Committee) – New Omnibus Provisions

Attachment A-2

Late last year, board staff was advised that the Office of Examination Resources (OER) was being renamed to the Office of Professional Examination Resources. SB 820 (Senate Business, Professions & Economic Development Committee) make conforming changes throughout the Business and Professions Code to reflect this name change.

3. SB 821 (Senate Business, Professions and Economic Development Committee) – New Omnibus Provisions

Attachment A-3

At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions. These provisions are contained in SB 821.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy

This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert

This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

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

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

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

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

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

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

Amend Section 4160 – Wholesaler Licenses

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

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

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

While we do not anticipate any opposition to these provisions, should any arise, board members will be advised.

4. **FOR INFORMATION** – SB 470 (Corbett) Prescription Labeling to add "Purpose" - - Proposal to amend B&PC §4040 and §4076.

Attachment A-4

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the

results of the board's prescription label survey where many consumers suggested that the purpose of the medicine be included on the label.

Senator Corbett is authoring this bill for the board. This bill will amend Business and Professions Code sections 4040 and 4076 to include the "condition or purpose" for which a medicine is prescribed. (Senator Corbett authored SB 472, Chapter 470, and Statutes of 2007, requiring the board to standardize the prescription label to make them patient-centered.)

Board staff has been working to establish a broad base of support for this proposal. The California Medical Association recently submitted a letter advising the author's office that it has taken a Support If Amended position and offered amendments. Senator Corbett's office has advised CMA that they will be accepting the amendments offered. Additionally, Senator Corbett's office is also working with the California Retailers Association and National Association of Chain Drug Stores who submitted an Oppose Unless Amended position.

Board staff continues to advocate for this proposal and continue to work with the Senator Corbett's Office as well as stakeholders who may have concerns.

This bill recently passed out of the Senate Business, Professions and Economic Development Committee and was referred to the Committee on Appropriations.

5. **FOR INFORMATION** – AB 977 (Skinner) Pharmacists: Immunization Administration – Proposal to Amend B&PC §4052 and Addition of §4052.8

Attachment A-5

At the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Assembly Member Skinner is authoring this bill for the board. This bill will amend Business and Professions Code section 4052 and add 4052.8 to allow a pharmacist to administer immunizations as specified. As stated above, as introduced, this bill would have allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP), however with the approval of the board president, this proposal will be amended to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a prescriber protocol. The National Vital Statistics Report published by the U.S. Department of Health and Human Services reports that combined, influenza and pneumonia are the eighth leading cause of death in people of all ages, and the sixth leading cause of death in people over 65.

Board staff has been working with stakeholders to establish a broad base of support. Unfortunately the California Medical Association (CMA) continues to oppose the bill, even with the proposed amendments.

This bill failed passage in the Assembly Business and Profession Committee; reconsideration was granted. Assembly Member Skinner's Office will be amending the bill. A copy of the amended bill will be provided at the meeting if available.

6. **FOR DISCUSSION and POSSIBLE ACTION** – AB 1071 (Emmerson) Pharmacy Fees - -
Proposal to Amend B&PC §4110, 4127.8, §4160, §4400 and Repeal §4127.5

Attachment A-6

At the January 2009 Board Meeting, the board voted to pursue a statutory change increase to its fees.

Assembly Member Emmerson is authoring this proposal for the board. AB 1071 adjusts application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. This bill also builds in a cap to increase future fees by no more than 30 percent.

During the January 2009 Board Meeting, significant discussion occurred regarding the best way to determine fees. The board voted to pursue the statutory fee increase, but did not reach consensus on the fees themselves. With approval of the board president, board staff drafted language that begins to reduce the current subsidy that exists between individual and site licenses. This language is contained in AB 1071.

B. FOR DISCUSSION and POSSIBLE ACTION: Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Attachment B-1

Several Legislative proposals were introduced this year that impact the practice of pharmacy or the board's jurisdiction. The board's Legislation and Regulation Committee recently reviewed several of these proposals. Committee Recommendations are indicated below where appropriate and the bill's current status is also provided. A copy of each active bill and an analysis are provided in the attachment. Updated analyses and copies of the bills will be provided during the board meeting.

1. AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements

This bill would alter the requirements for licensure as a pharmacy technician as well as establish continuing education requirements as a condition of renewal.

Committee Recommendation: Support AB 418

Bill Status: Failed Passage in Assembly Business and Professions Committee.

Reconsideration granted.

2. AB 484 (Eng) Franchise Tax Board: professional or occupational licenses

This bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity. The bill would also require the Franchise Tax Board, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, as specified, to mail a preliminary notice of suspension to the licensee.

Committee Recommendation: None

Bill Status: Failed Passage in Assembly Business and Professions Committee. A copy of the bill and analysis is not provided.

3. AB 718 (Emmerson) Prescription drugs: electronic transmissions

This bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission.

Committee Recommendation: Support AB 718
Bill Status: Heard in Assembly Health Committee on April 21, 2009

4. AB 830 (Cook) Drugs and devices

This bill would replace various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services.

Committee Recommendation: Oppose AB 830
Bill Status: Referred to Assembly Committee on Appropriations

5. AB 877 (Emmerson) Healing arts

This bill would declare the intent of the Legislature to enact legislation authorizing the Director of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice.

Committee Recommendation: No position
Bill Status: Scheduled for hearing in Assembly Business and Professions on April 28, 2009

6. AB 931 (Fletcher) Emergency supplies

This bill would increase the number of oral dosage form and suppository dosage form drugs for storage within this container to limit to 48. The current limit is 24.

Committee Recommendation: No position
Bill Status: Scheduled for hearing in Assembly Health on May 5, 2009

7. AB 1310 (Hernandez) Healing arts: database

This bill would require specified healing arts boards to add and label as "mandatory" specified fields on an application for initial licensure or a renewal form for applicants applying to those boards and would require the board to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse annually on or before January 1.

Committee Recommendation: No position
Bill Status: Referred to Assembly Appropriations Committee

8. AB 1370 (Solorio) Drugs and devices: labeling: expiration date: best before date

This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device.

Committee Recommendation: No position
Bill Status: Referred to Assembly Health Committee

9. AB 1458 (Davis) Drugs: Adverse Effects Reporting

This bill would mandate that licensed health professionals report to the FDA's MedWatch system when serious adverse reactions occur as specified.

Committee Recommendation: This bill was not discussed by the Leg/Reg Committee
Bill Status: Heard in Assembly Business and Professions Committee on April 21, 2009

10. SB 26 (Simitian) Home Generated Pharmaceutical Waste

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Committee Recommendation: No position
Bill Status: Referred to Senate Appropriations Committee

11. SB 43 (Alquist) Health professions

This bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards.

Committee Recommendation: Support SB 43
Bill Status: Referred to Senate Committee on Judiciary

12. SB 238 (Calderon) Medical Information

This bill would allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions.

Committee Recommendation: This bill was not discussed by the Leg/Reg Committee
Bill Status: Scheduled for hearing in Senate Health Committee on April 29, 2009

13. SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs

This bill would require the department to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in California as specified.

Committee Recommendation: This bill was not discussed by the Leg/Reg Committee
Bill Status: Referred to Senate Health Committee

14. SB 364 (Florez) Pharmacies

This bill would declare the intent of the Legislature to enact legislation authorizing the imposition of specified penalties on a pharmacy that fails to safeguard controlled substances.

Committee Recommendation: None
Bill Status: This bill was amended and is no longer related to the practice of pharmacy. A copy of the bill and analysis is not provided.

15. SB 389 (Negrete McLeod) Professions and vocations

The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

Committee Recommendation: Support SB 389
Bill Status: Referred to Committee on Public Safety

16. SB 484 (Wright) Ephedrine and pseudoephedrine

This bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription.

Committee Recommendation: None

Bill Status: Scheduled for hearing in Senate Committee on Public Safety on April 28, 2009.

17. SB 638 (Negrete McLeod) Regulatory boards: operations.

This bill would redefine the sunset review process.

Committee Recommendation: Support SB

Bill Status: Scheduled for hearing in Senate Committee on Public Safety on April 28, 2009.

18. SB 762 (Aanestad) Professions and vocations: healing arts

This bill would also make it unlawful for a city, county, or city and county to prohibit a healing arts licensee from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee, but would prohibit construing this provision to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, as specified.

Committee Recommendation: None

Bill Status: Scheduled for hearing in Senate Business, Professions and Economic Development on April 27, 2009.

C. FOR INFORMATION – Other Legislation Introduced

Attachment C-1

In addition to the legislation that board staff are tracking and have submitted to the board for consideration, there are other proposals that do not directly impact our jurisdiction but may be of interest to the board. Copies of these bills are provided in this packet for information only.

AB 832 (Jones) Clinic Licensing

AB 1094 (Conway) Disposal of Personal Information

AB 1201 (Perez) Immunizations (physician reimbursement)

D. FOR INFORMATION – Summary of the Legislation and Regulation Committee Meeting held April 16, 2009.

Attachment D-1

A summary of the committee meeting is provided in the board's packet.

E. FOR INFORMATION – Third Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

Attachment E-1

An updated on the committee's goals is provided in the board packet.

Attachment A-1

SB 819 (Senate Business, Professions and Economic Development)

AMENDED IN SENATE APRIL 20, 2009

AMENDED IN SENATE APRIL 13, 2009

SENATE BILL

No. 819

Introduced by Committee on Business, Professions and Economic Development (Negrete McLeod (chair), Aanestad, Corbett, Correa, Florez, Oropeza, Romero, Walters, Wyland, and Yee)

March 10, 2009

An act to amend Sections 27, 101, 128.5, 144, 146, 149, 683, 733, 800, 801, 801.01, 803, 2089.5, 2096, 2102, 2107, 2135, 2168.4, 2175, 2221, 2307, 2335, 2486, 2488, 2570.5, 2570.6, 2570.7, 2570.185, 2760.1, 3503, 3517, 3518, 3625, 3633.1, 3635, 3636, 3685, 3753.5, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, 4161, 4174, 4231, 4301, 4305, 4329, 4330, 4857, 4980.30, 4980.43, 4996.2, 4996.17, 4996.18, 5801, 6534, 6536, 6561, 7616, 7629, 8740, and 8746 of, to add Sections 2169, 2570.36, 4036.5, 4980.04, 4990.09, 5515.5, and 9855.15 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, 4996.21, and 6761 of, the Business and Professions Code, to amend Section 8659 of the Government Code, to amend Sections 8778.5, 11150, and 11165 of the Health and Safety Code, and to amend Section 14132.100 of the Welfare and Institutions Code, relating to professions and vocations, ~~and~~ making an appropriation therefor, *and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

SB 819, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

(1) Existing law provides for the licensure and regulation of various professions and vocations by boards and bureaus within the Department of Consumer Affairs.

1 repeal of this chapter renders the bureau subject to the review
2 required by Division 1.2 (commencing with Section 473).

3 (b) The bureau shall prepare the report required by Section 473.2
4 no later than September 1, 2008.

5 SEC. 43. Section 3753.5 of the Business and Professions Code
6 is amended to read:

7 3753.5. (a) In any order issued in resolution of a disciplinary
8 proceeding before the board, the board or the administrative law
9 judge may direct any practitioner or applicant found to have
10 committed a violation or violations of law or any term and
11 condition of board probation to pay to the board a sum not to
12 exceed the costs of the investigation and prosecution of the case.
13 A certified copy of the actual costs, or a good faith estimate of
14 costs where actual costs are not available, signed by the official
15 custodian of the record or his or her designated representative shall
16 be prima facie evidence of the actual costs of the investigation and
17 prosecution of the case.

18 (b) The costs shall be assessed by the administrative law judge
19 and shall not be increased by the board; however, the costs may
20 be imposed or increased by the board if it does not adopt the
21 proposed decision of the case.

22 Where an order for recovery of costs is made and timely payment
23 is not made as directed in the board's decision the board may
24 enforce the order for repayment in any appropriate court. This
25 right of enforcement shall be in addition to any other rights the
26 board may have as to any practitioner directed to pay costs.

27 (c) In any action for recovery of costs, proof of the board's
28 decision shall be conclusive proof of the validity of the order of
29 payment and the terms for payment.

30 (d) (1) The board shall not renew or reinstate the license of any
31 licensee who has failed to pay all of the costs ordered under this
32 section.

33 (2) Notwithstanding paragraph (1), the board may, in its
34 discretion, conditionally renew, for a maximum of one year, the
35 license of any licensee who demonstrates financial hardship,
36 through documentation satisfactory to the board, and who enters
37 into a formal agreement with the board to reimburse the board
38 within that one-year period for those unpaid costs.

39 SEC. 44. Section 4022.5 of the Business and Professions Code
40 is amended to read:

1 4022.5. (a) "Designated representative" means an individual
2 to whom a license has been granted pursuant to Section 4053. A
3 pharmacist fulfilling the duties of Section 4053 shall not be
4 required to obtain a license as a designated representative.

5 (b) "Designated representative-in-charge" means a designated
6 representative or a pharmacist proposed by a wholesaler or
7 veterinary food-animal drug retailer and approved by the board as
8 the supervisor or manager responsible for ensuring the wholesaler's
9 or veterinary food-animal drug retailer's compliance with all state
10 and federal laws and regulations pertaining to practice in the
11 applicable license category.

12 SEC. 45. Section 4027 of the Business and Professions Code
13 is amended to read:

14 4027. (a) As used in this chapter, the terms "skilled nursing
15 facility," "intermediate care facility," and other references to health
16 facilities shall be construed with respect to the definitions contained
17 in Article 1 (commencing with Section 1250) of Chapter 2 of
18 Division 2 of the Health and Safety Code.

19 (b) As used in Section 4052.1, "licensed health care facility"
20 means a facility licensed pursuant to Article 1 (commencing with
21 Section 1250) of Chapter 2 of Division 2 of the Health and Safety
22 Code or a facility, as defined in Section 1250 of the Health and
23 Safety Code, operated by a health care service plan licensed
24 pursuant to Chapter 2.2 (commencing with Section 1340) of
25 Division 2 of the Health and Safety Code.

26 (c) As used in Section 4052.2, "health care facility" means a
27 facility, other than a facility licensed under Division 2
28 (commencing with Section 1200) of the Health and Safety Code,
29 that is owned or operated by a health care service plan licensed
30 pursuant to Chapter 2.2 (commencing with Section 1340) of the
31 Health and Safety Code, or by an organization under common
32 ownership or control of the health care service plan; "licensed
33 home health agency" means a private or public organization
34 licensed by the State Department of Public Health pursuant to
35 Chapter 8 (commencing with Section 1725) of Division 2 of the
36 Health and Safety Code, as further defined in Section 1727 of the
37 Health and Safety Code; and "licensed clinic" means a clinic
38 licensed pursuant to Article 1 (commencing with Section 1200)
39 of Chapter 1 of Division 2 of the Health and Safety Code.

1 (d) "Licensed health care facility" or "facility," as used in
2 Section 4065, means a health facility licensed pursuant to Article
3 1 (commencing with Section 1250) of Chapter 2 of Division 2 of
4 the Health and Safety Code or a facility that is owned or operated
5 by a health care service plan licensed pursuant to Chapter 2.2
6 (commencing with Section 1340) of Division 2 of the Health and
7 Safety Code or by an organization under common ownership or
8 control with the health care service plan.

9 SEC. 46. Section 4036.5 is added to the Business and
10 Professions Code, to read:

11 4036.5. "Pharmacist-in-charge" means a pharmacist proposed
12 by a pharmacy and approved by the board as the supervisor or
13 manager responsible for ensuring the pharmacy's compliance with
14 all state and federal laws and regulations pertaining to the practice
15 of pharmacy.

16 SEC. 47. Section 4040 of the Business and Professions Code
17 is amended to read:

18 4040. (a) "Prescription" means an oral, written, or electronic
19 transmission order that is both of the following:

20 (1) Given individually for the person or persons for whom
21 ordered that includes all of the following:

22 (A) The name or names and address of the patient or patients.

23 (B) The name and quantity of the drug or device prescribed and
24 the directions for use.

25 (C) The date of issue.

26 (D) Either rubber stamped, typed, or printed by hand or typeset,
27 the name, address, and telephone number of the prescriber, his or
28 her license classification, and his or her federal registry number,
29 if a controlled substance is prescribed.

30 (E) A legible, clear notice of the condition for which the drug
31 is being prescribed, if requested by the patient or patients.

32 (F) If in writing, signed by the prescriber issuing the order, or
33 the certified nurse-midwife, nurse practitioner, physician assistant,
34 or naturopathic doctor who issues a drug order pursuant to Section
35 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist
36 who issues a drug order pursuant to either Section 4052.1 or
37 4052.2.

38 (2) Issued by a physician, dentist, optometrist, podiatrist,
39 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,
40 if a drug order is issued pursuant to Section 2746.51, 2836.1,

1 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,
2 physician assistant, or naturopathic doctor licensed in this state,
3 or pursuant to either Section 4052.1 or 4052.2 by a pharmacist
4 licensed in this state.

5 (b) Notwithstanding subdivision (a), a written order of the
6 prescriber for a dangerous drug, except for any Schedule II
7 controlled substance, that contains at least the name and signature
8 of the prescriber, the name and address of the patient in a manner
9 consistent with paragraph (2) of subdivision (a) of Section 11164
10 of the Health and Safety Code, the name and quantity of the drug
11 prescribed, directions for use, and the date of issue may be treated
12 as a prescription by the dispensing pharmacist as long as any
13 additional information required by subdivision (a) is readily
14 retrievable in the pharmacy. In the event of a conflict between this
15 subdivision and Section 11164 of the Health and Safety Code,
16 Section 11164 of the Health and Safety Code shall prevail.

17 (c) "Electronic transmission prescription" includes both image
18 and data prescriptions. "Electronic image transmission
19 prescription" means any prescription order for which a facsimile
20 of the order is received by a pharmacy from a licensed prescriber.
21 "Electronic data transmission prescription" means any prescription
22 order, other than an electronic image transmission prescription,
23 that is electronically transmitted from a licensed prescriber to a
24 pharmacy.

25 (d) The use of commonly used abbreviations shall not invalidate
26 an otherwise valid prescription.

27 (e) Nothing in the amendments made to this section (formerly
28 Section 4036) at the 1969 Regular Session of the Legislature shall
29 be construed as expanding or limiting the right that a chiropractor,
30 while acting within the scope of his or her license, may have to
31 prescribe a device.

32 SEC. 48. Section 4051 of the Business and Professions Code
33 is amended to read:

34 4051. (a) Except as otherwise provided in this chapter, it is
35 unlawful for any person to manufacture, compound, furnish, sell,
36 or dispense any dangerous drug or dangerous device, or to dispense
37 or compound any prescription pursuant to Section 4040 of a
38 prescriber unless he or she is a pharmacist under this chapter.

39 (b) Notwithstanding any other law, a pharmacist may authorize
40 the initiation of a prescription, pursuant to Section 4052.1, 4052.2,

1 or 4052.3, and otherwise provide clinical advice or information or
2 patient consultation if all of the following conditions are met:

3 (1) The clinical advice or information or patient consultation is
4 provided to a health care professional or to a patient.

5 (2) The pharmacist has access to prescription, patient profile,
6 or other relevant medical information for purposes of patient and
7 clinical consultation and advice.

8 (3) Access to the information described in paragraph (2) is
9 secure from unauthorized access and use.

10 SEC. 49. Section 4059.5 of the Business and Professions Code
11 is amended to read:

12 4059.5. (a) Except as otherwise provided in this chapter,
13 dangerous drugs or dangerous devices may only be ordered by an
14 entity licensed by the board and shall be delivered to the licensed
15 premises and signed for and received by a pharmacist. Where a
16 licensee is permitted to operate through a designated representative,
17 the designated representative shall sign for and receive the delivery.

18 (b) A dangerous drug or dangerous device transferred, sold, or
19 delivered to a person within this state shall be transferred, sold, or
20 delivered only to an entity licensed by the board, to a manufacturer,
21 or to an ultimate user or the ultimate user's agent.

22 (c) Notwithstanding subdivisions (a) and (b), deliveries to a
23 hospital pharmacy may be made to a central receiving location
24 within the hospital. However, the dangerous drugs or dangerous
25 devices shall be delivered to the licensed pharmacy premises within
26 one working day following receipt by the hospital, and the
27 pharmacist on duty at that time shall immediately inventory the
28 dangerous drugs or dangerous devices.

29 (d) Notwithstanding any other provision of law, a dangerous
30 drug or dangerous device may be ordered by and provided to a
31 manufacturer, physician, dentist, podiatrist, optometrist,
32 veterinarian, naturopathic doctor pursuant to Section 3640.7, or
33 laboratory, or a physical therapist acting within the scope of his
34 or her license. A person or entity receiving delivery of a dangerous
35 drug or dangerous device, or a duly authorized representative of
36 the person or entity, shall sign for the receipt of the dangerous drug
37 or dangerous device.

38 (e) A dangerous drug or dangerous device shall not be
39 transferred, sold, or delivered to a person outside this state, whether
40 foreign or domestic, unless the transferor, seller, or deliverer does

1 so in compliance with the laws of this state and of the United States
2 and of the state or country to which the dangerous drugs or
3 dangerous devices are to be transferred, sold, or delivered.
4 Compliance with the laws of this state and the United States and
5 of the state or country to which the dangerous drugs or dangerous
6 devices are to be delivered shall include, but not be limited to,
7 determining that the recipient of the dangerous drugs or dangerous
8 devices is authorized by law to receive the dangerous drugs or
9 dangerous devices.

10 (f) Notwithstanding subdivision (a), a pharmacy may take
11 delivery of dangerous drugs and dangerous devices when the
12 pharmacy is closed and no pharmacist is on duty if all of the
13 following requirements are met:

14 (1) The drugs are placed in a secure storage facility in the same
15 building as the pharmacy.

16 (2) Only the pharmacist-in-charge or a pharmacist designated
17 by the pharmacist-in-charge has access to the secure storage facility
18 after dangerous drugs or dangerous devices have been delivered.

19 (3) The secure storage facility has a means of indicating whether
20 it has been entered after dangerous drugs or dangerous devices
21 have been delivered.

22 (4) The pharmacy maintains written policies and procedures for
23 the delivery of dangerous drugs and dangerous devices to a secure
24 storage facility.

25 (5) The agent delivering dangerous drugs and dangerous devices
26 pursuant to this subdivision leaves documents indicating the name
27 and amount of each dangerous drug or dangerous device delivered
28 in the secure storage facility.

29 The pharmacy shall be responsible for the dangerous drugs and
30 dangerous devices delivered to the secure storage facility. The
31 pharmacy shall also be responsible for obtaining and maintaining
32 records relating to the delivery of dangerous drugs and dangerous
33 devices to a secure storage facility.

34 SEC. 50. Section 4060 of the Business and Professions Code
35 is amended to read:

36 4060. No person shall possess any controlled substance, except
37 that furnished to a person upon the prescription of a physician,
38 dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
39 pursuant to Section 3640.7, or furnished pursuant to a drug order
40 issued by a certified nurse-midwife pursuant to Section 2746.51,

1 a nurse practitioner pursuant to Section 2836.1, a physician
2 assistant pursuant to Section 3502.1, a naturopathic doctor pursuant
3 to Section 3640.5, or a pharmacist pursuant to either Section 4052.1
4 or 4052.2. This section shall not apply to the possession of any
5 controlled substance by a manufacturer, wholesaler, pharmacy,
6 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian,
7 naturopathic doctor, certified nurse-midwife, nurse practitioner,
8 or physician assistant, when in stock in containers correctly labeled
9 with the name and address of the supplier or producer.

10 Nothing in this section authorizes a certified nurse-midwife, a
11 nurse practitioner, a physician assistant, or a naturopathic doctor,
12 to order his or her own stock of dangerous drugs and devices.

13 SEC. 51. Section 4062 of the Business and Professions Code
14 is amended to read:

15 4062. (a) Notwithstanding Section 4059 or any other provision
16 of law, a pharmacist may, in good faith, furnish a dangerous drug
17 or dangerous device in reasonable quantities without a prescription
18 during a federal, state, or local emergency, to further the health
19 and safety of the public. A record containing the date, name, and
20 address of the person to whom the drug or device is furnished, and
21 the name, strength, and quantity of the drug or device furnished
22 shall be maintained. The pharmacist shall communicate this
23 information to the patient's attending physician as soon as possible.
24 Notwithstanding Section 4060 or any other provision of law, a
25 person may possess a dangerous drug or dangerous device
26 furnished without prescription pursuant to this section.

27 (b) During a declared federal, state, or local emergency, the
28 board may waive application of any provisions of this chapter or
29 the regulations adopted pursuant to it if, in the board's opinion,
30 the waiver will aid in the protection of public health or the
31 provision of patient care.

32 (c) During a declared federal, state, or local emergency, the
33 board shall allow for the employment of a mobile pharmacy in
34 impacted areas in order to ensure the continuity of patient care, if
35 all of the following conditions are met:

36 (1) The mobile pharmacy shares common ownership with at
37 least one currently licensed pharmacy in good standing.

38 (2) The mobile pharmacy retains records of dispensing, as
39 required by subdivision (a).

1 (3) A licensed pharmacist is on the premises and the mobile
2 pharmacy is under the control and management of a pharmacist
3 while the drugs are being dispensed.

4 (4) Reasonable security measures are taken to safeguard the
5 drug supply maintained in the mobile pharmacy.

6 (5) The mobile pharmacy is located within the declared
7 emergency area or affected areas.

8 (6) The mobile pharmacy ceases the provision of services within
9 48 hours following the termination of the declared emergency.

10 SEC. 52. Section 4076 of the Business and Professions Code
11 is amended to read:

12 4076. (a) A pharmacist shall not dispense any prescription
13 except in a container that meets the requirements of state and
14 federal law and is correctly labeled with all of the following:

15 (1) Except where the prescriber or the certified nurse-midwife
16 who functions pursuant to a standardized procedure or protocol
17 described in Section 2746.51, the nurse practitioner who functions
18 pursuant to a standardized procedure described in Section 2836.1,
19 or protocol, the physician assistant who functions pursuant to
20 Section 3502.1, the naturopathic doctor who functions pursuant
21 to a standardized procedure or protocol described in Section
22 3640.5, or the pharmacist who functions pursuant to a policy,
23 procedure, or protocol pursuant to either Section 4052.1 or 4052.2
24 orders otherwise, either the manufacturer's trade name of the drug
25 or the generic name and the name of the manufacturer. Commonly
26 used abbreviations may be used. Preparations containing two or
27 more active ingredients may be identified by the manufacturer's
28 trade name or the commonly used name or the principal active
29 ingredients.

30 (2) The directions for the use of the drug.

31 (3) The name of the patient or patients.

32 (4) The name of the prescriber or, if applicable, the name of the
33 certified nurse-midwife who functions pursuant to a standardized
34 procedure or protocol described in Section 2746.51, the nurse
35 practitioner who functions pursuant to a standardized procedure
36 described in Section 2836.1, or protocol, the physician assistant
37 who functions pursuant to Section 3502.1, the naturopathic doctor
38 who functions pursuant to a standardized procedure or protocol
39 described in Section 3640.5, or the pharmacist who functions

1 pursuant to a policy, procedure, or protocol pursuant to either
2 Section 4052.1 or 4052.2.

3 (5) The date of issue.

4 (6) The name and address of the pharmacy, and prescription
5 number or other means of identifying the prescription.

6 (7) The strength of the drug or drugs dispensed.

7 (8) The quantity of the drug or drugs dispensed.

8 (9) The expiration date of the effectiveness of the drug
9 dispensed.

10 (10) The condition for which the drug was prescribed if
11 requested by the patient and the condition is indicated on the
12 prescription.

13 (11) (A) Commencing January 1, 2006, the physical description
14 of the dispensed medication, including its color, shape, and any
15 identification code that appears on the tablets or capsules, except
16 as follows:

17 (i) Prescriptions dispensed by a veterinarian.

18 (ii) An exemption from the requirements of this paragraph shall
19 be granted to a new drug for the first 120 days that the drug is on
20 the market and for the 90 days during which the national reference
21 file has no description on file.

22 (iii) Dispensed medications for which no physical description
23 exists in any commercially available database.

24 (B) This paragraph applies to outpatient pharmacies only.

25 (C) The information required by this paragraph may be printed
26 on an auxiliary label that is affixed to the prescription container.

27 (D) This paragraph shall not become operative if the board,
28 prior to January 1, 2006, adopts regulations that mandate the same
29 labeling requirements set forth in this paragraph.

30 (b) If a pharmacist dispenses a prescribed drug by means of a
31 unit dose medication system, as defined by administrative
32 regulation, for a patient in a skilled nursing, intermediate care, or
33 other health care facility, the requirements of this section will be
34 satisfied if the unit dose medication system contains the
35 aforementioned information or the information is otherwise readily
36 available at the time of drug administration.

37 (c) If a pharmacist dispenses a dangerous drug or device in a
38 facility licensed pursuant to Section 1250 of the Health and Safety
39 Code, it is not necessary to include on individual unit dose
40 containers for a specific patient, the name of the certified

1 nurse-midwife who functions pursuant to a standardized procedure
2 or protocol described in Section 2746.51, the nurse practitioner
3 who functions pursuant to a standardized procedure described in
4 Section 2836.1, or protocol, the physician assistant who functions
5 pursuant to Section 3502.1, the naturopathic doctor who functions
6 pursuant to a standardized procedure or protocol described in
7 Section 3640.5, or the pharmacist who functions pursuant to a
8 policy, procedure, or protocol pursuant to either Section 4052.1
9 or 4052.2.

10 (d) If a pharmacist dispenses a prescription drug for use in a
11 facility licensed pursuant to Section 1250 of the Health and Safety
12 Code, it is not necessary to include the information required in
13 paragraph (11) of subdivision (a) when the prescription drug is
14 administered to a patient by a person licensed under the Medical
15 Practice Act (Chapter 5 (commencing with Section 2000)), the
16 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
17 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
18 with Section 2840)), who is acting within his or her scope of
19 practice.

20 SEC. 53. Section 4081 of the Business and Professions Code
21 is amended to read:

22 4081. (a) All records of manufacture and of sale, acquisition,
23 or disposition of dangerous drugs or dangerous devices shall be
24 at all times during business hours open to inspection by authorized
25 officers of the law, and shall be preserved for at least three years
26 from the date of making. A current inventory shall be kept by every
27 manufacturer, wholesaler, pharmacy, veterinary food-animal drug
28 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
29 clinic, hospital, institution, or establishment holding a currently
30 valid and unrevoked certificate, license, permit, registration, or
31 exemption under Division 2 (commencing with Section 1200) of
32 the Health and Safety Code or under Part 4 (commencing with
33 Section 16000) of Division 9 of the Welfare and Institutions Code
34 who maintains a stock of dangerous drugs or dangerous devices.

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

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

7 SEC. 54. Section 4110 of the Business and Professions Code
8 is amended to read:

9 4110. (a) No person shall conduct a pharmacy in the State of
10 California unless he or she has obtained a license from the board.
11 A license shall be required for each pharmacy owned or operated
12 by a specific person. A separate license shall be required for each
13 of the premises of any person operating a pharmacy in more than
14 one location. The license shall be renewed annually. The board
15 may, by regulation, determine the circumstances under which a
16 license may be transferred.

17 (b) The board may, at its discretion, issue a temporary permit,
18 when the ownership of a pharmacy is transferred from one person
19 to another, upon the conditions and for any periods of time as the
20 board determines to be in the public interest. A temporary permit
21 fee shall be established by the board at an amount not to exceed
22 the annual fee for renewal of a permit to conduct a pharmacy.
23 When needed to protect public safety, a temporary permit may be
24 issued for a period not to exceed 180 days, and may be issued
25 subject to terms and conditions the board deems necessary. If the
26 board determines a temporary permit was issued by mistake or
27 denies the application for a permanent license or registration, the
28 temporary license or registration shall terminate upon either
29 personal service of the notice of termination upon the permitholder
30 or service by certified mail, return receipt requested, at the
31 permitholder's address of record with the board, whichever comes
32 first. Neither for purposes of retaining a temporary permit nor for
33 purposes of any disciplinary or license denial proceeding before
34 the board shall the temporary permitholder be deemed to have a
35 vested property right or interest in the permit.

36 (c) The board may allow the temporary use of a mobile
37 pharmacy when a pharmacy is destroyed or damaged, the mobile
38 pharmacy is necessary to protect the health and safety of the public,
39 and the following conditions are met:

1 (1) The mobile pharmacy shall provide services only on or
2 immediately contiguous to the site of the damaged or destroyed
3 pharmacy.

4 (2) The mobile pharmacy is under the control and management
5 of the pharmacist-in-charge of the pharmacy that was destroyed
6 or damaged.

7 (3) A licensed pharmacist is on the premises while drugs are
8 being dispensed.

9 (4) Reasonable security measures are taken to safeguard the
10 drug supply maintained in the mobile pharmacy.

11 (5) The pharmacy operating the mobile pharmacy provides the
12 board with records of the destruction or damage of the pharmacy
13 and an expected restoration date.

14 (6) Within three calendar days of restoration of the pharmacy
15 services, the board is provided with notice of the restoration of the
16 permanent pharmacy.

17 (7) The mobile pharmacy is not operated for more than 48 hours
18 following the restoration of the permanent pharmacy.

19 SEC. 55. Section 4111 of the Business and Professions Code
20 is amended to read:

21 4111. (a) Except as otherwise provided in subdivision (b), (d),
22 or (e), the board shall not issue or renew a license to conduct a
23 pharmacy to any of the following:

24 (1) A person or persons authorized to prescribe or write a
25 prescription, as specified in Section 4040, in the State of California.

26 (2) A person or persons with whom a person or persons specified
27 in paragraph (1) shares a community or other financial interest in
28 the permit sought.

29 (3) Any corporation that is controlled by, or in which 10 percent
30 or more of the stock is owned by a person or persons prohibited
31 from pharmacy ownership by paragraph (1) or (2).

32 (b) Subdivision (a) shall not preclude the issuance of a permit
33 for an inpatient hospital pharmacy to the owner of the hospital in
34 which it is located.

35 (c) The board may require any information the board deems is
36 reasonably necessary for the enforcement of this section.

37 (d) Subdivision (a) shall not preclude the issuance of a new or
38 renewal license for a pharmacy to be owned or owned and operated
39 by a person licensed on or before August 1, 1981, under the
40 Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2

1 (commencing with Section 1340) of Division 2 of the Health and
2 Safety Code) and qualified on or before August 1, 1981, under
3 subsection (d) of Section 1310 of Title XIII of the federal Public
4 Health Service Act, as amended, whose ownership includes persons
5 defined pursuant to paragraphs (1) and (2) of subdivision (a).

6 (e) Subdivision (a) shall not preclude the issuance of a new or
7 renewal license for a pharmacy to be owned or owned and operated
8 by a pharmacist authorized to issue a drug order pursuant to either
9 Section 4052.1 or 4052.2.

10 SEC. 56. Section 4126.5 of the Business and Professions Code
11 is amended to read:

12 4126.5. (a) A pharmacy may furnish dangerous drugs only to
13 the following:

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

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

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

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

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

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

28 (7) To another pharmacy under common control.

29 (b) Notwithstanding any other provision of law, a violation of
30 this section may subject the person or persons who committed the
31 violation to a fine not to exceed the amount specified in Section
32 125.9 for each occurrence pursuant to a citation issued by the
33 board.

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

39 (d) For purposes of this section, "common control" means the
40 power to direct or cause the direction of the management and

1 policies of another person whether by ownership, by voting rights,
2 by contract, or by other means.

3 SEC. 57. Section 4161 of the Business and Professions Code
4 is amended to read:

5 4161. (a) A person located outside this state that (1) ships,
6 sells, mails, or delivers dangerous drugs or dangerous devices into
7 this state or (2) sells, brokers, or distributes dangerous drugs or
8 devices within this state shall be considered a nonresident
9 wholesaler.

10 (b) A nonresident wholesaler shall be licensed by the board
11 prior to shipping, selling, mailing, or delivering dangerous drugs
12 or dangerous devices to a site located in this state or selling,
13 brokering, or distributing dangerous drugs or devices within this
14 state.

15 (c) A separate license shall be required for each place of business
16 owned or operated by a nonresident wholesaler from or through
17 which dangerous drugs or dangerous devices are shipped, sold,
18 mailed, or delivered to a site located in this state or sold, brokered,
19 or distributed within this state. A license shall be renewed annually
20 and shall not be transferable.

21 (d) The following information shall be reported, in writing, to
22 the board at the time of initial application for licensure by a
23 nonresident wholesaler, on renewal of a nonresident wholesaler
24 license, or within 30 days of a change in that information:

25 (1) Its agent for service of process in this state.

26 (2) Its principal corporate officers, as specified by the board, if
27 any.

28 (3) Its general partners, as specified by the board, if any.

29 (4) Its owners if the applicant is not a corporation or partnership.

30 (e) A report containing the information in subdivision (d) shall
31 be made within 30 days of any change of ownership, office,
32 corporate officer, or partner.

33 (f) A nonresident wholesaler shall comply with all directions
34 and requests for information from the regulatory or licensing
35 agency of the state in which it is licensed, as well as with all
36 requests for information made by the board.

37 (g) A nonresident wholesaler shall maintain records of dangerous
38 drugs and dangerous devices sold, traded, or transferred to persons
39 in this state or within this state, so that the records are in a readily
40 retrievable form.

1 (h) A nonresident wholesaler shall at all times maintain a valid,
2 unexpired license, permit, or registration to conduct the business
3 of the wholesaler in compliance with the laws of the state in which
4 it is a resident. An application for a nonresident wholesaler license
5 in this state shall include a license verification from the licensing
6 authority in the applicant's state of residence.

7 (i) The board may not issue or renew a nonresident wholesaler
8 license until the nonresident wholesaler identifies a designated
9 representative-in-charge and notifies the board in writing of the
10 identity and license number of the designated
11 representative-in-charge.

12 (j) The designated representative-in-charge shall be responsible
13 for the nonresident wholesaler's compliance with state and federal
14 laws governing wholesalers. A nonresident wholesaler shall
15 identify and notify the board of a new designated
16 representative-in-charge within 30 days of the date that the prior
17 designated representative-in-charge ceases to be the designated
18 representative-in-charge.

19 (k) The board may issue a temporary license, upon conditions
20 and for periods of time as the board determines to be in the public
21 interest. A temporary license fee shall be five hundred fifty dollars
22 (\$550) or another amount established by the board not to exceed
23 the annual fee for renewal of a license to compound injectable
24 sterile drug products. When needed to protect public safety, a
25 temporary license may be issued for a period not to exceed 180
26 days, subject to terms and conditions that the board deems
27 necessary. If the board determines that a temporary license was
28 issued by mistake or denies the application for a permanent license,
29 the temporary license shall terminate upon either personal service
30 of the notice of termination upon the licenseholder or service by
31 certified mail, return receipt requested, at the licenseholder's
32 address of record with the board, whichever occurs first. Neither
33 for purposes of retaining a temporary license, nor for purposes of
34 any disciplinary or license denial proceeding before the board,
35 shall the temporary licenseholder be deemed to have a vested
36 property right or interest in the license.

37 (l) The registration fee shall be the fee specified in subdivision
38 (f) of Section 4400.

39 SEC. 58. Section 4174 of the Business and Professions Code
40 is amended to read:

1 4174. Notwithstanding any other provision of law, a pharmacist
2 may dispense drugs or devices upon the drug order of a nurse
3 practitioner functioning pursuant to Section 2836.1 or a certified
4 nurse-midwife functioning pursuant to Section 2746.51, a drug
5 order of a physician assistant functioning pursuant to Section
6 3502.1 or a naturopathic doctor functioning pursuant to Section
7 3640.5, or the order of a pharmacist acting under Section 4052.1,
8 4052.2, or 4052.3.

9 SEC. 59. Section 4231 of the Business and Professions Code
10 is amended to read:

11 4231. (a) The board shall not renew a pharmacist license unless
12 the applicant submits proof satisfactory to the board that he or she
13 has successfully completed 30 hours of approved courses of
14 continuing pharmacy education during the two years preceding
15 the application for renewal.

16 (b) Notwithstanding subdivision (a), the board shall not require
17 completion of continuing education for the first renewal of a
18 pharmacist license.

19 (c) If an applicant for renewal of a pharmacist license submits
20 the renewal application and payment of the renewal fee but does
21 not submit proof satisfactory to the board that the licensee has
22 completed 30 hours of continuing pharmacy education, the board
23 shall not renew the license and shall issue the applicant an inactive
24 pharmacist license. A licensee with an inactive pharmacist license
25 issued pursuant to this section may obtain an active pharmacist
26 license by paying the renewal fees due and submitting satisfactory
27 proof to the board that the licensee has completed 30 hours of
28 continuing pharmacy education.

29 (d) If, as part of an investigation or audit conducted by the board,
30 a pharmacist fails to provide documentation substantiating the
31 completion of continuing education as required in subdivision (a),
32 the board shall cancel the active pharmacist license and issue an
33 inactive pharmacist license in its place. A licensee with an inactive
34 pharmacist license issued pursuant to this section may obtain an
35 active pharmacist license by paying the renewal fees due and
36 submitting satisfactory proof to the board that the licensee has
37 completed 30 hours of continuing pharmacy education.

38 SEC. 60. Section 4301 of the Business and Professions Code
39 is amended to read:

1 4301. The board shall take action against any holder of a license
2 who is guilty of unprofessional conduct or whose license has been
3 procured by fraud or misrepresentation or issued by mistake.
4 Unprofessional conduct shall include, but is not limited to, any of
5 the following:

6 (a) Gross immorality.

7 (b) Incompetence.

8 (c) Gross negligence.

9 (d) The clearly excessive furnishing of controlled substances
10 in violation of subdivision (a) of Section 11153 of the Health and
11 Safety Code.

12 (e) The clearly excessive furnishing of controlled substances in
13 violation of subdivision (a) of Section 11153.5 of the Health and
14 Safety Code. Factors to be considered in determining whether the
15 furnishing of controlled substances is clearly excessive shall
16 include, but not be limited to, the amount of controlled substances
17 furnished, the previous ordering pattern of the customer (including
18 size and frequency of orders), the type and size of the customer,
19 and where and to whom the customer distributes its product.

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

24 (g) Knowingly making or signing any certificate or other
25 document that falsely represents the existence or nonexistence of
26 a state of facts.

27 (h) The administering to oneself, of any controlled substance,
28 or the use of any dangerous drug or of alcoholic beverages to the
29 extent or in a manner as to be dangerous or injurious to oneself,
30 to a person holding a license under this chapter, or to any other
31 person or to the public, or to the extent that the use impairs the
32 ability of the person to conduct with safety to the public the practice
33 authorized by the license.

34 (i) Except as otherwise authorized by law, knowingly selling,
35 furnishing, giving away, or administering, or offering to sell,
36 furnish, give away, or administer, any controlled substance to an
37 addict.

38 (j) The violation of any of the statutes of this state, of any other
39 state, or of the United States regulating controlled substances and
40 dangerous drugs.

1 (k) The conviction of more than one misdemeanor or any felony
2 involving the use, consumption, or self-administration of any
3 dangerous drug or alcoholic beverage, or any combination of those
4 substances.

5 (l) The conviction of a crime substantially related to the
6 qualifications, functions, and duties of a licensee under this chapter.
7 The record of conviction of a violation of Chapter 13 (commencing
8 with Section 801) of Title 21 of the United States Code regulating
9 controlled substances or of a violation of the statutes of this state
10 regulating controlled substances or dangerous drugs shall be
11 conclusive evidence of unprofessional conduct. In all other cases,
12 the record of conviction shall be conclusive evidence only of the
13 fact that the conviction occurred. The board may inquire into the
14 circumstances surrounding the commission of the crime, in order
15 to fix the degree of discipline or, in the case of a conviction not
16 involving controlled substances or dangerous drugs, to determine
17 if the conviction is of an offense substantially related to the
18 qualifications, functions, and duties of a licensee under this chapter.
19 A plea or verdict of guilty or a conviction following a plea of nolo
20 contendere is deemed to be a conviction within the meaning of
21 this provision. The board may take action when the time for appeal
22 has elapsed, or the judgment of conviction has been affirmed on
23 appeal or when an order granting probation is made suspending
24 the imposition of sentence, irrespective of a subsequent order under
25 Section 1203.4 of the Penal Code allowing the person to withdraw
26 his or her plea of guilty and to enter a plea of not guilty, or setting
27 aside the verdict of guilty, or dismissing the accusation,
28 information, or indictment.

29 (m) The cash compromise of a charge of violation of Chapter
30 13 (commencing with Section 801) of Title 21 of the United States
31 Code regulating controlled substances or of Chapter 7
32 (commencing with Section 14000) of Part 3 of Division 9 of the
33 Welfare and Institutions Code relating to the Medi-Cal program.
34 The record of the compromise is conclusive evidence of
35 unprofessional conduct.

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

39 (o) Violating or attempting to violate, directly or indirectly, or
40 assisting in or abetting the violation of or conspiring to violate any

1 provision or term of this chapter or of the applicable federal and
2 state laws and regulations governing pharmacy, including
3 regulations established by the board or by any other state or federal
4 regulatory agency.

5 (p) Actions or conduct that would have warranted denial of a
6 license.

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

9 (r) The selling, trading, transferring, or furnishing of drugs
10 obtained pursuant to Section 256b of Title 42 of the United States
11 Code to any person a licensee knows or reasonably should have
12 known, not to be a patient of a covered entity, as defined in
13 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
14 United States Code.

15 (s) The clearly excessive furnishing of dangerous drugs by a
16 wholesaler to a pharmacy that primarily or solely dispenses
17 prescription drugs to patients of long-term care facilities. Factors
18 to be considered in determining whether the furnishing of
19 dangerous drugs is clearly excessive shall include, but not be
20 limited to, the amount of dangerous drugs furnished to a pharmacy
21 that primarily or solely dispenses prescription drugs to patients of
22 long-term care facilities, the previous ordering pattern of the
23 pharmacy, and the general patient population to whom the
24 pharmacy distributes the dangerous drugs. That a wholesaler has
25 established, and employs, a tracking system that complies with
26 the requirements of subdivision (b) of Section 4164 shall be
27 considered in determining whether there has been a violation of
28 this subdivision. This provision shall not be interpreted to require
29 a wholesaler to obtain personal medical information or be
30 authorized to permit a wholesaler to have access to personal
31 medical information except as otherwise authorized by Section 56
32 and following of the Civil Code. For purposes of this section,
33 "long-term care facility" shall have the same meaning given the
34 term in Section 1418 of the Health and Safety Code.

35 SEC. 61. Section 4305 of the Business and Professions Code
36 is amended to read:

37 4305. (a) Failure by any pharmacist to notify the board in
38 writing that he or she has ceased to act as the pharmacist-in-charge
39 of a pharmacy, or by any pharmacy to notify the board in writing
40 that a pharmacist-in-charge is no longer acting in that capacity,

1 within the 30-day period specified in Sections 4101 and 4113 shall
2 constitute grounds for disciplinary action.

3 (b) Operation of a pharmacy for more than 30 days without
4 supervision or management by a pharmacist-in-charge shall
5 constitute grounds for disciplinary action.

6 (c) Any person who has obtained a license to conduct a
7 pharmacy, who willfully fails to timely notify the board that the
8 pharmacist-in-charge of the pharmacy has ceased to act in that
9 capacity, and who continues to permit the compounding or
10 dispensing of prescriptions, or the furnishing of drugs or poisons,
11 in his or her pharmacy, except by a pharmacist subject to the
12 supervision and management of a responsible pharmacist-in-charge,
13 shall be subject to summary suspension or revocation of his or her
14 license to conduct a pharmacy.

15 SEC. 62. Section 4329 of the Business and Professions Code
16 is amended to read:

17 4329. Any nonpharmacist who takes charge of or acts as
18 supervisor, manager, or pharmacist-in-charge of any pharmacy,
19 or who compounds or dispenses a prescription or furnishes
20 dangerous drugs except as otherwise provided in this chapter, is
21 guilty of a misdemeanor.

22 SEC. 63. Section 4330 of the Business and Professions Code
23 is amended to read:

24 4330. (a) Any person who has obtained a license to conduct
25 a pharmacy, who fails to place in charge of the pharmacy a
26 pharmacist, or any person, who by himself or herself, or by any
27 other person, permits the compounding or dispensing of
28 prescriptions, or the furnishing of dangerous drugs, in his or her
29 pharmacy, except by a pharmacist, or as otherwise provided in this
30 chapter, is guilty of a misdemeanor.

31 (b) Any pharmacy owner who commits any act that would
32 subvert or tend to subvert the efforts of the pharmacist-in-charge
33 to comply with the laws governing the operation of the pharmacy
34 is guilty of a misdemeanor.

35 SEC. 64. Section 4857 of the Business and Professions Code
36 is amended to read:

37 4857. (a) A veterinarian licensed under the provisions of this
38 chapter shall not disclose any information concerning an animal
39 receiving veterinary services, the client responsible for the animal

1 receiving veterinary services, or the veterinary care provided to
2 an animal, except under any one of the following circumstances:

3 (1) Upon written or witnessed oral authorization by knowing
4 and informed consent of the client responsible for the animal
5 receiving services or an authorized agent of the client.

6 (2) Upon authorization received by electronic transmission when
7 originated by the client responsible for the animal receiving
8 services or an authorized agent of the client.

9 (3) In response to a valid court order or subpoena.

10 (4) As may be required to ensure compliance with any federal,
11 state, county, or city law or regulation, including, but not limited
12 to, the California Public Records Act (Chapter 3.5 (commencing
13 with Section 6250) of Division 7 of Title 1 of the Government
14 Code).

15 (5) Nothing in this section is intended to prevent the sharing of
16 veterinary medical information between veterinarians or facilities
17 for the purpose of diagnosis or treatment of the animal who is the
18 subject of the medical records.

19 (6) As otherwise provided in this section.

20 (b) This section shall not apply to the extent that the client
21 responsible for an animal or an authorized agent of the client
22 responsible for the animal has filed or caused to be filed a civil or
23 criminal complaint that places the veterinarian's care and treatment
24 of the animal or the nature and extent of the injuries to the animal
25 at issue, or when the veterinarian is acting to comply with federal,
26 state, county, or city laws or regulations.

27 (c) A veterinarian shall be subject to the criminal penalties set
28 forth in Section 4831 or any other provision of this code for a
29 violation of this section. In addition, any veterinarian who
30 negligently releases confidential information shall be liable in a
31 civil action for any damages caused by the release of that
32 information.

33 (d) Nothing in this section is intended to prevent the sharing of
34 veterinary medical information between veterinarians and peace
35 officers, humane society officers, or animal control officers who
36 are acting to protect the welfare of animals.

37 SEC. 65. Section 4980.04 is added to the Business and
38 Professions Code, to read:

39 4980.04. This chapter shall be known and may be cited as the
40 Marriage and Family Therapist Act.

Attachment A-2

SB 820 (Senate Business, Profession and Economic Development Committee)

AMENDED IN SENATE APRIL 21, 2009

SENATE BILL

No. 820

Introduced by Committee on Business, Professions and Economic Development (Negrete McLeod (chair), Aanestad, Corbett, Correa, Florez, Oropeza, Romero, Walters, Wyland, and Yee)

March 10, 2009

An act to amend Sections 139, 146, 1632.5, 1634.2, 2493, 4200.3, 4200.4, 4938, 5016, 5021, 5022, 5023, 5651, 7028.7, 7044, 7159, 7159.5, 7159.14, 7303.2, 7500.1, 7505.5, 7507.9, 7507.12, 7606, 7616, 7641, 7643, 7646, 7647, 7662, 7665, 7666, 7671, 7725.5, 7729, 9884.2, 9884.7, 9884.12, 9889.3, and 10146 of, to add ~~Section 7044.01~~ *Sections 7044.01 and 7507.115* to, and to repeal and add Section 7108.5 of, the Business and Professions Code, ~~and to amend Section 44017.3 to amend Sections 44017.3, 44072.1, and 44072.2 of the Health and Safety Code, and to amend Sections 28, 5201, and 24603 of the Vehicle Code,~~ relating to consumer affairs.

LEGISLATIVE COUNSEL'S DIGEST

SB 820, as amended, Committee on Business, Professions and Economic Development. Consumer affairs: professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards and bureaus within the Department of Consumer Affairs. Existing law requires that certain examinations for licensure be developed by or in consultation with the Office of Examination Resources in the department, as specified.

This bill would rename that office the Office of Professional Examination Resources.

Existing law prohibits a person from holding himself or herself out to the public as a professional fiduciary without a license. Existing law

1 disposition. This report shall be a component of the evaluation of
2 the examination process that is based on psychometrically sound
3 principles for establishing minimum qualifications and levels of
4 competency.

5 SEC. 5. Section 2493 of the Business and Professions Code is
6 amended to read:

7 2493. (a) An applicant for a certificate to practice podiatric
8 medicine shall pass an examination in the subjects required by
9 Section 2483 in order to ensure a minimum of entry-level
10 competence.

11 (b) The board shall require a passing score on the National Board
12 of Podiatric Medical Examiners Part III examination that is
13 consistent with the postgraduate training requirement in Section
14 2484. The board, as of July 1, 2005, shall require a passing score
15 one standard error of measurement higher than the national passing
16 scale score until such time as the National Board of Podiatric
17 Medical Examiners recommends a higher passing score consistent
18 with Section 2484. In consultation with the Office of Professional
19 Examination Resources of the Department of Consumer Affairs,
20 the board shall ensure that the part III examination adequately
21 evaluates the full scope of practice established by Section 2472,
22 including amputation and other foot and ankle surgical procedures,
23 pursuant to Section 139.

24 SEC. 6. Section 4200.3 of the Business and Professions Code
25 is amended to read:

26 4200.3. (a) The examination process shall be regularly
27 reviewed pursuant to Section 139.

28 (b) The examination process shall meet the standards and
29 guidelines set forth in the Standards for Educational and
30 Psychological Testing and the Federal Uniform Guidelines for
31 Employee Selection Procedures. The board shall work with the
32 Office of Professional Examination Resources of the department
33 or with an equivalent organization who shall certify at minimum
34 once every five years that the examination process meets these
35 national testing standards. If the department determines that the
36 examination process fails to meet these standards, the board shall
37 terminate its use of the North American Pharmacy Licensure
38 Examination and shall use only the written and practical
39 examination developed by the board.

1 (c) The examination shall meet the mandates of subdivision (a)
2 of Section 12944 of the Government Code.

3 (d) The board shall work with the Office of Professional
4 Examination Resources or with an equivalent organization to
5 develop the state jurisprudence examination to ensure that
6 applicants for licensure are evaluated on their knowledge of
7 applicable state laws and regulations.

8 (e) The board shall annually publish the pass and fail rates for
9 the pharmacist's licensure examination administered pursuant to
10 Section 4200, including a comparison of historical pass and fail
11 rates before utilization of the North American Pharmacist Licensure
12 Examination.

13 (f) The board shall report to the Joint Committee on Boards,
14 Commissions, and Consumer Protection and the department as
15 part of its next scheduled review, the pass rates of applicants who
16 sat for the national examination compared with the pass rates of
17 applicants who sat for the prior state examination. This report shall
18 be a component of the evaluation of the examination process that
19 is based on psychometrically sound principles for establishing
20 minimum qualifications and levels of competency.

21 SEC. 7. Section 4200.4 of the Business and Professions Code
22 is amended to read:

23 4200.4. An applicant who fails the national examination may
24 not retake the examination for at least 90 days or for a period
25 established by regulations adopted by the board in consultation
26 with the Office of Professional Examination Resources of the
27 department.

28 SEC. 8. Section 4938 of the Business and Professions Code is
29 amended to read:

30 4938. The board shall issue a license to practice acupuncture
31 to any person who makes an application and meets the following
32 requirements:

33 (a) Is at least 18 years of age.

34 (b) Furnishes satisfactory evidence of completion of one of the
35 following:

36 (1) An educational and training program approved by the board
37 pursuant to Section 4939.

38 (2) Satisfactory completion of a tutorial program in the practice
39 of an acupuncturist which is approved by the board.

1 (3) In the case of an applicant who has completed education
2 and training outside the United States and Canada, documented
3 educational training and clinical experience which meets the
4 standards established pursuant to Sections 4939 and 4941.

5 (c) Passes a written examination administered by the board that
6 tests the applicant's ability, competency, and knowledge in the
7 practice of an acupuncturist. The written examination shall be
8 developed by the Office of Professional Examination Resources
9 of the Department of Consumer Affairs.

10 (d) Is not subject to denial pursuant to Division 1.5 (commencing
11 with Section 475).

12 (e) Completes a clinical internship training program approved
13 by the board. The clinical internship training program shall not
14 exceed nine months in duration and shall be located in a clinic in
15 this state, which is approved by the board pursuant to Section 4939.
16 The length of the clinical internship shall depend upon the grades
17 received in the examination and the clinical training already
18 satisfactorily completed by the individual prior to taking the
19 examination. On and after January 1, 1987, individuals with 800
20 or more hours of documented clinical training shall be deemed to
21 have met this requirement. The purpose of the clinical internship
22 training program shall be to ~~assure~~ *ensure* a minimum level of
23 clinical competence.

24 Each applicant who qualifies for a license shall pay, as a
25 condition precedent to its issuance and in addition to other fees
26 required, the initial licensure fee.

27 SEC. 9. Section 5016 of the Business and Professions Code is
28 amended to read:

29 5016. A majority of the board shall constitute a quorum for
30 the transaction of any business at any meeting of the board. Notice
31 of each meeting of the board shall be given in accordance with the
32 Bagley-Keene Open Meeting Act (Article 9 (commencing with
33 Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of
34 the Government Code). The board shall meet at the call of the
35 president and executive officer, but not less than twice each year.
36 Any two members of the board may request the executive officer
37 to call a special meeting, and the executive officer, upon receiving
38 that notice, shall call a meeting pursuant to the procedure
39 prescribed herein.

Attachment A-3

SB 821 (Senate Business, Profession and Economic Development Committee)

AMENDED IN SENATE APRIL 16, 2009

SENATE BILL

No. 821

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

March 10, 2009

An act to amend Sections 805, ~~821.5, 821.6~~, 2530.2, 2532.2, 2532.7, 2570.2, 2570.3, 2570.4, 2570.5, 2570.6, 2570.7, 2570.9, 2570.10, 2570.13, 2570.16, 2570.18, 2570.20, 2570.26, 2570.28, 2571, 2872.2, 3357, 3362, 3366, 3456, 3740, 3750.5, 3773, 4101, 4112, 4113, 4160, 4196, 4510.1, 4933, 4980.45, 4980.48, 4982, 4982.2, 4989.22, 4989.54, 4992.1, 4992.3, 4996.23, 4996.28, 4996.5, and 4999.2 of, ~~and to add~~ Sections 2532.25, 2570.17, 2570.186, 4013, 4146, 4989.49, 4992.2, and 4996.24 to, *and to repeal Sections 821.5 and 821.6 of*, the Business and Professions Code, ~~and to amend~~ Section 123105 of the Health and Safety Code, *and to amend Section 3 of Chapter 294 of the Statutes of 2004*, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 821, as amended, Committee on Business, Professions and Economic Development. Healing arts: licensees.

(1) Existing law provides for the professional review of specified healing arts licentiates through a peer review process, and requires the peer review body to report to the relevant agency upon certain circumstances, *including circumstances related to an obsolete diversion program*.

This bill would include within the definition of "licentiate" a holder of a special faculty permit to practice medicine within a medical school. ~~Within the peer review provisions, the~~ *The bill would also delete the*

1 ~~SEC. 30.~~

2 *SEC. 33.* Section 4013 is added to the Business and Professions
3 Code, to read:

4 4013. (a) Any facility licensed by the board shall join the
5 board's e-mail notification list within 60 days of obtaining a license
6 or at the time of license renewal.

7 (b) Any facility licensed by the board shall update ~~it's~~ *its* e-mail
8 address with the board's e-mail notification list within 30 days of
9 a change in the facility's e-mail address.

10 (c) This section shall become operative on July 1, 2010.

11 ~~SEC. 31.~~

12 *SEC. 34.* Section 4101 of the Business and Professions Code
13 is amended to read:

14 4101. (a) A pharmacist may take charge of and act as the
15 pharmacist-in-charge of a pharmacy upon application by the
16 pharmacy and approval by the board. Any pharmacist-in-charge
17 who ceases to act as the pharmacist-in-charge of the pharmacy
18 shall notify the board in writing within 30 days of the date of that
19 change in status.

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

28 ~~SEC. 32.~~

29 *SEC. 35.* Section 4112 of the Business and Professions Code
30 is amended to read:

31 4112. (a) Any pharmacy located outside this state that ships,
32 mails, or delivers, in any manner, controlled substances, dangerous
33 drugs, or dangerous devices into this state shall be considered a
34 nonresident pharmacy.

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

39 (c) A nonresident pharmacy shall disclose to the board the
40 location, names, and titles of (1) its agent for service of process in

1 this state, (2) all principal corporate officers, if any, (3) all general
2 partners, if any, and (4) all pharmacists who are dispensing
3 controlled substances, dangerous drugs, or dangerous devices to
4 residents of this state. A report containing this information shall
5 be made on an annual basis and within 30 days after any change
6 of office, corporate officer, partner, or pharmacist.

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

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

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

30 (g) The board shall adopt regulations that apply the same
31 requirements or standards for oral consultation to a nonresident
32 pharmacy that operates pursuant to this section and ships, mails,
33 or delivers any controlled substances, dangerous drugs, or
34 dangerous devices to residents of this state, as are applied to an
35 in-state pharmacy that operates pursuant to Section 4037 when the
36 pharmacy ships, mails, or delivers any controlled substances,
37 dangerous drugs, or dangerous devices to residents of this state.
38 The board shall not adopt any regulations that require face-to-face
39 consultation for a prescription that is shipped, mailed, or delivered
40 to the patient. The regulations adopted pursuant to this subdivision

1 shall not result in any unnecessary delay in patients receiving their
2 medication.

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

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

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

12 ~~SEC. 33.~~

13 *SEC. 36.* Section 4113 of the Business and Professions Code
14 is amended to read:

15 4113. (a) Every pharmacy shall be supervised or managed by
16 a pharmacist-in-charge. As part of its initial application for a
17 license, and for each renewal, each pharmacy shall, on a form
18 designed by the board, provide identifying information and the
19 California license number for a pharmacist proposed to serve as
20 the pharmacist-in-charge. The proposed pharmacist-in-charge shall
21 be subject to approval by the board. The board shall not issue or
22 renew a pharmacy license without identification of an approved
23 pharmacist-in-charge for the pharmacy.

24 (b) The pharmacist-in-charge shall be responsible for a
25 pharmacy's compliance with all state and federal laws and
26 regulations pertaining to the practice of pharmacy.

27 (c) Every pharmacy shall notify the board in writing, on a form
28 designed by the board, within 30 days of the date when a
29 pharmacist-in-charge ceases to act as *the* pharmacist-in-charge,
30 and shall on the same form propose another pharmacist to take
31 over as *the* pharmacist-in-charge. The proposed replacement
32 pharmacist-in-charge shall be subject to approval by the board. If
33 disapproved, the pharmacy shall propose another replacement
34 within 15 days of the date of disapproval and shall continue to
35 name proposed replacements until a pharmacist-in-charge is
36 approved by the board.

37 (d) If a pharmacy is unable, in the exercise of reasonable
38 diligence, to identify within 30 days a permanent replacement
39 pharmacist-in-charge to propose to the board on the notification
40 form, the pharmacy may instead provide on that form the name of

1 any pharmacist who is an employee, officer, or administrator of
2 the pharmacy or the entity that owns the pharmacy and who is
3 actively involved in the management of the pharmacy on a daily
4 basis, to act as the interim pharmacist-in-charge for a period not
5 to exceed 120 days. The pharmacy, or the entity that owns the
6 pharmacy, shall be prepared during normal business hours to
7 provide a representative of the board with the name of the interim
8 pharmacist-in-charge with documentation of the active involvement
9 of the interim pharmacist-in-charge in the daily management of
10 the pharmacy, and with documentation of the pharmacy's good
11 faith efforts prior to naming the interim pharmacist-in-charge to
12 obtain a permanent pharmacist-in-charge. By no later than 120
13 days following the identification of the interim
14 pharmacist-in-charge, the pharmacy shall propose to the board the
15 name of a pharmacist to serve as the permanent
16 pharmacist-in-charge. The proposed permanent
17 pharmacist-in-charge shall be subject to approval by the board. If
18 disapproved, the pharmacy shall propose another replacement
19 within 15 days of the date of disapproval, and shall continue to
20 name proposed replacements until a pharmacist-in-charge is
21 approved by the board.

22 ~~SEC. 34.~~

23 *SEC. 37.* Section 4146 is added to the Business and Professions
24 Code, to read:

25 4146. A pharmacy may accept the return of needles and
26 syringes from the public if contained in a sharps container, as
27 defined in Section 117750 of the Health and Safety Code.

28 ~~SEC. 35.~~

29 *SEC. 38.* Section 4160 of the Business and Professions Code
30 is amended to read:

31 4160. (a) A person may not act as a wholesaler of any
32 dangerous drug or dangerous device unless he or she has obtained
33 a license from the board.

34 (b) Upon approval by the board and the payment of the required
35 fee, the board shall issue a license to the applicant.

36 (c) A separate license shall be required for each place of business
37 owned or operated by a wholesaler. Each license shall be renewed
38 annually and shall not be transferable.

39 (d) Every wholesaler shall be supervised or managed by a
40 designated representative-in-charge. The designated

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

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

23 (f) A drug manufacturer premises licensed by the Food and
24 Drug Administration or licensed pursuant to Section 111615 of
25 the Health and Safety Code that only distributes dangerous drugs
26 and dangerous devices of its own manufacture is exempt from this
27 section and Section 4161.

28 (g) The board may issue a temporary license, upon conditions
29 and for periods of time as the board determines to be in the public
30 interest. A temporary license fee shall be five hundred fifty dollars
31 (\$550) or another amount established by the board not to exceed
32 the annual fee for renewal of a license to compound injectable
33 sterile drug products. When needed to protect public safety, a
34 temporary license may be issued for a period not to exceed 180
35 days, subject to terms and conditions that the board deems
36 necessary. If the board determines that a temporary license was
37 issued by mistake or denies the application for a permanent license,
38 the temporary license shall terminate upon either personal service
39 of the notice of termination upon the licenseholder or service by
40 certified mail, return receipt requested, at the licenseholder's

1 address of record with the board, whichever occurs first. Neither
2 for purposes of retaining a temporary license, nor for purposes of
3 any disciplinary or license denial proceeding before the board,
4 shall the temporary licenseholder be deemed to have a vested
5 property right or interest in the license.

6 ~~SEC. 36.~~

7 *SEC. 39.* Section 4196 of the Business and Professions Code
8 is amended to read:

9 4196. (a) No person shall conduct a veterinary food-animal
10 drug retailer in the State of California unless he or she has obtained
11 a license from the board. A license shall be required for each
12 veterinary food-animal drug retailer owned or operated by a
13 specific person. A separate license shall be required for each of
14 the premises of any person operating a veterinary food-animal
15 drug retailer in more than one location. The license shall be
16 renewed annually and shall not be transferable.

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

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

33 (d) Every veterinary food-animal drug retailer shall be
34 supervised or managed by a designated representative-in-charge.
35 The designated representative-in-charge shall be responsible for
36 the veterinary food-animal drug retailer's compliance with state
37 and federal laws governing veterinary food-animal drug retailers.
38 As part of its initial application for a license, and for each renewal,
39 each veterinary food-animal drug retailer shall, on a form designed
40 by the board, provide identifying information and the California

1 license number for a designated representative or pharmacist
2 proposed to serve as the designated representative-in-charge. The
3 proposed designated representative-in-charge shall be subject to
4 approval by the board. The board shall not issue or renew a
5 veterinary food-animal drug retailer license without identification
6 of an approved designated representative-in-charge for the
7 veterinary food-animal drug retailer.

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

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

23 ~~SEC. 37.~~

24 *SEC. 40.* Section 4510.1 of the Business and Professions Code
25 is amended to read:

26 4510.1. An applicant for license by examination shall submit
27 a written application in the form prescribed by the board. Provided
28 that the application for licensure is received by the board no later
29 than four months after completion of a board accredited psychiatric
30 technician program and approval of the application, the board may
31 issue an interim permit authorizing the applicant to practice all
32 skills included in the permittees basic course of study, pending the
33 results of the first licensing examination, or for a period of nine
34 months, whichever occurs first.

35 A permittee shall function under the supervision of a licensed
36 psychiatric technician or a registered nurse, who shall be present
37 and available on the premises during the time the permittee is
38 rendering professional services. The permittee may perform any
39 function taught in the permittee's basic psychiatric technician
40 program.

1 If the applicant passes the examination, the interim permit shall
2 remain in effect until an initial license is issued by the board or
3 for a maximum period of six months after passing the examination,
4 whichever occurs first. If the applicant fails the examination, the
5 interim permit shall terminate upon notice by certified mail, return
6 receipt requested, or if the applicant fails to receive the notice,
7 upon the date specified in the interim permit, whichever occurs
8 first. An interim permittee shall not use any title or designation
9 other than psychiatric technician interim permittee or "P.T.I.P."

10 ~~SEC. 38.~~

11 *SEC. 41.* Section 4933 of the Business and Professions Code
12 is amended to read:

13 4933. (a) The board shall administer this chapter.

14 (b) The board may adopt, amend, or repeal, in accordance with
15 the Administrative Procedure Act (Chapter 3.5 (commencing with
16 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
17 Code), regulations as may be necessary to enable it to carry into
18 effect the provisions of law relating to the practice of acupuncture.

19 (c) Four members of the board, including at least one
20 acupuncturist, shall constitute a quorum to conduct business.

21 (d) It shall require an affirmative vote of a majority of those
22 present at a meeting of the board to take any action or pass any
23 motion.

24 ~~SEC. 39.~~

25 *SEC. 42.* Section 4980.45 of the Business and Professions Code
26 is amended to read:

27 4980.45. (a) A licensed professional in private practice who
28 has satisfied the requirements of subdivision (g) of Section 4980.03
29 may supervise or employ, at any one time, no more than a total of
30 two individuals registered as either a marriage and family therapist
31 intern or associate clinical social worker in that private practice.

32 (b) A marriage and family therapy corporation may employ, at
33 any one time, no more than a total of two individuals registered
34 as either a marriage and family therapist intern or associate clinical
35 social worker for each employee or shareholder who has satisfied
36 the requirements of subdivision (g) of Section 4980.03. In no event
37 shall any corporation employ, at any one time, more than a total
38 of 10 individuals registered as either a marriage and family
39 therapist intern or associate clinical social worker. In no event
40 shall any supervisor supervise, at any one time, more than a total

SB 470 (Corbett) Prescription Labeling

Introduced by Senator Corbett

February 26, 2009

An act to amend Sections 4040 and 4076 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 470, as introduced, Corbett. Prescriptions.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and a knowing violation of the law is a crime. Existing law authorizes a prescription, as defined, to include the condition for which the drug is prescribed if requested by the patient. Existing law prohibits a pharmacist from dispensing any prescription unless it is in a specified container and the prescription label includes, among other information, the condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

This bill would revise that requirement to instead require the label to include the purpose for which the drug was prescribed if requested by the patient or if the purpose is indicated on the prescription. The bill would also make a conforming change.

By revising this requirement, the knowing violation of which would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4040 of the Business and Professions
2 Code is amended to read:

3 4040. (a) "Prescription" means an oral, written, or electronic
4 transmission order that is both of the following:

5 (1) Given individually for the person or persons for whom
6 ordered that includes all of the following:

7 (A) The name or names and address of the patient or patients.

8 (B) The name and quantity of the drug or device prescribed and
9 the directions for use.

10 (C) The date of issue.

11 (D) Either rubber stamped, typed, or printed by hand or typeset,
12 the name, address, and telephone number of the prescriber, his or
13 her license classification, and his or her federal registry number,
14 if a controlled substance is prescribed.

15 (E) A legible, clear notice of the ~~condition~~ *purpose* for which
16 the drug is being prescribed, if requested by the patient or patients.

17 (F) If in writing, signed by the prescriber issuing the order, or
18 the certified nurse-midwife, nurse practitioner, physician assistant,
19 or naturopathic doctor who issues a drug order pursuant to Section
20 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist
21 who issues a drug order pursuant to either subparagraph (D) of
22 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
23 (5) of, subdivision (a) of Section 4052.

24 (2) Issued by a physician, dentist, optometrist, podiatrist,
25 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,
26 if a drug order is issued pursuant to Section 2746.51, 2836.1,
27 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,
28 physician assistant, or naturopathic doctor licensed in this state,
29 or pursuant to either subparagraph (D) of paragraph (4) of, or
30 clause (iv) of subparagraph (A) of paragraph (5) of, subdivision
31 (a) of Section 4052 by a pharmacist licensed in this state.

32 (b) Notwithstanding subdivision (a), a written order of the
33 prescriber for a dangerous drug, except for any Schedule II
34 controlled substance, that contains at least the name and signature
35 of the prescriber, the name and address of the patient in a manner
36 consistent with paragraph (3) of subdivision (b) of Section 11164
37 of the Health and Safety Code, the name and quantity of the drug
38 prescribed, directions for use, and the date of issue may be treated

1 as a prescription by the dispensing pharmacist as long as any
2 additional information required by subdivision (a) is readily
3 retrievable in the pharmacy. In the event of a conflict between this
4 subdivision and Section 11164 of the Health and Safety Code,
5 Section 11164 of the Health and Safety Code shall prevail.

6 (c) "Electronic transmission prescription" includes both image
7 and data prescriptions. "Electronic image transmission
8 prescription" means any prescription order for which a facsimile
9 of the order is received by a pharmacy from a licensed prescriber.
10 "Electronic data transmission prescription" means any prescription
11 order, other than an electronic image transmission prescription,
12 that is electronically transmitted from a licensed prescriber to a
13 pharmacy.

14 (d) The use of commonly used abbreviations shall not invalidate
15 an otherwise valid prescription.

16 (e) Nothing in the amendments made to this section (formerly
17 Section 4036) at the 1969 Regular Session of the Legislature shall
18 be construed as expanding or limiting the right that a chiropractor,
19 while acting within the scope of his or her license, may have to
20 prescribe a device.

21 SEC. 2. Section 4076 of the Business and Professions Code is
22 amended to read:

23 4076. (a) A pharmacist shall not dispense any prescription
24 except in a container that meets the requirements of state and
25 federal law and is correctly labeled with all of the following:

26 (1) Except where the prescriber or the certified nurse-midwife
27 who functions pursuant to a standardized procedure or protocol
28 described in Section 2746.51, the nurse practitioner who functions
29 pursuant to a standardized procedure described in Section 2836.1,
30 or protocol, the physician assistant who functions pursuant to
31 Section 3502.1, the naturopathic doctor who functions pursuant
32 to a standardized procedure or protocol described in Section
33 3640.5, or the pharmacist who functions pursuant to a policy,
34 procedure, or protocol pursuant to either subparagraph (D) of
35 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
36 (5) of, subdivision (a) of Section 4052 orders otherwise, either the
37 manufacturer's trade name of the drug or the generic name and
38 the name of the manufacturer. Commonly used abbreviations may
39 be used. Preparations containing two or more active ingredients

- 1 may be identified by the manufacturer's trade name or the
2 commonly used name or the principal active ingredients.
- 3 (2) The directions for the use of the drug.
- 4 (3) The name of the patient or patients.
- 5 (4) The name of the prescriber or, if applicable, the name of the
6 certified nurse-midwife who functions pursuant to a standardized
7 procedure or protocol described in Section 2746.51, the nurse
8 practitioner who functions pursuant to a standardized procedure
9 described in Section 2836.1, or protocol, the physician assistant
10 who functions pursuant to Section 3502.1, the naturopathic doctor
11 who functions pursuant to a standardized procedure or protocol
12 described in Section 3640.5, or the pharmacist who functions
13 pursuant to a policy, procedure, or protocol pursuant to either
14 subparagraph (D) of paragraph (4) of, or clause (iv) of
15 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
16 4052.
- 17 (5) The date of issue.
- 18 (6) The name and address of the pharmacy, and prescription
19 number or other means of identifying the prescription.
- 20 (7) The strength of the drug or drugs dispensed.
- 21 (8) The quantity of the drug or drugs dispensed.
- 22 (9) The expiration date of the effectiveness of the drug
23 dispensed.
- 24 (10) ~~The condition~~ *purpose* for which the drug was prescribed
25 if requested by the patient ~~and or the condition~~ *purpose* is indicated
26 on the prescription.
- 27 (11) (A) Commencing January 1, 2006, the physical description
28 of the dispensed medication, including its color, shape, and any
29 identification code that appears on the tablets or capsules, except
30 as follows:
- 31 (i) Prescriptions dispensed by a veterinarian.
- 32 (ii) An exemption from the requirements of this paragraph shall
33 be granted to a new drug for the first 120 days that the drug is on
34 the market and for the 90 days during which the national reference
35 file has no description on file.
- 36 (iii) Dispensed medications for which no physical description
37 exists in any commercially available database.
- 38 (B) This paragraph applies to outpatient pharmacies only.
- 39 (C) The information required by this paragraph may be printed
40 on an auxiliary label that is affixed to the prescription container.

1 (D) This paragraph shall not become operative if the board,
2 prior to January 1, 2006, adopts regulations that mandate the same
3 labeling requirements set forth in this paragraph.

4 (b) If a pharmacist dispenses a prescribed drug by means of a
5 unit dose medication system, as defined by administrative
6 regulation, for a patient in a skilled nursing, intermediate care, or
7 other health care facility, the requirements of this section will be
8 satisfied if the unit dose medication system contains the
9 aforementioned information or the information is otherwise readily
10 available at the time of drug administration.

11 (c) If a pharmacist dispenses a dangerous drug or device in a
12 facility licensed pursuant to Section 1250 of the Health and Safety
13 Code, it is not necessary to include on individual unit dose
14 containers for a specific patient, the name of the certified
15 nurse-midwife who functions pursuant to a standardized procedure
16 or protocol described in Section 2746.51, the nurse practitioner
17 who functions pursuant to a standardized procedure described in
18 Section 2836.1, or protocol, the physician assistant who functions
19 pursuant to Section 3502.1, the naturopathic doctor who functions
20 pursuant to a standardized procedure or protocol described in
21 Section 3640.5, or the pharmacist who functions pursuant to a
22 policy, procedure, or protocol pursuant to either subparagraph (D)
23 of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
24 (5) of, subdivision (a) of Section 4052.

25 (d) If a pharmacist dispenses a prescription drug for use in a
26 facility licensed pursuant to Section 1250 of the Health and Safety
27 Code, it is not necessary to include the information required in
28 paragraph (11) of subdivision (a) when the prescription drug is
29 administered to a patient by a person licensed under the Medical
30 Practice Act (Chapter 5 (commencing with Section 2000)), the
31 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
32 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
33 with Section 2840)), who is acting within his or her scope of
34 practice.

35 SEC. 3. No reimbursement is required by this act pursuant to
36 Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 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.

O

AB 977 (Skinner) Pharmacies: Immunization Administration

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 977

Introduced by Assembly Member Skinner

February 26, 2009

An act to amend Section 4052 of, and to add Section 4052.8 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 977, as amended, Skinner. Pharmacists: immunization administration.

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

This bill would *additionally* authorize a pharmacist to ~~initiate and administer immunizations pursuant to a protocol with a prescriber or the recommended Immunization Schedules provided by the federal Centers for Disease Control and Prevention~~ *initiate and administer influenza and pneumococcal immunizations to any person 7 years of age or older*. The bill would require a pharmacist, prior to initiating and administering *those* immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist *initiating and administering immunizations* to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require ~~the~~ *a* pharmacist, at the time of administration of an immunization, to provide the patient with a Vaccine Information

Statement and to provide the patient's physician with documentation of administration of the immunization. The bill would also require a pharmacist *administering an immunization* to maintain a specified immunization administration record, ~~report any adverse event and provide documentation of administration to the California Immunization Registry, report any adverse event and assure proper storage and handling of vaccines. The bill would authorize a pharmacist initiating and administering vaccines to initiate and administer epinephrine for severe allergic reactions, and assure proper storage and handling of vaccines. The bill would also require a pharmacist to obtain the consent of a parent or guardian before administering any immunization to a patient under 18 years of age.~~

Because this bill would create new requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

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

- 1 SECTION 1. *The Legislature finds and declares all of the*
- 2 *following:*
- 3 (a) *Vaccines are a safe, effective, and efficient means to prevent*
- 4 *sickness and death from infectious diseases as reported by the*
- 5 *United States Department of Health and Human Services (HHS).*
- 6 (b) *The National Vital Statistics Report published by HHS*
- 7 *reports that influenza and pneumonia combined are the eighth*
- 8 *leading cause of death in people of all ages, and the sixth leading*
- 9 *cause of death in people over 65 years of age.*
- 10 (c) *The federal Centers for Disease Control and Prevention*
- 11 *report that 220,000,000 persons should get the influenza*
- 12 *vaccination annually, however, fewer than 100,000,000 do.*
- 13 (d) *According to the California Health Care Foundation,*
- 14 *6,600,000 Californians are uninsured and may not have access to*
- 15 *immunizations.*

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

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

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

11 ~~SECTION 1.~~

12 SEC. 2. Section 4052 of the Business and Professions Code is
13 amended to read:

14 4052. (a) Notwithstanding any other provision of law, a
15 pharmacist may:

16 (1) Furnish a reasonable quantity of compounded drug product
17 to a prescriber for office use by the prescriber.

18 (2) Transmit a valid prescription to another pharmacist.

19 (3) Administer, orally or topically, drugs and biologicals
20 pursuant to a prescriber's order.

21 (4) Perform procedures or functions in a licensed health care
22 facility as authorized by Section 4052.1.

23 (5) Perform procedures or functions as part of the care provided
24 by a health care facility, a licensed home health agency, a licensed
25 clinic in which there is a physician oversight, a provider who
26 contracts with a licensed health care service plan with regard to
27 the care or services provided to the enrollees of that health care
28 service plan, or a physician, as authorized by Section 4052.2.

29 (6) Manufacture, measure, fit to the patient, or sell and repair
30 dangerous devices or furnish instructions to the patient or the
31 patient's representative concerning the use of those devices.

32 (7) Provide consultation to patients and professional information,
33 including clinical or pharmacological information, advice, or
34 consultation to other health care professionals.

35 (8) Furnish emergency contraception drug therapy as authorized
36 by Section 4052.3.

37 (9) ~~Initiate~~ Administer or initiate and administer immunizations
38 pursuant to Section 4052.8.

39 (b) A pharmacist who is authorized to issue an order to initiate
40 or adjust a controlled substance therapy pursuant to this section

1 shall personally register with the federal Drug Enforcement
2 Administration.

3 (c) Nothing in this section shall affect the requirements of
4 existing law relating to maintaining the confidentiality of medical
5 records.

6 (d) Nothing in this section shall affect the requirements of
7 existing law relating to the licensing of a health care facility.

8 ~~SEC. 2.~~

9 *SEC. 3.* Section 4052.8 is added to the Business and Professions
10 Code, to read:

11 4052.8. (a) A pharmacist may ~~initiate and administer~~
12 ~~immunizations pursuant to~~ *do* either of the following:

13 (1) ~~Administer any immunization pursuant to~~ a protocol with
14 a prescriber.

15 (2) ~~The recommended Immunization Schedules for persons~~
16 ~~aged 7 through 18 years of age and adults provided by the federal~~
17 ~~Centers for Disease Control and Prevention, as they may be~~
18 ~~amended from time to time.~~

19 (2) *Initiate and administer influenza or pneumococcal*
20 *immunizations to any person seven years of age or older.*

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

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

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

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

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

4 (e) *A pharmacist shall obtain the consent of a parent or*
5 *guardian before administering an immunization to a patient under*
6 *18 years of age.*

7 ~~(e)~~

8 (f) At the time of administration of an immunization, the
9 pharmacist shall do ~~both~~ all of the following:

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

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

17 (3) *Provide documentation of administration of the immunization*
18 *to the California Immunization Registry (CAIR).*

19 ~~(f)~~

20 (g) The pharmacist shall maintain an immunization
21 administration record, which shall include, but not be limited to,
22 the name of the vaccine, the expiration date, the date of
23 administration, the manufacturer and lot number, the administration
24 site and route, the Vaccine Information Statement date, and the
25 name and title of the person administering, for the longer of the
26 following periods:

27 (1) Ten years from the date of administration.

28 (2) If the patient is younger than 18 years of age at the time of
29 administration, three years beyond the patient's 18th birthday.

30 ~~(g)~~

31 (h) Any pharmacist initiating and administering vaccines may
32 initiate and administer epinephrine by injection for severe allergic
33 reactions.

34 ~~(h)~~

35 (i) Any adverse event shall be reported to the Vaccine Adverse
36 Event Reporting System within the U.S. Department of Health
37 and Human Services.

38 ~~(i)~~

39 (j) Upon receipt of a vaccine as authorized by this section, a
40 pharmacist is responsible for assuring that proper vaccine

1 temperatures are maintained during subsequent storage and
2 handling to preserve the potency of the vaccine.

3 **SEC. 3.**

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

13

14

15 **CORRECTIONS:**

16 **Text—Pages 3 and 4.**

17

O

Attachment A-6

AB 1071 (Emmerson) Pharmacy Fees

ASSEMBLY BILL

No. 1071

Introduced by Assembly Member Emmerson

February 27, 2009

An act to amend Sections 4110, 4127.8, 4160, and 4400 of, and to repeal Section 4127.5 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1071, as introduced, Emmerson. Pharmacy: fees.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law imposes fees on these persons and pharmacies for, among other things, application, examination, licensure, and licensure renewal. Under existing law, these fees are fixed by the board based on a fee schedule that sets forth the minimum and maximum fees.

This bill would increase the minimum and maximum fees in that schedule and would make other conforming changes. Because the bill would increase fees that would be deposited into the Pharmacy Board Contingent Fund, which is continuously appropriated, the bill would make an appropriation.

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

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

1 SECTION 1. Section 4110 of the Business and Professions
2 Code is amended to read:

3 4110. (a) No person shall conduct a pharmacy in the State of
4 California unless he or she has obtained a license from the board.
5 A license shall be required for each pharmacy owned or operated
6 by a specific person. A separate license shall be required for each
7 of the premises of any person operating a pharmacy in more than
8 one location. The license shall be renewed annually. The board
9 may, by regulation, determine the circumstances under which a
10 license may be transferred.

11 (b) The board may, at its discretion, issue a temporary permit,
12 when the ownership of a pharmacy is transferred from one person
13 to another, upon the conditions and for any periods of time as the
14 board determines to be in the public interest. A temporary permit
15 fee shall be *required in an amount* established by the board ~~at an~~
16 ~~amount not to exceed the annual fee for renewal of a permit to~~
17 ~~conduct a pharmacy as specified in subdivision (a) of Section 4400.~~
18 When needed to protect public safety, a temporary permit may be
19 issued for a period not to exceed 180 days, and may be issued
20 subject to terms and conditions the board deems necessary. If the
21 board determines a temporary permit was issued by mistake or
22 denies the application for a permanent license or registration, the
23 temporary license or registration shall terminate upon either
24 personal service of the notice of termination upon the permitholder
25 or service by certified mail, return receipt requested, at the
26 permitholder's address of record with the board, whichever comes
27 first. Neither for purposes of retaining a temporary permit nor for
28 purposes of any disciplinary or license denial proceeding before
29 the board shall the temporary permitholder be deemed to have a
30 vested property right or interest in the permit.

31 SEC. 2. Section 4127.5 of the Business and Professions Code
32 is repealed.

33 ~~4127.5. The fee for the issuance of a nongovernmental license,~~
34 ~~or renewal of a license, to compound sterile drug products shall~~
35 ~~be five hundred dollars (\$500) and may be increased to six hundred~~
36 ~~dollars (\$600).~~

37 SEC. 3. Section 4127.8 of the Business and Professions Code
38 is amended to read:

1 4127.8. The board may, at its discretion, issue a temporary
2 license to compound injectable sterile drug products, when the
3 ownership of a pharmacy that is licensed to compound injectable
4 sterile drug products is transferred from one person to another,
5 upon the conditions and for any periods of time as the board
6 determines to be in the public interest. A temporary license fee
7 shall be ~~five hundred dollars (\$500) or another~~ *required in an*
8 ~~amount established by the board not to exceed the annual fee for~~
9 ~~renewal of a license to compound injectable sterile drug products~~
10 *as specified in subdivision (u) of Section 4400.* When needed to
11 protect public safety, a temporary license may be issued for a
12 period not to exceed 180 days, and may be issued subject to terms
13 and conditions the board deems necessary. If the board determines
14 a temporary license was issued by mistake or denies the application
15 for a permanent license, the temporary license shall terminate upon
16 either personal service of the notice of termination upon the
17 licenseholder or service by certified mail, return receipt requested
18 at the licenseholder's address of record with the board, whichever
19 comes first. Neither for purposes of retaining a temporary license
20 nor for purposes of any disciplinary or license denial proceeding
21 before the board shall the temporary licenseholder be deemed to
22 have a vested property right or interest in the license.

23 SEC. 4. Section 4160 of the Business and Professions Code is
24 amended to read:

25 4160. (a) A person may not act as a wholesaler of any
26 dangerous drug or dangerous device unless he or she has obtained
27 a license from the board.

28 (b) Upon approval by the board and the payment of the required
29 fee, the board shall issue a license to the applicant.

30 (c) A separate license shall be required for each place of business
31 owned or operated by a wholesaler. Each license shall be renewed
32 annually and shall not be transferable.

33 (d) The board shall not issue or renew a wholesaler license until
34 the wholesaler identifies a designated representative-in-charge and
35 notifies the board in writing of the identity and license number of
36 that designated representative. The designated
37 representative-in-charge shall be responsible for the wholesaler's
38 compliance with state and federal laws governing wholesalers. A
39 wholesaler shall identify and notify the board of a new designated
40 representative-in-charge within 30 days of the date that the prior

1 designated representative-in-charge ceases to be the designated
2 representative-in-charge. A pharmacist may be identified as the
3 designated representative-in-charge.

4 (e) A drug manufacturer premises licensed by the Food and
5 Drug Administration or licensed pursuant to Section 111615 of
6 the Health and Safety Code that only distributes dangerous drugs
7 and dangerous devices of its own manufacture is exempt from this
8 section and Section 4161.

9 (f) The board may issue a temporary license, upon conditions
10 and for periods of time as the board determines to be in the public
11 interest. A temporary license fee shall be ~~five hundred fifty dollars~~
12 ~~(\$550) or another amount required in an amount~~ established by
13 the board ~~not to exceed the annual fee for renewal of a license to~~
14 ~~compound injectable sterile drug products as specified in~~
15 ~~subdivision (f) of Section 4400.~~ When needed to protect public
16 safety, a temporary license may be issued for a period not to exceed
17 180 days, subject to terms and conditions that the board deems
18 necessary. If the board determines that a temporary license was
19 issued by mistake or denies the application for a permanent license,
20 the temporary license shall terminate upon either personal service
21 of the notice of termination upon the licenseholder or service by
22 certified mail, return receipt requested, at the licenseholder's
23 address of record with the board, whichever occurs first. Neither
24 for purposes of retaining a temporary license, nor for purposes of
25 any disciplinary or license denial proceeding before the board,
26 shall the temporary licenseholder be deemed to have a vested
27 property right or interest in the license.

28 (g) This section shall become operative on January 1, 2006.

29 SEC. 5. Section 4400 of the Business and Professions Code is
30 amended to read:

31 4400. The amount of fees and penalties prescribed by this
32 chapter, except as otherwise provided, is that fixed by the board
33 according to the following schedule:

34 (a) The fee for a nongovernmental pharmacy license shall be
35 ~~three hundred forty dollars (\$340) and may be increased to four~~
36 ~~hundred dollars (\$400) and may be increased to five hundred~~
37 ~~twenty dollars (\$520).~~ *The fee for the issuance of a temporary*
38 *nongovernmental pharmacy permit shall be two hundred fifty*
39 *dollars (\$250) and may be increased to three hundred twenty-five*
40 *dollars (\$325).*

1 (b) The fee for a nongovernmental pharmacy *license* annual
2 renewal shall be ~~one hundred seventy-five dollars (\$175)~~ and may
3 ~~be increased to two hundred fifty dollars (\$250)~~ and may be
4 *increased to three hundred twenty-five dollars (\$325)*.

5 (c) The fee for the pharmacist application and examination shall
6 be ~~one hundred fifty-five dollars (\$155)~~ and may be increased to
7 ~~one hundred eighty-five dollars (\$185)~~ *two hundred dollars (\$200)*
8 *and may be increased to two hundred sixty dollars (\$260)*.

9 (d) The fee for regrading an examination shall be ~~seventy-five~~
10 ~~dollars (\$75)~~ and may be increased to ~~eighty-five dollars (\$85)~~
11 *ninety dollars (\$90)* and may be increased to *one hundred fifteen*
12 *dollars (\$115)*. If an error in grading is found and the applicant
13 passes the examination, the regrading fee shall be refunded.

14 (e) The fee for a pharmacist license and biennial renewal shall
15 be ~~one hundred fifteen dollars (\$115)~~ and may be increased to one
16 hundred fifty dollars (\$150) and may be increased to *one hundred*
17 *ninety-five dollars (\$195)*.

18 (f) The fee for a nongovernmental wholesaler license and annual
19 renewal shall be ~~five hundred fifty dollars (\$550)~~ and may be
20 increased to six hundred dollars (\$600), ~~except as provided in~~
21 ~~subdivision (j)~~ and may be increased to *seven hundred eighty*
22 *dollars (\$780)*. *The application fee for any additional location*
23 *after licensure of the first 20 locations shall be two hundred*
24 *twenty-five dollars (\$225) and may be increased to three hundred*
25 *dollars (\$300)*. *A temporary license fee shall be five hundred fifty*
26 *dollars (\$550) and may be increased to seven hundred fifteen*
27 *dollars (\$715)*.

28 (g) The fee for a hypodermic license and renewal shall be ~~ninety~~
29 ~~dollars (\$90)~~ and may be increased to one hundred twenty-five
30 dollars (\$125) and may be increased to *one hundred sixty-five*
31 *dollars (\$165)*.

32 (h) (1) The fee for application, investigation, and issuance of
33 license as a designated representative pursuant to Section 4053
34 shall be ~~one hundred eighty-five dollars (\$185)~~ and may be
35 increased to two hundred fifty dollars (\$250). If the applicant is
36 not issued a license as a designated representative, the board shall
37 refund ~~one hundred ten dollars (\$110)~~ of the fee *two hundred*
38 *fifty-five dollars (\$255)* and may be increased to *three hundred*
39 *thirty dollars (\$330)*.

1 (2) The fee for the annual renewal of a license as a designated
2 representative shall be ~~one hundred ten dollars (\$110) and may be~~
3 ~~increased to one hundred fifty dollars (\$150) and may be increased~~
4 ~~to one hundred ninety-five dollars (\$195).~~

5 (i) (1) The fee for the application, investigation, and issuance
6 of a license as a designated representative for a veterinary
7 food-animal drug retailer pursuant to Section 4053 shall be ~~two~~
8 ~~hundred fifty dollars (\$250). If the applicant is not issued a license~~
9 ~~as a designated representative, the board shall refund one hundred~~
10 ~~fifty dollars (\$150) of the fee two hundred fifty-five dollars (\$255)~~
11 ~~and may be increased to three hundred thirty dollars (\$330).~~

12 (2) The fee for the annual renewal of a license as a designated
13 representative for a veterinary food-animal drug retailer shall be
14 ~~one hundred ten dollars (\$110) one hundred fifty dollars (\$150)~~
15 ~~and may be increased to one hundred ninety-five dollars (\$195).~~

16 (j) (1) The application fee for a nonresident wholesaler's license
17 issued pursuant to Section 4161 shall be ~~five hundred fifty dollars~~
18 ~~(\$550) and may be increased to six hundred dollars (\$600) and~~
19 ~~may be increased to seven hundred eighty dollars (\$780).~~

20 (2) For nonresident wholesalers who have 21 or more wholesaler
21 facilities operating nationwide the application fees for the first 20
22 locations shall be ~~five hundred fifty dollars (\$550) and may be~~
23 ~~increased to six hundred dollars (\$600) and may be increased to~~
24 ~~seven hundred eighty dollars (\$780).~~ The application fee for any
25 additional location after licensure of the first 20 locations shall be
26 two hundred twenty-five dollars (\$225) and may be increased to
27 three hundred dollars (\$300). *A temporary license fee shall be five*
28 *hundred fifty dollars (\$550) and may be increased to seven hundred*
29 *fifteen dollars (\$715).*

30 (3) The annual renewal fee for a nonresident wholesaler's license
31 issued pursuant to Section 4161 shall be ~~five hundred fifty dollars~~
32 ~~(\$550) and may be increased to six hundred dollars (\$600) and~~
33 ~~may be increased to seven hundred eighty dollars (\$780).~~

34 (k) The fee for evaluation of continuing education courses for
35 accreditation shall be set by the board at an amount not to exceed
36 forty dollars (\$40) per course hour.

37 (l) The fee for an intern pharmacist license shall be ~~sixty-five~~
38 ~~dollars (\$65) and may be increased to seventy-five dollars (\$75)~~
39 ~~ninety dollars (\$90) and may be increased to one hundred fifteen~~
40 ~~dollars (\$115).~~ The fee for transfer of intern hours or verification

1 of licensure to another state shall be fixed by the board not to
2 exceed twenty dollars (\$20) *twenty-five dollars (\$25) and may be*
3 *increased to thirty dollars (\$30).*

4 (m) The board may waive or refund the additional fee for the
5 issuance of a ~~certificate~~ *license* where the ~~certificate~~ *license* is
6 issued less than 45 days before the next regular renewal date.

7 (n) The fee for the reissuance of any license, or renewal thereof,
8 that has been lost or destroyed or reissued due to a name change
9 ~~is thirty dollars (\$30) shall be thirty-five dollars (\$35) and may be~~
10 *increased to forty-five dollars (\$45).*

11 (o) The fee for the reissuance of any license, or renewal thereof,
12 that must be reissued because of a change in the information, ~~is~~
13 ~~sixty dollars (\$60) and may be increased to shall be~~ one hundred
14 dollars (\$100) *and may be increased to one hundred thirty dollars*
15 *(\$130).*

16 (p) It is the intent of the Legislature that, in setting fees pursuant
17 to this section, the board shall seek to maintain a reserve in the
18 Pharmacy Board Contingent Fund equal to approximately one
19 year's operating expenditures.

20 (q) The fee for any applicant for a nongovernmental clinic ~~permit~~
21 ~~is three hundred forty dollars (\$340) and may be increased to~~
22 *license shall be four hundred dollars (\$400) and may be increased*
23 *to five hundred twenty dollars (\$520) for each permit license.* The
24 annual fee for renewal of the ~~permit is one hundred seventy-five~~
25 ~~dollars (\$175) and may be increased to license shall be~~ two hundred
26 fifty dollars (\$250) *and may be increased to three hundred*
27 *twenty-five dollars (\$325) for each permit license.*

28 (r) ~~The board shall charge a fee for the processing and issuance~~
29 ~~of a license to a pharmacy technician and a separate fee for the~~
30 ~~biennial renewal of the license. The license fee shall be twenty-five~~
31 ~~dollars (\$25) and may be increased to fifty dollars (\$50). The~~
32 ~~biennial renewal fee shall be twenty-five dollars (\$25) and may~~
33 ~~be increased to fifty dollars (\$50). The fee for the issuance of a~~
34 ~~pharmacy technician license shall be eighty dollars (\$80) and may~~
35 ~~be increased to one hundred five dollars (\$105). The fee for~~
36 ~~renewal of a pharmacy technician license shall be one hundred~~
37 ~~dollars (\$100) and may be increased to one hundred thirty dollars~~
38 ~~(\$130).~~

39 (s) The fee for a veterinary food-animal drug retailer license
40 shall be ~~four hundred dollars (\$400) four hundred five dollars~~

1 (~~\$405~~) and may be increased to four hundred twenty-five dollars
2 (~~\$425~~). The annual renewal fee for a veterinary food-animal drug
3 retailer license shall be two hundred fifty dollars (\$250) and may
4 be increased to three hundred twenty-five dollars (\$325).

5 (t) The fee for issuance of a retired license pursuant to Section
6 4200.5 shall be ~~thirty dollars (\$30)~~ thirty-five dollars (\$35) and
7 may be increased to forty-five dollars (\$45).

8 (u) The fee for issuance or renewal of a nongovernmental license
9 to compound sterile drug products shall be six hundred dollars
10 (\$600) and may be increased to seven hundred eighty dollars
11 (\$780). The fee for a temporary license shall be five hundred fifty
12 dollars (\$550) and may be increased to seven hundred fifteen
13 dollars (\$715).

Attachment B-1

Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction
Copy of bills
Bill analyses

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 418

VERSION: As Amended: April 13, 2009

AUTHOR: Emmerson

SPONSOR: California Society of Health-System Pharmacists

Committee Recommendation: SUPPORT

SUBJECT: Pharmacy technicians

EXISTING LAW:

1. Provides for the licensure and regulation of pharmacy technicians by the Board of Pharmacy.
2. Authorizes the board to issue a pharmacy technician license to an individual who is a high school graduate or who possesses a GED and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board (PTCB).
3. Requires the board to complete a criminal background check to determine if an applicant's criminal acts would constitute grounds for denial of licensure.

THIS BILL WOULD:

1. Authorize the board to issue a pharmacy technician license to an individual if that individual
 - a. has graduated from a school of pharmacy recognized by the board **OR**
 - b. is a high school graduate or who possesses a GED, passes a pharmacy technician examination recognized by the National Organization for Competency Assurance, **AND**
 - c. has either a obtained a specified associate's degree, completed a training course offered by an accreditation agency approved by the board, or graduated from a specified school of pharmacy.
2. Specify that these requirements become effective January 1, ~~2011~~ 2013.
3. ~~Require a pharmacy technician to successfully complete 20 hours of approved courses of continuing pharmacy technician education (CE) during the two years preceding an application for renewal and exempts this requirement for the first renewal cycle. Further it requires the board to issue an inactive pharmacy technician license if the licensee fails to submit proof of the CE as required.~~
4. ~~Specify the form and subject matter content for these continuing education courses.~~
5. ~~Provide that a pharmacy technician license that is not renewed within three years after expiration may not be renewed and shall be canceled at the end of the three-year period.~~

AUTHOR'S INTENT:

According to the sponsor, AB 418 (Emmerson) ensures that pharmacy technicians licensed by the California State Board of Pharmacy meet a universal standard by not only having a high school or equivalent degree but also pass training, a psychometrically sound pharmacy

technician exam, and complete approved continuing education and better protect Californian consumers.

FISCAL IMPACT:

As amended, the board no longer anticipates the addition of one staff person.

The board will need to solicit bids for evaluation of each pharmacy technician examination recognized by the National Organization for Competency Assurance as required by Business and Professions Code Section 139. The board estimates approximately \$15,000/examination.

COMMENTS:

The requirements for licensure as a pharmacy technician in California have remained largely unchanged since the board began issuing these licenses in 1992. Additionally, the role of the pharmacy technician has also remained fairly unchanged, with the major exception of the limited use of specially trained pharmacy technicians in the acute care pharmacy settings with the "tech check tech" provisions.

A board representative attended stakeholder meetings relating to pharmacy technician licensure, most recently in December 2008 and both the licensing committee and board have been updated on the status. Board staff is unclear if consensus within industry was reached on this legislative proposal.

The requirements for the PTCB include that the applicant has no felony conviction, no drug or pharmacy related convictions and no discipline by another state board of pharmacy. As part of the board's application process, the board conducts a criminal background check of an application to determine if he or she has committed acts that would constitute grounds for denial. On occasion, the board has denied an applicant licensure, but was later required to issue a license based on a decision rendered by an Administrative Law Judge. In its current form, the bill would automatically prohibit any application with a felony, drug or pharmacy related conviction from seeking licensure as a pharmacy technician. Board staff consulted with staff counsel, who expressed concern that the bill in its current form could constitute a de facto ban from licensure for those with a criminal background. This concern has been addressed with the amendments included in this version of the bill.

Also, from an implementation standpoint, pharmacy technician licenses are automatically cancelled after 90 days for when a licensee fails to renew their license. This proposal would instead allow a pharmacy technician license to remain delinquent for up to three years before the board could cancel such a license, increasing administrative duties on board staff. This concern has been addressed with the amendments include in this version of the bill.

In its current form, this bill would require the board to promulgate regulations to define the approval process for the acceptable pharmacy technician examinations for purposes of licensure as required in 4202 (a) as well as promulgate regulations to establish the criteria for approving an accreditation agency.

This bill failed passage on April 15, 2009. Reconsideration was granted. According to the author's office, they are exploring options to address opposition to this bill.

SUPPORT and OPPOSITION:

Support

California Society of Health-System Pharmacists (Sponsor)
American Society of Health-System Pharmacists
California Hospital Association
California Society of Health System Pharmacists, Central Valley
California Society of Health-System Pharmacists, Pacific Student Chapter
California Society of Health-System Pharmacists, San Gabriel
California Society of Health System Pharmacists Western University Chapter
Diablo Chapter, California Society of Health-System Pharmacists
Golden Gate Society of Health-System Pharmacists
Inland Society if Health-System Pharmacists
Loma Linda Student Chapter, Society of Health-System Pharmacists
Orange County Society of Health-System Pharmacists
San Diego Society of Health-System Pharmacists
San Fernando Valley Society of Health-System Pharmacists
San Gabriel Valley Society of Health-System Pharmacists
Sierra Society of Health-System Pharmacists
Sacramento Valley Society of Health-System Pharmacists
Society of Health System Pharmacists Student Chapter Society, Touro
South Bay/Long Beach – Society of Health-System Pharmacists
Southern California Society of Health-System Pharmacists
The Quaid Foundation
University of California, San Diego Student Chapter, Society of Health System Pharmacist
University of California, San Francisco Student Chapter, Society of Health System Pharmacists
University of Southern California Society of Health System Pharmacists
Numerous Individuals

Oppose

California Retailers Association
CVS/Caremark
National Association of Chain Drug Stores
Rite Aid
Target
United Food and Commercial Workers Union, Western States Council

HISTORY:

Apr. 29 Bill set for hearing in Assembly Business & Professions
Apr. 14 In committee: Set second hearing. Failed passage. Reconsideration granted.
Apr. 13 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended. Re-referred to Com. on B. & P.
Mar. 31 In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 9 Referred to Com. on B. & P.
Feb. 24 From printer. May be heard in committee March 26.
Feb. 23 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 418

Introduced by Assembly Member Emmerson

February 23, 2009

An act to amend Section 4231 of, to amend, repeal, and add Section 4202 of, and to add Sections 4230, 4230.5, and 4410 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 418, as amended, Emmerson. Pharmacy technicians: licensure requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy technicians by the California State Board of Pharmacy. Existing law authorizes the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board. Existing law prohibits the board from renewing a pharmacist license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal.

This bill would instead, on and after January 1, 2011 2013, authorize the board to issue a pharmacy technician license to an individual if that individual who has graduated from a school of pharmacy recognized by the board, or to an individual who is a high school graduate or

possesses a general educational development certificate equivalent, passes a pharmacy technician examination recognized by the National Organization for Competency Assurance and approved by the board, and has either obtained a specified *an associate's degree, in pharmacy technology or* completed a course of training offered by a specified accredited program, or graduated from a specified school of pharmacy. The bill would also prohibit the board from renewing a pharmacist technician license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 20 hours of continuing pharmacy education courses. The bill would specify the form and subject matter content for these courses and it would provide that a pharmacy technician license that is not renewed within 3 years after expiration may not be renewed and shall be canceled at the end of the 3-year period by the board.

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. This act shall be known, and may be cited, as the
- 2 California Pharmacy Technician Patient Safety and Protection Act.
- 3 SEC. 2. Section 4202 of the Business and Professions Code is
- 4 amended to read:
- 5 4202. (a) The board may issue a pharmacy technician license
- 6 to an individual if he or she is a high school graduate or possesses
- 7 a general educational development certificate equivalent, and meets
- 8 any one of the following requirements:
- 9 (1) Has obtained an associate's degree in pharmacy technology.
- 10 (2) Has completed a course of training specified by the board.
- 11 (3) Has graduated from a school of pharmacy recognized by
- 12 the board.
- 13 (4) Is certified by the Pharmacy Technician Certification Board.
- 14 (b) The board shall adopt regulations pursuant to this section
- 15 for the licensure of pharmacy technicians and for the specification
- 16 of training courses as set out in paragraph (2) of subdivision (a).
- 17 Proof of the qualifications of any applicant for licensure as a
- 18 pharmacy technician shall be made to the satisfaction of the board
- 19 and shall be substantiated by any evidence required by the board.
- 20 (c) The board shall conduct a criminal background check of the
- 21 applicant to determine if an applicant has committed acts that

1 would constitute grounds for denial of licensure, pursuant to this
2 chapter or Chapter 2 (commencing with Section 480) of Division
3 1.5.

4 (d) The board may suspend or revoke a license issued pursuant
5 to this section on any ground specified in Section 4301.

6 (e) Once licensed as a pharmacist, the pharmacy technician
7 registration is no longer valid and the pharmacy technician license
8 shall be returned to the board within 15 days.

9 (F)

10 (f) This section shall remain in effect only until January 1, ~~2011~~
11 ~~2013~~, and as of that date is repealed, unless a later enacted statute,
12 that is enacted before January 1, ~~2011~~ 2013, deletes or extends
13 that date.

14 SEC. 3. Section 4202 is added to the Business and Professions
15 Code, to read:

16 4202. (a) The board may issue a pharmacy technician license
17 to an individual ~~if he or she~~ *who has graduated from a school of*
18 *pharmacy recognized by the board; or to an individual who is a*
19 *high school graduate or possesses a general educational*
20 *development certificate equivalent, passes a pharmacy technician*
21 *examination recognized by the National Organization for*
22 *Competency Assurance and approved by the board, and meets any*
23 *one either of the following requirements:*

24 (1) Has obtained an associate's degree in pharmacy technology.

25 ~~(2) Has completed a course of training offered by a program~~
26 ~~accredited by an accreditation agency approved by the board.~~

27 ~~(A) For the purposes of this section, "accreditation agency"~~
28 ~~means a public or private organization that issues certificates of~~
29 ~~accreditation to pharmacy technician training programs.~~

30 ~~(B) The board shall adopt regulations that include criteria for~~
31 ~~approving an accreditation agency. These criteria may include the~~
32 ~~accreditation standards for pharmacy technician training programs~~
33 ~~issued by the American Society of Health-System Pharmacists.~~

34 ~~(3) Has graduated from a school of pharmacy recognized by~~
35 ~~the board.~~

36 (2) *Has completed a course of training specified by the board.*

37 (b) The board shall adopt regulations pursuant to this section
38 for the licensure of pharmacy technicians *and for the specification*
39 *of course of training as set forth in paragraph (2) of subdivision*
40 (a). Proof of the qualifications of any applicant for licensure as a

1 pharmacy technician shall be made to the satisfaction of the board
2 and shall be substantiated by any evidence required by the board.

3 (c) The board shall conduct a criminal background check of an
4 applicant to determine if the applicant has committed acts that
5 would constitute grounds for denial of licensure, pursuant to this
6 chapter or Chapter 2 (commencing with Section 480) of Division
7 1.5.

8 (d) The board may suspend or revoke a license issued pursuant
9 to this section on any ground of unprofessional conduct specified
10 in Section 4301.

11 (e) Once a pharmacy technician is licensed as a pharmacist, the
12 pharmacy technician registration is no longer valid and the
13 pharmacy technician license shall be returned to the board within
14 15 days.

15 (f) A pharmacy technician examination described in subdivision
16 (a) shall be subject to Section 139.

17 (g) This section shall become operative on January 1, ~~2011~~
18 ~~2013~~.

19 ~~SEC. 4.—Section 4230 is added to the Business and Professions~~
20 ~~Code, to read:~~

21 ~~4230. (a) The board shall not renew a pharmacy technician~~
22 ~~license unless the applicant submits proof satisfactory to the board~~
23 ~~that he or she has successfully completed 20 hours of approved~~
24 ~~courses of continuing pharmacy technician education as described~~
25 ~~in Section 4230.5 during the two years preceding the application~~
26 ~~for renewal.~~

27 ~~(b) Notwithstanding subdivision (a), the board shall not require~~
28 ~~completion of continuing education for the first renewal of a~~
29 ~~pharmacy technician license.~~

30 ~~(c) If an applicant for renewal of a pharmacy technician license~~
31 ~~submits the renewal application and payment of the renewal fee~~
32 ~~but does not submit proof satisfactory to the board that the licensee~~
33 ~~has completed 20 hours of continuing pharmacy education, the~~
34 ~~board shall not renew the license and shall issue the applicant an~~
35 ~~inactive pharmacy technician license. A licensee with an inactive~~
36 ~~pharmacy technician license issued pursuant to this section may~~
37 ~~obtain an active pharmacy technician license by paying the renewal~~
38 ~~fees due and submitting satisfactory proof to the board that the~~
39 ~~licensee has completed 20 hours of continuing pharmacy education.~~

1 SEC. 5. Section 4230.5 is added to the Business and Professions
2 Code, to read:

3 4230.5. (a) ~~The approved courses of continuing pharmacy~~
4 ~~technician education shall be in the form of studies, institutes,~~
5 ~~seminars, lectures, conferences, workshops, extension studies,~~
6 ~~correspondence courses, and other similar methods of conveying~~
7 ~~continuing professional pharmacy technician education.~~

8 (b) ~~The subject matter of the courses may be pertinent to the~~
9 ~~socioeconomic and legal aspects of health care, the properties and~~
10 ~~actions of drugs and dosage forms, and the etiology, characteristics,~~
11 ~~and therapeutics of the disease state.~~

12 (c) ~~The subject matter of the courses may also include, but shall~~
13 ~~not be limited to, the following: pharmacology, biochemistry,~~
14 ~~physiology, pharmaceutical chemistry, pharmacy administration,~~
15 ~~pharmacy jurisprudence, public health and communicable diseases,~~
16 ~~professional practice management, anatomy, and histology.~~

17 SEC. 6. Section 4231 of the Business and Professions Code is
18 amended to read:

19 4231. (a) ~~The board shall not renew a pharmacist license unless~~
20 ~~the applicant submits proof satisfactory to the board that he or she~~
21 ~~has successfully completed 30 hours of approved courses of~~
22 ~~continuing pharmacy education as described in Section 4232 during~~
23 ~~the two years preceding the application for renewal.~~

24 (b) ~~Notwithstanding subdivision (a), the board shall not require~~
25 ~~completion of continuing education for the first renewal of a~~
26 ~~pharmacist license.~~

27 (c) ~~If an applicant for renewal of a pharmacist license submits~~
28 ~~the renewal application and payment of the renewal fee but does~~
29 ~~not submit proof satisfactory to the board that the licensee has~~
30 ~~completed 30 hours of continuing pharmacy education, the board~~
31 ~~shall not renew the license and shall issue the applicant an inactive~~
32 ~~pharmacist license. A licensee with an inactive pharmacist license~~
33 ~~issued pursuant to this section may obtain an active pharmacist~~
34 ~~license by paying the renewal fees due and submitting satisfactory~~
35 ~~proof to the board that the licensee has completed 30 hours of~~
36 ~~continuing pharmacy education.~~

37 SEC. 7. Section 4410 is added to the Business and Professions
38 Code, to read:

39 4410. Any pharmacy technician license that is not renewed
40 within three years following its expiration may not be renewed

1 ~~and shall be canceled by operation of law at the end of the~~
2 ~~three-year period.~~

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 484

**VERSION: ~~As Amended: April 2, 2009~~
Amended April 20, 2009**

AUTHOR: Eng

SPONSOR: Franchise Tax Board

BOARD POSITION: None

SUBJECT: Franchise Tax Board: professional or occupational licenses

EXISTING LAW:

1. Allows tax return information to be disclosed in a judicial or administrative proceeding pertaining to tax administration under certain circumstances.
2. Requires every board, as defined under the Business and Professions Code, and the Department of Insurance, among other entities to, upon request of the Franchise Tax Board (FTB), furnish to the FTB certain information with respect to every licensee.

THIS BILL WOULD:

1. Require a state governmental licensing entity issuing professional licenses, certificates, registrations, or permits to provide to the FTB the name and social security number or federal identification number of each licensee of that entity.
2. Require the FTB, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, to send a notice of suspension to the applicable state governmental licensing entity and to the licensee.
3. Eliminate duplicative provisions that would exist between the Contractors State Licensing Board and FTB to exchange delinquent state tax information.
4. Allow the FTB to defer or cancel any suspension authorized by this bill if a licensee would experience substantial financial hardship.
5. Require the FTB to, if requested by the licensee in writing, provide for an administrative hearing to determine if the licensee will experience substantial financial hardship from the suspension.
6. Require that the notice of suspension shall be applicable *only* if the FTB mailed a preliminary notice that indicates that the licensee will be suspended by a date certain. This preliminary notice must be sent at least 60 days before that date certain.
7. Require that the request for a hearing be made in writing within 30 days from the mailing date of the preliminary notice of suspension.
8. Require that the FTB shall conduct a hearing within 30 days after the receipt of a request for the hearing.
9. Specify that a licensee seeking relief based on substantial financial hardship shall only be entitled to relief if the licensee provides the FTB with financial

- documents that substantiate financial hardship, and agrees to an acceptable payment arrangement.
10. Define "hardship" as financial hardship, as determined by the FTB, where the taxpayer is financially unable to pay any part of the amount of delinquent taxes, and is unable to qualify for an installment payment arrangement.
 11. Define "license" to include a certificate, registration, or any other authorization to engage in a business or profession issued by a state governmental licensing entity.
 12. Define "governmental licensing entity" as any entity listed in Section 101, 1000, or 19420 of the Business and Professions Code, the Office of the Attorney General, the Department of Insurance, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing a person to engage in a business or profession.
 13. Authorize a state governmental licensing entity, as specified, to impose a fee on a licensee with a suspended license in an amount necessary to cover its administrative costs.
 14. Make implementation of the provisions of this bill contingent on the appropriation of funds for the purposes of this bill in the annual budget act.
 15. Exempts the Contractors State License Board from those entities to whom the provisions of the bill apply.

AUTHOR'S INTENT:

According to the sponsor, current state law lacks an effective method to collect from a tax debtor who is an individual licensed to engage in an occupation or profession operating on a cash basis. This bill would provide a way for the Franchise Tax Board (FTB) to suspend one's licensing status because of unpaid tax liabilities.

FISCAL IMPACT:

Board staff anticipates fiscal impact to complete the necessary programming changes needed to our system as well as a half-time Management Services Technician to perform the administrative functions associated with this proposal.

COMMENTS:

While the majority of the administration of this provision would reside with the FTB, the board would be responsible for managing the licensee history and associated administrative functions. Board staff is seeking clarification from the department's legal office to determine any legal concerns as well as if a suspension imposed by the FTB would constitute administrative action.

April 21, 2009: Bill failed passage in Assembly Business & Professions Committee. Per Anne, we will no longer track, nor will we update an analysis for the Board.

SUPPORT/OPPOSITION:

None of file.

HISTORY:

Apr. 21 Failed passage ASM B&P.
Apr. 2 From committee chair, with author's amendments: Amend, and re-refer to
Com. on B. & P. Read second time and amended.
Mar. 16 Referred to Coms. on B. & P. and REV. & TAX.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 24 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 20, 2009

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 484

Introduced by Assembly Member Eng

February 24, 2009

An act to amend ~~Sections 31 and 7145.5~~ *Section 31* of the Business and Professions Code, and to add Sections 19265 and 19571 to the Revenue and Taxation Code, relating to taxes.

LEGISLATIVE COUNSEL'S DIGEST

AB 484, as amended, Eng. Franchise Tax Board: professional or occupational licenses.

The Personal Income Tax Law and the Bank and Corporation Tax Law impose taxes on, or measured by, income. Existing law allows a tax return or return information filed under those laws to be disclosed in a judicial or administrative proceeding pertaining to tax administration under certain circumstances. Existing law requires every board, as defined under the Business and Professions Code, and the Department of Insurance to, upon request of the Franchise Tax Board, furnish to the Franchise Tax Board certain information with respect to every licensee. Existing law authorizes many of these boards to impose fees on its licensees to cover its costs in administering its respective provisions and in some cases these funds are deposited into continuously appropriated funds.

This bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name

and social security number or federal taxpayer identification number of each individual licensee of that entity. The bill would require the Franchise Tax Board, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, as specified, to mail a preliminary notice of suspension to the licensee. The bill would provide that the license of a licensee who fails to satisfy the unpaid taxes by a certain date shall be automatically suspended, except as specified, would require the Franchise Tax Board to provide a notice of suspension to the applicable state governmental licensing entity and to mail a notice of suspension to the licensee, and would provide that the suspension be canceled upon compliance with the tax obligation. The bill would require the Franchise Tax Board to meet certain requirements and would make related changes. The bill would authorize a state governmental licensing entity, as specified, to impose a fee on a licensee with a suspended license in an amount necessary to cover its administrative costs. The bill would make implementation of its provisions contingent upon appropriation of funds for that purpose in the annual Budget Act.

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

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

- 1 SECTION 1. Section 31 of the Business and Professions Code
2 is amended to read:
3 31. (a) As used in this section, "board" means any entity listed
4 in Section 101, the entities referred to in Sections 1000 and 3600,
5 the State Bar, the Department of Real Estate, and any other state
6 agency that issues a license, certificate, or registration authorizing
7 a person to engage in a business or profession.
8 (b) Each applicant for the issuance or renewal of a license,
9 certificate, registration, or other means to engage in a business or
10 profession regulated by a board who is not in compliance with a
11 judgment or order for support shall be subject to Section 17520 of
12 the Family Code.
13 (c) "Compliance with a judgment or order for support," has the
14 meaning given in paragraph (4) of subdivision (a) of Section 17520
15 of the Family Code.
16 (d) Each licensee who has not paid any applicable state income
17 tax, including interest, penalties, and other fees, shall be subject
18 to Section 19265 of the Revenue and Taxation Code.

1 ~~SEC. 2. Section 7145.5 of the Business and Professions Code~~
2 ~~is amended to read:~~

3 ~~7145.5. — (a) The registrar may refuse to issue, reinstate,~~
4 ~~reactivate, or renew a license or may suspend a license for the~~
5 ~~failure of a licensee to resolve all outstanding final liabilities, which~~
6 ~~include taxes, additions to tax, penalties, interest, and any fees that~~
7 ~~may be assessed by the board, the Department of Industrial~~
8 ~~Relations, the Employment Development Department, or the~~
9 ~~Franchise Tax Board.~~

10 ~~(1) Until the debts covered by this section are satisfied, the~~
11 ~~qualifying person and any other personnel of record named on a~~
12 ~~license that has been suspended under this section shall be~~
13 ~~prohibited from serving in any capacity that is subject to licensure~~
14 ~~under this chapter, but shall be permitted to act in the capacity of~~
15 ~~a nonsupervising bona fide employee.~~

16 ~~(2) The license of any other renewable licensed entity with any~~
17 ~~of the same personnel of record that have been assessed an~~
18 ~~outstanding liability covered by this section shall be suspended~~
19 ~~until the debt has been satisfied or until the same personnel of~~
20 ~~record disassociate themselves from the renewable licensed entity.~~

21 ~~(b) The refusal to issue a license or the suspension of a license~~
22 ~~as provided by this section shall be applicable only if the registrar~~
23 ~~has mailed a notice preliminary to the refusal or suspension that~~
24 ~~indicates that the license will be refused or suspended by a date~~
25 ~~certain. This preliminary notice shall be mailed to the licensee at~~
26 ~~least 60 days before the date certain.~~

27 ~~(c) (1) In the case of outstanding final liabilities assessed by~~
28 ~~the Franchise Tax Board, this section shall be operative within 60~~
29 ~~days after the Contractors' State License Board has provided the~~
30 ~~Franchise Tax Board with the information required under Section~~
31 ~~30, relating to licensing information that includes the federal~~
32 ~~employee identification number or social security number.~~

33 ~~(2) All versions of the application for contractors' licenses shall~~
34 ~~include, as part of the application, an authorization by the applicant,~~
35 ~~in the form and manner mutually agreeable to the Franchise Tax~~
36 ~~Board and the board, for the Franchise Tax Board to disclose the~~
37 ~~tax information that is required for the registrar to administer this~~
38 ~~section. The Franchise Tax Board may from time to time audit~~
39 ~~these authorizations.~~

1 ~~(d) This section shall not be interpreted to conflict with the~~
2 ~~suspension of a license pursuant to Section 19265 of the Revenue~~
3 ~~and Taxation Code.~~

4 ~~SEC. 3.~~

5 SEC. 2. Section 19265 is added to the Revenue and Taxation
6 Code, to read:

7 19265. (a) (1) (A) State governmental licensing entities, as
8 defined in paragraph (4) of subdivision (e), shall provide to the
9 Franchise Tax Board the name and social security number or
10 federal taxpayer identification number, as applicable, of each
11 licensee of that state governmental licensing entity.

12 (B) State governmental licensing entities shall provide to the
13 Franchise Tax Board the information described in subparagraph
14 (A) at a time that the Franchise Tax Board may require.

15 (2) If any licensee has failed to pay taxes, including any
16 penalties, interest, and any applicable fees, imposed under Part 10
17 (commencing with Section 17001), Part 11 (commencing with
18 Section 23001), or this part, for which a notice of state tax lien has
19 been recorded in any county recorder's office in this state, pursuant
20 to Chapter 14 (commencing with Section 7150) of Division 7 of
21 Title 1 of the Government Code, the Franchise Tax Board shall
22 mail a preliminary notice of suspension to the licensee indicating
23 that the license will be suspended by a date certain, which shall
24 be no earlier than ~~60~~ 150 days after the mailing of the preliminary
25 notice of suspension, unless prior to the date certain the licensee
26 pays the unpaid taxes or enters into an installment payment
27 agreement, as described in Section 19008, to satisfy the unpaid
28 taxes. The preliminary notice of suspension shall also advise the
29 licensee of the opportunity to request deferral or cancellation of a
30 suspension pursuant to subdivision (b).

31 (3) If any licensee subject to paragraph (2) fails to pay the unpaid
32 taxes or to enter into an installment payment agreement, as
33 described in Section 19008, to satisfy the unpaid taxes prior to the
34 date certain provided in the preliminary notice of suspension, his
35 or her license shall be automatically suspended by operation of
36 this section, except as provided in subdivision (b), and the
37 Franchise Tax Board shall provide a notice of suspension to the
38 applicable state governmental licensing entity and shall mail a
39 notice of suspension to the licensee. The rights, powers, and
40 privileges of any licensee whose license has been suspended

1 pursuant to this section shall be subject to the same prohibitions,
2 limitations, and restrictions as if the license were suspended by
3 the state governmental licensing entity that issued the license.

4 (4) Upon compliance by the licensee with the tax obligation,
5 either by payment of the unpaid taxes or entry into an installment
6 payment agreement, as described in Section 19008, to satisfy the
7 unpaid taxes, a suspension pursuant to this subdivision shall be
8 canceled. The Franchise Tax Board shall, within 10 business days
9 of compliance by the licensee with the tax obligation, provide a
10 notice of cancellation to the state governmental licensing entity
11 and mail a notice of cancellation to the licensee indicating that the
12 unpaid taxes have been paid or that an installment payment
13 agreement, as described in Section 19008, has been entered into
14 to satisfy the unpaid taxes and that the suspension has been
15 canceled.

16 (5) If a license is not suspended, or if the suspension of a license
17 is canceled, based on the licensee entering into an installment
18 payment agreement as described in Section 19008, and the licensee
19 fails to comply with the terms of the installment payment
20 agreement, that license shall be suspended as of the date that is 30
21 days after the date of termination of that installment payment
22 agreement. If a license is suspended pursuant to this paragraph,
23 the Franchise Tax Board shall provide notice of suspension to the
24 applicable state governmental licensing entity and mail a notice
25 of suspension to the licensee.

26 (b) (1) The Franchise Tax Board may defer or cancel any
27 suspension authorized by this section if a licensee would experience
28 financial hardship. The Franchise Tax Board shall, if requested by
29 the licensee in writing, provide for an administrative hearing to
30 determine if the licensee would experience financial hardship from
31 the suspension of his or her license.

32 (2) The request for a hearing specified in paragraph (1) shall be
33 made in writing within 30 days from the mailing date of the
34 preliminary notice described in subdivision (a).

35 (3) The Franchise Tax Board shall conduct a hearing within 30
36 days after receipt of a request pursuant to paragraph (1), unless
37 the Franchise Tax Board postpones the hearing, upon a showing
38 of good cause by the licensee, in which case a suspension pursuant
39 to subdivision (a) shall be deferred until the hearing has been
40 completed.

1 (4) A licensee seeking relief under this subdivision shall only
2 be entitled to relief described in paragraph (1) if the licensee
3 provides the Franchise Tax Board with financial documents that
4 substantiate a financial hardship, and agrees to an installment
5 payment arrangement.

6 (5) If the deferral of a suspension of a license under this
7 subdivision is no longer operative, that license shall be suspended
8 as of the date that is 30 days after the date the deferral is no longer
9 operative. If a license is suspended pursuant to this paragraph, the
10 Franchise Tax Board shall provide notice of suspension to the
11 applicable state governmental licensing entity and mail a notice
12 of suspension to the licensee.

13 (c) Notwithstanding any other provision of law, a state
14 governmental licensing entity may, with the approval of the
15 appropriate department director or governing body, impose a fee
16 on licensees whose license has been suspended as described in
17 subdivision (a). The fee shall not exceed the amount necessary for
18 the licensing entity to cover its costs in carrying out the provisions
19 of this section. Fees imposed pursuant to this section shall be
20 deposited in the fund in which other fees imposed by the state
21 governmental licensing entity are deposited and shall be available
22 to that entity upon appropriation in the annual Budget Act.

23 (d) The process described in subdivision (b) shall constitute the
24 sole administrative remedy for contesting the suspension of a
25 license under this section. The procedures in the administrative
26 adjudication provisions of the Administrative Procedure Act
27 (Chapter 4.5 (commencing with Section 11400) and Chapter 5
28 (commencing with Section 11500) of Part 1 of Division 3 of Title
29 2 of the Government Code) shall not apply to the suspension of a
30 license pursuant to this section.

31 (e) For purposes of this section and Section 19571, the following
32 definitions shall apply:

33 (1) "Financial hardship" means financial hardship within the
34 meaning of Section 19008, as determined by the Franchise Tax
35 Board, where suspension of a license will result in the licensee
36 being financially unable to pay any part of the amount described
37 in subdivision (a) and the licensee is unable to qualify for an
38 installment payment arrangement as provided for by Section 19008.
39 In order to establish the existence of a financial hardship, the
40 licensee shall submit any information, including information related

1 to reasonable business and personal expenses, requested by the
2 Franchise Tax Board for the purpose of making that determination.

3 (2) "License" includes a certificate, registration, or any other
4 authorization to engage in a profession or occupation issued by a
5 state governmental licensing entity.

6 (3) "Licensee" means an individual authorized by a license,
7 certificate, registration, or other authorization to engage in a
8 profession or occupation issued by a state governmental licensing
9 entity.

10 (4) "State governmental licensing entity" means any entity listed
11 in Section 101, 1000, or 19420 of the Business and Professions
12 Code, the office of the Attorney General, the Department of
13 Insurance, the State Bar of California, the Department of Real
14 Estate, and any other state agency, board, or commission that issues
15 a license authorizing an individual to engage in a profession or
16 occupation. "State governmental licensing entity" shall not include
17 the Department of Motor Vehicles *or the Contractor's State*
18 *License Board.*

19 (f) Implementation of this section shall be contingent on the
20 appropriation of funds for the purposes of this section in the annual
21 Budget Act.

22 ~~SEC. 4.~~

23 *SEC. 3.* Section 19571 is added to the Revenue and Taxation
24 Code, to read:

25 19571. (a) The Franchise Tax Board may disclose to state
26 governmental licensing entities information regarding suspension
27 of a license pursuant to Section 19265.

28 (b) Neither the state governmental licensing entity, nor any
29 officer, employee, or agent, or former officer, employee, or agent
30 of a state governmental licensing entity, may disclose or use any
31 information obtained from the Franchise Tax Board, pursuant to
32 this section, except to inform the public of the suspension of a
33 license pursuant to Section 19265.

34 (c) For purposes of this section, the definitions in Section 19265
35 shall apply.

36 ~~SEC. 5.~~

37 *SEC. 4.* The Legislature hereby finds and declares the
38 following:

39 (a) It is the intent of the Legislature that, consistent with the
40 decision in *Gallo v. United States District Court* (9th Cir. 2003)

1 349 F.3d 1169, cert. den. (2004) 541 U.S. 1073, the suspension of
2 a professional or occupational license pursuant to this act for failure
3 to pay delinquent taxes is a legislative act, for which due process
4 is satisfied by the legislative notice and hearing procedures.

5 (b) To prevent financial hardship, Section 19265 of the Revenue
6 and Taxation Code, as added by this act, grants a delinquent
7 taxpayer the opportunity for an additional hearing for financial
8 hardship prior to the suspension of a professional or occupational
9 license.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 718

VERSION: As amended: April 22, 2009

AUTHOR: Emmerson

SPONSOR: Reed Elsevier, Inc.

Committee Recommendation: SUPPORT

SUBJECT: ~~Prescription Drugs: Electronic Transmission~~ Inland Empire Health Plan e-
Prescribing Pilot Program

EXISTING LAW:

1. Allows for the electronic transmission of all prescription drugs at the state level.
2. Established more stringent controls for controlled substances.
3. Does not allow the electronic transmission of controlled substances as identified by the Drug Enforcement Administration (DEA).

THIS BILL WOULD:

~~Require, on or before January 1, 2012, every licensed prescriber, prescriber's agent, or pharmacy operating in California shall have the ability to transmit and receive prescriptions by electronic data transmission to the extent consistent with federal law.~~

State legislative intent to create the Inland Empire Health Plan E-Prescribing Pilot which must meet all of the following requirements:

- Be administered by an entity with specified certification and a minimum of five years e-prescribing experience under Medi-Cal
- Promote health care quality and the exchange of health information
- Include: integrated clinical decisions, current payer formulary information, appropriate alternatives as specified and drug compendia approved by the Centers for Medicare and Medicaid Services, and electronic transmission of prescriptions.

AUTHOR'S INTENT:

According to the sponsor, electronic prescribing would improve safety and efficiency in the practices of medicine and pharmacy, streamline the prescribing process, and enhance communication among health care professionals. Further, the sponsor states that electronically created and transmitted prescriptions can reduce and eliminate errors both at the physician's office at the point of prescribing, and at the pharmacy when a written or oral prescription is entered into the pharmacy's computer system.

FISCAL IMPACT:

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

COMMENTS:

The board has long supported electronic prescribing. By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. A current deterrent is that controlled substances cannot be e-prescribed.

Last year, the federal DEA solicited comments on revised rules to allow the e-prescribing of controlled drugs. These proposed rules appeared to be cumbersome for both prescribers as well as pharmacies. To date the board is we are not aware of any additional actions taken by the federal government.

SUPPORT/OPPOSITION:

California Retired Teachers Association

HISTORY:

- Apr. 28 Set for hearing in ASM B & P
- Apr. 22 From committee: Do pass, and re-refer to Com. On B & P. Re-referred (Ayes 17. Noes 0) (April 21)
- Apr. 21 From committee chair, with author's amendments: Amend, and re-refer.

- Apr. 14 Re-referred to Com. on HEALTH.
- Apr. 13 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 26 Referred to Coms. on HEALTH and B. & P.
- Feb. 27 From printer. May be heard in committee March 29.
- Feb. 26 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 22, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 718

Introduced by Assembly Member Emmerson

February 26, 2009

An act to add Section 4071.2 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 718, as amended, Emmerson. ~~Prescription drugs: electronic transmissions.~~ *Inland Empire Health Plan E-Prescribing Pilot Program.*

The Pharmacy Law regulates, among other matters, the dispensing by prescription of dangerous devices and dangerous drugs, which include controlled substances. Existing law authorizes the electronic transmission of prescriptions under specified circumstances. ~~Under existing law, a violation of the Pharmacy Law is a crime.~~

~~This bill would require, to the extent consistent with federal law, every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2016, to transmit and receive prescriptions by electronic data transmission. Because a knowing violation of that provision would constitute a crime under the Pharmacy Law, the bill would impose a state-mandated local program.~~

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

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

This bill would state the intent of the Legislature to enact legislation that would create the Inland Empire Health Plan E-Prescribing Pilot Program, which would promote health care quality and the exchange of health care information, include specified components, and be administered by an entity with specified certification and at least 5 years of e-prescribing experience under the Medi-Cal program.

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

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

1 SECTION 1. *It is the intent of the Legislature to enact*
 2 *legislation that would create the Inland Empire Health Plan*
 3 *E-Prescribing Pilot Program, which would meet all of the following*
 4 *requirements:*

5 (a) *Be administered by an entity with certification from the*
 6 *Certification Commission for Health Information Technology and*
 7 *a minimum of five years of e-prescribing experience under the*
 8 *Medi-Cal program.*

9 (b) *Promote health care quality and the exchange of health care*
 10 *information.*

11 (c) *Include all of the following components:*

12 (1) *Integrated clinical decision support alerts for allergies,*
 13 *drug-drug interactions, duplications in therapy, and elderly alerts.*

14 (2) *Current payer formulary information.*

15 (3) *Appropriate alternatives, when needed, to support*
 16 *cost-effective prescribing at the point of care.*

17 (4) *Drug compendia approved by the Center for Medicare and*
 18 *Medicaid Services.*

19 (5) *Electronic transmission of prescriptions.*

20 ~~SECTION 1. Section 4071.2 is added to the Business and~~
 21 ~~Professions Code, to read:~~

22 ~~4071.2. To the extent consistent with federal law, on or before~~
 23 ~~January 1, 2016, every licensed prescriber, prescriber's authorized~~
 24 ~~agent, or pharmacy operating in California shall have the ability~~
 25 ~~to transmit and receive prescriptions by electronic data~~
 26 ~~transmission.~~

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

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 830

VERSION: As Amended: April 1, 2009

AUTHOR: Cook

SPONSOR: Medical Oncology Association of Southern
California (MOASC)
Association of Northern California Oncologists (ANCO)

COMMITTEE RECOMMENDATION: OPPOSE

SUBJECT: Drugs and Devices

EXISTING LAW:

1. References various drug compendia in various licensure, health care and social services provisions.
2. Makes it a crime to knowingly sell or keep or offer for sale, otherwise dispose of any drug that has been adulterated.
3. Defines adulterated as based upon the standard strength, quality and purity of the United States Pharmacopedia

THIS BILL WOULD:

1. Would replace these references with compendia approved by the federal Centers for Medicare and Medicaid Services including the definition of a drug in Health and Safety Code Section 11014 and the definition of device in Health and Safety Code section 1099220.
2. Redefine "Official compendium" to a compendia or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.

AUTHOR'S INTENT:

According to the author, AB 830 allows California codes to stay up to date and current with federal compendiums approved by the CMS by deleting the individual names of recognized reference guides. The problem is that there are many compendium reference guides, they are listed individually in statute, and CMS changes the list. This means that unless state statutes are updated as frequently as CMS changes the list of the compendium guides, a payer could refuse payment for a treatment because California law was not up to date.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to board operations. Any minor impact could be absorbed within existing resources.

COMMENTS:

Board staff will be seeking clarification from the author's office as well as the Department of Health Care Services.

Following discussion at its meeting held April 16, 2009, the Legislation and Regulation Committee recommends an "oppose" position to this bill.

HISTORY:

- Apr. 21 From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. (Ayes 19. Noes 0.) (April 14).
- Apr. 2 Re-referred to Com. on HEALTH.
- Apr. 1 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 23 Referred to Com. on HEALTH.
- Feb. 27 From printer. May be heard in committee March 29.
- Feb. 26 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 1, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 830

**Introduced by Assembly Member Cook
(Principal coauthor: Assembly Member Krekorian)**

February 26, 2009

An act to amend Sections 13, 4025, 4053, and 4342 of the Business and Professions Code, to amend Sections 1367.21, 1370.4, 11014, 109920, 109985, *111225, 111235*, 111656.4, and 150204 of the Health and Safety Code, to amend Sections 10123.195 and 10145.3 of the Insurance Code, to *amend Section 383 of the Penal Code*, to amend Section 47121 of the Public Resources Code, and to amend Sections 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 830, as amended, Cook. Drugs and devices.

Existing law references various drug compendia, including the United States Pharmacopoeia, in various *licensure*, health care, and *social services* provisions.

This bill would ~~include within~~ *replace* these references or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of *with* compendia approved by the federal Centers for Medicare and Medicaid Services.

Existing law makes it a crime to knowingly sell, or keep or offer for sale, or otherwise dispose of any drug or medicine, knowing that it is

adulterated. A drug is deemed to be adulterated based upon the standard of strength, quality, or purity in the United States Pharmacopoeia.

This bill would replace the above drug compendia with any compendia approved by the federal Centers for Medicare and Medicaid Services. By changing the definition of a 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: ~~no~~-yes.

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

1 SECTION 1. Section 13 of the Business and Professions Code
2 is amended to read:

3 13. The term "materia medica" as used in this code or in any
4 initiative act referred to in this code, means those substances listed
5 ~~in the official United States Pharmacopoeia, the official~~
6 ~~Homeopathic Pharmacopoeia of the United States, the official~~
7 ~~United States Dispensatory, New and Nonofficial Remedies, or~~
8 ~~the National Formulary, any supplement thereof, or any other~~
9 ~~similar drug compendium, as determined annually by the State~~
10 ~~Department of Health Care Services on the basis of factors,~~
11 ~~including, but not limited to, the breadth of listings, use of~~
12 ~~prespecified published criteria for weighing evidence, and inclusion~~
13 ~~on a list of compendia in a compendia or supplement thereof~~
14 approved by the federal Centers for Medicare and Medicaid
15 Services, except substances covered by subdivision (a) of Section
16 4052 and Section 4057.

17 SEC. 2. Section 4025 of the Business and Professions Code is
18 amended to read:

19 4025. "Drug" means any of the following:

20 (a) ~~Articles recognized in the official United States~~
21 ~~Pharmacopoeia, official National Formulary or official~~
22 ~~Homeopathic Pharmacopoeia of the United States, any supplement~~
23 ~~of any of them, or any other similar drug compendium, as~~

1 ~~determined annually by the State Department of Health Care~~
2 ~~Services on the basis of factors, including, but not limited to, the~~
3 ~~breadth of listings, use of prespecified published criteria for~~
4 ~~weighing evidence, and inclusion on a list of compendia approved~~
5 ~~a compendia or supplement thereof approved by the federal Centers~~
6 ~~for Medicare and Medicaid Services.~~

7 (b) Articles intended for use in the diagnosis, cure, mitigation,
8 treatment, or prevention of disease in humans or other animals.

9 (c) Articles (other than food) intended to affect the structure or
10 any function of the body of humans or other animals.

11 (d) Articles intended for use as a component of any article
12 specified in subdivision (a), (b), or (c).

13 SEC. 3. Section 4053 of the Business and Professions Code is
14 amended to read:

15 4053. (a) Notwithstanding Section 4051, the board may issue
16 a license as a designated representative to provide sufficient and
17 qualified supervision in a wholesaler or veterinary food-animal
18 drug retailer. The designated representative shall protect the public
19 health and safety in the handling, storage, and shipment of
20 dangerous drugs and dangerous devices in the wholesaler or
21 veterinary food-animal drug retailer.

22 (b) An individual may apply for a designated representative
23 license. In order to obtain and maintain that license, the individual
24 shall meet all of the following requirements:

25 (1) He or she shall be a high school graduate or possess a general
26 education development equivalent.

27 (2) He or she shall have a minimum of one year of paid work
28 experience, in the past three years, related to the distribution or
29 dispensing of dangerous drugs or dangerous devices or meet all
30 of the prerequisites to take the examination required for licensure
31 as a pharmacist by the board.

32 (3) He or she shall complete a training program approved by
33 the board that, at a minimum, addresses each of the following
34 subjects:

35 (A) Knowledge and understanding of California law and federal
36 law relating to the distribution of dangerous drugs and dangerous
37 devices.

38 (B) Knowledge and understanding of California law and federal
39 law relating to the distribution of controlled substances.

40 (C) Knowledge and understanding of quality control systems.

1 (D) Knowledge and understanding of the standards relating to
2 the safe storage and handling ~~of drugs in the United States~~
3 ~~Pharmacopoeia or any other similar drug compendium, as~~
4 ~~determined annually by the State Department of Health Care~~
5 ~~Services on the basis of factors, including, but not limited to, the~~
6 ~~breadth of listings, use of prespecified published criteria for~~
7 ~~weighing evidence, and inclusion on a list of compendia of drugs~~
8 ~~in a compendia~~ approved by the federal Centers for Medicare and
9 Medicaid Services.

10 (E) Knowledge and understanding of prescription terminology,
11 abbreviations, dosages and format.

12 (4) The board may, by regulation, require training programs to
13 include additional material.

14 (5) The board may not issue a license as a designated
15 representative until the applicant provides proof of completion of
16 the required training to the board.

17 (c) The veterinary food-animal drug retailer or wholesaler shall
18 not operate without a pharmacist or a designated representative
19 on its premises.

20 (d) Only a pharmacist or a designated representative shall
21 prepare and affix the label to veterinary food-animal drugs.

22 (e) Section 4051 shall not apply to any laboratory licensed under
23 Section 351 of Title III of the Public Health Service Act (Public
24 Law 78-410).

25 SEC. 4. Section 4342 of the Business and Professions Code is
26 amended to read:

27 4342. (a) The board may institute any action or actions as may
28 be provided by law and that, in its discretion, are necessary, to
29 prevent the sale of pharmaceutical preparations and drugs that do
30 not conform to the standard and tests as to quality and strength,
31 ~~provided in the United States Pharmacopoeia, the National~~
32 ~~Formulary, or any other similar drug compendium, as determined~~
33 ~~annually by the State Department of Health Care Services on the~~
34 ~~basis of factors, including, but not limited to, the breadth of listings,~~
35 ~~use of prespecified published criteria for weighing evidence, and~~
36 ~~inclusion on a list of compendia approved~~ *provided in the latest*
37 *edition of a compendia approved* by the federal Centers for
38 Medicare and Medicaid Services or that violate any provision of
39 the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing

1 with Section 109875) of Division 104 of the Health and Safety
2 Code).

3 (b) Any knowing or willful violation of any regulation adopted
4 pursuant to Section 4006 shall be subject to punishment in the
5 same manner as is provided in Sections 4336 and 4321.

6 SEC. 5. Section 1367.21 of the Health and Safety Code is
7 amended to read:

8 1367.21. (a) No health care service plan contract which covers
9 prescription drug benefits shall be issued, amended, delivered, or
10 renewed in this state if the plan limits or excludes coverage for a
11 drug on the basis that the drug is prescribed for a use that is
12 different from the use for which that drug has been approved for
13 marketing by the federal Food and Drug Administration (FDA),
14 provided that all of the following conditions have been met:

15 (1) The drug is approved by the FDA.

16 (2) (A) The drug is prescribed by a participating licensed health
17 care professional for the treatment of a life-threatening condition;
18 or

19 (B) The drug is prescribed by a participating licensed health
20 care professional for the treatment of a chronic and seriously
21 debilitating condition, the drug is medically necessary to treat that
22 condition, and the drug is on the plan formulary. If the drug is not
23 on the plan formulary, the participating subscriber's request shall
24 be considered pursuant to the process required by Section 1367.24.

25 (3) The drug has been recognized for treatment of that condition
26 by ~~one~~ *either* of the following:

27 ~~(A) The American Medical Association Drug Evaluations.~~

28 ~~(B) The American Hospital Formulary Service Drug
29 Information.~~

30 ~~(C) The United States Pharmacopoeia Dispensing Information;
31 Volume 1, "Drug Information for the Health Care Professional"
32 or any other similar drug compendium, as determined annually by
33 the State Department of Health Care Services on the basis of
34 factors, including, but not limited to, the breadth of listings, use
35 of prespecified published criteria for weighing evidence, and
36 inclusion on a list of compendia approved~~

37 ~~(A) A compendia approved by the federal Centers for Medicare
38 and Medicaid Services.~~

39 ~~(D)~~

1 (B) Two articles from major peer reviewed medical journals
2 that present data supporting the proposed off-label use or uses as
3 generally safe and effective unless there is clear and convincing
4 contradictory evidence presented in a major peer reviewed medical
5 journal.

6 (b) It shall be the responsibility of the participating prescriber
7 to submit to the plan documentation supporting compliance with
8 the requirements of subdivision (a), if requested by the plan.

9 (c) Any coverage required by this section shall also include
10 medically necessary services associated with the administration
11 of a drug, subject to the conditions of the contract.

12 (d) For purposes of this section, "life-threatening" means either
13 or both of the following:

14 (1) Diseases or conditions where the likelihood of death is high
15 unless the course of the disease is interrupted.

16 (2) Diseases or conditions with potentially fatal outcomes, where
17 the end point of clinical intervention is survival.

18 (e) For purposes of this section, "chronic and seriously
19 debilitating" means diseases or conditions that require ongoing
20 treatment to maintain remission or prevent deterioration and cause
21 significant long-term morbidity.

22 (f) The provision of drugs and services when required by this
23 section shall not, in itself, give rise to liability on the part of the
24 plan.

25 (g) Nothing in this section shall be construed to prohibit the use
26 of a formulary, copayment, technology assessment panel, or similar
27 mechanism as a means for appropriately controlling the utilization
28 of a drug that is prescribed for a use that is different from the use
29 for which that drug has been approved for marketing by the FDA.

30 (h) If a plan denies coverage pursuant to this section on the basis
31 that its use is experimental or investigational, that decision is
32 subject to review under Section 1370.4.

33 (i) Health care service plan contracts for the delivery of
34 Medi-Cal services under the Waxman-Duffy Prepaid Health Plan
35 Act (Chapter 8 (commencing with Section 14200) of Part 3 of
36 Division 9 of the Welfare and Institutions Code) are exempt from
37 the requirements of this section.

38 SEC. 6. Section 1370.4 of the Health and Safety Code is
39 amended to read:

1 1370.4. (a) Every health care service plan shall provide an
2 external, independent review process to examine the plan's
3 coverage decisions regarding experimental or investigational
4 therapies for individual enrollees who meet all of the following
5 criteria:

6 (1) (A) The enrollee has a life-threatening or seriously
7 debilitating condition.

8 (B) For purposes of this section, "life-threatening" means either
9 or both of the following:

10 (i) Diseases or conditions where the likelihood of death is high
11 unless the course of the disease is interrupted.

12 (ii) Diseases or conditions with potentially fatal outcomes, where
13 the end point of clinical intervention is survival.

14 (C) For purposes of this section, "seriously debilitating" means
15 diseases or conditions that cause major irreversible morbidity.

16 (2) The enrollee's physician certifies that the enrollee has a
17 condition, as defined in paragraph (1), for which standard therapies
18 have not been effective in improving the condition of the enrollee,
19 for which standard therapies would not be medically appropriate
20 for the enrollee, or for which there is no more beneficial standard
21 therapy covered by the plan than the therapy proposed pursuant
22 to paragraph (3).

23 (3) Either (A) the enrollee's physician, who is under contract
24 with or employed by the plan, has recommended a drug, device,
25 procedure or other therapy that the physician certifies in writing
26 is likely to be more beneficial to the enrollee than any available
27 standard therapies, or (B) the enrollee, or the enrollee's physician
28 who is a licensed, board-certified or board-eligible physician
29 qualified to practice in the area of practice appropriate to treat the
30 enrollee's condition, has requested a therapy that, based on two
31 documents from the medical and scientific evidence, as defined
32 in subdivision (d), is likely to be more beneficial for the enrollee
33 than any available standard therapy. The physician certification
34 pursuant to this subdivision shall include a statement of the
35 evidence relied upon by the physician in certifying his or her
36 recommendation. Nothing in this subdivision shall be construed
37 to require the plan to pay for the services of a nonparticipating
38 physician provided pursuant to this subdivision, that are not
39 otherwise covered pursuant to the plan contract.

1 (4) The enrollee has been denied coverage by the plan for a
2 drug, device, procedure, or other therapy recommended or
3 requested pursuant to paragraph (3).

4 (5) The specific drug, device, procedure, or other therapy
5 recommended pursuant to paragraph (3) would be a covered
6 service, except for the plan's determination that the therapy is
7 experimental or investigational.

8 (b) The plan's decision to delay, deny, or modify experimental
9 or investigational therapies shall be subject to the independent
10 medical review process under Article 5.55 (commencing with
11 Section 1374.30) except that, in lieu of the information specified
12 in subdivision (b) of Section 1374.33, an independent medical
13 reviewer shall base his or her determination on relevant medical
14 and scientific evidence, including, but not limited to, the medical
15 and scientific evidence defined in subdivision (d).

16 (c) The independent medical review process shall also meet the
17 following criteria:

18 (1) The plan shall notify eligible enrollees in writing of the
19 opportunity to request the external independent review within five
20 business days of the decision to deny coverage.

21 (2) If the enrollee's physician determines that the proposed
22 therapy would be significantly less effective if not promptly
23 initiated, the analyses and recommendations of the experts on the
24 panel shall be rendered within seven days of the request for
25 expedited review. At the request of the expert, the deadline shall
26 be extended by up to three days for a delay in providing the
27 documents required. The timeframes specified in this paragraph
28 shall be in addition to any otherwise applicable timeframes
29 contained in subdivision (c) of Section 1374.33.

30 (3) Each expert's analysis and recommendation shall be in
31 written form and state the reasons the requested therapy is or is
32 not likely to be more beneficial for the enrollee than any available
33 standard therapy, and the reasons that the expert recommends that
34 the therapy should or should not be provided by the plan, citing
35 the enrollee's specific medical condition, the relevant documents
36 provided, and the relevant medical and scientific evidence,
37 including, but not limited to, the medical and scientific evidence
38 as defined in subdivision (d), to support the expert's
39 recommendation.

1 (4) Coverage for the services required under this section shall
2 be provided subject to the terms and conditions generally applicable
3 to other benefits under the plan contract.

4 (d) For the purposes of subdivision (b), “medical and scientific
5 evidence” means the following sources:

6 (1) Peer-reviewed scientific studies published in or accepted
7 for publication by medical journals that meet nationally recognized
8 requirements for scientific manuscripts and that submit most of
9 their published articles for review by experts who are not part of
10 the editorial staff.

11 (2) Peer-reviewed literature, biomedical compendia, and other
12 medical literature that meet the criteria of the National Institutes
13 of Health’s National Library of Medicine for indexing in Index
14 Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS
15 data base Health Services Technology Assessment Research
16 (HSTAR).

17 (3) Medical journals recognized by the Secretary of Health and
18 Human Services, under Section 1861(t)(2) of the Social Security
19 Act.

20 ~~(4) The following standard reference compendia: The American
21 Hospital Formulary Service Drug Information, the American
22 Medical Association Drug Evaluation, the American Dental
23 Association Accepted Dental Therapeutics, the United States
24 Pharmacopocia Drug Information, or any other similar drug
25 compendium, as determined annually by the State Department of
26 Health Care Services on the basis of factors, including, but not
27 limited to, the breadth of listings, use of prespecified published
28 criteria for weighing evidence, and inclusion on a list of compendia~~

29 ~~(4) A compendia approved by the federal Centers for Medicare
30 and Medicaid Services.~~

31 (5) Findings, studies, or research conducted by or under the
32 auspices of federal government agencies and nationally recognized
33 federal research institutes, including the Federal Agency for Health
34 Care Policy and Research, National Institutes of Health, National
35 Cancer Institute, National Academy of Sciences, Health Care
36 Financing Administration, Congressional Office of Technology
37 Assessment, and any national board recognized by the National
38 Institutes of Health for the purpose of evaluating the medical value
39 of health services.

1 (6) Peer-reviewed abstracts accepted for presentation at major
2 medical association meetings.

3 (e) The independent review process established by this section
4 shall be required on and after January 1, 2001.

5 SEC. 7. Section 11014 of the Health and Safety Code is
6 amended to read:

7 11014. "Drug" means (a) substances recognized as drugs in
8 ~~the official United States Pharmacopoeia, official Homeopathic~~
9 ~~Pharmacopoeia of the United States, official National Formulary,~~
10 ~~any supplement to any of them, or any other similar drug~~
11 ~~compendium, as determined annually by the State Department of~~
12 ~~Health Care Services on the basis of factors, including, but not~~
13 ~~limited to, the breadth of listings, use of prespecified published~~
14 ~~criteria for weighing evidence, and inclusion on a list of compendia~~
15 *a compendia* approved by the federal Centers for Medicare and
16 Medicaid Services; (b) substances intended for use in the diagnosis,
17 cure, mitigation, treatment, or prevention of disease in man or
18 animals; (c) substances (other than food) intended to affect the
19 structure or any function of the body of man or animals; and (d)
20 substances intended for use as a component of any article specified
21 in subdivision (a), (b), or (c) of this section. It does not include
22 devices or their components, parts, or accessories.

23 SEC. 8. Section 109920 of the Health and Safety Code is
24 amended to read:

25 109920. "Device" means any instrument, apparatus, implement,
26 machine, contrivance, implant, in vitro reagent, or other similar
27 or related article, including any component, part, or accessory, that
28 is any of the following:

29 ~~(a) Recognized in the official National Formulary, the United~~
30 ~~States Pharmacopoeia, any supplement to them, or any other similar~~
31 ~~drug compendium, as determined annually by the State Department~~
32 ~~of Health Care Services on the basis of factors, including, but not~~
33 ~~limited to, the breadth of listings, use of prespecified published~~
34 ~~criteria for weighing evidence, and inclusion on a list of compendia~~

35 *(a) Recognized in a compendia or supplement thereof* approved
36 by the federal Centers for Medicare and Medicaid Services.

37 *(b) Intended for use in the diagnosis of disease or other*
38 *condition, or in the cure, mitigation, treatment, or prevention of*
39 *disease in humans or any other animal.*

1 (c) Intended to affect the structure or any function of the body
2 of humans or any other animal and that does not achieve any of
3 its principal intended purposes through chemical action within or
4 on the body of humans or other animals and that is not dependent
5 upon being metabolized for the achievement of any of its principal
6 intended purposes.

7 SEC. 9. Section 109985 of the Health and Safety Code is
8 amended to read:

9 109985. "~~Official compendium~~" means ~~the latest edition of~~
10 ~~the United States Pharmacopoeia, the latest edition of the~~
11 ~~Homeopathic Pharmacopoeia of the United States, or the latest~~
12 ~~edition of the National Formulary, any supplement to any of these,~~
13 ~~or any other similar drug compendium, as determined annually by~~
14 ~~the State Department of Health Care Services on the basis of~~
15 ~~factors, including, but not limited to, the breadth of listings, use~~
16 ~~of prespecified published criteria for weighing evidence, and~~
17 ~~inclusion on a list of compendia a compendia or supplement thereof~~
18 approved by the federal Centers for Medicare and Medicaid
19 Services.

20 SEC. 10. Section 111225 of the Health and Safety Code is
21 amended to read:

22 111225. As used in this chapter, with respect to a drug or drug
23 ingredient, "established name" means either of the following:

24 (a) The name designated pursuant to Section 508 of the federal
25 act (21 U.S.C. Sec. 358).

26 (b) If there is no ~~such~~ *designated* name and the drug or
27 ingredient is an article recognized in ~~an official compendium a~~
28 ~~compendia approved by the federal Centers for Medicare and~~
29 ~~Medicaid Services, then the official title in the compendium~~
30 ~~compendia~~ is the established name.

31 If neither subdivision (a) or (b) of this section applies, the
32 common or usual name, if any, of the drug or of the ingredient is
33 the established name. When an article is recognized in ~~the United~~
34 ~~States Pharmacopoeia a compendia approved by the federal~~
35 ~~Centers for Medicare and Medicaid Services and in the~~
36 Homeopathic Pharmacopoeia under different official titles, the
37 official title used in ~~the United States Pharmacopoeia approved~~
38 ~~compendia~~ shall apply unless it is labeled and offered for sale as
39 a homeopathic drug. If it is labeled and offered for sale as a

1 homeopathic drug, the official title used in the Homeopathic
2 Pharmacopoeia shall apply.

3 *SEC. 11. Section 111235 of the Health and Safety Code is*
4 *amended to read:*

5 111235. Whenever a drug is recognized in both ~~the United~~
6 ~~States Pharmacopoeia a compendia approved by the federal~~
7 ~~Centers for Medicare and Medicaid Services~~ and the Homeopathic
8 Pharmacopoeia of the United States, it shall be subject to the
9 requirements of the ~~United States Pharmacopoeia approved~~
10 ~~compendia~~ unless it is labeled and offered for sale as a homeopathic
11 drug. If it is labeled and offered for sale as a homeopathic drug, it
12 shall be subject to the ~~provisions of the~~ Homeopathic
13 Pharmacopoeia of the United States and not to those of the ~~United~~
14 ~~States Pharmacopoeia approved compendia.~~

15 ~~SEC. 10:~~

16 *SEC. 12. Section 111656.4 of the Health and Safety Code is*
17 *amended to read:*

18 111656.4. Section 4051 of the Business and Professions Code
19 shall not prohibit a home medical device retail facility from selling
20 or dispensing prescription devices if the department finds that
21 sufficient qualified supervision is employed by the home medical
22 device retail facility to adequately safeguard and protect the public
23 health. Each person applying to the department for this exemption
24 shall meet the following requirements to obtain and maintain the
25 exemption:

26 (a) A licensed pharmacist or an exemptee who meets the
27 requirements set forth in paragraphs (1) to (5), inclusive, and whose
28 license of exemption is currently valid, shall be in charge of the
29 home medical device retail facility.

30 (1) He or she shall be a high school graduate or possess a general
31 education development equivalent.

32 (2) He or she shall have a minimum of one year of paid work
33 experience related to the distribution or dispensing of dangerous
34 drugs or dangerous devices.

35 (3) He or she shall complete a training program that addresses
36 each of the following subjects that are applicable to his or her
37 duties:

38 (A) Knowledge and understanding of state and federal laws
39 relating to the distribution of dangerous drugs and dangerous
40 devices.

1 (B) Knowledge and understanding of state and federal laws
2 relating the distribution of controlled substances.

3 (C) Knowledge and understanding of quality control systems.

4 (D) Knowledge and understanding of the standards relating to
5 the safe storage and handling of drugs in the United States
6 Pharmacopocia or any other similar drug compendium, as
7 determined annually by the State Department of Health Care
8 Services on the basis of factors, including, but not limited to, the
9 breadth of listings, use of prespecified published criteria for
10 weighing evidence, and inclusion on a list of compendia of drugs
11 in a compendia approved by the federal Centers for Medicare and
12 Medicaid Services.

13 (E) Knowledge and understanding relating to the safe storage
14 and handling of home medical devices.

15 (F) Knowledge and understanding of prescription terminology,
16 abbreviations, and format.

17 (4) The department may, by regulation, require training
18 programs that include additional material.

19 (5) The department shall not issue an exemptee a license until
20 the applicant provides proof of completion of the required training
21 that the department determines is adequate to fulfill these
22 requirements.

23 (b) The licensed pharmacist or exemptee shall be on the premises
24 at all times that prescription devices are available for sale or fitting
25 unless the prescription devices are stored separately from other
26 merchandise and are under the exclusive control of the licensed
27 pharmacist or exemptee. A licensed pharmacist or an exemptee
28 need not be present in the warehouse facility of a home medical
29 device retail facility unless the department establishes that
30 requirement by regulation based upon the need to protect the
31 public.

32 (c) The department may require an exemptee to complete a
33 designated number of hours of coursework in department-approved
34 courses of home health education in the disposition of any
35 disciplinary action taken against the exemptee.

36 (d) Each premises maintained by a home medical device retail
37 facility shall have a license issued by the department and shall
38 have a licensed pharmacist or exemptee on the premises if
39 prescription devices are furnished, sold, or dispensed.

1 (e) A home medical device retail facility may establish locked
2 storage (a lock box or locked area) for emergency or after working
3 hours furnishing of prescription devices. Locked storage may be
4 installed or placed in a service vehicle of the home medical device
5 retail facility for emergency or after hours service to patients having
6 prescriptions for prescription devices.

7 (f) The department may by regulation authorize a licensed
8 pharmacist or exemptee to direct an employee of the home medical
9 device retail facility who operates the service vehicle equipped
10 with locked storage described in subdivision (e) to deliver a
11 prescription device from the locked storage to patients having
12 prescriptions for prescription devices. These regulations shall
13 establish inventory requirements for the locked storage by a
14 licensed pharmacist or exemptee to take place shortly after a
15 prescription device has been delivered from the locked storage to
16 a patient.

17 ~~SEC. 11.~~

18 *SEC. 13.* Section 150204 of the Health and Safety Code is
19 amended to read:

20 150204. (a) A county may establish, by ordinance, a repository
21 and distribution program for purposes of this division. Only
22 pharmacies that are county-owned or that contract with the county
23 pursuant to this division may participate in this program to dispense
24 medication donated to the drug repository and distribution program.

25 (b) A county that elects to establish a repository and distribution
26 program pursuant to this division shall establish procedures for,
27 at a minimum, all of the following:

28 (1) Establishing eligibility for medically indigent patients who
29 may participate in the program.

30 (2) Ensuring that patients eligible for the program shall not be
31 charged for any medications provided under the program.

32 (3) Developing a formulary of medications appropriate for the
33 repository and distribution program.

34 (4) Ensuring proper safety and management of any medications
35 collected by and maintained under the authority of a county-owned
36 or county-contracted, licensed pharmacy.

37 (5) Ensuring the privacy of individuals for whom the medication
38 was originally prescribed.

39 (c) Any medication donated to the repository and distribution
40 program shall comply with the requirements specified in this

1 division. Medication donated to the repository and distribution
2 program shall meet all of the following criteria:

3 (1) The medication shall not be a controlled substance.
4 (2) The medication shall not have been adulterated, misbranded,
5 or stored under conditions contrary to standards set by the United
6 States Pharmacopocia (USP) or in any other similar drug
7 compendium, as determined annually by the State Department of
8 Health Care Services on the basis of factors, including, but not
9 limited to, the breadth of listings, use of prespecified published
10 criteria for weighing evidence, and inclusion on a list of compendia
11 *a compendia* approved by the federal Centers for Medicare and
12 Medicaid Services or the product manufacturer.

13 (3) The medication shall not have been in the possession of a
14 patient or any individual member of the public, and in the case of
15 medications donated by a skilled nursing facility, shall have been
16 under the control of staff of the skilled nursing facility.

17 (d) Only medication that is donated in unopened, tamper-evident
18 packaging or modified unit dose containers that meet standards in
19 the USP or in any other similar drug compendium, as determined
20 annually by the State Department of Health Care Services on the
21 basis of factors, including, but not limited to, the breadth of listings,
22 use of prespecified published criteria for weighing evidence, and
23 inclusion on a list of compendia approved standards in a
24 *compendia approved* by the federal Centers for Medicare and
25 Medicaid Services is eligible for donation to the repository and
26 distribution program, provided lot numbers and expiration dates
27 are affixed. Medication donated in opened containers shall not be
28 dispensed by the repository and distribution program.

29 (e) A pharmacist shall use his or her professional judgment in
30 determining whether donated medication meets the standards of
31 this division before accepting or dispensing any medication under
32 the repository and distribution program.

33 (f) A pharmacist shall adhere to standard pharmacy practices,
34 as required by state and federal law, when dispensing all
35 medications.

36 (g) Medication that is donated to the repository and distribution
37 program shall be handled in any of the following ways:

- 38 (1) Dispensed to an eligible patient.
39 (2) Destroyed.
40 (3) Returned to a reverse distributor.

1 (h) Medication that is donated to the repository and distribution
2 program that does not meet the requirements of this division shall
3 not be distributed under this program and shall be either destroyed
4 or returned to a reverse distributor. This medication shall not be
5 sold, dispensed, or otherwise transferred to any other entity.

6 (i) Medication donated to the repository and distribution program
7 shall be maintained in the donated packaging units until dispensed
8 to an eligible patient under this program, who presents a valid
9 prescription. When dispensed to an eligible patient under this
10 program, the medication shall be in a new and properly labeled
11 container, specific to the eligible patient and ensuring the privacy
12 of the individuals for whom the medication was initially dispensed.
13 Expired medication shall not be dispensed.

14 (j) Medication donated to the repository and distribution program
15 shall be segregated from the pharmacy's other drug stock by
16 physical means, for purposes including, but not limited to,
17 inventory, accounting, and inspection.

18 (k) The pharmacy shall keep complete records of the acquisition
19 and disposition of medication donated to and dispensed under the
20 repository and distribution program. These records shall be kept
21 separate from the pharmacy's other acquisition and disposition
22 records and shall conform to the Pharmacy Law (Chapter 9
23 commencing with Section 4000) of Division 2 of the Business
24 and Professions Code), including being readily retrievable.

25 (l) Local and county protocols established pursuant to this
26 division shall conform to the Pharmacy Law regarding packaging,
27 transporting, storing, and dispensing all medications.

28 (m) County protocols established for packaging, transporting,
29 storing, and dispensing medications that require refrigeration,
30 including, but not limited to, any biological product as defined in
31 Section 351 of the Public Health and Service Act (42 U.S.C. Sec.
32 262), an intravenously injected drug, or an infused drug, include
33 specific procedures to ensure that these medications are packaged,
34 transported, stored, and dispensed at their appropriate temperatures
35 and in accordance with ~~DrugPoint standards~~ *standards in a*
36 *compendia approved by the federal Centers for Medicare and*
37 *Medicaid Services* and the Pharmacy Law.

38 (n) Notwithstanding any other provision of law, a participating
39 county-owned or county-contracted pharmacy shall follow the
40 same procedural drug pedigree requirements for donated drugs as

1 it would follow for drugs purchased from a wholesaler or directly
2 from a drug manufacturer.

3 ~~SEC. 12.~~

4 ~~SEC. 14.~~ Section 10123.195 of the Insurance Code is amended
5 to read:

6 10123.195. (a) No group or individual disability insurance
7 policy issued, delivered, or renewed in this state or certificate of
8 group disability insurance issued, delivered, or renewed in this
9 state pursuant to a master group policy issued, delivered, or
10 renewed in another state that, as a provision of hospital, medical,
11 or surgical services, directly or indirectly covers prescription drugs
12 shall limit or exclude coverage for a drug on the basis that the drug
13 is prescribed for a use that is different from the use for which that
14 drug has been approved for marketing by the federal Food and
15 Drug Administration (FDA), provided that all of the following
16 conditions have been met:

17 (1) The drug is approved by the FDA.

18 (2) (A) The drug is prescribed by a contracting licensed health
19 care professional for the treatment of a life-threatening condition;
20 or

21 (B) The drug is prescribed by a contracting licensed health care
22 professional for the treatment of a chronic and seriously debilitating
23 condition, the drug is medically necessary to treat that condition,
24 and the drug is on the insurer's formulary, if any.

25 (3) The drug has been recognized for treatment of that condition
26 by ~~one~~ *either* of the following:

27 ~~(A) The American Medical Association Drug Evaluations.~~

28 ~~(B) The American Hospital Formulary Service Drug~~
29 ~~Information.~~

30 ~~(C) The United States Pharmacopoeia Dispensing Information,~~
31 ~~Volume 1, "Drug Information for the Health Care Professional"²²~~
32 ~~or any other similar drug compendium, as determined annually by~~
33 ~~the State Department of Health Care Services on the basis of~~
34 ~~factors, including, but not limited to, the breadth of listings, use~~
35 ~~of prespecified published criteria for weighing evidence, and~~
36 ~~inclusion on a list of compendia approved~~

37 ~~(A) A compendia approved by the federal Centers for Medicare~~
38 ~~and Medicaid Services.~~

39 ~~(D)~~

- 1 (B) Two articles from major peer reviewed medical journals
2 that present data supporting the proposed off-label use or uses as
3 generally safe and effective unless there is clear and convincing
4 contradictory evidence presented in a major peer reviewed medical
5 journal.
- 6 (b) It shall be the responsibility of the contracting prescriber to
7 submit to the insurer documentation supporting compliance with
8 the requirements of subdivision (a), if requested by the insurer.
- 9 (c) Any coverage required by this section shall also include
10 medically necessary services associated with the administration
11 of a drug subject to the conditions of the contract.
- 12 (d) For purposes of this section, "life-threatening" means either
13 or both of the following:
- 14 (1) Diseases or conditions where the likelihood of death is high
15 unless the course of the disease is interrupted.
- 16 (2) Diseases or conditions with potentially fatal outcomes, where
17 the end point of clinical intervention is survival.
- 18 (e) For purposes of this section, "chronic and seriously
19 debilitating" means diseases or conditions that require ongoing
20 treatment to maintain remission or prevent deterioration and cause
21 significant long-term morbidity.
- 22 (f) The provision of drugs and services when required by this
23 section shall not, in itself, give rise to liability on the part of the
24 insurer.
- 25 (g) This section shall not apply to a policy of disability insurance
26 that covers hospital, medical, or surgical expenses which is issued
27 outside of California to an employer whose principal place of
28 business is located outside of California.
- 29 (h) Nothing in this section shall be construed to prohibit the use
30 of a formulary, copayment, technology assessment panel, or similar
31 mechanism as a means for appropriately controlling the utilization
32 of a drug that is prescribed for a use that is different from the use
33 for which that drug has been approved for marketing by the FDA.
- 34 (i) If an insurer denies coverage pursuant to this section on the
35 basis that its use is experimental or investigational, that decision
36 is subject to review under the Independent Medical Review System
37 of Article 3.5 (commencing with Section 10169).
- 38 (j) This section is not applicable to vision-only, dental-only,
39 Medicare or Champus supplement, disability income, long-term

1 care, accident-only, specified disease or hospital confinement
2 indemnity insurance.

3 ~~SEC. 13.~~

4 *SEC. 15.* Section 10145.3 of the Insurance Code is amended
5 to read:

6 10145.3. (a) Every disability insurer that covers hospital,
7 medical, or surgical benefits shall provide an external, independent
8 review process to examine the insurer's coverage decisions
9 regarding experimental or investigational therapies for individual
10 insureds who meet all of the following criteria:

11 (1) (A) The insured has a life-threatening or seriously
12 debilitating condition.

13 (B) For purposes of this section, "life-threatening" means either
14 or both of the following:

15 (i) Diseases or conditions where the likelihood of death is high
16 unless the course of the disease is interrupted.

17 (ii) Diseases or conditions with potentially fatal outcomes, where
18 the end point of clinical intervention is survival.

19 (C) For purposes of this section, "seriously debilitating" means
20 diseases or conditions that cause major irreversible morbidity.

21 (2) The insured's physician certifies that the insured has a
22 condition, as defined in paragraph (1), for which standard therapies
23 have not been effective in improving the condition of the insured,
24 for which standard therapies would not be medically appropriate
25 for the insured, or for which there is no more beneficial standard
26 therapy covered by the insurer than the therapy proposed pursuant
27 to paragraph (3).

28 (3) Either (A) the insured's contracting physician has
29 recommended a drug, device, procedure, or other therapy that the
30 physician certifies in writing is likely to be more beneficial to the
31 insured than any available standard therapies, or (B) the insured,
32 or the insured's physician who is a licensed, board-certified or
33 board-eligible physician qualified to practice in the area of practice
34 appropriate to treat the insured's condition, has requested a therapy
35 that, based on two documents from the medical and scientific
36 evidence, as defined in subdivision (d), is likely to be more
37 beneficial for the insured than any available standard therapy. The
38 physician certification pursuant to this subdivision shall include a
39 statement of the evidence relied upon by the physician in certifying
40 his or her recommendation. Nothing in this subdivision shall be

1 construed to require the insurer to pay for the services of a
2 noncontracting physician, provided pursuant to this subdivision,
3 that are not otherwise covered pursuant to the contract.

4 (4) The insured has been denied coverage by the insurer for a
5 drug, device, procedure, or other therapy recommended or
6 requested pursuant to paragraph (3), unless coverage for the
7 specific therapy has been excluded by the insurer's contract.

8 (5) The specific drug, device, procedure, or other therapy
9 recommended pursuant to paragraph (3) would be a covered service
10 except for the insurer's determination that the therapy is
11 experimental or under investigation.

12 (b) The insurer's decision to deny, delay, or modify experimental
13 or investigational therapies shall be subject to the independent
14 medical review process established under Article 3.5 (commencing
15 with Section 10169) of Chapter 1 of Part 2 of Division 2, except
16 that in lieu of the information specified in subdivision (b) of
17 Section 10169.3, an independent medical reviewer shall base his
18 or her determination on relevant medical and scientific evidence,
19 including, but not limited to, the medical and scientific evidence
20 defined in subdivision (d).

21 (c) The independent medical review process shall also meet the
22 following criteria:

23 (1) The insurer shall notify eligible insureds in writing of the
24 opportunity to request the external independent review within five
25 business days of the decision to deny coverage.

26 (2) If the insured's physician determines that the proposed
27 therapy would be significantly less effective if not promptly
28 initiated, the analyses and recommendations of the experts on the
29 panel shall be rendered within seven days of the request for
30 expedited review. At the request of the expert, the deadline shall
31 be extended by up to three days for a delay in providing the
32 documents required. The timeframes specified in this paragraph
33 shall be in addition to any otherwise applicable timeframes
34 contained in subdivision (c) of Section 10169.3.

35 (3) Each expert's analysis and recommendation shall be in
36 written form and state the reasons the requested therapy is or is
37 not likely to be more beneficial for the insured than any available
38 standard therapy, and the reasons that the expert recommends that
39 the therapy should or should not be covered by the insurer, citing
40 the insured's specific medical condition, the relevant documents,

1 and the relevant medical and scientific evidence, including, but
2 not limited to, the medical and scientific evidence as defined in
3 subdivision (d), to support the expert's recommendation.

4 (4) Coverage for the services required under this section shall
5 be provided subject to the terms and conditions generally applicable
6 to other benefits under the contract.

7 (d) For the purposes of subdivision (b), "medical and scientific
8 evidence" means the following sources:

9 (1) Peer-reviewed scientific studies published in or accepted
10 for publication by medical journals that meet nationally recognized
11 requirements for scientific manuscripts and that submit most of
12 their published articles for review by experts who are not part of
13 the editorial staff.

14 (2) Peer-reviewed literature, biomedical compendia and other
15 medical literature that meet the criteria of the National Institutes
16 of Health's National Library of Medicine for indexing in Index
17 Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS
18 data base Health Services Technology Assessment Research
19 (HSTAR).

20 (3) Medical journals recognized by the Secretary of Health and
21 Human Services, under Section 1861(t)(2) of the Social Security
22 Act.

23 ~~(4) The following standard reference compendia: The American
24 Hospital Formulary Service Drug Information, the American
25 Medical Association Drug Evaluation, the American Dental
26 Association Accepted Dental Therapeutics, the United States
27 Pharmacopocia Drug Information, or any other similar drug
28 compendium, as determined annually by the State Department of
29 Health Care Services on the basis of factors, including, but not
30 limited to, the breadth of listings, use of prespecified published
31 criteria for weighing evidence, and inclusion on a list of compendia~~

32 ~~(4) A compendia approved by the federal Centers for Medicare
33 and Medicaid Services.~~

34 (5) Findings, studies, or research conducted by or under the
35 auspices of federal government agencies and nationally recognized
36 federal research institutes, including the Federal Agency for Health
37 Care Policy and Research, National Institutes of Health, National
38 Cancer Institute, National Academy of Sciences, Health Care
39 Financing Administration, Congressional Office of Technology
40 Assessment, and any national board recognized by the National

1 Institutes of Health for the purpose of evaluating the medical value
2 of health services.

3 (6) Peer-reviewed abstracts accepted for presentation at major
4 medical association meetings.

5 (e) The independent review process established by this section
6 shall be required on and after January 1, 2001.

7 *SEC. 16. Section 383 of the Penal Code is amended to read:*

8 383. Every person who knowingly sells, or keeps or offers for
9 sale, or otherwise disposes of any article of food, drink, drug, or
10 medicine, knowing that the same is adulterated or has become
11 tainted, decayed, spoiled, or otherwise unwholesome or unfit to
12 be eaten or drunk, with intent to permit the same to be eaten or
13 drunk, is guilty of a misdemeanor, and must be fined not exceeding
14 one thousand dollars (\$1,000), or imprisoned in the county jail not
15 exceeding six months, or both, and may, in the discretion of the
16 court, be adjudged to pay, in addition, all the necessary expenses,
17 not exceeding one thousand dollars (\$1,000), incurred in inspecting
18 and analyzing ~~such~~ *these* articles. The term "drug," as used herein,
19 includes all medicines for internal or external use, antiseptics,
20 disinfectants, and cosmetics. The term "food," as used herein,
21 includes all articles used for food or drink by man, whether simple,
22 mixed, or compound. Any article is deemed to be adulterated within
23 the meaning of this section:

24 (a) In case of drugs: (1) if, when sold under or by a name
25 recognized in ~~the United States Pharmacopoeia~~ *a compendia*
26 *approved by the federal Centers of Medicare and Medicaid*
27 *Services*, it differs materially from the standard of strength, quality,
28 or purity laid down therein; (2) if, when sold under or by a name
29 not recognized in ~~the United States Pharmacopoeia~~ *a compendia*
30 *approved by the federal Centers of Medicare and Medicaid*
31 *Services*, but which is found in some other pharmacopoeia or other
32 standard work on materia medica, it differs materially from the
33 standard of strength, quality, or purity laid down in such work;
34 (3) if its strength, quality, or purity falls below the professed
35 standard under which it is sold.

36 (b) In the case of food: (1) if any substance or substances have
37 been mixed with it, so as to lower or depreciate, or injuriously
38 affect its quality, strength, or purity; (2) if any inferior or cheaper
39 substance or substances have been substituted wholly or in part
40 for it; (3) if any valuable or necessary constituent or ingredient

1 has been wholly or in part abstracted from it; (4) if it is an
2 imitation of, or is sold under the name of, another article; (5) if it
3 consists wholly, or in part, of a diseased, decomposed, putrid,
4 infected, tainted, or rotten animal or vegetable substance or article,
5 whether manufactured or not; or in the case of milk, if it is the
6 produce of a diseased animal; (6) if it is colored, coated, polished,
7 or powdered, whereby damage or inferiority is concealed, or if by
8 any means it is made to appear better or of greater value than it
9 really is; (7) if it contains any added substance or ingredient which
10 is poisonous or injurious to health.

11 ~~SEC. 14.~~

12 *SEC. 17.* Section 47121 of the Public Resources Code is
13 amended to read:

14 47121. For the purposes of this article, the following terms
15 have the following meanings, unless the context clearly requires
16 otherwise:

17 (a) "Consumer" means an individual purchaser or owner of a
18 drug. "Consumer" does not include a business, corporation, limited
19 partnership, or an entity involved in a wholesale transaction
20 between a distributor and retailer.

21 (b) "Drug" means any of the following:

22 ~~(1) Articles recognized in the official United States~~
23 ~~Pharmacopocia, the official National Formulary, the official~~
24 ~~Homeopathic Pharmacopocia of the United States, any supplement~~
25 ~~of the formulary or those pharmacopocias, or any other similar~~
26 ~~drug compendium, as determined annually by the State Department~~
27 ~~of Health Care Services on the basis of factors, including, but not~~
28 ~~limited to, the breadth of listings, use of prespecified published~~
29 ~~criteria for weighing evidence, and inclusion on a list of compendia~~
30 ~~approved by the federal Centers for~~

31 *(1) Articles recognized in a compendia or supplement thereof*
32 *approved by the federal Centers for Medicare and Medicaid*
33 *Services.*

34 (2) Articles intended for use in the diagnosis, cure, mitigation,
35 treatment, or prevention of disease in humans or other animals.

36 (3) Articles, excluding food, intended to affect the structure or
37 function of the body of humans or other animals.

38 (4) Articles intended for use as a component of an article
39 specified in paragraph (1), (2), or (3).

1 (c) "Participant" means any entity which the board deems
 2 appropriate for implementing and evaluating a model program and
 3 which chooses to participate, including, but not limited to,
 4 governmental entities, pharmacies, veterinarians, clinics, and other
 5 medical settings.

6 (d) "Sale" includes, but is not limited to, transactions conducted
 7 through sales outlets, catalogs, or the Internet, or any other similar
 8 electronic means, but does not include a sale that is a wholesale
 9 transaction with a distributor or retailer.

10 ~~SEC. 15.~~

11 *SEC. 18.* Section 14105.43 of the Welfare and Institutions
 12 Code is amended to read:

13 14105.43. (a) (1) Notwithstanding other provisions of this
 14 chapter, any drug which is approved by the federal Food and Drug
 15 Administration for use in the treatment of acquired
 16 immunodeficiency syndrome (AIDS) or an AIDS-related condition
 17 shall be deemed to be approved for addition to the Medi-Cal list
 18 of contract drugs only for the purpose of treating AIDS or an
 19 AIDS-related condition, for the period prior to the completion of
 20 the procedures established pursuant to Section 14105.33.

21 (2) (A) In addition to any drug that is deemed to be approved
 22 pursuant to paragraph (1), any drug that meets any of the following
 23 criteria shall be a Medi-Cal benefit, subject to utilization controls:

24 (i) Any vaccine to protect against human immunodeficiency
 25 virus (HIV) infection.

26 (ii) Any antiviral agent, immune modulator, or other agent to
 27 be administered to persons who have been infected with human
 28 immunodeficiency virus to counteract the effects of that infection.

29 (iii) Any drug or biologic used to treat opportunistic infections
 30 associated with acquired immune deficiency syndrome, that have
 31 been found to be medically accepted indications and that has either
 32 been approved by the federal Food and Drug Administration or
 33 recognized for that use in ~~one~~ *either* of the following:

34 ~~(I) The American Medical Association Drug Evaluations.~~

35 ~~(II) The United States Pharmacopoeia Dispensing Information~~
 36 ~~or any other similar drug compendium, as determined annually by~~
 37 ~~the State Department of Health Care Services on the basis of~~
 38 ~~factors, including, but not limited to, the breadth of listings, use~~
 39 ~~of prespecified published criteria for weighing evidence, and~~
 40 ~~inclusion on a list of compendia approved by the federal Centers~~

1 (I) A compendia approved by the federal Centers for Medicare
2 and Medicaid Services.

3 (H)

4 (II) Two articles from peer reviewed medical journals that
5 present data supporting the proposed use or uses as generally safe
6 and effective.

7 (iv) Any drug or biologic used to treat the chemotherapy-induced
8 suppression of the human immune system resulting from the
9 treatment of acquired immune deficiency syndrome.

10 (3) The department shall add any drug deemed to be approved
11 pursuant to paragraph (1) to the Medi-Cal list of contract drugs or
12 allow the provision of the drug as a Medi-Cal benefit, subject to
13 utilization controls, pursuant to paragraph (2), only if the
14 manufacturer of the drug has executed a contract with the Centers
15 for Medicare and Medicaid Services which provides for rebates
16 in accordance with Section 1396r-8 of Title 42 of the United States
17 Code.

18 (b) Any drug deemed to be approved pursuant to paragraph (1)
19 of subdivision (a) shall be immediately added to the Medi-Cal list
20 of contract drugs, and shall be exempt from the contract
21 requirements of Section 14105.33.

22 (c) If it is determined pursuant to subdivision (c) of Section
23 14105.39 that a drug to which subdivision (a) applies should not
24 be placed on the Medi-Cal list of contract drugs, that drug shall
25 no longer be deemed to be approved for addition to the list of
26 contract drugs pursuant to subdivision (a).

27 ~~SEC. 16.~~

28 *SEC. 19.* Section 14133.2 of the Welfare and Institutions Code
29 is amended to read:

30 14133.2. (a) The director shall include in the Medi-Cal list of
31 contract drugs any drug approved for the treatment of cancer by
32 the federal Food and Drug Administration, so long as the
33 manufacturer has executed a contract with the Health Care
34 Financing Administration which provides for rebates in accordance
35 with Section 1396r-8 of Title 42 of the United States Code. These
36 drugs shall be exempt from the contract requirements of Section
37 14105.33.

38 (b) In addition to any drug added to the list of contract drugs
39 pursuant to subdivision (a), any drug that meets either of the
40 following criteria and for which the manufacturer has executed a

1 contract with the Health Care Financing Administration that
2 provides for rebates in accordance with Section 1396r-8 of Title
3 42 of the United States Code, shall be a Medi-Cal benefit, subject
4 to utilization controls, unless the contract requirements of Section
5 14105.33 have been complied with:

6 (1) Any drug approved by the federal Food and Drug
7 Administration for treatment of opportunistic infections associated
8 with cancer.

9 (2) Any drug or biologic used in an anticancer chemotherapeutic
10 regimen for a medically accepted indication, which has either been
11 approved by the federal Food and Drug Administration, or
12 recognized for that use in *one either* of the following:

13 ~~(A) The American Medical Association Drug Evaluations.~~

14 ~~(B) The United States Pharmacopoeia Dispensing Information~~
15 ~~or any other similar drug compendium, as determined annually by~~
16 ~~the State Department of Health Care Services on the basis of~~
17 ~~factors, including, but not limited to, the breadth of listings, use~~
18 ~~of prespecified published criteria for weighing evidence, and~~
19 ~~inclusion on a list of compendia approved by the federal Centers~~

20 (A) *A compendia approved by the federal Centers for Medicare*
21 *and Medicaid Services.*

22 ~~(C)~~

23 (B) Two articles from peer reviewed medical journals that
24 present data supporting the proposed use or uses as generally safe
25 and effective.

26 *SEC. 20. No reimbursement is required by this act pursuant*
27 *to Section 6 of Article XIII B of the California Constitution because*
28 *the only costs that may be incurred by a local agency or school*
29 *district will be incurred because this act creates a new crime or*
30 *infraction, eliminates a crime or infraction, or changes the penalty*
31 *for a crime or infraction, within the meaning of Section 17556 of*
32 *the Government Code, or changes the definition of a crime within*
33 *the meaning of Section 6 of Article XIII B of the California*
34 *Constitution.*

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 877

VERSION: As amended: April 14, 2009

AUTHOR: Emmerson

SPONSOR: Author Sponsored

BOARD POSITION: None

SUBJECT: Healing Arts: Scope of Practice: Committee

EXISTING LAW:

Provides for the licensure and regulation of various healing arts practitioners by boards, as well as bureaus within the Department of Consumer Affairs.

THIS BILL WOULD:

1. State that it is the intent of the Legislature to enact legislation that would authorize the Director of Consumer Affairs to appoint a committee to perform occupational analyses on various healing arts practices, including education, training, and experience. It would require a written report on any bill introduced that seeks to expand the scope of a healing arts practice.
2. State that it is the intent of the Legislature that the committee be comprised of ~~seven~~ five members and ~~specifies the committee composition:~~ two academics representing each side of the scope of practice issue; one practitioner representing each side of the issue; and one public member.
3. Require the appropriate legislative committee to provide any bill expanding the scope of practice to the committee to review.
4. Require the committee to prepare a written report within 90 days of receipt of the bill.
5. Require the committee to evaluate the education, training and experience of all the healing arts practices that would be affected by the proposal, evaluation the quality and quantity of training provided with regard to the increased scope of practice, review other states that have scope of practice similar to the proposed change.
6. Specify that it is the intent of the Legislature that the cost of the occupational analyses and written reports be borne on the healing arts practice requesting the expanded scope of practice. Specify that the reasonable cost of an occupational analysis and written report shall be paid by the licensing for the healing arts practice that would be subject to the proposed expanded scope of practice.

AUTHOR'S INTENT:

The intent is to establish a committee as specified to perform an occupational analysis on proposed increased scope of work proposals.

FISCAL IMPACT:

As introduced the board did not anticipate and fiscal impact. However, as amended, the bill requires the board to pay the costs of the occupational analysis.

COMMENTS:

The board current completes an occupational analysis once every five years for pharmacists. This information is used to revise the content outline used to develop the pharmacist licensure exam.

On April 16, 2009, the Legislation and Regulation Committee discussed this proposal, including the intent of the Legislature to enact legislation authorizing the Department of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice. The committee composition was discussed, as well as the indication that the bill includes a provision that the cost will be born by the regulatory agency.

Following discussion, the committee did not recommend a position on this legislation.

SUPPORT/OPPOSITION:

None on file

HISTORY:

- Apr. 28. Hearing scheduled in ASM B & P
- Apr. 15 Re-referred to Com. on Business & Professions
- Apr. 14 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Apr. 13 Referred to Com. on B. & P.
- Feb. 27 From printer. May be heard in committee March 29.
- Feb. 26 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 14, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 877

Introduced by Assembly Member Emmerson

February 26, 2009

An act to *add Section 687 to the Business and Professions Code*, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 877, as amended, Emmerson. ~~Healing arts. arts: scope of practice.~~

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs and the department is under the control of the Director of Consumer Affairs.

~~This bill would declare the intent of the Legislature to enact legislation authorizing the Director of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice.~~

This bill would require the Director of Consumer Affairs to appoint a scope of practice committee of 5 members, as specified, to perform occupational analyses and prepare written reports, as specified, on any bills seeking to substantively expand the scope of a healing arts practice. The bill would require that the reasonable cost of an analysis and report be paid by the affected licensing board, as specified.

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. *It is the intent of the Legislature to provide a*
2 *procedure for objective review of proposed changes in the scope*
3 *of practice of health professionals licensed by the state in order*
4 *to ensure that the changes contribute to the improvement of the*
5 *overall health of the people of California.*

6 SEC. 2. *Section 687 is added to the Business and Professions*
7 *Code, to read:*

8 687. (a) (1) *The Director of Consumer Affairs shall appoint*
9 *a scope of practice committee to perform occupational analyses*
10 *and prepare written reports on any bills introduced in either house*
11 *of the Legislature that seek to substantively expand the scope of*
12 *practice of any person licensed under this division or under any*
13 *initiative act referred to in this division.*

14 (2) *The committee shall be comprised of five members as*
15 *follows:*

16 (A) *Two academics, one representing each side of the scope of*
17 *practice issue.*

18 (B) *Two practitioners, one representing each side of the scope*
19 *of practice issue.*

20 (C) *One public member.*

21 (b) *The Assembly Committee on Business and Professions or*
22 *the Senate Committee on Business, Professions and Economic*
23 *Development, upon notification of an introduced bill proposing*
24 *to substantively expand the scope of a healing arts practice, shall*
25 *provide the bill to the scope of practice committee for performance*
26 *of the occupational analysis pursuant to subdivision (a).*

27 (c) *The committee shall, within 90 days of receipt of the bill,*
28 *prepare a written report of its analysis pursuant to subdivision*
29 *(a). The written report shall do all of the following:*

30 (1) *Evaluate the education, training, and experience of all*
31 *healing arts practices that would be affected by the proposed*
32 *substantive expansion of the scope of practice.*

33 (2) *Evaluate the quality and quantity of the training provided*
34 *by the health care professional degree curricula and postgraduate*
35 *training programs to health care practitioners in active practice*
36 *with regard to the increased scope of practice proposed.*

37 (3) *Review other states that have a scope of practice for the*
38 *relevant healing arts practice that is identical or similar to the*

1 *proposed change and any available information on how that scope*
2 *of practice has affected the quality and cost of health care in those*
3 *states.*

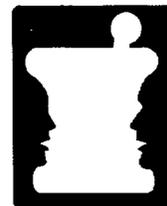
4 *(d) The reasonable cost of an occupational analysis and written*
5 *report shall be paid by the licensing board for the healing arts*
6 *practice that would be subject to the proposed expanded scope of*
7 *practice from funds made available to the board for that purpose.*

8 ~~SECTION 1. (a) It is the intent of the Legislature to enact~~
9 ~~legislation that would authorize the Director of Consumer Affairs~~
10 ~~to appoint a committee to perform occupational analyses on various~~
11 ~~healing arts practices, to include, but not be limited to, education,~~
12 ~~training, and experience, and to prepare a written report on any~~
13 ~~bill introduced in either house of the Legislature that seeks to~~
14 ~~expand the scope of a healing arts practice as described in Division~~
15 ~~2 of the Business and Professions Code.~~

16 ~~(b) It is the intent of the Legislature that the committee be~~
17 ~~comprised of seven members as follows: two academics~~
18 ~~representing each side of the scope of practice issue, one~~
19 ~~practitioner representing each side of the scope of practice issue,~~
20 ~~and one public member.~~

21 ~~(c) It is further the intent of the Legislature that the cost of the~~
22 ~~occupational analyses and the written reports be borne on the~~
23 ~~healing arts practice requesting the expanded scope of practice.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 931

VERSION: Amended March 26, 2009

AUTHOR: Fletcher

SPONSOR: California Pharmacists Association

BOARD POSITION:

SUBJECT: Emergency Supplies

EXISTING LAW

1. The California Department of Public Health (CDPH) licenses and regulates health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities. (Title 22 CCR and H&SC §1261.5)
2. Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the Board of Pharmacy and establishes requirements for the dispensing of dangerous drugs and dangerous devices. (B&PC Chapter 9, Division 2, Articles 1-24)
3. B&P Code §4119 authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container (emergency kit, or e-kit) maintained in a facility in accordance with CDPH regulations.
4. H&SC §1261.5 limits the number of doses of any one drug (currently 4 doses), and limits the total number of dangerous drugs or dangerous devices in an emergency kit to 24.

THIS BILL WOULD

1. Amend §1261.5 of the Health and Safety Code to increase the total number of oral and suppository drugs stored in an e kit at specified facilities to from 24 to 48.
2. The number of doses of any one drug in an e-kit will remain limited to 4.

AUTHOR'S INTENT

According to the sponsor, this bill would improve the quality of care for all patients in long term care facilities. Specifically, it would protect vulnerable populations like the elderly, patients who are rehabilitating from a major medical event, and those who reside in Long-Term Care Facilities in rural areas in the event of emergencies.

By increasing the number of medications in an e-kit, doctors can provide a wider scope of treatment available to patients in an emergency situation. This change will also bring government policy up to date with modern medicine, which has made significant

advancements in pharmaceutical treatments since the current limit was put in place fifteen years ago.

FISCAL IMPACT

The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS

Emergency kit medications are approved by a Pharmacy and Therapeutics Committee, which is comprised of a facility's director of nurses, the medical director and the consultant pharmacist. E-kits generally include pain medications, antibiotics, and anti-anxiety medications for other conditions producing patient discomfort. The e-kit provides the first dose, and is NOT meant to refill a prescription. After a first dose is provided, a new prescription would still need to be filled by a pharmacy. The medications can also be used to start medication orders for patients in a disaster situation, when drugs cannot be readily accessed by a pharmacy (for example during an earthquake or flood).

Increasing the number of drugs available does not modify the security measures that are currently in place and working. E-kits are monitored by a pharmacist. Once the lock has been broken on the e-kit, the entire contents must be accounted for and replaced by a pharmacist within 72 hours.

Following discussion on April 16, 2009, the Legislation and Regulation Committee did not recommend a position on this bill.

PROPOSERS

California Pharmacists Association

OPPOSITION

None of file.

HISTORY:

- Mar 27 Hearing Set for 05/05/09 in ASM Health
- Mar. 27 Re-referred to Com. on HEALTH.
- Mar. 26 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 26 Referred to Com. on HEALTH.
- Feb. 27 From printer. May be heard in committee March 29.
- Feb. 26 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 26, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 931

Introduced by Assembly Member Fletcher

February 26, 2009

An act to amend Section 1261.5 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 931, as amended, Fletcher. Emergency supplies.

Existing law provides for the licensing and regulation by the State Department of Public Health of health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities.

Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy and establishes requirements for the dispensing of drugs.

Existing law authorizes a pharmacy to furnish dangerous drugs or devices to a licensed health facility for storage in a secure emergency pharmaceutical supplies container that is maintained within the facility under regulations of the department. Existing law *limits the number of oral dosage form and suppository dosage form drugs for storage within this container to 24*. It also authorizes the department to limit the number of doses of each drug available to a skilled nursing facility or intermediate care facility to not more than 4 doses of any separate drug dosage form in each emergency supply.

This bill would increase the ~~authorized amount in an emergency supply to 6 doses~~ *storage container limit to 48*.

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 1261.5 of the Health and Safety Code is
2 amended to read:

3 1261.5. (a) The number of oral dosage form or suppository
4 form drugs provided by a pharmacy to a health facility licensed
5 pursuant to subdivision (c) or (d), or both (c) and (d), of Section
6 1250 for storage in a secured emergency supplies container,
7 pursuant to Section 4119 of the Business and Professions Code,
8 shall be limited to ~~24~~ 48. The State Department of Public Health
9 may limit the number of doses of each drug available to not more
10 than ~~six~~ four doses of any separate drug dosage form in ~~an~~ each
11 emergency supply.

12 (b) Any limitations established pursuant to subdivision (a) on
13 the number and quantity of oral dosage or suppository form drugs
14 provided by a pharmacy to a health facility licensed pursuant to
15 subdivision (c), (d), or both (c) and (d), of Section 1250 for storage
16 in a secured emergency supplies container shall not apply to an
17 automated drug delivery system, as defined in Section 1261.6,
18 when a pharmacist controls access to the drugs.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1310 **VERSION:** **As Amended April 2, 2009**

AUTHOR: Hernandez **SPONSOR:** **Author sponsored**

BOARD POSITION:

SUBJECT: **Healing Arts: Database**

EXISTING LAW:

Existing law defines the required information an applicant for licensure or renewal must provide.

THIS BILL WOULD:

Add section 857 to the Business and Professions Code to:

- A. Require all specified healing arts board to add and label "mandatory" the following fields on an application for initial licensure or renewal:
1. First, middle and last name
 2. Last four digits of social security number
 3. Complete mailing address
 4. Education training as specified
 5. Birth date and place of birth
 6. Sex
 7. Race and Ethnicity
 8. Location of high school
 9. Mailing address of primary practice, if applicable
 10. Number of hours per week spent at primary practice location, if applicable
 11. Description of practice setting, if applicable
 12. Primary practice information, including, but not limited to primary specialty practice, practice location, ZIP Code, and county
 13. Information regarding any additional practice, including, but not limited to, a description of practice setting, practice location ZIP Code and county.
- B. Require the board, in consultation with the Healthcare Workforce Development Division to select a database and in the information specified in items 5 through 13 above.
- C. Require the board to collect this information and submit it to Health Care Workforce Clearinghouse annually as specified
- D. Required the Health Care Workforce Clearinghouse to prepare a written report to the legislature as specified.

AUTHOR'S INTENT:

Staff continues to seek information related to this specific legislation and will update the committee as information is available.

FISCAL IMPACT:

The board will require funding for additional staff as well as funding to purchase a database. The board would require additional staff Office Technicians to collect and input specified data for all new and renewal applicants. However, if the department's I-Licensing system is available and can collect this information, we would only need minimal staff support, perhaps a quarter-time PY.

COMMENTS:

The board does not currently collect several of the required elements including worksite information, number of hours worked, as well as race and ethnicity. Some of the additional required elements are reported as part of the application, but are not collected in a database, rather just used to confirm compliance with licensure requirements.

The Legislation and Regulation committee discussed this bill on April 16, 2009. Dr. Schell sought clarification on whether it is intended that the bill will be revenue neutral. Assistant Executive Officer Anne Sodergren summarized the provisions of the bill and its anticipated impact on the board. The committee did not take a position on this bill.

SUPPORT/OPPOSITION:

None on file.

HISTORY:

- Apr. 14 From committee. Do pass and re-refer to Com. On APPR with recommendation: to consent calendar. Re-referred (Ayes 9, Noes 0)
- Apr. 2 Hearing set for 04/14/09 – ASM Business & Professions
- Apr. 2 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Mar. 31 Referred to Com. on B. & P.
- Mar. 2 Read first time.
- Mar. 1 From printer. May be heard in committee March 30.
- Feb. 27 Introduced. To print.

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1310

Introduced by Assembly Member Hernandez

February 27, 2009

An act to add Section 857 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1310, as amended, Hernandez. Healing arts: database.

Existing law provides for the licensure and regulation of various healing arts professions and vocations by boards within the Department of Consumer Affairs. Under existing law, there exists the Healthcare Workforce Development Division within the Office of Statewide Health Planning and Development (OSHPD) that supports health care accessibility through the promotion of a diverse and competent workforce and provides analysis of California's health care infrastructure. Under existing law, there is also the Health Care Workforce Clearinghouse, established by OSHPD, that serves as the central source for collection, analysis, and distribution of information on the health care workforce employment and educational data trends for the state.

This bill would require ~~the department~~ *specified healing arts boards* to add and label as "mandatory" specified fields on an application for initial licensure or a renewal form for applicants applying to ~~specified healing arts~~ *those* boards. The bill would require the department, in consultation with the division and the clearinghouse, to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse

annually on or before January 1. The bill would require the clearinghouse to prepare a written report relating to the data and to submit the report annually to the Legislature no later than March 1, commencing March 1, 2012.

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 857 is added to the Business and
2 Professions Code, to read:
3 857. (a) ~~The department~~ *Every healing arts board specified*
4 *in subdivision (c) shall add and label as "mandatory" the following*
5 *fields on an application for initial licensure or renewal for a person*
6 *applying to a board described in subdivision (e) that board:*
7 (1) First name, middle name, and last name.
8 (2) Last four digits of social security number.
9 (3) Complete mailing address.
10 (4) Educational background and training, including, but not
11 limited to, degree, related school name and location, and year of
12 graduation, and, as applicable, the highest professional degree
13 obtained, related professional school name and location, and year
14 of graduation.
15 (5) Birth date and place of birth.
16 (6) Sex.
17 (7) Race and ethnicity.
18 (8) Location of high school.
19 (9) Mailing address of primary practice, if applicable.
20 (10) Number of hours per week spent at primary practice
21 location, if applicable.
22 (11) Description of primary practice setting, if applicable.
23 (12) Primary practice information, including, but not limited
24 to, primary specialty practice, practice location ZIP Code, and
25 county.
26 (13) Information regarding any additional practice, including,
27 but not limited to, a description of practice setting, practice location
28 ZIP Code, and county.
29 (b) The department, in consultation with the Healthcare
30 Workforce Development Division and the Health Care Workforce
31 Clearinghouse, shall select a database and shall add the data

1 specified in paragraphs (5) to (13) ~~of subdivision (a), inclusive,~~
2 *inclusive, of subdivision (a)* to that database.

3 (c) The following boards are subject to subdivision (a):

4 (1) The Acupuncture Board.

5 (2) The Dental Hygiene Committee of California.

6 (3) The Dental Board of California.

7 (4) The Medical Board of California.

8 (5) The Bureau of Naturopathic Medicine.

9 (6) The California Board of Occupational Therapy.

10 (7) The State Board of Optometry.

11 (8) The Osteopathic Medical Board of California.

12 (9) The California State Board of Pharmacy.

13 (10) The Physical Therapy Board of California.

14 (11) The Physician Assistant Committee, Medical Board of
15 California.

16 (12) The California Board of Podiatric Medicine.

17 (13) The Board of Psychology.

18 (14) The Board of Registered Nursing.

19 (15) The Respiratory Care Board of California.

20 (16) The Speech-Language Pathology and Audiology Board.

21 (17) The Board of Vocational Nursing and Psychiatric
22 Technicians of the State of California.

23 (d) (1) The department shall collect the specified data in the
24 database pursuant to subdivision (b) and shall submit that data to
25 Health Care Workforce Clearinghouse annually on or before
26 January 1.

27 (2) The Health Care Workforce Clearinghouse shall prepare a
28 written report containing the findings of this data and shall submit
29 the written report annually to the Legislature no later than March
30 1, commencing March 1, 2012.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1370 **VERSION:** Introduced February 27, 2009

AUTHOR: Solorio **SPONSOR:** California Senior Legislature

RECOMMENDED POSITION: None

SUBJECT: Drugs and devices: labeling: expiration date: best before date

EXISTING LAW:

1. Authorizes the California Department of Public Health (CDPH) to regulate the packaging of a drug or device, if it deems it is liable to deterioration and, by regulation, may require a statement of precaution on a label.
2. B&P 4076 mandates the labeling requirements of a dispensed prescription, including (a)(9) "the expiration date of the effectiveness of the drug dispensed."
3. B&P 4076.5 mandates that the Board of Pharmacy develop standardized, patient-centered labels on all prescription medicine dispensed to patients in California.

THIS BILL WOULD:

1. As introduced, this bill adds to those provisions the CDPH may regulate, to include a "best before" date on a label (H&SC 111385).

AUTHOR'S INTENT

The California Senior Legislature's concern is that consumers may be needlessly throwing away costly medications because a label shows an "expiration date" when, in fact, the manufacturer's lot of that medication may expire at a time later than that which is on the label.

While this bill does not currently specify the label requirements of a "prescription" the author's office indicates prescriptions are the main focus of the bill and that the bill may be amended to amend provisions in Pharmacy Law (versus H&S).

The author's goal is to indicate on a prescription label the actual (manufacturer's) expiration date of the drug or device dispensed, and not a "one-year default date" that many pharmacies choose to use as the expiration date.

FISCAL IMPACT:

As introduced, this bill has no fiscal impact on the Board of Pharmacy. However, if the bill is amended as stated by the author's staff, Board staff will need to seek clarification from legal counsel about the enforcement of any amended provisions to Pharmacy Law. Based on the results of any related discussion with counsel, staff can estimate fiscal impact to the board, if any.

COMMENTS:

Information was provided to the author's office related to the SB 472 Medication Label Subcommittee, including an agenda for the March 12, 2009, public forum to seek feedback from consumers on the topic of prescription drug labels. The author's office indicated they would provide the Board of Pharmacy with a Fact Sheet on AB 1370 when it is available.

The Legislation and Regulation Committee discussed the bill at its meeting held April 16, 2009. Executive Officer Virginia Herold stated the bill is expected to be dropped by the author. She indicated that the Enforcement Committee will further evaluate the date and its implications. Following discussion, the Committee did not take a position on this bill.

HISTORY:

- Apr. 15 From committee: Do pass, and re-refer to Com. on APPR. With recommendation: To Consent Calendar. Re-referred. (Ayes 9. Noes 0.) (April 14).
- Apr. 13 Re-referred to Com. on B. & P.
- Apr. 2 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Mar. 31 Referred to Com. on B. & P.
- Mar. 2 Read first time.
- Mar. 1 From printer. May be heard in committee March 30.
- Feb. 27 Introduced. To print.

ASSEMBLY BILL

No. 1370

Introduced by Assembly Member Solorio

February 27, 2009

An act to amend Section 111385 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1370, as introduced, Solorio. Drugs and devices: labeling: expiration date: best before date.

Existing law, the Sherman Food, Drug, and Cosmetic Law, requires the State Department of Public Health to regulate manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.

Existing law classifies a drug or device as misbranded if the department determines that the drug or device is liable to deterioration and the drug or device is not packaged and labeled in a form and manner and set forth in regulations of the department.

This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device. By expanding 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. Section 111385 of the Health and Safety Code
2 is amended to read:
3 111385. Any drug or device is misbranded if the department
4 determines that the drug or device is liable to deterioration, unless
5 it is packaged in that form and manner and its label bears a
6 statement of the precautions, as the department, by regulation, may
7 require as necessary for the protection of public health, *including,*
8 *but not limited to, "best before" date in addition to the expiration*
9 *date of the effectiveness of the drug or device.* ~~Such~~ The regulations
10 shall not be established for any drug or device recognized in an
11 official compendium, unless the department has informed the
12 appropriate body, charged with the revision of the official
13 compendium, of the need for that packaging or labeling
14 requirements and that body has not prescribed the requirements
15 in a reasonable length of time.
16 SEC. 2. 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.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1458 **VERSION:** As Amended: April 15, 2009
AUTHOR: Davis **SPONSOR:** Constituent Marvin Maskowitz
BOARD POSITION: None
SUBJECT: Drugs: adverse effects: reporting

EXISTING LAW

Establishes a voluntary reporting system for adverse drug reactions known as the MedWatch System.

THIS BILL WOULD

1. Make legislative declarations.
2. Add in the health and safety code, mandatory reporting of all suspected serious adverse drug events that are discovered or observed in medical practice to MedWatch.
3. Specify that serious adverse drug events will adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or that require intervention to prevent permanent impairment or damage.
4. Specify the report form that any health professions that is required to report shall use.
5. States that violation of these provisions will not be subject to penalties and remedies as specified.

AUTHOR'S INTENT

Requiring licensed health professionals to report adverse drug events to the Medwatch system would increase the amount of data available to the FDA. This would then enable the FDA to safeguard the public health in a more effectual manner.

FISCAL IMPACT

The board does not anticipate any significant fiscal impact to board operations. Any minor impact could be absorbed within resources.

COMMENTS

According to the author, the FDA estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA. The author states that

Bill Analysis: AB 1458 (Davis) As Amended April 15, 2009

given the prevalence of pharmaceutical and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market because of safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

SPONSORS

Congress of California Seniors

OPPOSITION

California Hospital Association (previous bill version)

HISTORY:

- Apr. 22 From committee: Do pass, and re-refer to Com. on HEALTH. Re-referred. (Ayes 7. Noes 3.) (April 21).
- Apr. 16 Re-referred to Com. on B. & P.
- Apr. 15 Re-referred to Com. on B. & P. In committee: Set, first hearing. Hearing canceled at the request of author. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
 - Apr. 13 Re-referred to Com. on B. & P. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Apr. 2 Referred to Coms. on B. & P. and HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Mar. 2 Read first time.
- Mar. 1 From printer. May be heard in committee March 30.
- Feb. 27 Introduced. To print.

AMENDED IN ASSEMBLY APRIL 15, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 1458

Introduced by Assembly Member Davis

February 27, 2009

An act to add Article 7 (commencing with Section 111657.10) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1458, as amended, Davis. Drugs: adverse effects: reporting.

Existing law establishes various programs for the prevention of disease and the promotion of health to be administered by the State Department of Public Health, including, but not limited to, a program *Health*. Existing law also contains provisions for the licensing and regulation of health facilities and clinics *professionals*. Existing law requires certain health facilities to report adverse events, as defined, relating to patient care. Existing law requires the department to regulate the manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.

This bill would require ~~clinics, health facilities, and health professionals~~ to report serious adverse drug events to the federal Food and Drug Administration and would exempt violations from related criminal 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. The Legislature finds and declares all of the
2 following:

3 (a) The federal Food and Drug Administration (FDA) operates
4 a voluntary reporting system for adverse drug reactions known as
5 the MedWatch system.

6 (b) The FDA currently estimates that only 10 percent of the
7 adverse drug reactions or events that occur each year are reported
8 to the FDA.

9 (c) Given the prevalence of pharmaceuticals and their use for
10 treatment of hundreds of chronic diseases and conditions, and
11 given recent highly publicized instances of commonly used
12 prescription drugs being taken off the market due to safety concerns
13 that were discovered after the drugs were approved for use, the
14 systematic underreporting of adverse drug events represents a
15 serious public health problem.

16 (d) Requiring licensed health professionals and health facilities
17 to report adverse drug events to the FDA would increase the
18 amount of data available to the FDA about adverse drug reactions,
19 thereby enabling the FDA to discern problems with drugs that arise
20 after they are approved and to take action to protect the public
21 health in a more timely manner.

22 SEC. 2. Article 7 (commencing with Section 111657.10) is
23 added to Chapter 6 of Part 5 of Division 104 of the Health and
24 Safety Code, to read:

25

26 Article 7. Adverse Event Reporting

27

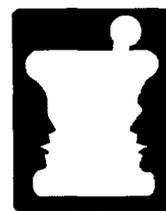
28 111657.10. (a) A licensed health professional, including, but
29 not limited to, a physician and surgeon, dentist, or pharmacist, ~~a~~
30 ~~health facility as defined in Section 1250, or a clinic as defined~~
31 ~~under Chapter 1 (commencing with Section 1200);~~ shall report all
32 suspected serious adverse drug events that are spontaneously
33 discovered or observed in medical practice to MedWatch, the drug
34 safety information and adverse event reporting program operated
35 by the federal Food and Drug Administration (FDA).

1 (b) For purposes of this section, serious adverse drug events
2 shall include adverse health outcomes involving patients that result
3 in death, life-threatening conditions, hospitalization, disability,
4 congenital anomaly, or that require intervention to prevent
5 permanent impairment or damage.

6 (c) Any ~~health professional, health facility, or clinic~~ *professional*
7 that is required to report an adverse drug event pursuant to this
8 section shall use the FDA 3500 Voluntary form developed by the
9 FDA for MedWatch.

10 111657.15. A licensed ~~health professional, health facility, or~~
11 ~~clinic~~ *professional* that violates any provision of this article shall
12 not be subject to the penalties and remedies outlined in Chapter 8
13 (commencing with Section 111825). Nothing in this section affects
14 otherwise existing duties, rights, or remedies under the law.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 26

VERSION: As Introduced
(Amended 4/15/09)

AUTHOR: Simitian

SPONSOR: Simitian

RECOMMENDED POSITION: NONE

SUBJECT: Home Generated Pharmaceutical Waste

EXISTING LAW:

1. Regulates the methods of consolidation, storage and transportation of medical waste and home-generated sharps waste.
2. Prohibits the disposal of home generated sharps from being disposed of in the solid waste stream and requires that sharps be transported only in certain types of containers.
3. Required the California Integrated Waste Management Board (CIWMB), by July 1, 2008, to consult with local, state, and federal agencies including the Board of Pharmacy to establish model disposal programs for waste pharmaceuticals.
4. Requires the CIWMB to establish minimum requirements for model programs including safety, oversight, diversion prevention, and ease of use for consumers and authorizes the CIWMB to develop related emergency regulations if necessary. These guidelines were released in December 2008 and a modified version in February 2009.
5. Requires the CIWMB to report to the Legislature by December 1, 2010, about the efficacy, safety, and cost-effectiveness of the program, as well as the potential for replicating model programs statewide.

THIS BILL WOULD:

1. Require the Board of Pharmacy to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop a program for the take back of pharmaceutical waste and specifically allow pharmacies to accept the return of pharmaceutical and sharps waste.
2. Authorize pharmacies to accept home-generated sharps and pharmaceutical waste, as defined. Define "home-generated pharmaceutical waste" (HGPW) as prescribed and over-the-counter drugs derived from a household.
3. Remove HGPW from the definition of medical waste.
4. Authorize as consolidated points for collection of pharmaceutical waste entities, including: pharmacies, health care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, government offices.

The bill would exempt "home-generated pharmaceutical waste consolidation points" from permit requirements with the Department of Public Health.

5. Define "common carrier" as person or company that hauls for hire goods, including but not limited to, pharmaceutical waste or home-generated pharmaceutical waste and specifies that home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point. There would be no license required to pickup HGPW.
6. Require that consolidation points for HGPW be approved by the local enforcement agency, and.
 - a) The HGPW collected and consolidated at the facility must be collected and contained in a leak-resistant and tamper-proof container and placed in a secure area not accessible by unauthorized persons.
 - b) Disposal-ready containers cannot be held for more than 90 days without the written approval of the enforcement agency.
 - c) Specifies that the HGPW consolidation point operator is not considered a generator of that waste.
 - d) Requires the end disposal facilities that treat the HGPW to maintain tracking documents for the pharmaceutical waste.
7. Require that the name of the common carrier used by small and large quantity generators to transport the pharmaceutical waste for offsite treatment and disposal to be included on the medical waste management plan submitted to the local enforcement agency. This applies only to those small quantity generators required to register with the enforcement agency.
8. Require small quantity generators who are not required to register with the local enforcement agency to maintain office records, for no less than two years, the name of the common carrier used to haul pharmaceutical waste.
9. Exempt small quantity generators or common carriers transporting HGPW from the medical waste transportation requirements.
10. Allow pharmaceutical waste to be shipped by common carrier if the generator or HGPW consolidation point meets the following requirements:
 - a) The facility meets all documentation requirements in governing the transportation and tracking required for medical waste.
 - b) The waste products are transported to a medical waste facility, hazardous waste facilities or a reverse distributor with the final destination of a medical or hazardous waste facility.
11. Subject pharmaceutical waste, HGPW consolidated by a HPGW consolidation point and HGPW to the same documentation requirements governing the transportation and tracking required for medical waste.
12. Require pharmaceutical waste transporters to maintain a tracking document of all the waste removed for treatment and disposal, requires a copy of the tracking documents to be included in the pharmaceutical waste container and specifies the requirements of the tracking documents, which include the following:

- a) The name, address and telephone number and registration number of the generator.
 - b) Specific information on the pharmaceutical waste being transported.
 - c) The name, address, and telephone of the person transporting the waste.
 - d) The name, address, telephone number and permit number of the treatment facility or transfer station to which the waste is being sent.
 - e) The date the waste was collected or removed from the generator or the HGPW consolidation point.
13. Require HGPW transporters to keep the tracking document in his or her possession while transporting waste and to show the document, upon demand, to any enforcement agency personnel or Highway Patrol officer.
 14. Require medical waste treatment facilities and transfer stations to verify the amount of the waste being delivered, date and sign a copy of the tracking document and maintain a copy of the tracking document for three years.
 15. Require pharmaceutical waste transported out of state to be consigned to a permitted medical waste treatment in the receiving state and specifies that if the receiving state does not have a permitted medical waste treatment facility or the waste crosses an international border, the waste must be treated in accordance with state law.
 16. Provide that registered medical waste facility may accept home-generated sharps waste and HGPW under the following conditions:
 - a) The generator of the waste, a member of the generator's family or a person authorized by the enforcement agency transports the waste to the medical waste generator's facility.
 - b) The home-generated sharps waste or HGPW is accepted at a central location at the medical waste generator's facility.
 17. Require medical waste treatment operators to maintain copies of the tracking documents received from offsite generators, hazardous waste haulers or common carriers for three years and report or submit, upon request, the documents to the enforcement agency.
 18. Allow the CIWMB to expend funds from the Household Hazardous Waste Grant account in order to make grants to local governments for the management of HGPW and sharps waste.

AUTHOR'S INTENT:

To strengthen the ability of counties and communities to operate drug take back programs for home-generated pharmaceutical waste by deregulating how the waste is classified, minimize costs, ensure a diverse and broad variety of collection sites and by allowing common carriers to pickup and transport the waste.

FISCAL IMPACT:

To the degree that such deregulated HGPW reenters the pharmaceutical supply chain for "re-dispensing" to the public, there would be substantial, but indeterminate fiscal impact to the board as it would need to identify the origin of prescription drugs where there are no or inadequate acquisition records (this requires audits).

The board would need one position to implement the provisions of this bill that require the board to “coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop a program for the take back of pharmaceutical waste and specifically allow pharmacies to accept the return of pharmaceutical and sharps waste.”

COMMENTS:

1. According to the Author, this measure is necessary to make it explicit which entities may accept HGPW and establishes requirements to ensure that the HGPW is managed safely and appropriately. This bill is follow-up legislation to the Author’s SB 966 (Chapter 542, Statutes of 2007) which required the CIWMB to work with stakeholders to develop model programs for the safe, efficient take back of HGPW. The intent of that measure was to provide a product stewardship approach to the management of waste pharmaceuticals.

The board has been actively involved in the development of the CIWMB’s model program guidelines. These guidelines were finalized in February 2009. One principal weakness is that there are no regulations or statutory law enacted for regulatory agencies to enforce these provisions, and the CIWMB has indicated that it will not develop these regulations.

2. Existing law requires facilities that handle medical waste, including waste over-the-counter and prescription drugs, to have a full medical waste facility permit. This has been prohibitive to those locations, such as pharmacies, who only want to handle pharmaceutical waste from their customers as a customer service. Traditionally medical waste is biohazardous and infectious waste – waste that requires a high level of treatment and oversight. The take-back of waste pharmaceuticals is a new practice and not considered when the permitting requirements were established.
3. The Medical Waste Management Act (MWMA) currently requires HGPW to be managed as “medical waste” which includes such material as infectious and biohazardous waste and other types of waste that have posed a potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. While this is appropriate for large scale medical waste, the management of HGPW needs a protective, yet different approach. Changes to the MWMA are necessary to remove barriers to the establishment of a network of take back opportunities for HGPW. Many pharmacies and other retail establishments have expressed an interest in providing collection opportunities for their customers and while are willing and able to provide safe and appropriate collection, they do not want to become licensed medical waste collectors.
4. **Home-Generated Sharps Waste Model.** This bill uses the approach established for the management of “sharps waste” (e.g., needles, lancets.) generated by households

that provides an appropriate level of oversight, but acknowledges the need to provide many options for users of sharps to encourage their proper management and prevent illegal or improper disposal that leads to public health and safety and environmental pollution problems. It establishes a wide array of entities to, if they wish, serve as consolation points for HGPW and creates a statutory framework for the safe management, tracking and disposal of HGPW.

5. Concerns have been raised regarding the issue of theft of HGPW at collection points, including pharmacies. Pharmacies have the responsibility of keeping the drug supply safe and it is of utmost importance that HGPW are not diverted to unauthorized users. To ensure the safety and integrity of California's pharmaceutical drug supply chain, it is imperative that HGPW does not re-enter the drug supply, nor be scavenged to be sold illegally. The Author has indicated that he is exploring ways to address these concerns.

LEGISLATION AND REGULATION COMMITTEE:

At its meeting held April 16, 2009, the Legislation and Regulation Committee discussed SB 26. Executive Officer Virginia Herold reviewed comments that were provided to the California Integrated Waste Management Board. She stated that the author's office indicated the amended version would remove provisions regarding the "common carrier." Copies of the amended bill were provided to the committee members.

After discussion, the Committee did not take a position on this bill.

SUPPORT/OPPOSITION:

American Federation of State, County and Municipal Employees
City of Glendora
Contra Costa Water District
East Bay Municipal Utility District
Environmental Working Group
Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force
Regional Council of Rural Counties
San Luis Obispo County Integrated Waste Management Authority
Santa Clara County Board of Supervisors
Santa Clara Valley Water District
Solid Waste Association of North America

HISTORY:

Apr. 16 Set for hearing April 20.
Apr. 15 Read second time. Amended. Re-referred to Com. on EQ.
Apr. 14 From committee: Do pass as amended, but first amend, and re-refer to Com. on EQ.
(Ayes 8. Noes 1.)
Mar. 27 Set for hearing April 13.

Jan. 29 To Coms. on B., P. & E.D. and EQ. 2008
Dec. 2 From print. May be acted upon on or after January 1.
Dec. 1 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 15, 2009

SENATE BILL

No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, ~~117935, 117945, 117960, 118000, 118040, 118147, and 118165~~ and *118147* of, and to add Sections ~~117642,~~ 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as amended, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation

of a disposal facility. The act requires the board to expend moneys from the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by ~~both hazardous waste haulers and common carriers, as defined~~. By expanding the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

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

- 1 SECTION 1. Section 4001.2 is added to the Business and
- 2 Professions Code, to read:
- 3 4001.2. To further the purposes of Section 4001.1, and to
- 4 protect the public from hazards caused by the improper

1 management and disposal of ~~waste drugs and devices~~
2 *pharmaceutical waste*, the California State Board of Pharmacy
3 shall coordinate with other state agencies, local governments, drug
4 manufacturers, and pharmacies to develop sustainable, efficient
5 policies and programs to properly manage pharmaceutical wastes
6 and the disposal of these wastes.

7 SEC. 2. Section 4068.1 is added to the Business and Professions
8 Code, to read:

9 4068.1. A pharmacy may accept the return of home-generated
10 pharmaceutical waste, as defined in Section 117769 of the Health
11 and Safety Code, from the public.

12 SEC. 3. Section 4146 is added to the Business and Professions
13 Code, to read:

14 4146. A pharmacy may accept the return of home-generated
15 sharps waste, as defined in Section 117671 of the Health and Safety
16 Code, from a person if the waste is contained in a sharps container.

17 ~~SEC. 4. Section 117642 is added to the Health and Safety Code,~~
18 ~~to read:~~

19 ~~117642. "Common carrier" means a person or company that~~
20 ~~hauls for hire goods, including, but not limited to, pharmaceutical~~
21 ~~waste or home-generated pharmaceutical waste. Home-generated~~
22 ~~pharmaceutical waste must have been consolidated at a location~~
23 ~~approved by the enforcement agency as a home-generated~~
24 ~~pharmaceutical waste consolidation point.~~

25 ~~SEC. 5.~~

26 ~~SEC. 4.~~ Section 117669 is added to the Health and Safety Code,
27 to read:

28 117669. "Home-generated pharmaceutical waste" means
29 ~~prescribed and over-the-counter drugs~~ *pharmaceutical waste*
30 derived from a household.

31 ~~SEC. 6.~~

32 ~~SEC. 5.~~ Section 117700 of the Health and Safety Code is
33 amended to read:

34 117700. Medical waste does not include any of the following:

35 (a) Waste generated in food processing or biotechnology that
36 does not contain an infectious agent as defined in Section 117675.

37 (b) Waste generated in biotechnology that does not contain
38 human blood or blood products or animal blood or blood products
39 suspected of being contaminated with infectious agents known to
40 be communicable to humans.

1 (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
2 or vomitus, unless it contains fluid blood, as provided in
3 subdivision (d) of Section 117635.

4 (d) Waste that is not biohazardous, such as paper towels, paper
5 products, articles containing nonfluid blood, and other medical
6 solid waste products commonly found in the facilities of medical
7 waste generators.

8 (e) Hazardous waste, radioactive waste, or household waste,
9 including, but not limited to, home-generated sharps waste, as
10 defined in Section 117671, and home-generated pharmaceutical
11 waste, as defined in Section 117669.

12 (f) Waste generated from normal and legal veterinarian,
13 agricultural, and animal livestock management practices on a farm
14 or ranch.

15 ~~SEC. 7.~~

16 *SEC. 6.* Section 117748 is added to the Health and Safety Code,
17 to read:

18 117748. "Pharmaceutical waste" means any pharmaceutical,
19 prescription, or over-the-counter human or veterinary drug,
20 including, but not limited to, a drug, as defined in Section 109925,
21 or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec.
22 321(g)(1)) that meets any of the following requirements:

23 ~~(a) The drug may no longer be sold or dispensed because it has~~
24 ~~expired.~~

25 ~~(b)~~

26 (a) The drug can no longer be used for its intended purpose.

27 ~~(c)~~

28 (b) The drug has been discarded.

29 ~~(d)~~

30 (c) The drug has been consolidated at a location approved by
31 the enforcement agency as a home-generated pharmaceutical waste
32 consolidation point.

33 ~~SEC. 8.~~

34 *SEC. 7.* Section 117904.5 is added to the Health and Safety
35 Code, to read:

36 117904.5. (a) In addition to the consolidation points authorized
37 pursuant to Section 118147, the enforcement agency may approve
38 a location as a point of consolidation for the collection of
39 home-generated pharmaceutical waste. These locations may
40 include, but are not limited to, pharmacies, health care facilities,

1 veterinarian offices, clinics, household hazardous waste programs,
2 solid waste facilities, ~~senior centers~~ *nursing homes*, or government
3 offices.

4 (b) A consolidation location approved pursuant to this section
5 shall be known as a home-generated pharmaceutical waste
6 consolidation point.

7 (c) A home-generated pharmaceutical waste consolidation point
8 is not subject to the requirements of Chapter 9 (commencing with
9 Section 118275) of Part 14 of Division-4 104, to the permit
10 requirements of this part, or to any permit or registration fees, with
11 regard to the activity of consolidating home-generated
12 pharmaceutical waste pursuant to this section.

13 (d) A home-generated pharmaceutical waste consolidation point
14 shall comply with all of the following requirements:

15 (1) It shall be approved by the enforcement agency for this
16 purpose.

17 (2) The home-generated pharmaceutical waste collected and
18 consolidated at the facility shall be collected and contained in a
19 leak-resistant *and tamper-proof* container and placed in a secure
20 area that does not allow the waste to be accessed or salvaged by
21 unauthorized persons.

22 (3) Containers ready for disposal shall not be held for more than
23 90 days without the written approval of the enforcement agency.

24 (e) An operator of a home-generated pharmaceutical waste
25 consolidation point that is approved pursuant to this section shall
26 not be considered a generator of that waste.

27 (f) The end disposal facility that treats the home-generated
28 pharmaceutical waste shall maintain the tracking documents
29 required by Section 118040 or 118041, as applicable, and Section
30 118165 with regard to the pharmaceutical waste.

31 (g) Nothing in this section shall exempt any person from any
32 federal or state law governing pharmaceuticals.

33 ~~SEC. 9. Section 117935 of the Health and Safety Code is~~
34 ~~amended to read:~~

35 ~~117935. Any small quantity generator required to register with~~
36 ~~the enforcement agency pursuant to Section 117930 shall file with~~
37 ~~the enforcement agency a medical waste management plan, on~~
38 ~~forms prescribed by the enforcement agency containing, but not~~
39 ~~limited to, all of the following:~~

40 (a) ~~The name of the person.~~

- 1 (b) The business address of the person.
2 (c) The type of business.
3 (d) The types, and the estimated average monthly quantity, of
4 medical waste generated.
5 (e) The type of treatment used onsite.
6 (f) The name and business address of the registered hazardous
7 waste hauler used by the generator for backup treatment and
8 disposal, for waste when the onsite treatment method is not
9 appropriate due to the hazardous or radioactive characteristics of
10 the waste, the name of the registered hazardous waste hauler used
11 by the generator to have untreated medical waste removed for
12 treatment and disposal, and, if applicable, the name of the common
13 carrier used by the generator to transport pharmaceutical waste
14 offsite for treatment and disposal.
15 (g) A statement indicating that the generator is hauling the
16 medical waste generated in his or her business pursuant to Section
17 118030 and the name and any business address of the treatment
18 and disposal facilities to which the waste is being hauled, if
19 applicable.
20 (h) The name and business address of the registered hazardous
21 waste hauler service provided by the building management to
22 which the building tenants may subscribe or are required by the
23 building management to subscribe and the name and business
24 address of the treatment and disposal facilities used, if applicable.
25 (i) A statement certifying that the information provided is
26 complete and accurate.
27 SEC. 10. Section 117945 of the Health and Safety Code is
28 amended to read:
29 117945. Small quantity generators who are not required to
30 register pursuant to this chapter shall maintain on file in their office
31 all of following:
32 (a) An information document stating how the generator contains,
33 stores, treats, and disposes of any medical waste generated through
34 any act or process of the generator.
35 (b) Records of any medical waste transported offsite for
36 treatment and disposal, including the quantity of waste transported,
37 the date transported, and the name of the registered hazardous
38 waste hauler or individual hauling the waste pursuant to Section
39 118030, or the name of the common carrier hauling pharmaceutical

1 ~~waste pursuant to Section 118031. The small quantity generator~~
2 ~~shall maintain these records for not less than two years.~~

3 ~~SEC. 11. Section 117960 of the Health and Safety Code is~~
4 ~~amended to read:~~

5 ~~117960. Any large quantity generator required to register with~~
6 ~~the enforcement agency pursuant to Section 117950 shall file with~~
7 ~~the enforcement agency a medical waste management plan, on~~
8 ~~forms prescribed by the enforcement agency containing, but not~~
9 ~~limited to, all of the following:~~

10 ~~(a) The name of the person.~~

11 ~~(b) The business address of the person.~~

12 ~~(c) The type of business.~~

13 ~~(d) The types, and the estimated average monthly quantity, of~~
14 ~~medical waste generated.~~

15 ~~(e) The type of treatment used onsite, if applicable. For~~
16 ~~generators with onsite medical waste treatment facilities, including~~
17 ~~incinerators or steam sterilizers or other treatment facilities as~~
18 ~~determined by the enforcement agency, the treatment capacity of~~
19 ~~the onsite treatment facility.~~

20 ~~(f) The name and business address of the registered hazardous~~
21 ~~waste hauler used by the generator to have untreated medical waste~~
22 ~~removed for treatment, if applicable, or the name of the common~~
23 ~~carrier hauling pharmaceutical waste pursuant to Section 118031.~~

24 ~~(g) The name and business address of the registered hazardous~~
25 ~~waste hauler service provided by the building management to~~
26 ~~which the building tenants may subscribe or are required by the~~
27 ~~building management to subscribe, if applicable.~~

28 ~~(h) The name and business address of the offsite medical waste~~
29 ~~treatment facility to which the medical waste is being hauled, if~~
30 ~~applicable.~~

31 ~~(i) An emergency action plan complying with regulations~~
32 ~~adopted by the department.~~

33 ~~(j) A statement certifying that the information provided is~~
34 ~~complete and accurate.~~

35 ~~SEC. 12.~~

36 ~~SEC. 8. Section 118000 of the Health and Safety Code is~~
37 ~~amended to read:~~

38 ~~118000. (a) Except as otherwise exempted pursuant to Section~~
39 ~~118030 or 118031, all medical waste transported to an offsite~~
40 ~~medical waste treatment facility shall be transported in accordance~~

1 with this chapter by a registered hazardous waste transporter issued
2 a registration certificate pursuant to Chapter 6 (commencing with
3 Section 118025) and Article 6.5 (commencing with Section
4 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
5 transporter transporting medical waste shall have a copy of the
6 transporter's valid hazardous waste transporter registration
7 certificate in the transporter's possession while transporting
8 medical waste. The transporter shall show the certificate, upon
9 demand, to any enforcement agency personnel or authorized
10 employee of the Department of the California Highway Patrol.

11 (b) Except for small quantity generators transporting medical
12 waste pursuant to Section 118030 or small quantity generators or
13 common carriers transporting home-generated pharmaceutical
14 waste pursuant to Section 118031, medical waste shall be
15 transported to a permitted offsite medical waste treatment facility
16 or a permitted transfer station in leak-resistant and fully enclosed
17 rigid secondary containers that are then loaded into an enclosed
18 cargo body.

19 (c) A person shall not transport medical waste in the same
20 vehicle with other waste unless the medical waste is separately
21 contained in rigid containers or kept separate by barriers from
22 other waste, or unless all of the waste is to be handled as medical
23 waste in accordance with this part.

24 (d) Medical waste shall only be transported to a permitted
25 medical waste treatment facility, or to a transfer station or another
26 registered generator for the purpose of consolidation before
27 treatment and disposal, pursuant to this part.

28 (e) Facilities for the transfer of medical waste shall be annually
29 inspected and issued permits in accordance with the regulations
30 adopted pursuant to this part.

31 (f) Any persons manually loading or unloading containers of
32 medical waste shall be provided by their employer at the beginning
33 of each shift with, and shall be required to wear, clean and
34 protective gloves and coveralls, changeable lab coats, or other
35 protective clothing. The department may require, by regulation,
36 other protective devices appropriate to the type of medical waste
37 being handled.

38 ~~SEC. 13. Section 118031 is added to the Health and Safety~~
39 ~~Code, to read:~~

1 118031. ~~Pharmaceutical waste may be shipped by a common~~
2 ~~carrier if the generator or home-generated pharmaceutical waste~~
3 ~~consolidation point meets the following requirements:~~

4 ~~(a) The facility shall maintain documentation as required in~~
5 ~~Sections 118040 and 118041.~~

6 ~~(b) The waste products are transported to any of the following:~~

7 ~~(1) A medical waste facility.~~

8 ~~(2) A hazardous waste facility.~~

9 ~~(3) A reverse distributor, with the final destination of a medical~~
10 ~~or hazardous waste facility.~~

11 *SEC. 9. Section 118031 is added to the Health and Safety Code,*
12 *to read:*

13 *118031. (a) Except for a person who generated the*
14 *home-generated pharmaceutical waste, or a family member or*
15 *other designated person who is not subject to this part, no person*
16 *may transport home-generated pharmaceutical waste unless the*
17 *person is one of the following:*

18 *(1) A currently registered hazardous waste hauler.*

19 *(2) In possession of a limited-quantity hauling exemption*
20 *granted pursuant to Section 118030, provided that the person may*
21 *transport no more than five pounds of home-generated*
22 *pharmaceutical waste.*

23 *(3) An operator of a home-generated pharmaceutical waste*
24 *consolidation point provided that the person transports the*
25 *home-generated pharmaceutical waste only from the consolidation*
26 *point to a permitted treatment facility or transfer station and*
27 *maintains tracking documentation, as required by Sections 118040*
28 *and 118041.*

29 *(b) Nothing in this section shall prohibit the operator of a*
30 *home-generated pharmaceutical waste consolidation point from*
31 *using a registered hazardous waste hauler for transporting the*
32 *home-generated pharmaceutical waste to a permitted medical*
33 *waste treatment or transfer station facility.*

34 ~~SEC. 14.~~

35 *SEC. 10. Section 118040 of the Health and Safety Code is*
36 *amended to read:*

37 *118040. (a) Except with regard to sharps waste consolidated*
38 *by a home-generated sharps consolidation point approved pursuant*
39 *to Section 117904, pharmaceutical waste or home-generated*
40 *pharmaceutical waste consolidated by a home-generated*

1 pharmaceutical waste consolidation point approved pursuant to
2 Section 117904.5, or home-generated pharmaceutical waste
3 transported pursuant to Section 118031, a hazardous waste
4 transporter or generator transporting medical waste shall maintain
5 a completed tracking document of all medical waste removed for
6 treatment or disposal. A hazardous waste transporter or generator
7 who transports medical waste to a facility, other than the final
8 medical waste treatment facility, shall also maintain tracking
9 documents which show the name, address, and telephone number
10 of the medical waste generator, for purposes of tracking the
11 generator of medical waste when the waste is transported to the
12 final medical waste treatment facility. At the time that the medical
13 waste is received by a hazardous waste transporter, the transporter
14 shall provide the medical waste generator with a copy of the
15 tracking document for the generator's medical waste records. The
16 transporter or generator transporting medical waste shall maintain
17 its copy of the tracking document for three years.

18 (b) The tracking document shall include, but not be limited to,
19 all of the following information:

20 (1) The name, address, telephone number, and registration
21 number of the transporter, unless transported pursuant to Section
22 118030.

23 (2) The type and quantity of medical waste transported.

24 (3) The name, address, and telephone number of the generator.

25 (4) The name, address, telephone number, permit number, and
26 the signature of an authorized representative of the permitted
27 facility receiving the medical waste.

28 (5) The date that the medical waste is collected or removed from
29 the generator's facility, the date that the medical waste is received
30 by the transfer station, the registered large quantity generator, or
31 point of consolidation, if applicable, and the date that the medical
32 waste is received by the treatment facility.

33 (c) Any hazardous waste transporter or generator transporting
34 medical waste in a vehicle shall have a tracking document in his
35 or her possession while transporting the medical waste. The
36 tracking document shall be shown upon demand to any
37 enforcement agency personnel or officer of the Department of the
38 California Highway Patrol. If the medical waste is transported by
39 rail, vessel, or air, the railroad corporation, vessel operator, or
40 airline shall enter on the shipping papers any information

1 concerning the medical waste that the enforcement agency may
2 require.

3 (d) A hazardous waste transporter or a generator transporting
4 medical waste shall provide the facility receiving the medical waste
5 with the original tracking document.

6 (e) Each hazardous waste transporter and each medical waste
7 treatment facility shall provide tracking data periodically and in a
8 format as determined by the department.

9 (f) Medical waste transported out of state shall be consigned to
10 a permitted medical waste treatment facility in the receiving state.
11 If there is no permitted medical waste treatment facility in the
12 receiving state or if the medical waste is crossing an international
13 border, the medical waste shall be treated in accordance with
14 Chapter 8 (commencing with Section 118215) prior to being
15 transported out of the state.

16 ~~SEC. 15.~~

17 *SEC. 11.* Section 118041 is added to the Health and Safety
18 Code, to read:

19 118041. (a) A person transporting pharmaceutical waste shall
20 maintain a completed tracking document of all pharmaceutical
21 waste removed for treatment or disposal. A copy of the tracking
22 document shall be included with the container holding the
23 pharmaceutical waste.

24 (b) The tracking document shall include, but not be limited to,
25 all of the following information:

26 (1) The name, address, and telephone number of the generator.

27 (2) Specific information indicating that pharmaceutical waste
28 is being transported.

29 (3) The name, address, and telephone number of the person
30 transporting the waste.

31 (4) The name, address, telephone number, and permit number
32 of the permitted treatment facility or transfer station to which the
33 pharmaceutical waste is being sent.

34 (5) The date that the pharmaceutical waste was collected or
35 removed from the generator or home-generated pharmaceutical
36 waste consolidation point.

37 (6) *The amount of pharmaceutical waste being transported.*

38 (c) A person ~~tracking~~ transporting pharmaceutical waste shall
39 have a tracking document for the waste in his or her possession
40 while transporting the waste. The tracking document shall be

1 shown, upon demand, to any enforcement agency personnel or
2 officer of the Department of the California Highway Patrol.

3 (d) A medical waste treatment facility and transfer station shall
4 *verify the amount of pharmaceutical waste being delivered*, date
5 and sign a copy of the tracking document upon receipt, periodically
6 provide data in a format determined by the department, and shall
7 maintain a copy of the tracking document for three years.

8 (e) This section does not prohibit the use of a single document
9 to verify the return of more than one container to a parent
10 organization or another health care facility for the purpose of
11 consolidation before treatment and disposal of the pharmaceutical
12 waste over a period of time, if the form or log is maintained in the
13 files of the parent organization or other health care facility that
14 receives the waste.

15 (f) Pharmaceutical waste transported out of state shall be
16 consigned to a permitted medical waste treatment facility in the
17 ~~receiving state. If there is no permitted medical waste treatment~~
18 ~~facility in the receiving state, or if the waste is crossing an~~
19 ~~international border, the home-generated pharmaceutical waste~~
20 ~~shall be treated pursuant to Section 118222 prior to being~~
21 ~~transported out of state. receiving state.~~

22 ~~SEC. 16.~~

23 *SEC. 12.* Section 118147 of the Health and Safety Code is
24 amended to read:

25 118147. Notwithstanding any other provision of this chapter,
26 a registered medical waste generator, which is a facility specified
27 in subdivisions (a) and (b) of Section 117705, may accept
28 home-generated sharps waste and home-generated pharmaceutical
29 waste, to be consolidated with the facility's medical waste stream,
30 subject to all of the following conditions:

31 (a) The generator of the home-generated sharps waste or
32 home-generated pharmaceutical waste, a member of the generator's
33 family, or a person authorized by the enforcement agency transports
34 the sharps waste or pharmaceutical waste to the medical waste
35 generator's facility.

36 (b) The home-generated sharps waste or home-generated
37 pharmaceutical waste is accepted at a central location at the medical
38 waste generator's facility.

1 (c) A reference to, and a description of, the actions taken
2 pursuant to this section are included in the facility's medical waste
3 management plan adopted pursuant to Section 117960.

4 ~~SEC. 17. Section 118165 of the Health and Safety Code is~~
5 ~~amended to read:~~

6 ~~118165. On and after April 1, 1991, all persons operating a~~
7 ~~medical waste treatment facility shall maintain individual records~~
8 ~~for a period of three years and shall report or submit to the~~
9 ~~enforcement agency upon request, all of the following information:~~

10 (a) ~~The type of treatment facility and its capacity.~~

11 (b) ~~All treatment facility operating records.~~

12 (c) ~~Copies of the tracking documents for all medical waste it~~
13 ~~receives for treatment from offsite generators or from hazardous~~
14 ~~waste haulers or common carriers, pursuant to Section 118041.~~

15 ~~SEC. 18.~~

16 ~~SEC. 13. Section 47200 of the Public Resources Code is~~
17 ~~amended to read:~~

18 47200. (a) The board shall expend funds from the account,
19 upon appropriation by the Legislature, for the making of grants to
20 cities, counties, or other local agencies with responsibility for solid
21 waste management, and for local programs to help prevent the
22 disposal of home-generated sharps waste, as defined in Section
23 117671 of the Health and Safety Code, ~~home-generated~~
24 ~~pharmaceutical waste, as defined in Section 117669 of the Health~~
25 ~~and Safety Code, and hazardous wastes at disposal sites, including,~~
26 ~~but not limited to, programs to expand or initially implement~~
27 ~~household hazardous waste programs. In making grants pursuant~~
28 ~~to this section, the board shall give priority to funding programs~~
29 ~~that provide for the following:~~

30 (1) New programs for rural areas, underserved areas, and for
31 small cities.

32 (2) Expansion of existing programs to provide for the collection
33 of additional waste types, innovative or more cost-effective
34 collection methods, or expanded public education services.

35 (3) Regional household hazardous waste programs.

36 (b) (1) The total amount of grants made by the board pursuant
37 to this section shall not exceed, in any one fiscal year, three million
38 dollars (\$3,000,000).

39 (2) Notwithstanding paragraph (1), the total amount of grants
40 made by the board pursuant to this section may exceed three

1 million dollars (\$3,000,000) but shall not exceed six million dollars
2 (\$6,000,000), in any one fiscal year, if sufficient funds are
3 appropriated from the Integrated Waste Management Account for
4 this purpose.

5 ~~SEC. 19.~~

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 43

VERSION: Amended April 20, 2009

AUTHOR: Alquist

SPONSOR: Author Sponsored

COMMITTEE RECOMMENDATION: Support (*as Introduced 1/6/09*)

SUBJECT: Health Professions: Cultural and Linguistic Competency

EXISTING LAW:

1. Establishes the Task Force on Culturally and Linguistically Competent Physicians and Dentists and assigns the task force various duties, including, among other things, identifying the key cultural elements necessary to meet cultural competency.
2. Authorizes physicians and surgeons, dentists, and dental auxiliaries to report information regarding their cultural background and foreign language proficiency to their respective licensing boards and requires those boards to collect that information, as specified.

THIS BILL WOULD:

1. Allow a healing arts board to collect information regarding the cultural and linguistic competency of persons licensed, certified or otherwise subject to regulation by the board.
2. Require that such information collected be used for the purpose of meeting cultural and linguistic concerns of the state's diverse patient population.
3. Specify that personally identifiable information will be kept confidential and not subject to public inspection.
4. Define board for purposes of this requirement.
5. Amend the Unemployment Insurance Code to allow the Office of Statewide Health Planning and Development (OSHPD) to obtain this data for inclusion in the health care workforce clearinghouse.

AUTHOR'S INTENT:

As introduced, SB 43 will improve data available for workforce policy and development efforts. Licensing boards will be allowed to collect data on the cultural and linguistic competency of a variety of healthcare professionals, including physicians, nurses, dentists and dental auxiliaries. OSHPD will have access to valuable labor market data.

FISCAL IMPACT:

It is unclear if there would be any fiscal impact to the board as this proposal is permissive rather than mandatory.

COMMENTS:

This bill does not create a mandate, rather it is permissive. Board staff will consult with agencies that do collect this information to identify any implementation issues, should the bill become law and should the board decide to collect this information.

At its public meeting held April 16, 2009, the Legislation and Regulation Committee moved to recommend that the Board have a "Support" position on this measure, as Introduced.

Staff have summarized amendments to the bill (4/20/09) and have determined that the amendments further protect personally identifiable information that would be collected in accordance with this measure.

SUPPORT/OPPOSITION:

None of file.

HISTORY:

Apr. 20 From committee: Do pass, but first be re-referred to Com. on JUD. (Ayes 8. Noes 1.) Re-referred to Com. on JUD. From committee with author's amendments.

Read second time. Amended. Re-referred to Com. on JUD.

Mar. 27 Set for hearing April 20.

Jan. 29 To Coms. on B., P. & E.D. and JUD.

Jan. 7 From print. May be acted upon on or after February 6.

Jan. 6 Introduced. Read first time. To Com. on RLS. for assignment. To print. Mar. 27 Set for hearing April 20.

Jan. 29 To Coms. on B., P. & E.D. and JUD.

Jan. 7 From print. May be acted upon on or after February 6.

Jan. 6 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 20, 2009

SENATE BILL

No. 43

Introduced by Senator Alquist

January 6, 2009

An act to add Section 851.5 to the Business and Professions Code, to amend Section 128051 of the Health and Safety Code, and to amend Section 1095 of the Unemployment Insurance Code, relating to health professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 43, as amended, Alquist. Health professions.

Existing law provides for the licensure and regulation of various healing arts by boards within the Department of Consumer Affairs. Existing law establishes the Task Force on Culturally and Linguistically Competent Physicians and Dentists and assigns the task force various duties, including, among other things, identifying the key cultural elements necessary to meet cultural competency. Existing law authorizes physicians and surgeons, dentists, and dental auxiliaries to report information regarding their cultural background and foreign language proficiency to their respective licensing boards and requires those boards to collect that information, as specified.

This bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards. The bill would require that this information be used *only* for the purpose of meeting the cultural and linguistic concerns of the state's diverse patient population.

Existing law requires the Office of Statewide Health Planning and Development to establish a health care workforce clearinghouse to serve

as the central source of health care workforce and educational data in the state *and requires the office to work with specified entities to collect that data*. Existing law requires the Director of the Employment Development Department to permit the use of information in his or her possession for specified purposes.

This bill would additionally require the director to permit the use of that information in order to enable the Office of Statewide Health Planning and Development to obtain specified data for the health care workforce clearinghouse. *The bill would specify that personally identifiable information obtained by that office for the health care workforce clearinghouse is confidential and not subject to public inspection.*

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 851.5 is added to the Business and
2 Professions Code, to read:

3 851.5. (a) A healing arts board referred to in this division may,
4 in a manner deemed appropriate by the board, collect information
5 regarding the cultural and linguistic competency of persons
6 licensed, certified, registered, or otherwise subject to regulation
7 by that board.

8 (b) The information collected pursuant to this section shall be
9 used for the purpose of meeting the cultural and linguistic concerns
10 of the state's diverse patient population. *Any other use of the*
11 *information collected pursuant to this section is prohibited.*

12 (c) Personally identifiable information collected pursuant to this
13 section shall be confidential and not subject to public inspection.

14 (d) The authority provided in this section shall be in addition
15 to, and not a limitation on, the authority provided under subdivision
16 (c) of Section 2425.3 and subdivision (d) of Section 1717.5.

17 (e) For purposes of this section, "board" refers to any healing
18 arts board, division, or examining committee that licenses, certifies,
19 or regulates health professionals pursuant to this division.

20 SEC. 2. Section 128051 of the Health and Safety Code is
21 amended to read:

22 128051. (a) The Office of Statewide Health Planning and
23 Development shall work with the Employment Development

1 Department's Labor Market Information Division, state licensing
2 boards, and state higher education entities to collect, to the extent
3 available, all of the following data:

4 (a)

5 (1) The current supply of health care workers, by specialty.

6 (b)

7 (2) The geographical distribution of health care workers, by
8 specialty.

9 (c)

10 (3) The diversity of the health care workforce, by specialty,
11 including, but not necessarily limited to, data on race, ethnicity,
12 and languages spoken.

13 (d)

14 (4) The current and forecasted demand for health care workers,
15 by specialty.

16 (e)

17 (5) The educational capacity to produce trained, certified, and
18 licensed health care workers, by specialty and by geographical
19 distribution, including, but not necessarily limited to, the number
20 of educational slots, the number of enrollments, the attrition rate,
21 and wait time to enter the program of study.

22 (b) *Personally identifiable information collected for purposes*
23 *of this article shall be confidential and not subject to public*
24 *inspection.*

25 ~~SEC. 2.~~

26 ~~SEC. 3.~~ Section 1095 of the Unemployment Insurance Code
27 is amended to read:

28 1095. The director shall permit the use of any information in
29 his or her possession to the extent necessary for any of the
30 following purposes and may require reimbursement for all direct
31 costs incurred in providing any and all information specified in
32 this section, except information specified in subdivisions (a) to
33 (e), inclusive:

34 (a) To enable the director or his or her representative to carry
35 out his or her responsibilities under this code.

36 (b) To properly present a claim for benefits.

37 (c) To acquaint a worker or his or her authorized agent with his
38 or her existing or prospective right to benefits.

39 (d) To furnish an employer or his or her authorized agent with
40 information to enable him or her to fully discharge his or her

1 obligations or safeguard his or her rights under this division or
2 Division 3 (commencing with Section 9000).

3 (e) To enable an employer to receive a reduction in contribution
4 rate.

5 (f) To enable federal, state, or local government departments
6 or agencies, subject to federal law, to verify or determine the
7 eligibility or entitlement of an applicant for, or a recipient of, public
8 social services provided pursuant to Division 9 (commencing with
9 Section 10000) of the Welfare and Institutions Code, or Part A of
10 Title IV of the Social Security Act, where the verification or
11 determination is directly connected with, and limited to, the
12 administration of public social services.

13 (g) To enable county administrators of general relief or
14 assistance, or their representatives, to determine entitlement to
15 locally provided general relief or assistance, where the
16 determination is directly connected with, and limited to, the
17 administration of general relief or assistance.

18 (h) To enable state or local governmental departments or
19 agencies to seek criminal, civil, or administrative remedies in
20 connection with the unlawful application for, or receipt of, relief
21 provided under Division 9 (commencing with Section 10000) of
22 the Welfare and Institutions Code or to enable the collection of
23 expenditures for medical assistance services pursuant to Part 5
24 (commencing with Section 17000) of Division 9 of the Welfare
25 and Institutions Code.

26 (i) To provide any law enforcement agency with the name,
27 address, telephone number, birth date, social security number,
28 physical description, and names and addresses of present and past
29 employers, of any victim, suspect, missing person, potential
30 witness, or person for whom a felony arrest warrant has been
31 issued, when a request for this information is made by any
32 investigator or peace officer as defined by Sections 830.1 and
33 830.2 of the Penal Code, or by any federal law enforcement officer
34 to whom the Attorney General has delegated authority to enforce
35 federal search warrants, as defined under Sections 60.2 and 60.3
36 of Title 28 of the Code of Federal Regulations, as amended, and
37 when the requesting officer has been designated by the head of
38 the law enforcement agency and requests this information in the
39 course of and as a part of an investigation into the commission of
40 a crime when there is a reasonable suspicion that the crime is a

1 felony and that the information would lead to relevant evidence.
2 The information provided pursuant to this subdivision shall be
3 provided to the extent permitted by federal law and regulations,
4 and to the extent the information is available and accessible within
5 the constraints and configurations of existing department records.
6 Any person who receives any information under this subdivision
7 shall make a written report of the information to the law
8 enforcement agency that employs him or her, for filing under the
9 normal procedures of that agency.

10 (1) This subdivision shall not be construed to authorize the
11 release to any law enforcement agency of a general list identifying
12 individuals applying for or receiving benefits.

13 (2) The department shall maintain records pursuant to this
14 subdivision only for periods required under regulations or statutes
15 enacted for the administration of its programs.

16 (3) This subdivision shall not be construed as limiting the
17 information provided to law enforcement agencies to that pertaining
18 only to applicants for, or recipients of, benefits.

19 (4) The department shall notify all applicants for benefits that
20 release of confidential information from their records will not be
21 protected should there be a felony arrest warrant issued against
22 the applicant or in the event of an investigation by a law
23 enforcement agency into the commission of a felony.

24 (j) To provide public employee retirement systems in California
25 with information relating to the earnings of any person who has
26 applied for or is receiving a disability income, disability allowance,
27 or disability retirement allowance, from a public employee
28 retirement system. The earnings information shall be released only
29 upon written request from the governing board specifying that the
30 person has applied for or is receiving a disability allowance or
31 disability retirement allowance from its retirement system. The
32 request may be made by the chief executive officer of the system
33 or by an employee of the system so authorized and identified by
34 name and title by the chief executive officer in writing.

35 (k) To enable the Division of Labor Standards Enforcement in
36 the Department of Industrial Relations to seek criminal, civil, or
37 administrative remedies in connection with the failure to pay, or
38 the unlawful payment of, wages pursuant to Chapter 1
39 (commencing with Section 200) of Part 1 of Division 2 of, and

1 Chapter 1 (commencing with Section 1720) of Part 7 of Division
2 2 of, the Labor Code.

3 (l) To enable federal, state, or local governmental departments
4 or agencies to administer child support enforcement programs
5 under Title IV of the Social Security Act (42 U.S.C. Sec. 651 et
6 seq.).

7 (m) To provide federal, state, or local governmental departments
8 or agencies with wage and claim information in its possession that
9 will assist those departments and agencies in the administration
10 of the Victims of Crime Program or in the location of victims of
11 crime who, by state mandate or court order, are entitled to
12 restitution that has been or can be recovered.

13 (n) To provide federal, state, or local governmental departments
14 or agencies with information concerning any individuals who are
15 or have been:

16 (1) Directed by state mandate or court order to pay restitution,
17 fines, penalties, assessments, or fees as a result of a violation of
18 law.

19 (2) Delinquent or in default on guaranteed student loans or who
20 owe repayment of funds received through other financial assistance
21 programs administered by those agencies. The information released
22 by the director for the purposes of this paragraph shall not include
23 unemployment insurance benefit information.

24 (o) To provide an authorized governmental agency with any or
25 all relevant information that relates to any specific workers'
26 compensation insurance fraud investigation. The information shall
27 be provided to the extent permitted by federal law and regulations.
28 For the purposes of this subdivision, "authorized governmental
29 agency" means the district attorney of any county, the office of
30 the Attorney General, the Department of Industrial Relations, and
31 the Department of Insurance. An authorized governmental agency
32 may disclose this information to the State Bar, the Medical Board
33 of California, or any other licensing board or department whose
34 licensee is the subject of a workers' compensation insurance fraud
35 investigation. This subdivision shall not prevent any authorized
36 governmental agency from reporting to any board or department
37 the suspected misconduct of any licensee of that body.

38 (p) To enable the Director of the Bureau for Private
39 Postsecondary and Vocational Education, or his or her
40 representatives, to access unemployment insurance quarterly wage

1 data on a case-by-case basis to verify information on school
2 administrators, school staff, and students provided by those schools
3 who are being investigated for possible violations of Chapter 7
4 (commencing with Section 94700) of Part 59 of the Education
5 Code.

6 (q) To provide employment tax information to the tax officials
7 of Mexico, if a reciprocal agreement exists. For purposes of this
8 subdivision, "reciprocal agreement" means a formal agreement to
9 exchange information between national taxing officials of Mexico
10 and taxing authorities of the State Board of Equalization, the
11 Franchise Tax Board, and the Employment Development
12 Department. Furthermore, the reciprocal agreement shall be limited
13 to the exchange of information that is essential for tax
14 administration purposes only. Taxing authorities of the State of
15 California shall be granted tax information only on California
16 residents. Taxing authorities of Mexico shall be granted tax
17 information only on Mexican nationals.

18 (r) To enable city and county planning agencies to develop
19 economic forecasts for planning purposes. The information shall
20 be limited to businesses within the jurisdiction of the city or county
21 whose planning agency is requesting the information, and shall
22 not include information regarding individual employees.

23 (s) To provide the State Department of Developmental Services
24 with wage and employer information that will assist in the
25 collection of moneys owed by the recipient, parent, or any other
26 legally liable individual for services and supports provided pursuant
27 to Chapter 9 (commencing with Section 4775) of Division 4.5 of,
28 and Chapter 2 (commencing with Section 7200) and Chapter 3
29 (commencing with Section 7500) of Division 7 of, the Welfare
30 and Institutions Code.

31 (t) Nothing in this section shall be construed to authorize or
32 permit the use of information obtained in the administration of this
33 code by any private collection agency.

34 (u) The disclosure of the name and address of an individual or
35 business entity that was issued an assessment that included
36 penalties under Section 1128 or 1128.1 shall not be in violation
37 of Section 1094 if the assessment is final. The disclosure may also
38 include any of the following:

39 (1) The total amount of the assessment.

1 (2) The amount of the penalty imposed under Section 1128 or
2 1128.1 that is included in the assessment.

3 (3) The facts that resulted in the charging of the penalty under
4 Section 1128 or 1128.1.

5 (v) To enable the Contractors' State License Board to verify
6 the employment history of an individual applying for licensure
7 pursuant to Section 7068 of the Business and Professions Code.

8 (w) To provide any peace officer with the Division of
9 Investigation in the Department of Consumer Affairs information
10 pursuant to subdivision (i) when the requesting peace officer has
11 been designated by the Chief of the Division of Investigation and
12 requests this information in the course of and as part of an
13 investigation into the commission of a crime or other unlawful act
14 when there is reasonable suspicion to believe that the crime or act
15 may be connected to the information requested and would lead to
16 relevant information regarding the crime or unlawful act.

17 (x) To enable the Labor Commissioner of the Division of Labor
18 Standards Enforcement in the Department of Industrial Relations
19 to identify, pursuant to Section 90.3 of the Labor Code, unlawfully
20 uninsured employers. The information shall be provided to the
21 extent permitted by federal law and regulations.

22 (y) To enable the Chancellor of the California Community
23 Colleges, in accordance with the requirements of Section 84754.5
24 of the Education Code, to obtain quarterly wage data, commencing
25 January 1, 1993, on students who have attended one or more
26 community colleges, to assess the impact of education on the
27 employment and earnings of students, to conduct the annual
28 evaluation of district-level and individual college performance in
29 achieving priority educational outcomes, and to submit the required
30 reports to the Legislature and the Governor. The information shall
31 be provided to the extent permitted by federal statutes and
32 regulations.

33 (z) To enable the Public Employees' Retirement System to seek
34 criminal, civil, or administrative remedies in connection with the
35 unlawful application for, or receipt of, benefits provided under
36 Part 3 (commencing with Section 20000) of Division 5 of Title 2
37 of the Government Code.

38 (aa) To enable the Office of Statewide Health Planning and
39 Development to obtain labor market, workforce, and earnings data
40 for the purpose of collecting health care workforce data for the

1 health care workforce clearinghouse established pursuant to Section
2 128050 of the Health and Safety Code. *Personally identifiable*
3 *information obtained by the Office of Statewide Health Planning*
4 *and Development pursuant to this subdivision shall be confidential*
5 *and not subject to public inspection.*

6 ~~SEC. 3.~~

7 *SEC. 4.* The Legislature finds and declares that ~~Section 1 of~~
8 ~~this act, which adds Section 851.5 to the Business and Professions~~
9 ~~Code, imposes Sections 1, 2, and 3 of this act impose~~ a limitation
10 on the public's right of access to the meetings of public bodies or
11 the writings of public officials and agencies within the meaning
12 of Section 3 of Article I of the California Constitution. Pursuant
13 to that constitutional provision, the Legislature makes the following
14 findings to demonstrate the interest protected by this limitation
15 and the need for protecting that interest:

16 In order to protect the privacy of ~~healing arts licensees~~ *individual*
17 *members of the health care workforce*, it is necessary to ensure
18 that personally identifiable information ~~submitted by licensees~~
19 ~~pursuant to this act regarding those individuals~~ is protected as
20 confidential.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 238

VERSION: Amended April 2, 2009

AUTHOR: Calderon (30 - D)

SPONSOR:

RECOMMENDED POSITION:

SUBJECT: Confidentiality of Medical Information Act – Written Communications From the Pharmacy to the Patient re: Prescribed Course of Medical Treatment

EXISTING LAW:

1. The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. (Civil Code §56.10)
2. Violations of the CMIA are subject to civil action for compensatory and punitive damages and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor.
3. Pharmacy regulations provide that common electronic files, as authorized, shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.). (Ref: 16 CCR §1717.1(d), Authority B&P §4005, §4075)
4. Pharmacy regulations authorize the board to issue a citation which may contain either or both an administrative fine and an order of abatement for a violation of the Confidentiality of Medical Information Act (Ref: 16 CCR §1775(a)(3), Authority B&P 4005, 4075)

THIS BILL WOULD:

1. Allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions. Those conditions include, among other things
 - That the written communication be written in the same language as the prescription label;
 - That it instruct the patient when to contact the health care professional;
 - That it shall pertain only to the prescribed course of medical treatment;
 - That it may not mention any other pharmaceutical products;
 - That it shall be limited to specified diseases;

- That further written communication may not be provided under certain circumstances;
 - That all product related information be consistent with the current federal Food and Drug Administration (FDA) approved product package insert, and provide fair and balanced information regarding the products benefits and risks in accordance with the FDA requirements and policies;
 - That a copy of each version shall be submitted to the federal Food and Drug Administration prior to program implementation;
 - That it shall include specified disclosures regarding whether the pharmacy receives direct or indirect remuneration for making that written communication; and
 - That the patient shall receive an opportunity to opt out of the written communication at the time the patient picks up his or her initial prescription. If the patient does not opt out at the time of pick up of an initial prescription, any written communication shall contain instructions for opting out of future communications;
 - Limits access to personally identifiable medical information collected, used and disclosed and provides that a pharmacy must have a written agreement with any entity receiving the information, and specifies criteria related to the confidentiality of that information.
2. Makes other non-substantive changes to provisions within Civil Code §56.10.

AUTHOR'S INTENT

Staff has contacted the author's office to determine the intent. This bill appears to be a reintroduction of SB 1096 (Calderon) [prior session]. SB 1096's intent provided for "adherence" interventions that would allow a pharmacy to mail communications to patients about the importance of following treatment prescribed by their doctors, including refill reminders. Health care information that is designed to encourage proper use of prescribed medications has a proven benefit to individual patients and public health and it is a vital component of an effective treatment regime. Communications include pharmacy reminders to a patient to completely finish a course of treatment and information about the benefits of adhering to therapy and the risks associated with not doing so, what side effects to expect, or when it is important to contact the doctor.

FISCAL IMPACT:

Legislature: As introduced or amended, the bill is not keyed as Fiscal.

Board of Pharmacy: The board does not anticipate any substantial fiscal impact to its operations.

COMMENTS:

This bill appears to be a reintroduced version of last session's SB 1096 (Calderon). The board held an **OPPOSE** position to **SB 1096** (see Legislation and Regulation Committee minutes 4/18/08).

In addition to those provisions introduced last year, this version also specifies a listing of diseases for which a written communication may be issued; specifies under what circumstances a written communication shall be discontinued; and provides "opt-out" provisions for the patient.

HISTORY:

2009

Apr 29 - Bill set for hearing in SEN Health.

Apr. 13 Re-referred to Coms. on HEALTH and JUD.

Apr. 2 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on RLS.

Mar. 9 To Com. on RLS.

Feb. 25 From print. May be acted upon on or after March 27.

Feb. 24 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 2, 2009

SENATE BILL

No. 238

Introduced by Senator Calderon

February 24, 2009

An act to amend Section 56.10 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 238, as amended, Calderon. Medical information.

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor.

~~This bill would state the Legislature's intent to amend these provisions to ensure that patients adhere to prescription refill requirements.~~

This bill would, under those provisions, allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions. Those conditions include, among other things, that the written communication be written in the same language as the prescription label, that it instruct the patient when to contact the health care professional, that it shall pertain only to the prescribed course of medical treatment, that it may not mention any other pharmaceutical products, that it shall be limited to specified

diseases, that further written communication may not be provided under certain circumstances, that a copy of each version shall be submitted to the federal Food and Drug Administration, that it shall include specified disclosures regarding whether the pharmacy receives direct or indirect remuneration for making that written communication, and that the patient shall receive an opportunity to opt out of the written communication.

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

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

1 SECTION 1. Section 56.10 of the Civil Code is amended to
2 read:

3 56.10. (a) No provider of health care, health care service plan,
4 or contractor shall disclose medical information regarding a patient
5 of the provider of health care or an enrollee or subscriber of a
6 health care service plan without first obtaining an authorization,
7 except as provided in subdivision ~~(b)~~ or ~~(c)~~ (b), (c), or (d).

8 (b) A provider of health care, a health care service plan, or a
9 contractor shall disclose medical information if the disclosure is
10 compelled by any of the following:

11 (1) By a court pursuant to an order of that court.

12 (2) By a board, commission, or administrative agency for
13 purposes of adjudication pursuant to its lawful authority.

14 (3) By a party to a proceeding before a court or administrative
15 agency pursuant to a subpoena, subpoena duces tecum, notice to
16 appear served pursuant to Section 1987 of the Code of Civil
17 Procedure, or any provision authorizing discovery in a proceeding
18 before a court or administrative agency.

19 (4) By a board, commission, or administrative agency pursuant
20 to an investigative subpoena issued under Article 2 (commencing
21 with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title
22 2 of the Government Code.

23 (5) By an arbitrator or arbitration panel, when arbitration is
24 lawfully requested by either party, pursuant to a subpoena duces
25 tecum issued under Section 1282.6 of the Code of Civil Procedure,
26 or ~~another~~ any other provision authorizing discovery in a
27 proceeding before an arbitrator or arbitration panel.

1 (6) By a search warrant lawfully issued to a governmental law
2 enforcement agency.

3 (7) By the patient or the patient's representative pursuant to
4 Chapter 1 (commencing with Section 123100) of Part 1 of Division
5 106 of the Health and Safety Code.

6 (8) By a coroner, when requested in the course of an
7 investigation by the coroner's office for the purpose of identifying
8 the decedent or locating next of kin, or when investigating deaths
9 that may involve public health concerns, organ or tissue donation,
10 child abuse, elder abuse, suicides, poisonings, accidents, sudden
11 infant deaths, suspicious deaths, unknown deaths, or criminal
12 deaths, or when otherwise authorized by the decedent's
13 representative. Medical information requested by the coroner under
14 this paragraph shall be limited to information regarding the patient
15 who is the decedent and who is the subject of the investigation and
16 shall be disclosed to the coroner without delay upon request.

17 (9) When otherwise specifically required by law.

18 (c) A provider of health care or a health care service plan may
19 disclose medical information as follows:

20 (1) The information may be disclosed to providers of health
21 care, health care service plans, contractors, or other health care
22 professionals or facilities for purposes of diagnosis or treatment
23 of the patient. This includes, in an emergency situation, the
24 communication of patient information by radio transmission or
25 other means between emergency medical personnel at the scene
26 of an emergency, or in an emergency medical transport vehicle,
27 and emergency medical personnel at a health facility licensed
28 pursuant to Chapter 2 (commencing with Section 1250) of Division
29 2 of the Health and Safety Code.

30 (2) The information may be disclosed to an insurer, employer,
31 health care service plan, hospital service plan, employee benefit
32 plan, governmental authority, contractor, or any other person or
33 entity responsible for paying for health care services rendered to
34 the patient, to the extent necessary to allow responsibility for
35 payment to be determined and payment to be made. If (A) the
36 patient is, by reason of a comatose or other disabling medical
37 condition, unable to consent to the disclosure of medical
38 information and (B) no other arrangements have been made to pay
39 for the health care services being rendered to the patient, the
40 information may be disclosed to a governmental authority to the

1 extent necessary to determine the patient's eligibility for, and to
2 obtain, payment under a governmental program for health care
3 services provided to the patient. The information may also be
4 disclosed to another provider of health care or health care service
5 plan as necessary to assist the other provider or health care service
6 plan in obtaining payment for health care services rendered by that
7 provider of health care or health care service plan to the patient.

8 (3) The information may be disclosed to a person or entity that
9 provides billing, claims management, medical data processing, or
10 other administrative services for providers of health care or health
11 care service plans or for any of the persons or entities specified in
12 paragraph (2). However, *no* information so disclosed shall not be
13 further disclosed by the recipient in *any* way that would violate
14 this part.

15 (4) The information may be disclosed to organized committees
16 and agents of professional societies or of medical staffs of licensed
17 hospitals, licensed health care service plans, professional standards
18 review organizations, independent medical review organizations
19 and their selected reviewers, utilization and quality control peer
20 review organizations as established by Congress in Public Law
21 97-248 in 1982, contractors, or persons or organizations insuring,
22 responsible for, or defending professional liability that a provider
23 may incur, if the committees, agents, health care service plans,
24 organizations, reviewers, contractors, or persons are engaged in
25 reviewing the competence or qualifications of health care
26 professionals or in reviewing health care services with respect to
27 medical necessity, level of care, quality of care, or justification of
28 charges.

29 (5) The information in the possession of a provider of health
30 care or health care service plan may be reviewed by a private or
31 public body responsible for licensing or accrediting the provider
32 of health care or health care service plan. However, no
33 patient-identifying medical information may be removed from the
34 premises except as expressly permitted or required elsewhere by
35 law, nor shall that information be further disclosed by the recipient
36 in a way that would violate this part.

37 (6) The information may be disclosed to the county coroner in
38 the course of an investigation by the coroner's office when
39 requested for all purposes not included in paragraph (8) of
40 subdivision (b).

1 (7) The information may be disclosed to public agencies, clinical
2 investigators, including investigators conducting epidemiologic
3 studies, health care research organizations, and accredited public
4 or private nonprofit educational or health care institutions for bona
5 fide research purposes. However, no information so disclosed shall
6 be further disclosed by the recipient in ~~a~~ *any* way that would
7 disclose the identity of a patient or violate this part.

8 (8) A provider of health care or health care service plan that has
9 created medical information as a result of employment-related
10 health care services to an employee conducted at the specific prior
11 written request and expense of the employer may disclose to the
12 employee's employer that part of the information that:

13 (A) Is relevant in a lawsuit, arbitration, grievance, or other claim
14 or challenge to which the employer and the employee are parties
15 and in which the patient has placed in issue his or her medical
16 history, mental or physical condition, or treatment, provided that
17 information may only be used or disclosed in connection with that
18 proceeding.

19 (B) Describes functional limitations of the patient that may
20 entitle the patient to leave from work for medical reasons or limit
21 the patient's fitness to perform his or her present employment,
22 provided that no statement of medical cause is included in the
23 information disclosed.

24 (9) Unless the provider of health care or health care service plan
25 is notified in writing of an agreement by the sponsor, insurer, or
26 administrator to the contrary, the information may be disclosed to
27 a sponsor, insurer, or administrator of a group or individual insured
28 or uninsured plan or policy that the patient seeks coverage by or
29 benefits from, if the information was created by the provider of
30 health care or health care service plan as the result of services
31 conducted at the specific prior written request and expense of the
32 sponsor, insurer, or administrator for the purpose of evaluating the
33 application for coverage or benefits.

34 (10) The information may be disclosed to a health care service
35 plan by providers of health care that contract with the health care
36 service plan and may be transferred among providers of health
37 care that contract with the health care service plan, for the purpose
38 of administering the health care service plan. Medical information
39 ~~shall~~ *may* not otherwise be disclosed by a health care service plan
40 except in accordance with *the provisions of* this part.

1 (11) ~~This part does not~~ *Nothing in this part shall* prevent the
2 disclosure by a provider of health care or a health care service plan
3 to an insurance institution, agent, or support organization, subject
4 to Article 6.6 (commencing with Section 791) of ~~Chapter 1 of Part~~
5 2 of Division 1 of the Insurance Code, of medical information if
6 the insurance institution, agent, or support organization has
7 complied with all of the requirements for obtaining the information
8 pursuant to Article 6.6 (commencing with Section 791) of ~~Chapter~~
9 ~~1 of Part 2 of Division 1 of the Insurance Code.~~

10 (12) The information relevant to the patient's ~~condition, care,~~
11 ~~and condition and care and~~ treatment provided may be disclosed
12 to a probate court investigator in the course of ~~an any~~ investigation
13 required or authorized in a conservatorship proceeding under the
14 Guardianship-Conservatorship Law as defined in Section 1400 of
15 the Probate Code, or to a probate court investigator, probation
16 officer, or domestic relations investigator engaged in determining
17 the need for an initial guardianship or continuation of an ~~existing~~
18 *existent* guardianship.

19 (13) The information may be disclosed to an organ procurement
20 organization or a tissue bank processing the tissue of a decedent
21 for transplantation into the body of another person, but only with
22 respect to the donating decedent, for the purpose of aiding the
23 transplant. For the purpose of this paragraph, *the terms* "tissue
24 bank" and "tissue" have the same ~~meanings~~ *meaning* as defined
25 in Section 1635 of the Health and Safety Code.

26 (14) The information may be disclosed when the disclosure is
27 otherwise specifically authorized by law, including, but not limited
28 to, the voluntary reporting, either directly or indirectly, to the
29 federal Food and Drug Administration of adverse events related
30 to drug products or medical device problems.

31 (15) Basic information, including the patient's name, city of
32 residence, age, sex, and general condition, may be disclosed to a
33 ~~state-recognized~~ *state* or federally recognized disaster relief
34 organization for the purpose of responding to disaster welfare
35 inquiries.

36 (16) The information may be disclosed to a third party for
37 purposes of encoding, encrypting, or otherwise anonymizing data.
38 However, no information so disclosed shall be further disclosed
39 by the recipient in ~~a any~~ way that would violate this part, including
40 the unauthorized manipulation of coded or encrypted medical

1 information that reveals individually identifiable medical
2 information.

3 (17) For purposes of disease management programs and services
4 as defined in Section 1399.901 of the Health and Safety Code,
5 information may be disclosed as follows: (A) to an entity
6 contracting with a health care service plan or the health care service
7 plan's contractors to monitor or administer care of enrollees for a
8 covered benefit, if the disease management services and care are
9 authorized by a treating physician, or (B) to a disease management
10 organization, as defined in Section 1399.900 of the Health and
11 Safety Code, that complies fully with the physician authorization
12 requirements of Section 1399.902 of the Health and Safety Code,
13 if the health care service plan or its contractor provides or has
14 provided a description of the disease management services to a
15 treating physician or to the health care service plan's or contractor's
16 network of physicians. ~~This paragraph does not~~ *Nothing in this*
17 *paragraph shall be construed to* require physician authorization
18 for the care or treatment of the adherents of a well-recognized
19 church or religious denomination who depend solely upon prayer
20 or spiritual means for healing in the practice of the religion of that
21 church or denomination.

22 (18) The information may be disclosed, as permitted by state
23 and federal law or regulation, to a local health department for the
24 purpose of preventing or controlling disease, injury, or disability,
25 including, but not limited to, the reporting of disease, injury, vital
26 events, including, but not limited to, birth or death, and the conduct
27 of public health surveillance, public health investigations, and
28 public health interventions, as authorized or required by state or
29 federal law or regulation.

30 (19) The information may be disclosed, consistent with
31 applicable law and standards of ethical conduct, by a
32 psychotherapist, as defined in Section 1010 of the Evidence Code,
33 if the psychotherapist, in good faith, believes the disclosure is
34 necessary to prevent or lessen a serious and imminent threat to the
35 health or safety of a reasonably foreseeable victim or victims, and
36 the disclosure is made to a person or persons reasonably able to
37 prevent or lessen the threat, including the target of the threat.

38 (20) The information may be disclosed as described in Section
39 56.103.

1 (d) Except to the extent expressly authorized by ~~a~~ *the* patient
2 or enrollee or subscriber or as provided by subdivisions (b) and
3 (c), ~~a~~ *no* provider of health care, health care service plan,
4 contractor, or corporation and its subsidiaries and affiliates shall
5 ~~not~~ intentionally share, sell, use for marketing, or otherwise use
6 *any* medical information for ~~a~~ *any* purpose not necessary to provide
7 health care services to the patient. *For purposes of this section, a*
8 *written communication mailed to a patient by a pharmacy shall*
9 *be deemed to be necessary to provide health care services to the*
10 *patient and shall not require prior authorization, if all of the*
11 *following conditions are met:*

12 (1) *The written communication encourages the patient to adhere*
13 *to the prescribed course of medical treatment as prescribed by a*
14 *licensed health care professional and may include information*
15 *about that particular pharmaceutical drug as authorized in this*
16 *section.*

17 (2) *The communication is written in the same language as the*
18 *prescription label produced by the pharmacy when the medication*
19 *was dispensed.*

20 (3) *The written communication instructs the patient to contact*
21 *the prescribing or dispensing health care professional if:*

22 (A) *The patient has questions about the medication.*

23 (B) *The patient is having difficulty adhering to the medication*
24 *due to adverse effects, dosing requirements, or other causes.*

25 (4) *The written communication pertains only to the prescribed*
26 *course of medical treatment, and does not describe or mention*
27 *any other pharmaceutical products. The written communication*
28 *shall be limited to the following diseases:*

29 (A) *Diabetes.*

30 (B) *Osteoporosis.*

31 (C) *Asthma.*

32 (D) *Chronic obstructive pulmonary disease.*

33 (E) *Cancer.*

34 (F) *Gastric disorder.*

35 (G) *Hypertension.*

36 (H) *Cardiovascular disease.*

37 (I) *Thyroid disorder.*

38 (J) *Organ transplantation.*

39 (K) *Chronic eye disorder.*

40 (L) *Rheumatoid arthritis and osteoarthritis.*

- 1 (M) Renal disorders.
- 2 (N) Parkinson's disease.
- 3 (O) Seizures.
- 4 (P) Multiple sclerosis.
- 5 (Q) Depression.
- 6 (R) Schizophrenia.
- 7 (S) Bipolar disorder.
- 8 (T) Anxiety disorders.
- 9 (U) Attention deficit disorder.
- 10 (5) Further written communication shall not be provided if there
11 are no refills remaining on the prescribed course of therapy and
12 there are no doses remaining on the final prescribed refill, or the
13 pharmacy has been notified by a health care provider that a
14 prescribed course of therapy has been discontinued or substituted
15 with a different drug.
- 16 (6) All product-related information in the written communication
17 shall be consistent with the current federal Food and Drug
18 Administration (FDA) approved product package insert, and
19 provide fair and balanced information regarding the product's
20 benefits and risks in accordance with the FDA requirements and
21 policies.
- 22 (7) A copy of each written communication version shall be
23 submitted to the FDA Center for Drug Evaluation and Research,
24 Division of Drug Marketing, Advertising and Communications,
25 prior to program implementation.
- 26 (8) Evidence-based or consensus-based practice guidelines
27 shall be the basis of any information that is provided to patients
28 in order to improve their overall health, prevent clinical
29 exacerbations or complications, or promote patient
30 self-management strategies.
- 31 (9) All personally identifiable medical information collected,
32 used, and disclosed pursuant to this subdivision shall be
33 confidential and shall be used solely to deliver the written
34 communication to the patient. Access to the information shall be
35 limited to authorized persons. Any entity that receives the
36 information pursuant to this subdivision shall comply with existing
37 requirements, including Sections 56.101 and 1798.84, concerning
38 confidentiality and security of information. The pharmacy must
39 have a written agreement with any entity that receives the
40 information. The written agreement shall require the entity to

1 *maintain the confidentiality of the information it receives from the*
2 *pharmacy and prohibit the entity from disclosing or using the*
3 *information for any purpose other than to deliver to the patient*
4 *the written communication that is the subject of the written*
5 *agreement.*

6 *(10) If the written communication is paid for, in whole or in*
7 *part, by a manufacturer, distributor, or provider of a health care*
8 *product or service, the written communication shall disclose*
9 *whether the pharmacy receives direct or indirect remuneration,*
10 *including, but not limited to, gifts, fees, payments, subsidies, or*
11 *other economic benefits from a third party for making the written*
12 *communication and shall disclose, in a clear and conspicuous*
13 *location, the source of any sponsorship in a typeface no smaller*
14 *than 14-point type.*

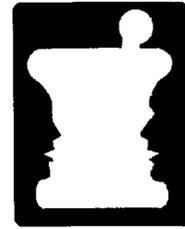
15 *(11) A pharmacy offers the patient, at the time the patient picks*
16 *up his or her initial prescription, an opportunity to opt out of*
17 *receiving a written communication from a pharmacy. If the patient*
18 *opts out, then no sponsored message shall be made to the patient.*
19 *If, at the time the patient picks up his or her initial prescription,*
20 *the patient does not opt out, then the written communication shall*
21 *contain instructions in a typeface no smaller than 14-point type*
22 *describing how the patient may opt out of future communications*
23 *by, for example, calling a toll-free telephone number or visiting*
24 *an Internet Web site, and no further sponsored message shall be*
25 *made to the patient after 30 calendar days from the date the*
26 *individual makes the opt out request.*

27 *(e) Except to the extent expressly authorized by a the patient or*
28 *enrollee or subscriber or as provided by subdivisions (b) and (c),*
29 *a no contractor or corporation and its subsidiaries and affiliates*
30 *shall not further disclose medical information regarding a patient*
31 *of the provider of health care or an enrollee or subscriber of a*
32 *health care service plan or insurer or self-insured employer received*
33 *under this section to a person or entity that is not engaged in*
34 *providing direct health care services to the patient or his or her*
35 *provider of health care or health care service plan or insurer or*
36 *self-insured employer.*

1 ~~SECTION 1. It is the intent of the Legislature to amend Section~~
2 ~~56.10 of the Civil Code, relating to medical information, to ensure~~
3 ~~that patients adhere to prescription refill requirements.~~

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 341

VERSION: Amended March 31, 2009

AUTHOR: DeSaulnier

SPONSOR: California Alliance for Retired Americans

BOARD POSITION:

SUBJECT: Pharmaceuticals: adverse drug reactions: Drug Safety and Effectiveness Program

EXISTING LAW:

Existing federal law establishes the United States Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), to regulate the manufacture, labeling, sale and distribution of drugs in the United States under the authority of the Federal Food, Drug, and Cosmetic Act.

Federal law requires the FDA to protect public health by ensuring the safety and efficacy of all regulated marketed medical products. Additionally, the FDA is required to ensure that prescription drug information is truthful, balanced, and accurately communicated to the public.

Existing state law establishes the Sherman, Food, Drug, and Cosmetics Act to regulate the processing, labeling, advertising, and sale of food, drugs, devices, and cosmetics under the California Department of Public Health (CDPH).

THIS BILL WOULD:

Enact the Drug Safety and Effectiveness Program and require the Department of Public Health (CDPH) to make every effort to enter into a contract or agreement with the University of California (UC) to establish a program to evaluate scientific literature that UC determines is relevant to the safety and effectiveness of prescription drugs in the state.

Specifically, SB 341 adds

Add Article 7 (commencing with Section 111657) to the Health and Safety Code to

- Require the CDPH to report annually by December 1, 2011 and every year thereafter until December 1, 2015, to the Assembly and Senate Committees on Health a report on the development of the prescription education service established.
- Require the State Department of Public Health to enter into a contract or agreement with the University of California to establish a program to evaluate scientific literature that the UC determines relevant to the safety and effectiveness of prescription drugs;

Such a program shall

- Include, until January 1, 2015, a prescription education service, as specified.

- Determine the classes of prescription drugs to be advertised to consumers, marketed to physicians, or both, in the state
- An Internet web site to report information on the safety and effectiveness of the drugs identified and what information will be included on that web site;
- Prescribe that the UC rely on the best scientific information available, as specified;
- Specify provisions within the contract or agreement scope, including the methodology, reports, due dates, and other deliverables;
- Specify the criteria for a prescription education service, including outreach and education sessions.
- Provides for a pilot project to provide health care professionals who are licensed to prescribe or dispense prescription drugs with information and education, as specified. The pilot project would be operated in Contra Costa and one other county, as determined by CDPH.
- Establish a clinical advisory panel comprised of physician specialists in the drug class being reviewed, physicians and pharmacists serving diverse communities, patient advocates, and senior citizen organizations;
- Specify what drugs shall be excluded from evaluation; and other provisions.
- Require CDPH to adopt regulations, as specified.

Add section 111657.1 to the Health and Safety Code to

- Impose a fee on manufacturers of drugs sold in the state for the purpose of supporting the department and the UC in implementing this article, and specifying a maximum assessment on drug manufacturers of \$3,500,000.
- Provide that the CDPH shall establish the fee to be assessed and the basis of that fee.
- Provides that fees not be assessed on drug manufacturers that do not manufacture drugs that are advertised to consumers or marketed to physicians in the state.
- Provides the fee shall be assessed and collected annually by the Board of Equalization, as specified.
- Creates the Drug Safety and Effectiveness Fund to which fees shall be deposited.
- Provides that section 111657.1 shall not be implemented until such time that the CDPH and the UC enter into a contract or agreement pursuant to 111657.

AUTHOR'S INTENT

According to the author, SB 341 addresses the need for patients and physicians to have access to scientific information about the relative safety and effectiveness of prescription drugs. The author provides that to protect consumer health, Californians need the most reliable, unbiased, scientific information about the safety and effectiveness of the prescription drugs that are advertised and marketed in California.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact to its operations.

COMMENT:

This bill is *of interest*. As introduced or amended, this bill does not directly impact Pharmacy Law or the board's jurisdiction. Staff will continue to monitor the bill and any subsequent amendments. The bill failed passage in Senate Health but was granted reconsideration.

SUPPORT / OPPOSITION:

Support:

California Alliance for Retired Americans (sponsor)
American Association of Retired Persons
American Federation of State, County and Municipal Employees
California Council of Community Mental Health Agencies
California Federation of Teachers
California Labor Federation, AFL-CIO
California Nurses Association
California Rural Legal Assistance Foundation
California School Employees Association
Community Catalyst
Congress of California Seniors
Health Access California
Health Care for All-California
Mental Health Association in California
Service Employees International Union
Western States Council of the United Food and Commercial Workers
One individual

Oppose:

AstraZeneca
BIOCOM
California Healthcare Institute
Novartis Pharmaceuticals Corporation
Pharmaceutical Research and Manufacturers of America

HISTORY:

2009

Apr. 15 Set, first hearing. Failed passage in committee. Reconsideration granted (SEN Health).
Mar. 31 From committee with author's amendments. Read second time. Amended. Re-referred to
Com. on HEALTH.
Mar. 26 Set for hearing April 15.
Mar. 25 Hearing postponed by committee.
Mar. 19 Set for hearing April 1.
Mar. 9 To Coms. on HEALTH and REV. & TAX.
Feb. 26 From print. May be acted upon on or after March 28.
Feb. 25 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MARCH 31, 2009

SENATE BILL

No. 341

Introduced by Senator DeSaulnier

February 25, 2009

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 341, as amended, DeSaulnier. Pharmaceuticals: adverse drug reactions: Drug Safety and Effectiveness Program.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Public Health.

This bill would require the department to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in California. This bill would require, if the department and the University of California enter into a contract or agreement to establish the program, that the program include specified components, including, among other things, a determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in California, and an Internet Web site designed to disseminate information to health care professionals and consumers on the relative safety and effectiveness of those drugs, as specified. *The program shall include, until January 1, 2015, a prescription education service, as specified.*

This bill would impose a fee, to be established by the department, on any manufacturer of drugs to which the bill applies, in an amount determined by the department, in consultation with the University of

California, and limited to the amount necessary to fund the actual and necessary expenses of the University of California in implementing the program. This bill would require the fee to be collected by the State Board of Equalization, and to be deposited into the Drug Safety and Effectiveness Fund, which would be created by the bill, and used, upon appropriation by the Legislature, for purposes of the bill.

This bill would specify that the provisions relating to the establishment and the collection of this fee shall not be implemented until the department and the University of California enter into a contract or agreement, as provided for in the bill.

The bill would require the department to provide an annual report on the service to specified legislative committees.

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. The Legislature finds and declares all of the
2 following:
- 3 (a) Since 1997, when the United States Food and Drug
4 Administration (FDA) allowed drug manufacturers to advertise
5 directly to consumers, the amount spent on advertising has risen
6 dramatically.
- 7 (b) According to the United States General Accounting Office
8 (GAO) report, the pharmaceutical industry spent \$2.7 billion in
9 2001 on direct-to-consumer advertising. A December 6, 2004,
10 New York Times report states that such spending has reached \$3.8
11 billion.
- 12 (c) According to the same GAO report, while overall spending
13 on drug promotion was less than spending on research and
14 development (\$19.1 billion versus \$30.3 billion), spending on
15 direct-to-consumer advertising is increasing at a faster rate than
16 overall drug promotion spending or spending on research and
17 development. Between 1997 and 2001, the increase in
18 direct-to-consumer advertising was 145 percent compared to a 59
19 percent increase for research and development.
- 20 (d) Although the FDA is responsible for postmarket surveillance
21 of prescription drugs, numerous concerns have been raised about
22 the adequacy of these efforts.

1 (e) An unpublished internal FDA study from 2002 revealed that
2 18 percent of FDA scientists reported being pressured to approve
3 a new drug “despite reservations about the safety, efficacy or
4 quality of the drug.”

5 (f) A 1999 FDA survey and a Kaiser Family Foundation survey
6 both found that more than 50 million people respond to drug
7 advertisements by asking their doctor whether the advertised
8 medications might work for them. At the same time, both surveys
9 showed that almost 60 percent of consumers found the side-effect
10 warnings in these advertisements to be inadequate.

11 (g) Pressure to get new drugs to market, combined with the vast
12 amount of drug marketing undertaken by manufacturers, make it
13 difficult to address a threat once it is identified. Recent studies
14 linking the use of popular, widely promoted prescription drugs to
15 serious public health concerns point to the need for greater
16 oversight to protect the public.

17 (h) Drugs that are frequently advertised to consumers present
18 special safety concerns because direct-to-consumer advertising is
19 likely to minimize potential side effects and safety concerns and
20 because advertised drugs are likely to be highly utilized by
21 Californians.

22 (i) Californians do not have a reliable central repository of
23 information about prescription drug safety and effectiveness.

24 (j) California physicians and other prescribers could benefit
25 from a reliable central repository of information about prescription
26 drug safety and effectiveness.

27 (k) Various nationally respected sources of clinical information
28 are available as sources for a central repository of information
29 about prescription drug safety and effectiveness.

30 (l) Safer and more effective prescription drugs within a class
31 may also be among the less expensive prescription drugs within
32 that class, meaning that a reliable central repository of information
33 about prescription drug safety and effectiveness would create
34 opportunities for prescription drug cost savings.

35 SEC. 2. Article 7 (commencing with Section 111657) is added
36 to Chapter 6 of Part 5 of Division 104 of the Health and Safety
37 Code, to read:

1 Article 7. Drug Safety and Effectiveness Program

2
3 111657. (a) The State Department of Public Health shall make
4 every effort to enter into a contract or agreement with the
5 University of California to establish a program to evaluate scientific
6 literature that the University of California, if it enters into the
7 agreement or contract with the department, determines relevant to
8 the safety and effectiveness of prescription drugs in the state.

9 (b) The program shall have all of the following components:

10 (1) A determination of the classes of prescription drugs that are
11 advertised to consumers, marketed to physicians, or both, in the
12 state.

13 (2) (A) An Internet Web site that will report information on
14 the safety and effectiveness of brand name and generic drugs in
15 the classes that are identified pursuant to paragraph (1), including,
16 when available, direct comparisons of relative safety and
17 effectiveness, and differential safety and effectiveness of specific
18 drugs according to age, gender, race, or ethnicity.

19 (B) This Web site shall be designed to disseminate information
20 to health care professionals and consumers in the state, and may
21 include links to other relevant Web-based information, if that
22 information has been reviewed and approved by the University of
23 California. The Internet Web site shall include the following
24 statement: "Many factors enter into selecting the proper drug for
25 individual patients, and different patients may respond differently
26 to medications. The information in those reports aims to promote
27 dialogue and responsible consumer choice. Before changing any
28 medication, a patient should consult with his or her treating
29 physician or other prescriber." The statement may be supplemented
30 by any other advisory statements, as are deemed appropriate by
31 the University of California.

32 (C) The Web site design shall ensure that the dissemination of
33 information is done in a culturally competent manner. The
34 information disseminated shall address the differential impact of
35 medications within a class based on gender, age, race and ethnicity,
36 and other factors when that information becomes available. Where
37 studies are relied upon, the demographics of the individuals studied
38 shall be included in the information disseminated.

39 (3) (A) *A prescription education service to provide health care*
40 *professionals who are licensed to prescribe or dispense*

1 *prescription drugs with information and education on the*
2 *comparative efficacy, safety, and cost-effectiveness of commonly*
3 *used prescription drugs and on the use of the Internet Web site*
4 *established pursuant to paragraph (2).*

5 *(B) The prescription education service shall conduct in-person*
6 *outreach and education sessions with health care professionals*
7 *in their place of work. The sessions shall be facilitated by qualified*
8 *and appropriately trained clinician educators and shall be*
9 *conducted on a one-to-one basis, whenever practicable. This*
10 *service shall be made available until January 1, 2015, as a pilot*
11 *project in Contra Costa County to health care professionals who*
12 *participate in, contract with, or are reimbursed by, state-funded*
13 *health care programs. The department shall determine a second*
14 *county in which the prescription education service shall be*
15 *established until January 1, 2015.*

16 *(C) The department shall adopt regulations that establish all*
17 *of the following:*

18 *(i) Minimum clinical and educational qualifications for*
19 *prescriber and dispenser educators employed by or under contract*
20 *with the service.*

21 *(ii) Required training for educators.*

22 *(iii) A code of conduct that governs the behavior of educators*
23 *in their interactions with health care professionals and that*
24 *establishes conflict of interest guidelines for educators and others*
25 *involved in advising, developing, and administering the service.*

26 *(c) In implementing this article, any contract or agreement*
27 *between the department and the University of California entered*
28 *into pursuant to this section shall rely on the best scientific*
29 *information that is available, as determined by the University of*
30 *California, in consultation with the clinical advisory panel, giving*
31 *due consideration to the diversity of the population of the State of*
32 *California. When compiling evidence, any contract or agreement*
33 *between the department and the University of California entered*
34 *into pursuant to this section shall do all of the following:*

35 *(1) Employ a methodology that is transparent, publicly available,*
36 *and open and responsive to public comment.*

37 *(2) Fully disclose its methodology, findings, and limitations.*

38 *(3) Acknowledge that no conclusion can be drawn about*
39 *effectiveness if sufficient evidence is not available.*

1 (4) Have the evidence reviewed by specialists qualified to review
2 medical literature.

3 (5) Consider good quality peer-reviewed clinical trials and
4 observational studies that provide research evidence on the
5 comparative effectiveness, safety, and effect on subpopulations of
6 prescription drugs, and good quality studies that link patient
7 adherence, compliance, and tolerance and alternatives to drug
8 therapy, such as surgery, diet, and exercise, to improved health
9 outcomes.

10 (6) Consider good quality peer-reviewed research evidence that
11 documents variations among individuals of differing age, gender,
12 race, and ethnic subpopulations, the effect of comorbidities and
13 co-occurring disorders, and different patient outcomes based on
14 adherence, compliance, and tolerance.

15 (7) Report any identified gaps in research and opportunities to
16 improve on currently available research.

17 (8) Provide a 30-day comment period during which the public,
18 including manufacturers, providers, and payers, can provide
19 feedback, including additional information and studies that might
20 have been overlooked. The 30-day comment period shall be
21 followed by a revision period before the posting of any final
22 reviews on the Internet Web site.

23 (d) Any contract or agreement entered into between the
24 department and the University of California pursuant to this section
25 shall require the establishment of a clinical advisory panel that
26 includes physician specialists in the drug class being reviewed,
27 physicians and pharmacists serving diverse communities, and
28 patient advocates, including representatives of voluntary health
29 organizations, and senior citizen organizations to serve as advisers
30 to the program at various stages in the process of compiling and
31 disseminating information.

32 (e) The program created by this article shall not include an
33 evaluation of any drug that is used primarily to treat mental illness,
34 except that, where the drug has other therapeutic indications, an
35 evaluation of the drug's safety and efficacy may be performed in
36 relation to those other therapeutic indications.

37 (f) In implementing this article, the Legislature requests that
38 the University of California consider obtaining the assistance of
39 other research universities and medical research centers in the
40 state.

1 (g) It is the intent of the Legislature that the information posted
2 on the program's Internet Web site be used to assist prescribers
3 and patients in choosing the most appropriate therapy for each
4 patient, and that the information not be used to exclude, restrict,
5 or limit coverage and reimbursement for a medication
6 recommended by a patient's prescriber.

7 (h) Any contract or agreement entered into between the
8 department and the University of California pursuant to this section
9 shall require that the University of California begin reporting on
10 the safety and effectiveness of prescription drugs pursuant to this
11 article on a date certain specified in the contract between the
12 department and the University of California. It is the intent of the
13 Legislature that this reporting begin as soon as it is feasible to do
14 so.

15 (i) In order to avoid conflicts of interest, any contract or
16 agreement entered into between the department and the University
17 of California pursuant to this section shall require that the
18 University of California develop and implement conflict-of-interest
19 policies to prohibit a person from participating in the
20 implementation or operation of the program's evaluation of a given
21 class of prescription drugs when he or she knows or has reason to
22 know that he or she has a material financial or other interest,
23 including, but not limited to, a person who has a consulting or
24 other agreement with an organization, that would be affected by
25 the program's evaluation of that given class of prescription drugs.
26 The contract shall require that these conflict-of-interest policies
27 be consistent with, and as rigorous as, the policies utilized by the
28 California Health Benefits Review Program pursuant to Section
29 127663.

30 *SEC. 3. (j) The department shall, by December 1, 2011, and*
31 *every year thereafter, until December 1, 2015, present to the*
32 *Assembly Committee on Health and the Senate Committee on*
33 *Health a report on the development of the prescription education*
34 *service established pursuant to this section.*

35 111657.1. (a) In order to effectively support the department
36 and the University of California in implementing this article, there
37 is hereby imposed, pursuant to this section, a fee on manufacturers
38 of drugs sold in the state. The amount of the fee shall be determined
39 by the department, in consultation with the University of California,
40 and shall be limited to the amount necessary to fund the actual and

1 necessary expenses of the university, the department, and the State
2 Board of Equalization in implementing this article. The total annual
3 assessment on drug manufacturers shall not exceed three million
4 five hundred thousand dollars (\$3,500,000).

5 (b) (1) The specific fee to be assessed on a drug manufacturer
6 shall be established by the department, to the maximum extent
7 practicable, on the basis of a drug manufacturer's market share of
8 the total amount of prescription drugs sold in the state, based on
9 the total dispensed retail dollar amount in the year prior to the
10 assessment.

11 (2) A fee shall not be assessed on a drug manufacturer that can
12 demonstrate, as determined by the department, that it does not
13 manufacture drugs that are advertised to consumers or marketed
14 to physicians in the state.

15 (c) The fee shall be assessed and collected annually by the State
16 Board of Equalization.

17 (1) For purposes of this section, the State Board of Equalization
18 shall collect the drug manufacturer fee in accordance with the Fee
19 Collection Procedures Law (Part 20 (commencing with Section
20 55001) of Division 2 of the Revenue and Taxation Code). The
21 State Board of Equalization may prescribe, adopt, and enforce
22 regulations to carry out this article, including, but not limited to,
23 provisions governing collections, reporting, refunds, and appeals.

24 (2) The department shall provide to the State Board of
25 Equalization the name and address of each person or entity who
26 is liable for a fee or expense, the amount of the fee, and date the
27 fee is due.

28 (3) No petition for redetermination of fees determined by the
29 department pursuant to this section shall be considered by the State
30 Board of Equalization if the petition is founded upon the grounds
31 that the department has improperly or erroneously calculated the
32 amount of the fee or has incorrectly determined that the person is
33 subject to the fee. Any appeal of a determination based on the
34 grounds that the amount of the fee was improperly or erroneously
35 calculated or that the person is not responsible for the fee shall be
36 accepted by the State Board of Equalization and forwarded to the
37 department for consideration and decision.

38 (4) No claim for the refund of fees paid pursuant to this section
39 shall be considered by the State Board of Equalization if the claim
40 is founded upon the grounds that the department has improperly

1 or erroneously calculated the amount of the fee or has incorrectly
2 determined that the person is subject to the fee. Any claim for
3 refund based on the grounds that the amount of the fee was
4 improperly or erroneously calculated or that the person is not
5 responsible for the fee shall be accepted by the State Board of
6 Equalization and forwarded to the department for consideration
7 and decision.

8 (d) The fees collected shall be deposited into the Drug Safety
9 and Effectiveness Fund, which is hereby established in the State
10 Treasury. Moneys in the fund shall be expended, upon
11 appropriation by the Legislature, for the purposes of this article,
12 including, but not limited to, paying refunds of the manufacturer
13 drug fee imposed pursuant to this section, and to reimbursing
14 administrative costs of the State Board of Equalization for
15 collection of the fee. All interest earned on the moneys that have
16 been deposited into the Drug Safety and Effectiveness Fund shall
17 be retained in the fund.

18 (e) The fees collected pursuant to this section and the earnings
19 therefrom shall be used solely for the purposes of implementing
20 this article. The department shall not establish fees pursuant to this
21 section in excess of the amount reasonably anticipated by the
22 University of California and the department, and the State Board
23 of Equalization to fully implement this article.

24 (f) This section shall not be implemented until the department
25 and the University of California enter into a contract or agreement
26 pursuant to Section 111657. The department shall notify the State
27 Board of Equalization when this contract or agreement has been
28 entered into. The State Board of Equalization may delay collection
29 of the first payment of the fee imposed by this section until seven
30 and one-half months after the date that the department and the
31 University of California enter into a contract or agreement pursuant
32 to Section 111657.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 389

VERSION: Introduced: February 26, 2009

AUTHOR: Negrete McLeod

SPONSOR: Author Sponsored

RECOMMENDED POSITION: SUPPORT

SUBJECT: Professions and vocations: Fingerprint Requirements

EXISTING LAW:

1. Requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.
2. Authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

THIS BILL WOULD:

1. Require an applicant for licensure to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice (DOJ) as provided.
2. Require each licensing agency to direct applicants for a license to submit the fingerprint images for the purpose of obtaining information as to the existence or content of a state or federal criminal record.
3. Require the DOJ to forward fingerprint images to the FBI and request federal criminal history information.
4. Require each agency to request subsequent arrest notification from the DOJ.
5. Require every licensee who has not previously submitted fingerprints or for whom a record of submission no longer exists to, as a condition of renewal, complete a state and federal criminal offender record information search.
6. Require all licensees, as a condition of renewal, to certify on the renewal application that he or she has complied with this record information search and require the licensee to retain proof for at least three years.
7. Prohibit the agency from renewing a license until the application for renewal is complete.
8. Allow an agency to waive this requirement if the license is inactive or retired or if the licensee is actively serving in the military. Prohibits the agency from activating a license until the criminal record information search is completed.
9. Require each agency to develop regulations to specify which owners, officers, directors, shareholders, members, agents, employees or other natural persons who are representative of a business entity licensed to complete a state and federal criminal offender record information search.
10. Specify that a licensee that falsely certifies completion of this search may be subject to disciplinary action.
11. Require each agency to require a licensee, as a condition of renewal, to notify the board of a felony or misdemeanor since his or her last renewal.

AUTHOR'S INTENT:

To require fingerprint background checks on all applicants and licensees within the Department of Consumer Affairs.

FISCAL IMPACT:

The board anticipates four limited term Personnel Year (PY) and two permanent full time staff person's to implement the changes. Specifically, the board will require a three year limited term SSA/AGPA to lead over implementation of these requirements as well as three Office Technicians to process the incoming fingerprint results. The board will require one full-time, permanent Management Services Technician to address all renewal related holds that result from this proposal as well as one full-time SSA to complete investigations on the subsequent arrest notifications received as a result of this proposal.

Further, the board will require an increase in its funding for subsequent arrest notifications from the DOJ and will incur programming costs to our CAS system to ensure appropriate implementation.

COMMENTS:

As part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process. However, this bill goes beyond current board requirements, and will require the board to fingerprint existing licensees.

To implement these changes, the board will need some limited term and permanent staff as specified above. Further, the board will need a listing from the DOJ to identify which licensees do not have fingerprint records on file with the DOJ/FBI. Absent such a list, the board will be required to manually pull the files for all of its licensees, to identify who will be affected by this proposal.

At is public meeting held April 16, 2009, the Legislation and Regulation Committee recommends that the Board adopt a "Support" position on this bill.

SUPPORT/OPPOSITION:

Support

Medical Board of California

Oppose Unless Amended

Contractors Board

HISTORY:

- Apr. 21 From committee: Do pass, but first be re-referred to Com. On PUB. S. (Ayes 9. Noes 0. Page 580.) Re-referred to Com. On PUB. S.
- Mar. 27 Set for hearing April 20.
- Mar. 12 To Coms. on B., P. & E.D. and PUB. S.
- Feb. 27 From print. May be acted upon on or after March 28.
- Feb. 26 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Negrete McLeodFebruary 26, 2009

An act to amend Section 144 of, and to add Sections 144.5 and 144.6 to, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 389, as introduced, Negrete McLeod. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.

This bill would make that fingerprinting requirement applicable to the Dental Board of California, the Dental Hygiene Committee of California, the Professional Fiduciary Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would require licensees to certify compliance with that requirement, as specified, and would subject a licensee to disciplinary action for making a false certification. The bill

would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

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 144 of the Business and Professions Code
2 is amended to read:
3 144. (a) Notwithstanding any other provision of law, an agency
4 designated in subdivision (b) shall require an applicant *for a license*
5 to furnish to the agency a full set of fingerprints for purposes of
6 conducting criminal history record checks *and shall require the*
7 *applicant to successfully complete a state and federal level criminal*
8 *offender record information search conducted through the*
9 *Department of Justice as provided in subdivision (c) or as*
10 *otherwise provided in this code. ~~Any agency designated in~~*
11 *subdivision (b) may obtain and receive, at its discretion, criminal*
12 *history information from the Department of Justice and the United*
13 *States Federal Bureau of Investigation.
14 (b) Subdivision (a) applies to the following:
15 (1) California Board of Accountancy.
16 (2) State Athletic Commission.
17 (3) Board of Behavioral Sciences.
18 (4) Court Reporters Board of California.
19 (5) State Board of Guide Dogs for the Blind.
20 (6) California State Board of Pharmacy.
21 (7) Board of Registered Nursing.
22 (8) Veterinary Medical Board.
23 (9) Registered Veterinary Technician Committee.
24 (10) Board of Vocational Nursing and Psychiatric Technicians.
25 (11) Respiratory Care Board of California.
26 (12) Hearing Aid Dispensers ~~Advisory Commission~~ *Bureau*.
27 (13) Physical Therapy Board of California.
28 (14) Physician Assistant Committee of the Medical Board of
29 California.
30 (15) Speech-Language Pathology and Audiology Board.*

- 1 (16) Medical Board of California.
- 2 (17) State Board of Optometry.
- 3 (18) Acupuncture Board.
- 4 (19) Cemetery and Funeral Bureau.
- 5 (20) Bureau of Security and Investigative Services.
- 6 (21) Division of Investigation.
- 7 (22) Board of Psychology.
- 8 (23) ~~The~~ California Board of Occupational Therapy.
- 9 (24) Structural Pest Control Board.
- 10 (25) Contractors' State License Board.
- 11 (26) Bureau of Naturopathic Medicine.
- 12 (27) *Dental Board of California.*
- 13 (28) *Dental Hygiene Committee of California.*
- 14 (27) *Professional Fiduciaries Bureau.*
- 15 (28) *California Board of Podiatric Medicine.*
- 16 (29) *Osteopathic Medical Board of California.*
- 17 (30) *State Board of Chiropractic Examiners.*

18 (e) ~~The provisions of paragraph (24) of subdivision (b) shall~~
19 ~~become operative on July 1, 2004. The provisions of paragraph~~
20 ~~(25) of subdivision (b) shall become operative on the date on which~~
21 ~~sufficient funds are available for the Contractors' State License~~
22 ~~Board and the Department of Justice to conduct a criminal history~~
23 ~~record check pursuant to this section or on July 1, 2005, whichever~~
24 ~~occurs first.~~

25 (c) *Except as otherwise provided in this code, each agency listed*
26 *in subdivision (b) shall direct applicants for a license to submit to*
27 *the Department of Justice fingerprint images and related*
28 *information required by the Department of Justice for the purpose*
29 *of obtaining information as to the existence and content of a state*
30 *or federal criminal record. The Department of Justice shall forward*
31 *the fingerprint images and related information received to the*
32 *Federal Bureau of Investigation and request federal criminal*
33 *history information. The Department of Justice shall compile and*
34 *disseminate state and federal responses to the agency pursuant to*
35 *subdivision (p) of Section 11105 of the Penal Code. The agency*
36 *shall request from the Department of Justice subsequent arrest*
37 *notification service, pursuant to Section 11105.2 of the Penal Code,*
38 *for each person who submitted information pursuant to this*
39 *subdivision. The Department of Justice shall charge a fee sufficient*
40 *to cover the cost of processing the request described in this section.*

1 SEC. 2. Section 144.5 is added to the Business and Professions
2 Code, to read:

3 144.5. (a) Notwithstanding any other provision of law, an
4 agency designated in subdivision (b) of Section 144 shall require
5 a licensee who has not previously submitted fingerprints or for
6 whom a record of the submission of fingerprints no longer exists
7 to, as a condition of license renewal, successfully complete a state
8 and federal level criminal offender record information search
9 conducted through the Department of Justice as provided in
10 subdivision (d).

11 (b) (1) A licensee described in subdivision (a) shall, as a
12 condition of license renewal, certify on the renewal application
13 that he or she has successfully completed a state and federal level
14 criminal offender record information search pursuant to subdivision
15 (d).

16 (2) The licensee shall retain for at least three years, as evidence
17 of the certification made pursuant to paragraph (1), either a receipt
18 showing that he or she has electronically transmitted his or her
19 fingerprint images to the Department of Justice or, for those
20 licensees who did not use an electronic fingerprinting system, a
21 receipt evidencing that the licensee's fingerprints were taken.

22 (c) Failure to provide the certification required by subdivision
23 (b) renders an application for renewal incomplete. An agency shall
24 not renew the license until a complete application is submitted.

25 (d) Each agency listed in subdivision (b) of Section 144 shall
26 direct licensees described in subdivision (a) to submit to the
27 Department of Justice fingerprint images and related information
28 required by the Department of Justice for the purpose of obtaining
29 information as to the existence and content of a state or federal
30 criminal record. The Department of Justice shall forward the
31 fingerprint images and related information received to the Federal
32 Bureau of Investigation and request federal criminal history
33 information. The Department of Justice shall compile and
34 disseminate state and federal responses to the agency pursuant to
35 subdivision (p) of Section 11105 of the Penal Code. The agency
36 shall request from the Department of Justice subsequent arrest
37 notification service, pursuant to Section 11105.2 of the Penal Code,
38 for each person who submitted information pursuant to this
39 subdivision. The Department of Justice shall charge a fee sufficient
40 to cover the cost of processing the request described in this section.

1 (e) An agency may waive the requirements of this section if the
2 license is inactive or retired, or if the licensee is actively serving
3 in the military. The agency may not activate an inactive license or
4 return a retired license to full licensure status for a licensee
5 described in subdivision (a) until the licensee has successfully
6 completed a state and federal level criminal offender record
7 information search pursuant to subdivision (d).

8 (f) With respect to licensees that are business entities, each
9 agency listed in subdivision (b) of Section 144 shall, by regulation,
10 determine which owners, officers, directors, shareholders,
11 members, agents, employees, or other natural persons who are
12 representatives of the business entity are required to submit
13 fingerprint images to the Department of Justice and disclose the
14 information on its renewal forms, as required by this section.

15 (g) A licensee who falsely certifies completion of a state and
16 federal level criminal record information search under subdivision
17 (b) may be subject to disciplinary action by his or her licensing
18 agency.

19 (h) This section shall become operative on January 1, 2011.

20 SEC. 3. Section 144.6 is added to the Business and Professions
21 Code, to read:

22 144.6. (a) An agency described in subdivision (b) of Section
23 144 shall require a licensee, as a condition of license renewal, to
24 notify the board on the license renewal form if he or she has been
25 convicted, as defined in Section 490, of a felony or misdemeanor
26 since his or her last renewal, or if this is the licensee's first renewal,
27 since the initial license was issued.

28 (b) The reporting requirement imposed under this section shall
29 apply in addition to any other reporting requirement imposed under
30 this code.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 484

VERSION: Introduced February 26, 2009

AUTHOR: Wright

SPONSOR: Attorney General's Office

RECOMMENDED POSITION: NONE

SUBJECT: Ephedrine and Pseudoephedrine to Schedule 5

EXISTING LAW:

Under existing law, ephedrine and pseudoephedrine are over-the-counter drugs. In 2006, the federal "Combat Methamphetamine Epidemic Act of 2005" was signed into law. This law requires restrictive sale conditions for over-the-counter sales of products containing ephedrine, pseudoephedrine and phenylpropranolamine (these compounds are used in many cough, cold and allergy products). However, ephedrine and pseudoephedrine also are precursor ingredients used illegally to produce methamphetamine or amphetamine. The federal sales restrictions include daily sales limits, monthly purchase limits, placement of products out of direct customer access, sales logbooks, customer identification at point of sale and employee training.

THIS BILL WOULD:

Add ephedrine and pseudoephedrine to California's Controlled Substances in Schedule 5. Thus a prescription (and presumably at some point, a prescriber's office visit) would be required before a consumer could purchase ephedrine or pseudoephedrine.

AUTHOR'S INTENT:

Ephedrine and pseudoephedrine are over-the-counter drugs. Despite the 2006 sales restrictions implemented by the federal government, the AG's Office believes that additional restrictions are needed for sales of these products.

Methamphetamine production is a serious law enforcement issue – it is highly addictive, and the production of which creates serious public safety and environmental problems.

FISCAL IMPACT:

We anticipate an increase inspector workload to verify compliance and complete investigations associated with this proposal. Addition of this product to Schedule V would not require it be tracked by CURES – which requires computer monitoring of Schedule II – IV drugs.

According to information received, 5,180,246 boxes of ephedrine OTC products were sold last year in California.

COMMENTS:

The scheduling of an OTC to a schedule V on such a widely used product will potentially impact board operations and will have a significant impact of pharmacy operations. Currently the law

requires pharmacies, retailers, manufacturers and wholesalers to report the sales of such products to the Department of Justice. This proposal would require all Californians to obtain a prescription, either written on a security form or oral to obtain any ephedrine product, however would no longer require a pharmacy to report the sales of these products to the DOJ.

Committee Discussion:

The Legislation and Regulation Committee discussed this bill at its public meeting held April 16, 2009. At that time, Kent Shaw, Assistant Chief of the California Bureau of Narcotic Enforcement, California Department of Justice provided information to the committee regarding the increase in methamphetamine labs in California, and those that "smurf" pseudoephedrine purchased from retail outlets in California. Through this legislation, the Attorney General's Office (the sponsor) moves to add pseudoephedrine to Schedule V (thus making it available from a pharmacy). Mr. Shaw provided information related to precursors and the various methods of manufacture of methamphetamine and urged the committee's support of this legislation.

The Committee discussed possible impacts the bill may have on pharmacies, the potential for pharmacy errors, and if alternative products (to pseudoephedrine) are available to those without medical insurance.. Public comment was received by Cookie Quandt representing Longs Drugs, stating that Longs is a proponent of making pseudoephedrine a scheduled drug. Lynn Rolston stated the California Pharmacists Association (CPhA) is in support of this initiative. She sought clarification on why the bill is seeking to add pseudoephedrine to Schedule V as opposed to a schedule that would be tracked through CURES. Mr. Shaw stated that successfully requiring a prescription for this drug is the primary and most achievable challenge.

Executive Officer Virginia Herold discussed the purchase of pseudoephedrine via mail-order. She proposed the consideration of a sunset date of five years.

The Committee concluded their discussion and did not take a position on this bill.

HISTORY:

Apr. 28. Hearing Set for SEN Public Safety
Mar. 12 To Com. on PUB. S.
Feb. 27 From print. May be acted upon on or after March 28.
Feb. 26 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator WrightFebruary 26, 2009

An act to amend Sections 11058, 11100, and 11106 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as introduced, Wright. Ephedrine and pseudoephedrine.

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

This bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription. The bill would make conforming changes to related provisions. By creating new crimes or revising the penalties for existing crimes involving ephedrine, pseudoephedrine, and specified related drugs, involving ephedrine, pseudoephedrine, and specified related drugs, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 11058 of the Health and Safety Code is
2 amended to read:

3 11058. (a) The controlled substances listed in this section are
4 included in Schedule V.

5 (b) Schedule V shall consist of the drugs and other substances,
6 by whatever official name, common or usual name, chemical name,
7 or brand name designated, listed in this section.

8 (c) Narcotic drugs containing nonnarcotic active medicinal
9 ingredients. Any compound, mixture, or preparation containing
10 any of the following narcotic drugs, or their salts calculated as the
11 free anhydrous base or alkaloid, in limited quantities as set forth
12 below, which shall include one or more nonnarcotic active
13 medicinal ingredients in sufficient proportion to confer upon the
14 compound, mixture, or preparation valuable medicinal qualities
15 other than those possessed by narcotic drugs alone:

16 (1) Not more than 200 milligrams of codeine per 100 milliliters
17 or per 100 grams.

18 (2) Not more than 100 milligrams of dihydrocodeine per 100
19 milliliters or per 100 grams.

20 (3) Not more than 100 milligrams of ethylmorphine per 100
21 milliliters or per 100 grams.

22 (4) Not more than 2.5 milligrams of diphenoxylate and not less
23 than 25 micrograms of atropine sulfate per dosage unit.

24 (5) Not more than 100 milligrams of opium per 100 milliliters
25 or per 100 grams.

26 (6) Not more than 0.5 milligram of difenoxin and not less than
27 25 micrograms of atropine sulfate per dosage unit.

28 (7) *Products containing ephedrine, pseudoephedrine,*
29 *norpseudoephedrine, phenylpropanolamine, N-methylephedrine,*
30 *N-ethylephedrine, N-methylpseudoephedrine,*

1 *N*-ethylpseudoephedrine, chloroephedrine, or
2 chloropseudoephedrine, except for pediatric liquid forms as
3 specified in subdivision (h) of Section 11100.

4 (d) Buprenorphine.

5 SEC. 2. Section 11100 of the Health and Safety Code is
6 amended to read:

7 11100. (a) Any manufacturer, or wholesaler, retailer, or other
8 person or entity in this state that sells, transfers, or otherwise
9 furnishes any of the following substances to any person or entity
10 in this state or any other state shall submit a report to the
11 Department of Justice of all of those transactions:

- 12 (1) Phenyl-2-propanone.
- 13 (2) Methylamine.
- 14 (3) Ethylamine.
- 15 (4) D-lysergic acid.
- 16 (5) Ergotamine tartrate.
- 17 (6) Diethyl malonate.
- 18 (7) Malonic acid.
- 19 (8) Ethyl malonate.
- 20 (9) Barbituric acid.
- 21 (10) Piperidine.
- 22 (11) N-acetylanthranilic acid.
- 23 (12) Pyrrolidine.
- 24 (13) Phenylacetic acid.
- 25 (14) Anthranilic acid.
- 26 (15) Morpholine.
- 27 ~~(16) Ephedrine.~~
- 28 ~~(17) Pseudoephedrine.~~
- 29 ~~(18) Norpseudoephedrine.~~
- 30 ~~(19) Phenylpropanolamine.~~
- 31 (20) Propionic anhydride.
- 32 (21) Isosafrole.
- 33 (22) Safrole.
- 34 (23) Piperonal.
- 35 (24) Thionylchloride.
- 36 (25) Benzyl cyanide.
- 37 (26) Ergonovine maleate.
- 38 ~~(27) N-methylephedrine.~~
- 39 ~~(28) N-ethylephedrine.~~
- 40 ~~(29) N-methylpseudoephedrine.~~

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

1 purchaser. The manufacturer; ~~or wholesaler; retailer; or other~~
2 ~~person or entity~~ in this state shall retain this information in a readily
3 available manner for three years. The requirement for a full
4 description of how the substance is to be used does not require the
5 person or business entity to reveal their chemical processes that
6 are typically considered trade secrets and proprietary information.

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

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

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

33 (d) (1) Any manufacturer, wholesaler, retailer, or other person
34 or entity in this state that sells, transfers, or otherwise furnishes a
35 substance specified in subdivision (a) to a person or business entity
36 in this state or any other state shall, not less than 21 days prior to
37 delivery of the substance, submit a report of the transaction, which
38 includes the identification information specified in subdivision
39 (c), to the Department of Justice. The Department of Justice may
40 authorize the submission of the reports on a monthly basis with

1 respect to repeated, regular transactions between the furnisher and
2 the recipient involving the substance or substances if the
3 Department of Justice determines that a pattern of regular supply
4 of the substance or substances exists between the manufacturer or
5 wholesaler, retailer, or other person or entity that sells, transfers,
6 or otherwise furnishes the substance or substances and the recipient
7 of the substance or substances, and the recipient has established a
8 record of utilization of the substance or substances for lawful
9 purposes.

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

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

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

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

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

29 (4)

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

33 (5)

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

36 (6) (A) ~~Any sale, transfer, furnishing, or receipt of any product~~
37 ~~that contains ephedrine, pseudoephedrine, norpseudoephedrine,~~
38 ~~or phenylpropanolamine and which is lawfully sold, transferred,~~
39 ~~or furnished over the counter without a prescription pursuant to~~
40 ~~the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et~~

1 ~~seq.) or regulations adopted thereunder. However, this section~~
2 ~~shall apply to preparations in solid or liquid dosage form, except~~
3 ~~pediatric liquid forms, as defined, containing ephedrine,~~
4 ~~pseudoephedrine, norpseudoephedrine, or phenylpropanolamine~~
5 ~~where the individual transaction involves more than three packages~~
6 ~~or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine,~~
7 ~~or phenylpropanolamine.~~

8 ~~(B)~~

9 ~~(5) Any ephedrine, pseudoephedrine, norpseudoephedrine, or~~
10 ~~phenylpropanolamine sale, transfer, furnishing, or receipt of a~~
11 ~~product specified in paragraph (7) of subdivision (c) of Section~~
12 ~~11058 pursuant to prescription, shall not be subject to reporting~~
13 ~~or permitting requirements of this section, unless a product is~~
14 ~~subsequently removed from exemption pursuant to Section 814~~
15 ~~of Title 21 of the United States Code, in which case the product~~
16 ~~shall similarly no longer be exempt from any state reporting or~~
17 ~~permitting requirement, unless otherwise reinstated pursuant to~~
18 ~~subdivision (d) or (e) of Section 814 of Title 21 of the United States~~
19 ~~Code as an exempt product.~~

20 ~~(7)~~

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

26 ~~(8)~~

27 ~~(7) Any transfer of a substance specified in subdivision (a) for~~
28 ~~purposes of lawful disposal as waste.~~

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

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

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

6 (2) Except as otherwise provided in subparagraph (A) of
7 paragraph (6) of subdivision (e), it is unlawful for any person under
8 18 years of age to possess a substance specified in subdivision (a).

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

25 (4)

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

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

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

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

37 (2) "General merchandise store" is any entity described in Codes
38 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial
39 Classification (SIC) Manual published by the United States Office
40 of Management and Budget, 1987 edition.

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

4 (4) "Pediatric liquid" means a nonencapsulated liquid whose
5 unit measure according to product labeling is stated in milligrams,
6 ounces, or other similar measure. In no instance shall the dosage
7 units exceed 15 milligrams of ~~phenylpropanolamine~~ or
8 ~~pseudoephedrine~~ *any product specified in paragraph (7) of*
9 *subdivision (c) of Section 11058* per five milliliters of liquid
10 product, except for liquid products primarily intended for
11 administration to children under two years of age for which the
12 recommended dosage unit does not exceed two milliliters and the
13 total package content does not exceed one fluid ounce.

14 (5) "Retail distributor" means a grocery store, general
15 merchandise store, drugstore, or other related entity, the activities
16 of which, as a distributor of ~~ephedrine, pseudoephedrine,~~
17 ~~norpseudoephedrine, or phenylpropanolamine~~ products, are limited
18 exclusively to the sale of ~~ephedrine, pseudoephedrine,~~
19 ~~norpseudoephedrine, or phenylpropanolamine~~ products for personal
20 use ~~both in number of sales and volume of sales, any product~~
21 ~~specified in paragraph (7) of subdivision (c) of Section 11058~~ are
22 ~~limited to the sale of those products upon prescription only, except~~
23 ~~for pediatric liquids, either directly to walk-in customers or in~~
24 ~~face-to-face transactions by direct sales.~~ "Retail distributor"
25 includes an entity that makes a direct sale, but does not include
26 the parent company of that entity if the company is not involved
27 in direct sales regulated by this article.

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

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

1 SEC. 3. Section 11106 of the Health and Safety Code is
2 amended to read:

3 11106. (a) (1) (A) Any manufacturer, ~~or wholesaler, retailer,~~
4 ~~or any other person or entity~~ in this state that sells, transfers, or
5 otherwise furnishes any substance specified in subdivision (a) of
6 Section 11100 to a person or business entity in this state or any
7 other state or who obtains from a source outside of the state any
8 substance specified in subdivision (a) of Section 11100 shall submit
9 an application to, and obtain a permit for the conduct of that
10 business from, the Department of Justice. For any substance added
11 to the list set forth in subdivision (a) of Section 11100 on or after
12 January 1, 2002, the Department of Justice may postpone the
13 effective date of the requirement for a permit for a period not to
14 exceed six months from the listing date of the substance.

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

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

34 (D) This paragraph shall not apply to the sale, transfer,
35 furnishing, or receipt of any betadine or povidone solution with
36 an iodine content not exceeding 1 percent in containers of eight
37 ounces or less, or any tincture of iodine not exceeding 2 percent
38 in containers of one ounce or less, that is sold over the counter.

39 ~~(2) Except as provided in paragraph (3), no permit shall be~~
40 ~~required of any manufacturer, wholesaler, retailer, or other person~~

1 or entity for the sale, transfer, furnishing, or obtaining of any
2 product which contains ephedrine, pseudoephedrine,
3 norpseudoephedrine, or phenylpropanolamine and which is
4 lawfully sold, transferred, or furnished over the counter without a
5 prescription or by a prescription pursuant to the federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations
7 adopted thereunder.

8 (3)

9 (2) A permit shall be required for the sale, transfer, furnishing,
10 or obtaining of preparations in solid or liquid dosage form
11 containing ephedrine, pseudoephedrine, norpseudoephedrine, or
12 phenylpropanolamine, unless (A) the transaction involves the sale
13 of ephedrine, pseudoephedrine, norpseudoephedrine, or
14 phenylpropanolamine products by retail distributors as defined by
15 this article over the counter and without a prescription, or (B) the
16 transaction is made by a person or business entity exempted from
17 the permitting requirements of this subdivision under paragraph
18 (1) any product as specified in paragraph (7) of subdivision (c) of
19 Section 11058.

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

34 (2) The requirement for the specific purpose for the use, sale,
35 or transfer of those substances specified in subdivision (a) of
36 Section 11100 does not require applicants or permittees to reveal
37 their chemical processes that are typically considered trade secrets
38 and proprietary business information.

39 (c) Applicants and permittees shall authorize the department,
40 or any of its duly authorized representatives, as a condition of

1 being permitted, to make any examination of the books and records
2 of any applicant, permittee, or other person, or visit and inspect
3 the business premises of any applicant or permittee during normal
4 business hours, as deemed necessary to enforce this chapter.

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

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

10 (2) If any individual owner, manager, agent, representative, or
11 employee for the applicant who has direct access, management,
12 or control for any substance listed under subdivision (a) of Section
13 11100, is or has been convicted of a misdemeanor or felony relating
14 to any of the substances listed under subdivision (a) of Section
15 11100, any misdemeanor drug-related offense, or any felony under
16 the laws of this state or the United States.

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

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

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

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

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

35 (8) If any individual owner, manager, agent, representative, or
36 employee for the applicant who has direct access, management,
37 or control for any substance listed under subdivision (a) of Section
38 11100, willfully violates or has been convicted of violating, any
39 federal, state, or local criminal statute, rule, or ordinance regulating

1 the manufacture, maintenance, disposal, sale, transfer, or furnishing
2 of any of those substances.

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

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

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

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

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

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

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

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

38 (l) (1) An applicant, or an applicant's employees who have
39 direct access, management, or control of any substance listed under
40 subdivision (a) of Section 11100, for an initial permit shall submit

1 with the application one set of 10-print fingerprints for each
2 individual acting in the capacity of an owner, manager, agent, or
3 representative for the applicant, unless the applicant's employees
4 are exempted from this requirement by the Department of Justice.
5 These exemptions may only be obtained upon the written request
6 of the applicant.

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

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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 638 **VERSION:** **Introduced: February 27, 2009**

AUTHOR: Negrete McLeod **SPONSOR:** **Author Sponsored**

RECOMMENDED POSITION: **SUPPORT**

SUBJECT: **Regulatory boards: Operations**

EXISTING LAW

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs (DCA) shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD

1. Provide that if the terms of office of the members of the board are terminated, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor members shall be appointed by the same appointing authorities for the remainder of the previous members' terms.
2. Require that if the term of office for a bureau chief is terminated, a successor bureau chief shall be appointed who shall succeed to and be vested with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor shall be appointed by the same appointing authorities for the remainder of the previous bureau chief's terms.
3. Specify that the provisions apply to all boards, bureaus and entities as listed, including the Board of Pharmacy.
4. Establishes new, yet to be determined sunset dates.
5. Requires that the appropriate policy committees of the Legislature shall review boards and bureaus as specified.
6. Require all boards and bureaus to prepare an analysis and submit a report to the appropriate policy committees of the Legislature no later than 22 months before the sunset date specified.
7. Specify the content of the report to include:
 - The number of complaints received annually, the number that proceeded to investigation, the number of accusations filed per year and the number and kind of disciplinary actions taken.

- The average processing times for complaints and administrative case resolution as specified.
 - The average processing time per year between the final disposition of a complaint and notice to the complainant.
 - A copy of the enforcement priorities including criteria for seeking an interim suspension order.
 - Brief description of the board or bureau's fund condition, sources of revenue and expenditures for the last four fiscal years.
 - A brief description of the cost per year required to implement and administer a licensing examination, ownership of the license examination, the last assessment of the relevancy and validity of the licensing examination and passage rates for each of the last four years.
 - A copy of sponsored legislation and description of budget change proposals.
 - A brief assessment of licensing fees as to whether they are sufficient, too high or too low.
 - A brief statement detailing how enforcement, public disclosure, accessibility to the public has improved over the last four years.
8. Require that the report be posted on the board or bureau's Web site.
 9. Specify that the appropriate policy committees may hold public hearings to receive testimony regarding whether the board's or bureau's policies and practices are sufficient to protect consumers and are fair to licensees and prospective licensees and whether licensure of the profession is required to protect the public and whether an enforcement monitor is necessary to obtain further information on operations.
 10. Allow the appropriate policy committees of the Legislature to evaluate and determine whether a board or program has a demonstrated public need for the continued existence of the regulatory program.

AUTHOR'S INTENT

SB 638 is needed to update and streamline the sunset review process.

FISCAL IMPACT

The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS

This bill provides that when a professional licensing board in the Department of Consumer Affairs becomes inoperative or is repealed, a successor board is created to succeed to, and be vested with all of the duties, powers, purposes, responsibilities, and jurisdiction of the prior board. In effect, this bill makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau under the Department of Consumer Affairs.

This bill removes references to the Joint Committee on Boards Commissions and Consumer Protection, and instead, would provide that the relevant Legislative policy committees shall review the regulatory boards under DCA. The bill revises the review schedule for regulatory boards, and also provides for the review of DCA bureaus.

The board currently collects and reports several of the elements detailed above as part of its quarterly and annual statistics.

At its public meeting held April 16, 2009, the Legislation and Regulation Committee moved to recommend a "Support" position to this bill.

SUPPORT/OPPOSITION

None of file.

HISTORY:

Mar. 27 Set for hearing April 20.

Mar. 19 To Coms. on B., P. & E.D. and RLS.

Mar. 2 Read first time.

Feb. 28 From print. May be acted upon on or after March 30.

Feb. 27 Introduced. To Com. on RLS. for assignment. To print.

Introduced by Senator Negrete McLeodFebruary 27, 2009

An act to amend Sections 22, 473.1, 473.15, 473.2, 473.3, 473.4, 473.6, and 9882 of, to add Sections 473.12 and 473.7 to, to repeal Sections 473.16 and 473.5 of, and to repeal and add Sections 101.1 and 473 of, the Business and Professions Code, relating to regulatory boards.

LEGISLATIVE COUNSEL'S DIGEST

SB 638, as introduced, Negrete McLeod. Regulatory boards: operations.

Existing law creates various regulatory boards, as defined, within the Department of Consumer Affairs, with board members serving specified terms of office. Existing law generally makes the regulatory boards inoperative and repealed on specified dates, unless those dates are deleted or extended by subsequent legislation, and subjects these boards that are scheduled to become inoperative and repealed as well as other boards in state government, as specified, to review by the Joint Committee on Boards, Commissions, and Consumer Protection. Under existing law, that committee, following a specified procedure, recommends whether the board should be continued or its functions modified. Existing law requires the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California to submit certain analyses and reports to the committee on specified dates and requires the committee to review those boards and hold hearings as specified, and to make certain evaluations and findings.

This bill would abolish the Joint Committee on Boards, Commissions, and Consumer Protection and would authorize the appropriate policy committees of the Legislature to carry out its duties. The bill would terminate the terms of office of each board member or bureau chief

within the department on unspecified dates and would authorize successor board members and bureau chiefs to be appointed, as specified. The bill would also subject interior design organizations, the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, and the Tax Education Council to review on unspecified dates. The bill would authorize the appropriate policy committees of the Legislature to review the boards, bureaus, or entities that are scheduled to have their board membership or bureau chief so terminated or reviewed, as specified, and would authorize the appropriate policy committees of the Legislature to investigate their operations and to hold specified public hearings. The bill would require a board, bureau, or entity, if their annual report contains certain information, to post it on its Internet Web site. The bill would make other conforming changes.

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

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

1 SECTION 1. Section 22 of the Business and Professions Code
2 is amended to read:

3 22. (a) "Board," as used in any provision of this code, refers
4 to the board in which the administration of the provision is vested,
5 and unless otherwise expressly provided, shall include "bureau,"
6 "commission," "committee," "department," "division," "examining
7 committee," "program," and "agency."

8 (b) ~~Whenever the regulatory program of a board that is subject~~
9 ~~to review by the Joint Committee on Boards, Commissions, and~~
10 ~~Consumer Protection, as provided for in Division 1.2 (commencing~~
11 ~~with Section 473), is taken over by the department, that program~~
12 ~~shall be designated as a "bureau."~~

13 SEC. 2. Section 101.1 of the Business and Professions Code
14 is repealed.

15 ~~101.1. (a) It is the intent of the Legislature that all existing~~
16 ~~and proposed consumer-related boards or categories of licensed~~
17 ~~professionals be subject to a review every four years to evaluate~~
18 ~~and determine whether each board has demonstrated a public need~~
19 ~~for the continued existence of that board in accordance with~~
20 ~~enumerated factors and standards as set forth in Division 1.2~~
21 ~~(commencing with Section 473).~~

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

7 ~~(2) Any provision of existing law that provides for the~~
8 ~~appointment of board members and specifies the qualifications~~
9 ~~and tenure of board members shall not be implemented and shall~~
10 ~~have no force or effect while that board is inoperative or repealed.~~
11 ~~Every reference to the inoperative or repealed board, as defined~~
12 ~~in Section 477, shall be deemed to be a reference to the department.~~

13 ~~(3) Notwithstanding Section 107, any provision of law~~
14 ~~authorizing the appointment of an executive officer by a board~~
15 ~~subject to the review described in Division 1.2 (commencing with~~
16 ~~Section 473), or prescribing his or her duties, shall not be~~
17 ~~implemented and shall have no force or effect while the applicable~~
18 ~~board is inoperative or repealed. Any reference to the executive~~
19 ~~officer of an inoperative or repealed board shall be deemed to be~~
20 ~~a reference to the director or his or her designee.~~

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

24 SEC. 3. Section 101.1 is added to the Business and Professions
25 Code, to read:

26 101.1. (a) Notwithstanding any other provision of law, if the
27 terms of office of the members of a board are terminated in
28 accordance with the act that added this section or by subsequent
29 acts, successor members shall be appointed that shall succeed to,
30 and be vested with, all the duties, powers, purposes,
31 responsibilities, and jurisdiction not otherwise repealed or made
32 inoperative of the members that they are succeeding. The successor
33 members shall be appointed by the same appointing authorities,
34 for the remainder of the previous members' terms, and shall be
35 subject to the same membership requirements as the members they
36 are succeeding.

37 (b) Notwithstanding any other provision of law, if the term of
38 office for a bureau chief is terminated in accordance with the act
39 that added this section or by subsequent acts, a successor bureau
40 chief shall be appointed who shall succeed to, and be vested with,

1 all the duties, powers, purposes, responsibilities, and jurisdiction
2 not otherwise repealed or made inoperative of the bureau chief
3 that he or she is succeeding. The successor bureau chief shall be
4 appointed by the same appointing authorities, for the remainder
5 of the previous bureau chief's term, and shall be subject to the
6 same requirements as the bureau chief he or she is succeeding.

7 SEC. 4. Section 473 of the Business and Professions Code is
8 repealed.

9 ~~473. (a) There is hereby established the Joint Committee on~~
10 ~~Boards, Commissions, and Consumer Protection.~~

11 ~~(b) The Joint Committee on Boards, Commissions, and~~
12 ~~Consumer Protection shall consist of three members appointed by~~
13 ~~the Senate Committee on Rules and three members appointed by~~
14 ~~the Speaker of the Assembly. No more than two of the three~~
15 ~~members appointed from either the Senate or the Assembly shall~~
16 ~~be from the same party. The Joint Rules Committee shall appoint~~
17 ~~the chairperson of the committee.~~

18 ~~(c) The Joint Committee on Boards, Commissions, and~~
19 ~~Consumer Protection shall have and exercise all of the rights,~~
20 ~~duties, and powers conferred upon investigating committees and~~
21 ~~their members by the Joint Rules of the Senate and Assembly as~~
22 ~~they are adopted and amended from time to time, which provisions~~
23 ~~are incorporated herein and made applicable to this committee and~~
24 ~~its members.~~

25 ~~(d) The Speaker of the Assembly and the Senate Committee on~~
26 ~~Rules may designate staff for the Joint Committee on Boards,~~
27 ~~Commissions, and Consumer Protection.~~

28 ~~(e) The Joint Committee on Boards, Commissions, and~~
29 ~~Consumer Protection is authorized to act until January 1, 2012, at~~
30 ~~which time the committee's existence shall terminate.~~

31 SEC. 5. Section 473 is added to the Business and Professions
32 Code, to read:

33 473. Whenever the provisions of this code refer to the Joint
34 Committee on Boards, Commissions and Consumer Protection,
35 the reference shall be construed to be a reference to the appropriate
36 policy committees of the Legislature.

37 SEC. 6. Section 473.1 of the Business and Professions Code
38 is amended to read:

39 473.1. This chapter shall apply to all of the following:

1 (a) Every board, as defined in Section 22, that is scheduled to
2 ~~become inoperative and to be repealed~~ *have its membership*
3 *reconstituted* on a specified date as provided by ~~the specific act~~
4 *relating to the board subdivision (a) of Section 473.12.*

5 ~~(b) The Bureau for Postsecondary and Vocational Education.~~
6 ~~For purposes of this chapter, "board" includes the bureau~~
7 *bureau that is named in subdivision (b) of Section 473.12.*

8 ~~(c) The Cemetery and Funeral Bureau~~
9 *Every entity that is named in subdivision (c) of Section 473.12.*

10 SEC. 7. Section 473.12 is added to the Business and Professions
11 Code, to read:

12 473.12. (a) Notwithstanding any other provision of law, the
13 term of office of each member of the following boards in the
14 department shall terminate on the date listed, unless a later enacted
15 statute, that is enacted before the date listed for that board, deletes
16 or extends that date:

- 17 (1) The Dental Board of California: January 1, ____.
- 18 (2) The Medical Board of California: January 1, ____.
- 19 (3) The State Board of Optometry: January 1, ____.
- 20 (4) The California State Board of Pharmacy: January 1, ____.
- 21 (5) The Veterinary Medical Board: January 1, ____.
- 22 (6) The California Board of Accountancy: January 1, ____.
- 23 (7) The California Architects Board: January 1, ____.
- 24 (8) The State Board of Barbering and Cosmetology: January 1,
- 25 ____.
- 26 (9) The Board for Professional Engineers and Land Surveyors:
- 27 January 1, ____.
- 28 (10) The Contractors' State License Board: January 1, ____.
- 29 (11) The Structural Pest Control Board: January 1, ____.
- 30 (12) The Board of Registered Nursing: January 1, ____.
- 31 (13) The Board of Behavioral Sciences: January 1, ____.
- 32 (14) The State Athletic Commission: January 1, ____.
- 33 (15) The State Board of Guide Dogs for the Blind: January 1,
- 34 ____.
- 35 (16) The Court Reporters Board of California: January 1, ____.
- 36 (17) The Board of Vocational Nursing and Psychiatric
- 37 Technicians: January 1, ____.
- 38 (18) The Landscape Architects Technical Committee: January
- 39 1, ____.

- 1 (19) The Board for Geologists and Geophysicists: January 1,
2 ____.
- 3 (20) The Respiratory Care Board of California: January 1, ____.
- 4 (21) The Acupuncture Board: January 1, ____.
- 5 (22) The Board of Psychology: January 1, ____.
- 6 (23) The California Board of Podiatric Medicine: January 1,
7 ____.
- 8 (24) The Physical Therapy Board of California: January 1, ____.
- 9 (25) The Physician Assistant Committee, Medical Board of
10 California: January 1, ____.
- 11 (26) The Speech-Language Pathology and Audiology Board:
12 January 1, ____.
- 13 (27) The California Board of Occupational Therapy: January
14 1, ____.
- 15 (28) The Dental Hygiene Committee of California: January 1,
16 ____.
- 17 (b) Notwithstanding any other provision of law, the term of
18 office for the bureau chief of each of the following bureaus shall
19 terminate on the date listed, unless a later enacted statute, that is
20 enacted before the date listed for that bureau, deletes or extends
21 that date:
- 22 (1) Arbitration Review Program: January 1, ____.
- 23 (2) Bureau for Private Postsecondary Education: January 1,
24 ____.
- 25 (3) Bureau of Automotive Repair: January 1, ____.
- 26 (4) Bureau of Electronic and Appliance Repair: January 1, ____.
- 27 (5) Bureau of Home Furnishings and Thermal Insulation:
28 January 1, ____.
- 29 (6) Bureau of Naturopathic Medicine: January 1, ____.
- 30 (7) Bureau of Security and Investigative Services: January 1,
31 ____.
- 32 (8) Cemetery and Funeral Bureau: January 1, ____.
- 33 (9) Hearing Aid Dispensers Bureau: January 1, ____.
- 34 (10) Professional Fiduciaries Bureau: January 1, ____.
- 35 (11) Telephone Medical Advice Services Bureau: January 1,
36 ____.
- 37 (12) Division of Investigation: January 1, ____.
- 38 (c) Notwithstanding any other provision of law, the following
39 shall be subject to review under this chapter on the following dates:
- 40 (1) Interior design certification organizations: January 1, ____.

1 (2) State Board of Chiropractic Examiners pursuant to Section
2 473.15: January 1, ____.

3 (3) Osteopathic Medical Board of California pursuant to Section
4 473.15: January 1, ____.

5 (4) California Tax Education Council: January 1, ____.

6 (d) Nothing in this section or in Section 101.1 shall be construed
7 to preclude, prohibit, or in any manner alter the requirement of
8 Senate confirmation of a board member, chief officer, or other
9 appointee that is subject to confirmation by the Senate as otherwise
10 required by law.

11 (e) It is not the intent of the Legislature in enacting this section
12 to amend the initiative measure that established the State Board
13 of Chiropractic Examiners or the Osteopathic Medical Board of
14 California.

15 SEC. 8. Section 473.15 of the Business and Professions Code
16 is amended to read:

17 473.15. (a) ~~The Joint Committee on Boards, Commissions,~~
18 ~~and Consumer Protection established pursuant to Section 473~~
19 *appropriate policy committees of the Legislature* shall review the
20 following boards established by initiative measures, as provided
21 in this section:

22 (1) The State Board of Chiropractic Examiners established by
23 an initiative measure approved by electors November 7, 1922.

24 (2) The Osteopathic Medical Board of California established
25 by an initiative measure approved June 2, 1913, and acts
26 amendatory thereto approved by electors November 7, 1922.

27 (b) The Osteopathic Medical Board of California shall prepare
28 an analysis and submit a report as described in subdivisions (a) to
29 (e), inclusive, of Section 473.2, to the ~~Joint Committee on Boards,~~
30 ~~Commissions, and Consumer Protection~~ *appropriate policy*
31 *committees of the Legislature* on or before September 1, 2010.

32 (c) The State Board of Chiropractic Examiners shall prepare an
33 analysis and submit a report as described in subdivisions (a) to (e),
34 inclusive, of Section 473.2, to the ~~Joint Committee on Boards,~~
35 ~~Commissions, and Consumer Protection~~ *appropriate policy*
36 *committees of the Legislature* on or before September 1, 2011.

37 (d) ~~The Joint Committee on Boards, Commissions, and~~
38 ~~Consumer Protection~~ *appropriate policy committees of the*
39 *Legislature* shall, during the interim recess of ~~2004~~ 2011 for the
40 Osteopathic Medical Board of California, and during the interim

1 recess of 2011 for the State Board of Chiropractic Examiners, hold
2 public hearings to receive testimony from the Director of Consumer
3 Affairs, the board involved, the public, and the regulated industry.
4 In that hearing, each board shall be prepared to demonstrate a
5 compelling public need for the continued existence of the board
6 or regulatory program, and that its licensing function is the least
7 restrictive regulation consistent with the public health, safety, and
8 welfare.

9 ~~(e) The Joint Committee on Boards, Commissions, and~~
10 ~~Consumer Protection appropriate policy committees of the~~
11 ~~Legislature shall evaluate and make determinations pursuant to~~
12 ~~Section 473.4 and shall report its findings and recommendations~~
13 ~~to the department as provided in Section 473.5.~~

14 (f) In the exercise of its inherent power to make investigations
15 and ascertain facts to formulate public policy and determine the
16 necessity and expediency of contemplated legislation for the
17 protection of the public health, safety, and welfare, it is the intent
18 of the Legislature that the State Board of Chiropractic Examiners
19 and the Osteopathic Medical Board of California be reviewed
20 pursuant to this section.

21 (g) It is not the intent of the Legislature ~~in requiring a review~~
22 ~~under enacting~~ this section to amend the initiative measures that
23 established the State Board of Chiropractic Examiners or the
24 Osteopathic Medical Board of California.

25 SEC. 9. Section 473.16 of the Business and Professions Code
26 is repealed.

27 ~~473.16. The Joint Committee on Boards, Commissions, and~~
28 ~~Consumer Protection shall examine the composition of the Medical~~
29 ~~Board of California and its initial and biennial fees and report to~~
30 ~~the Governor and the Legislature its findings no later than July 1,~~
31 ~~2008.~~

32 SEC. 10. Section 473.2 of the Business and Professions Code
33 is amended to read:

34 473.2. (a) All boards ~~to which this chapter applies or bureaus~~
35 ~~listed in Section 473.12~~ shall, with the assistance of the Department
36 of Consumer Affairs, prepare an analysis and submit a report to
37 ~~the Joint Committee on Boards, Commissions, and Consumer~~
38 ~~Protection appropriate policy committees of the Legislature~~ no
39 later than 22 months before that ~~board~~ board's membership or the
40 bureau chief's term shall ~~become inoperative~~ be terminated

1 *pursuant to Section 473.12. The analysis and report shall include,*
2 *at a minimum, all of the following:*

3 ~~(a) A comprehensive statement of the board's mission, goals,~~
4 ~~objectives and legal jurisdiction in protecting the health, safety,~~
5 ~~and welfare of the public.~~

6 ~~(b) The board's enforcement priorities, complaint and~~
7 ~~enforcement data, budget expenditures with average and~~
8 ~~median costs per case, and case aging data specific to post and~~
9 ~~preaccusation cases at the Attorney General's office.~~

10 ~~(c) The board's~~

11 *(1) The number of complaints it received per year, the number*
12 *of complaints per year that proceeded to investigation, the number*
13 *of accusations filed per year, and the number and kind of*
14 *disciplinary actions taken, including, but not limited to, interim*
15 *suspension orders, revocations, probations, and suspensions.*

16 *(2) The average amount of time per year that elapsed between*
17 *receipt of a complaint and the complaint being closed or referred*
18 *to investigation; the average amount of time per year elapsed*
19 *between the commencement of an investigation and the complaint*
20 *either being closed or an accusation being filed; the average*
21 *amount of time elapsed per year between the filing of an accusation*
22 *and a final decision, including appeals; and the average and*
23 *median costs per case.*

24 *(3) The average amount of time per year between final*
25 *disposition of a complaint and notice to the complainant.*

26 *(4) A copy of the enforcement priorities including criteria for*
27 *seeking an interim suspension order.*

28 *(5) A brief description of the board's or bureau's fund*
29 *conditions, sources of revenues, and expenditure categories for*
30 *the last four fiscal years by program component.*

31 ~~(d) The board's description of its licensing process including~~
32 ~~the time and costs~~

33 *(6) A brief description of the cost per year required to implement*
34 *and administer its licensing examination, ownership of the license*
35 *examination, the last assessment of the relevancy and validity of*
36 *the licensing examination, and the passage rate for each of the last*
37 *four years, and areas of examination.*

38 ~~(e) The board's initiation of legislative efforts, budget change~~
39 ~~proposals, and other initiatives it has taken to improve its legislative~~
40 ~~mandate.~~

1 (7) *A copy of sponsored legislation and a description of its*
2 *budget change proposals.*

3 (8) *A brief assessment of its licensing fees as to whether they*
4 *are sufficient, too high, or too low.*

5 (9) *A brief statement detailing how the board or bureau over*
6 *the prior four years has improved its enforcement, public*
7 *disclosure, accessibility to the public, including, but not limited*
8 *to, Web casts of its proceedings, and fiscal condition.*

9 (b) *If an annual report contains information that is required by*
10 *this section, a board or bureau may submit the annual report to*
11 *the committees and it shall post it on the board's or bureau's*
12 *Internet Web site.*

13 SEC. 11. Section 473.3 of the Business and Professions Code
14 is amended to read:

15 473.3. ~~(a) Prior to the termination, continuation, or~~
16 ~~reestablishment of the terms of office of the membership of any~~
17 ~~board or any of the board's functions, the Joint Committee on~~
18 ~~Boards, Commissions, and Consumer Protection shall the chief of~~
19 ~~any bureau described in Section 473.12, the appropriate policy~~
20 ~~committees of the Legislature, during the interim recess preceding~~
21 ~~the date upon which a board becomes inoperative board member's~~
22 ~~or bureau chief's term of office is to be terminated, may hold public~~
23 ~~hearings to receive and consider testimony from the Director of~~
24 ~~Consumer Affairs, the board or bureau involved, and the Attorney~~
25 ~~General, members of the public, and representatives of the~~
26 ~~regulated industry. In that hearing, each board shall have the burden~~
27 ~~of demonstrating a compelling public need for the continued~~
28 ~~existence of the board or regulatory program, and that its licensing~~
29 ~~function is the least restrictive regulation consistent with the public~~
30 ~~health, safety, and welfare regarding whether the board's or~~
31 ~~bureau's policies and practices, including enforcement, disclosure,~~
32 ~~licensing exam, and fee structure, are sufficient to protect~~
33 ~~consumers and are fair to licensees and prospective licensees,~~
34 ~~whether licensure of the profession is required to protect the public,~~
35 ~~and whether an enforcement monitor may be necessary to obtain~~
36 ~~further information on operations.~~

37 (b) ~~In addition to subdivision (a), in 2002 and every four years~~
38 ~~thereafter, the committee, in cooperation with the California~~
39 ~~Postsecondary Education Commission, shall hold a public hearing~~
40 ~~to receive testimony from the Director of Consumer Affairs, the~~

1 Bureau for Private Postsecondary and Vocational Education;
2 private postsecondary educational institutions regulated by the
3 bureau, and students of those institutions. In those hearings, the
4 bureau shall have the burden of demonstrating a compelling public
5 need for the continued existence of the bureau and its regulatory
6 program, and that its function is the least restrictive regulation
7 consistent with the public health, safety, and welfare.

8 (c) The committee, in cooperation with the California
9 Postsecondary Education Commission, shall evaluate and review
10 the effectiveness and efficiency of the Bureau for Private
11 Postsecondary and Vocational Education, based on factors and
12 minimum standards of performance that are specified in Section
13 473.4. The committee shall report its findings and
14 recommendations as specified in Section 473.5. The bureau shall
15 prepare an analysis and submit a report to the committee as
16 specified in Section 473.2.

17 (d) In addition to subdivision (a), in 2003 and every four years
18 thereafter, the committee shall hold a public hearing to receive
19 testimony from the Director of Consumer Affairs and the Bureau
20 of Automotive Repair. In those hearings, the bureau shall have the
21 burden of demonstrating a compelling public need for the continued
22 existence of the bureau and its regulatory program, and that its
23 function is the least restrictive regulation consistent with the public
24 health, safety, and welfare.

25 (e) The committee shall evaluate and review the effectiveness
26 and efficiency of the Bureau of Automotive Repair based on factors
27 and minimum standards of performance that are specified in
28 Section 473.4. The committee shall report its findings and
29 recommendations as specified in Section 473.5. The bureau shall
30 prepare an analysis and submit a report to the committee as
31 specified in Section 473.2.

32 SEC. 12. Section 473.4 of the Business and Professions Code
33 is amended to read:

34 473.4. (a) The Joint Committee on Boards, Commissions, and
35 Consumer Protection shall *appropriate policy committees of the*
36 *Legislature may* evaluate and determine whether a board or
37 regulatory program has demonstrated a public need for the
38 continued existence of the board or regulatory program and for
39 the degree of regulation the board or regulatory program

1 implements based on the following factors and minimum standards
2 of performance:

3 (1) Whether regulation by the board is necessary to protect the
4 public health, safety, and welfare.

5 (2) Whether the basis or facts that necessitated the initial
6 licensing or regulation of a practice or profession have changed.

7 (3) Whether other conditions have arisen that would warrant
8 increased, decreased, or the same degree of regulation.

9 (4) If regulation of the profession or practice is necessary,
10 whether existing statutes and regulations establish the least
11 restrictive form of regulation consistent with the public interest,
12 considering other available regulatory mechanisms, and whether
13 the board rules enhance the public interest and are within the scope
14 of legislative intent.

15 (5) Whether the board operates and enforces its regulatory
16 responsibilities in the public interest and whether its regulatory
17 mission is impeded or enhanced by existing statutes, regulations,
18 policies, practices, or any other circumstances, including budgetary,
19 resource, and personnel matters.

20 (6) Whether an analysis of board operations indicates that the
21 board performs its statutory duties efficiently and effectively.

22 (7) Whether the composition of the board adequately represents
23 the public interest and whether the board encourages public
24 participation in its decisions rather than participation only by the
25 industry and individuals it regulates.

26 (8) Whether the board and its laws or regulations stimulate or
27 restrict competition, and the extent of the economic impact the
28 board's regulatory practices have on the state's business and
29 technological growth.

30 (9) Whether complaint, investigation, powers to intervene, and
31 disciplinary procedures adequately protect the public and whether
32 final dispositions of complaints, investigations, restraining orders,
33 and disciplinary actions are in the public interest; or if it is, instead,
34 self-serving to the profession, industry or individuals being
35 regulated by the board.

36 (10) Whether the scope of practice of the regulated profession
37 or occupation contributes to the highest utilization of personnel
38 and whether entry requirements encourage affirmative action.

39 (11) Whether administrative and statutory changes are necessary
40 to improve board operations to enhance the public interest.

1 ~~(b) The Joint Committee on Boards, Commissions, and~~
2 ~~Consumer Protection shall consider alternatives to placing~~
3 ~~responsibilities and jurisdiction of the board under the Department~~
4 ~~of Consumer Affairs.~~

5 (e)

6 (b) Nothing in this section precludes any board from submitting
7 other appropriate information to the ~~Joint Committee on Boards,~~
8 ~~Commissions, and Consumer Protection.~~ *appropriate policy*
9 *committees of the Legislature.*

10 SEC. 13. Section 473.5 of the Business and Professions Code
11 is repealed.

12 ~~473.5. The Joint Committee on Boards, Commissions, and~~
13 ~~Consumer Protection shall report its findings and preliminary~~
14 ~~recommendations to the department for its review, and, within 90~~
15 ~~days of receiving the report, the department shall report its findings~~
16 ~~and recommendations to the Joint Committee on Boards,~~
17 ~~Commissions, and Consumer Protection during the next year of~~
18 ~~the regular session that follows the hearings described in Section~~
19 ~~473.3. The committee shall then meet to vote on final~~
20 ~~recommendations. A final report shall be completed by the~~
21 ~~committee and made available to the public and the Legislature.~~
22 ~~The report shall include final recommendations of the department~~
23 ~~and the committee and whether each board or function scheduled~~
24 ~~for repeal shall be terminated, continued, or reestablished, and~~
25 ~~whether its functions should be revised. If the committee or the~~
26 ~~department deems it advisable, the report may include proposed~~
27 ~~bills to carry out its recommendations.~~

28 SEC. 14. Section 473.6 of the Business and Professions Code
29 is amended to read:

30 473.6. The chairpersons of the appropriate policy committees
31 of the Legislature may refer to the ~~Joint Committee on Boards,~~
32 ~~Commissions, and Consumer Protection~~ for *interim study* review
33 of any legislative issues or proposals to create new licensure or
34 regulatory categories, change licensing requirements, modify scope
35 of practice, or create a new licensing board under the provisions
36 of this code or pursuant to Chapter 1.5 (commencing with Section
37 9148) of Part 1 of Division 2 of Title 2 of the Government Code.

38 SEC. 15. Section 473.7 is added to the Business and Professions
39 Code, to read:

1 473.7. The appropriate policy committees of the Legislature
2 may, through their oversight function, investigate the operations
3 of any entity to which this chapter applies and hold public hearings
4 on any matter subject to public hearing under Section 473.3.

5 SEC. 16. Section 9882 of the Business and Professions Code
6 is amended to read:

7 9882. (a) There is in the Department of Consumer Affairs a
8 Bureau of Automotive Repair under the supervision and control
9 of the director. The duty of enforcing and administering this chapter
10 is vested in the chief who is responsible to the director. The director
11 may adopt and enforce those rules and regulations that he or she
12 determines are reasonably necessary to carry out the purposes of
13 this chapter and declaring the policy of the bureau, including a
14 system for the issuance of citations for violations of this chapter
15 as specified in Section 125.9. These rules and regulations shall be
16 adopted pursuant to Chapter 3.5 (commencing with Section 11340)
17 of Part 1 of Division 3 of Title 2 of the Government Code.

18 (b) In 2003 and every four years thereafter, ~~the Joint Committee~~
19 ~~on Boards, Commissions, and Consumer Protection~~ *appropriate*
20 *policy committees of the Legislature* shall hold a public hearing to
21 receive *and consider* testimony from the Director of Consumer
22 Affairs ~~and, the bureau. In those hearings, the bureau shall have~~
23 ~~the burden of demonstrating a compelling public need for the~~
24 ~~continued existence of the bureau and its regulatory program, and~~
25 ~~that its function is the least restrictive regulation consistent with~~
26 ~~the public health, safety, and welfare, the Attorney General,~~
27 ~~members of the public, and representatives of this industry~~
28 ~~regarding the bureau's policies and practices as specified in~~
29 ~~Section 473.3. The committee shall~~ *appropriate policy committees*
30 *of the Legislature may* evaluate and review the effectiveness and
31 efficiency of the bureau based on factors and minimum standards
32 of performance that are specified in Section 473.4. ~~The committee~~
33 ~~shall report its findings and recommendations as specified in~~
34 ~~Section 473.5. The bureau shall prepare an analysis and submit a~~
35 ~~report to the committee~~ *appropriate policy committees of the*
36 *Legislature* as specified in Section 473.2.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 762

VERSION: Introduced: February 27, 2009

AUTHOR: Aanestad

SPONSOR:

RECOMMENDED POSITION: NONE

SUBJECT: Professions and Vocations: healing arts

EXISTING LAW:

States that no city or county shall prohibit a person, authorized by one of the agencies in the Department of Consumer Affairs from engaging in the business for which the license has been obtained.

THIS BILL WOULD:

1. Clarify that no city or county shall prohibit a person, or group of persons from engaging in the business for which the license has been obtained.
2. Specify that no city, county, or city and county shall prohibit a healing arts professional from engaging in any activity that falls within the professionally recognized scope of practice of the licensee. Clarify that the provisions of the section become effective January 1, 2010.
3. Clarify that the above will not prohibit any city, county or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purposes of covering the cost of regulation.

AUTHOR'S INTENT:

FISCAL IMPACT:

The board does not anticipate any fiscal impact to its operations. Any minor impact could be absorbed within existing resources.

COMMENTS:

At is public meeting held April 16, 2009, the Legislation and Regulation Committee discussed the intent and focus of the bill as it relates to pharmacy. Mark Mason, representing the Department of Consumer Affairs, stated the Department does not have a position on this bill. provisions of SB 762 and its impact to pharmacy. The committee did not make a recommendation to the board on this bill.

SUPPORT/OPPOSITION:

HISTORY:

Apr. 27 Set for Hearing in SEN Business, Professions and Economic Development

Mar. 19 To Com. on B., P. & E.D.

Mar. 2 Read first time.

Feb. 28 From print. May be acted upon on or after March 30.

Feb. 27 Introduced. To Com. on RLS. for assignment. To print.

Introduced by Senator AanestadFebruary 27, 2009

An act to amend Section 460 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 762, as introduced, Aanestad. Professions and vocations: healing arts.

Existing law makes it unlawful for a city or county to prohibit a person, authorized by one of the agencies of the Department of Consumer Affairs to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

This bill would also make it unlawful for a city, county, or city and county to prohibit a healing arts licensee from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee, but would prohibit construing this provision to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, as specified.

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 460 of the Business and Professions Code
2 is amended to read:
3 460. (a) No city or county shall prohibit a person *or group of*
4 *persons*, authorized by one of the agencies in the Department of
5 Consumer Affairs by a license, certificate, or other such means to
6 engage in a particular business, from engaging in that business,

1 occupation, or profession or any portion thereof. Nothing in this
2 section shall prohibit any city or county or city and county from
3 levying a business license tax solely for revenue purposes nor any
4 city or county from levying a license tax solely for the purpose of
5 covering the cost of regulation.

6 *(b) No city, county, or city and county shall prohibit a healing*
7 *arts professional licensed with the state under Division 2*
8 *(commencing with Section 500) from engaging in any act or*
9 *performing any procedure that falls within the professionally*
10 *recognized scope of practice of that licensee. This subdivision*
11 *shall not be construed to prohibit the enforcement of a local*
12 *ordinance effective prior to January 1, 2010, related to any act or*
13 *procedure that falls within the professionally recognized scope of*
14 *practice of a healing arts professional licensed under Division 2*
15 *(commencing with Section 500).*

16 *(c) Nothing in this section shall prohibit any city, county, or*
17 *city and county from levying a business license tax solely for*
18 *revenue purposes, nor any city or county from levying a license*
19 *tax solely for the purpose of covering the cost of regulation.*

Attachment c-1

Other Legislation Introduced
Copy of bills

AMENDED IN ASSEMBLY APRIL 22, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 832

Introduced by Assembly Member Jones

February 26, 2009

An act to amend Sections 1200, 1204, 1206, and 1248.1 of, and to add Sections 1204.6, 1204.65, 1212.5, 1212.6, and 1212.7 to, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 832, as amended, Jones. Clinic licensing.

(1) Existing law establishes various programs for the prevention of disease and the promotion of the public health under the jurisdiction of the State Department of Public Health, including, but not limited to, provisions for the licensing, with certain exceptions, of clinics, as defined. A violation of these provisions is a crime.

This bill would exclude a place, establishment, or institution that solely provides immunizations, or screenings for blood pressure, cholesterol, or bone density, or a combination of those services, from the definition of "clinic" for these purposes.

(2) Existing law defines "surgical clinic" as a clinic that provides ambulatory surgical care and is not part of a hospital or is a place that is owned, leased, or operated as a clinic or office by one or more physicians or dentists.

This bill would ~~repeal~~ *revise* that definition, would define "ambulatory surgical care" for this purpose, and would delete the exemption for a place that is owned, leased, or operated by one or more physicians or dentists. The bill would *also* require surgical clinics to be licensed regardless of physician ownership, but would exclude a doctor's office

or other place that ~~provides only prescribed~~ *does not provide ambulatory surgical care services and dental offices that provide only conscious sedation and not general sedation*, and would make conforming changes.

This bill would require any person seeking licensure as a surgical clinic to ~~provide documentation of satisfactory completion of prescribed structural building requirements~~ *meet specified standards*.

This bill would require a surgical clinic that was in operation prior to January 1, 2010, and that is required to become licensed as a result of the passage of the bill to submit a completed application and the required application fee no later than June 30, 2010, but would allow the surgical clinic to remain in operation until the department grants or denies a provisional license.

By changing the definition of an existing crime, this bill would impose a state-mandated local program.

This bill would declare the intent of the Legislature to subsequently appropriate funds to the department as a loan to support the licensing and certification program relating to surgical clinics.

(3) 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. This act shall be known, and may be cited, as the
2 California Outpatient Surgery Patient Safety and Improvement
3 Act.

4 SEC. 2. Section 1200 of the Health and Safety Code is amended
5 to read:

6 1200. As used in this chapter, "clinic" means an organized
7 outpatient health facility that provides direct medical, surgical,
8 dental, optometric, or podiatric advice, services, or treatment to
9 patients who remain less than 24 hours, and which may also
10 provide diagnostic or therapeutic services to patients in the home
11 as an incident to care provided at the clinic facility. Nothing in
12 this section shall be construed to prohibit the provision of nursing
13 services in a clinic licensed pursuant to this chapter. In no case

1 shall a clinic be deemed to be a health facility subject to the
2 provisions of Chapter 2 (commencing with Section 1250) of this
3 division. A place, establishment, or institution that solely provides
4 advice, counseling, information, or referrals on the maintenance
5 of health or on the means and measures to prevent or avoid
6 sickness, disease, or injury, where ~~such~~ *the* advice, counseling,
7 information, or referrals ~~does~~ *do* not constitute the practice of
8 medicine, surgery, dentistry, optometry, or podiatry, shall not be
9 deemed a clinic for purposes of this chapter. A place,
10 establishment, or institution that solely provides immunizations,
11 or screenings for blood pressure, cholesterol, or bone density, or
12 any combination of these services, shall not be deemed a clinic
13 for purposes of this chapter.

14 References in this chapter to "primary care clinics" shall mean
15 and designate all the types of clinics specified in subdivision (a)
16 of Section 1204, including community clinics and free clinics.
17 References in this chapter to specialty clinics shall mean and
18 designate all the types of clinics specified in subdivision (b) of
19 Section 1204, including surgical clinics, chronic dialysis clinics,
20 and rehabilitation clinics.

21 SEC. 3. Section 1204 of the Health and Safety Code is amended
22 to read:

23 1204. Clinics eligible for licensure pursuant to this chapter are
24 primary care clinics and specialty clinics.

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

27 (A) A "community clinic" means a clinic operated by a
28 tax-exempt nonprofit corporation that is supported and maintained
29 in whole or in part by donations, bequests, gifts, grants, government
30 funds or contributions, that may be in the form of money, goods,
31 or services. In a community clinic, any charges to the patient shall
32 be based on the patient's ability to pay, utilizing a sliding fee scale.
33 No corporation other than a nonprofit corporation, exempt from
34 federal income taxation under paragraph (3) of subsection (c) of
35 Section 501 of the Internal Revenue Code of 1954 as amended, or
36 a statutory successor thereof, shall operate a community clinic;
37 provided, that the licensee of any community clinic so licensed on
38 the effective date of this section shall not be required to obtain
39 tax-exempt status under either federal or state law in order to be

1 eligible for, or as a condition of, renewal of its license. No natural
2 person or persons shall operate a community clinic.

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

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

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

30 (1) A "surgical clinic" means a clinic that is not part of a hospital
31 or a primary care clinic that is either licensed pursuant to this
32 section, or exempt pursuant to subdivision (b) of Section 1206,
33 and that provides ambulatory surgical care as defined in Section
34 1204.6 for patients who remain less than 24 hours. Surgical clinics
35 shall be subject to licensure by the department regardless of
36 physician ownership.

37 (2) A "chronic dialysis clinic" means a clinic that provides less
38 than 24-hour care for the treatment of patients with end-stage renal
39 disease, including renal dialysis services.

1 (3) A "rehabilitation clinic" means a clinic that, in addition to
2 providing medical services directly, also provides physical
3 rehabilitation services for patients who remain less than 24 hours.
4 Rehabilitation clinics shall provide at least two of the following
5 rehabilitation services: physical therapy, occupational therapy,
6 social, speech pathology, and audiology services. A rehabilitation
7 clinic does not include the offices of a private physician in
8 individual or group practice.

9 (4) An "alternative birth center" means a clinic that is not part
10 of a hospital and that provides comprehensive perinatal services
11 and delivery care to pregnant women who remain less than 24
12 hours at the facility.

13 (c) In accordance with subdivision (d) of Section 1248.1,
14 licensure as a surgical clinic shall satisfy the requirements of
15 Chapter 1.3 (commencing with Section 1248).

16 SEC. 4. Section 1204.6 is added to the Health and Safety Code,
17 to read:

18 1204.6. (a) "Ambulatory surgical care" for purposes of
19 licensure as a surgical clinic, means the incision, partial or complete
20 excision, destruction, resection, or other structural alteration of
21 human tissue by any means except any of the following:

22 (1) Minor skin repair procedures, including, but not limited to,
23 any of the following:

24 (A) Repair of minor lacerations.

25 (B) Excision of moles, warts, or other minor skin lesions.

26 (C) Incision and drainage of superficial abscesses.

27 (2) Procedures using only local anesthesia, topical anesthesia,
28 or no anesthesia.

29 (3) Procedures not using general anesthesia or conscious
30 sedation.

31 (b) "General anesthesia" for purposes of licensure as a surgical
32 clinic, means a controlled state of depressed consciousness or
33 unconsciousness, accompanied by partial or complete loss of
34 protective reflexes, produced by a pharmacologic or
35 nonpharmacologic method, or a combination thereof.

36 (c) "Conscious sedation" for purposes of licensure as a surgical
37 clinic, means a minimally depressed level of consciousness
38 produced by a pharmacologic or nonpharmacologic method, or a
39 combination thereof, that retains the patient's ability to maintain
40 independently and continuously an airway, and respond

1 appropriately to physical stimulation or verbal command.
2 Conscious sedation does not include the administration of oral
3 medications or the administration of a mixture of nitrous oxide
4 and oxygen, whether administered alone or in combination with
5 each other.

6 (d) A doctor's office or other place, establishment, or institution
7 ~~that provides no surgical services~~ *does not provide ambulatory*
8 *surgical care, as defined in subdivision (a), other than those the*
9 *exceptions described in paragraphs (1), (2), and (3) of subdivision*
10 *(a), shall not be required to obtain licensure as a surgical clinic.*

11 (e) *A dental office or other place, establishment, or institution*
12 *that does not use general anesthesia but does use conscious*
13 *sedation, with a permit issued pursuant to Article 2.8 (commencing*
14 *with Section 1647) of Chapter 4 of Division 2 of the Business and*
15 *Professions Code, shall not be required to obtain licensure as a*
16 *surgical clinic.*

17 *SEC. 5. Section 1204.65 is added to the Health and Safety*
18 *Code, to read:*

19 *1204.65. A surgical clinic that was in operation prior to*
20 *January 1, 2010, and is required to become licensed due to the*
21 *enactment of Section 1204.6 and the amendments to Section 1206,*
22 *as contained in the act adding this section, shall submit a*
23 *completed application for licensure as a surgical clinic,*
24 *accompanied by the required application fee, not later than June*
25 *30, 2010, but may continue to operate as a surgical clinic until*
26 *the department conducts a licensing visit and grants or denies a*
27 *provisional license pursuant to Sections 1219 or 1219.1. A surgical*
28 *clinic that is denied a license shall cease operating immediately*
29 *upon receipt of the denial.*

30 ~~SEC. 5.~~

31 *SEC. 6. Section 1206 of the Health and Safety Code is amended*
32 *to read:*

33 *1206. The requirement of licensure and other requirements of*
34 *this chapter do not apply to any of the following:*

35 (a) *Any place or establishment owned or leased and operated*
36 *as a clinic or office by one or more licensed health care*
37 *practitioners and used by the practitioner as an office for the*
38 *practice of his or her profession, within the scope of his or her*
39 *license in any lawful form of organization, so long as each licensed*
40 *health care practitioner who practices at the clinic has some*

1 ownership or leasehold interest in, and some degree of control
2 over and responsibility for, the operation of the clinic, regardless
3 of the *unless the clinic or office is providing ambulatory surgical*
4 *services, as defined in subdivision (a) of Section 1204.6, other*
5 *than the exceptions described in paragraphs (1), (2), and (3) of*
6 *subdivision (a) of Section 1204.6, regardless of the name used*
7 publicly to identify the place or establishment. The exemption
8 pursuant to this subdivision shall not apply to either of the
9 following:

10 (1) Any surgical clinic as described in paragraph (1) of
11 subdivision (b) of Section 1204, regardless of any health care
12 practitioner ownership interest in the clinic.

13 (2) Any chronic dialysis clinic as described in paragraph (2) of
14 subdivision (b) of Section 1204.

15 (b) Any clinic directly conducted, maintained, or operated by
16 the United States or by any of its departments, officers, or agencies,
17 and any primary care clinic specified in subdivision (a) of Section
18 1204 that is directly conducted, maintained, or operated by this
19 state or by any of its political subdivisions or districts, or by any
20 city. Nothing in this subdivision precludes the state department
21 from adopting regulations that utilize clinic licensing standards as
22 eligibility criteria for participation in programs funded wholly or
23 partially under Title XVIII or XIX of the federal Social Security
24 Act.

25 (c) Any clinic conducted, maintained, or operated by a federally
26 recognized Indian tribe or tribal organization, as defined in Section
27 450 or 1601 of Title 25 of the United States Code, that is located
28 on land recognized as tribal land by the federal government.

29 (d) Clinics conducted, operated, or maintained as outpatient
30 departments of hospitals.

31 (e) Any facility licensed as a health facility under Chapter 2
32 (commencing with Section 1250).

33 (f) Any freestanding clinical or pathological laboratory licensed
34 under Chapter 3 (commencing with Section 1200) of Division 2
35 of the Business and Professions Code.

36 (g) A clinic operated by, or affiliated with, any institution of
37 learning that teaches a recognized healing art and is approved by
38 the state board or commission vested with responsibility for
39 regulation of the practice of that healing art. The exemption

1 pursuant to this subdivision shall not apply to any surgical clinic
2 as described in paragraph (1) of subdivision (b) of Section 1204.

3 (h) A clinic that is operated by a primary care community or
4 free clinic and that is operated on separate premises from the
5 licensed clinic and is only open for limited services of no more
6 than 20 hours a week. An intermittent clinic as described in this
7 subdivision shall, however, meet all other requirements of law,
8 including administrative regulations and requirements, pertaining
9 to fire and life safety.

10 (i) The offices of physicians in group practice who provide a
11 preponderance of their services to members of a comprehensive
12 group practice prepayment health care service plan subject to
13 Chapter 2.2 (commencing with Section 1340).

14 (j) Student health centers operated by public institutions of
15 higher education.

16 (k) Nonprofit speech and hearing centers, as defined in Section
17 1201.5. Any nonprofit speech and hearing clinic desiring an
18 exemption under this subdivision shall make application therefor
19 to the director, who shall grant the exemption to any facility
20 meeting the criteria of Section 1201.5. Notwithstanding the
21 licensure exemption contained in this subdivision, a nonprofit
22 speech and hearing center shall be deemed to be an organized
23 outpatient clinic for purposes of qualifying for reimbursement as
24 a rehabilitation center under the Medi-Cal Act (Chapter 7
25 (commencing with Section 14000) of Part 3 of Division 9 of the
26 Welfare and Institutions Code).

27 (l) A clinic operated by a nonprofit corporation exempt from
28 federal income taxation under paragraph (3) of subsection (c) of
29 Section 501 of the Internal Revenue Code of 1954, as amended,
30 or a statutory successor thereof, that conducts medical research
31 and health education and provides health care to its patients through
32 a group of 40 or more physicians and surgeons, who are
33 independent contractors representing not less than 10
34 board-certified specialties, and not less than two-thirds of whom
35 practice on a full-time basis at the clinic.

36 (m) Any clinic, limited to in vivo diagnostic services by
37 magnetic resonance imaging functions or radiological services
38 under the direct and immediate supervision of a physician and
39 surgeon who is licensed to practice in California. This shall not

1 be construed to permit cardiac catheterization or any treatment
2 modality in these clinics.

3 (n) A clinic operated by an employer or jointly by two or more
4 employers for their employees only, or by a group of employees,
5 or jointly by employees and employers, without profit to the
6 operators thereof or to any other person, for the prevention and
7 treatment of accidental injuries to, and the care of the health of,
8 the employees comprising the group.

9 (o) A community mental health center, as defined in Section
10 5601.5 of the Welfare and Institutions Code.

11 (p) (1) A clinic operated by a nonprofit corporation exempt
12 from federal income taxation under paragraph (3) of subsection
13 (c) of Section 501 of the Internal Revenue Code of 1954, as
14 amended, or a statutory successor thereof, as an entity organized
15 and operated exclusively for scientific and charitable purposes and
16 that satisfied all of the following requirements on or before January
17 1, 2005:

18 (A) Commenced conducting medical research on or before
19 January 1, 1982, and continues to conduct medical research.

20 (B) Conducted research in, among other areas, prostatic cancer,
21 cardiovascular disease, electronic neural prosthetic devices,
22 biological effects and medical uses of lasers, and human magnetic
23 resonance imaging and spectroscopy.

24 (C) Sponsored publication of at least 200 medical research
25 articles in peer-reviewed publications.

26 (D) Received grants and contracts from the National Institutes
27 of Health.

28 (E) Held and licensed patents on medical technology.

29 (F) Received charitable contributions and bequests totaling at
30 least five million dollars (\$5,000,000).

31 (G) Provides health care services to patients only:

32 (i) In conjunction with research being conducted on procedures
33 or applications not approved or only partially approved for payment
34 (I) under the Medicare program pursuant to Section 1359y(a)(1)(A)
35 of Title 42 of the United States Code, or (II) by a health care service
36 plan registered under Chapter 2.2 (commencing with Section 1340),
37 or a disability insurer regulated under Chapter 1 (commencing
38 with Section 10110) of Part 2 of Division 2 of the Insurance Code;
39 provided that services may be provided by the clinic for an
40 additional period of up to three years following the approvals, but

1 only to the extent necessary to maintain clinical expertise in the
2 procedure or application for purposes of actively providing training
3 in the procedure or application for physicians and surgeons
4 unrelated to the clinic.

5 (ii) Through physicians and surgeons who, in the aggregate,
6 devote no more than 30 percent of their professional time for the
7 entity operating the clinic, on an annual basis, to direct patient care
8 activities for which charges for professional services are paid.

9 (H) Makes available to the public the general results of its
10 research activities on at least an annual basis, subject to good faith
11 protection of proprietary rights in its intellectual property.

12 (I) Is a freestanding clinic, whose operations under this
13 subdivision are not conducted in conjunction with any affiliated
14 or associated health clinic or facility defined under this division,
15 except a clinic exempt from licensure under subdivision (m). For
16 purposes of this subparagraph, a freestanding clinic is defined as
17 "affiliated" only if it directly, or indirectly through one or more
18 intermediaries, controls, or is controlled by, or is under common
19 control with, a clinic or health facility defined under this division,
20 except a clinic exempt from licensure under subdivision (m). For
21 purposes of this subparagraph, a freestanding clinic is defined as
22 "associated" only if more than 20 percent of the directors or trustees
23 of the clinic are also the directors or trustees of any individual
24 clinic or health facility defined under this division, except a clinic
25 exempt from licensure under subdivision (m). Any activity by a
26 clinic under this subdivision in connection with an affiliated or
27 associated entity shall fully comply with the requirements of this
28 subdivision. This subparagraph shall not apply to agreements
29 between a clinic and any entity for purposes of coordinating
30 medical research.

31 (2) By January 1, 2007, and every five years thereafter, the
32 Legislature shall receive a report from each clinic meeting the
33 criteria of this subdivision and any other interested party
34 concerning the operation of the clinic's activities. The report shall
35 include, but not be limited to, an evaluation of how the clinic
36 impacted competition in the relevant health care market, and a
37 detailed description of the clinic's research results and the level
38 of acceptance by the payer community of the procedures performed
39 at the clinic. The report shall also include a description of
40 procedures performed both in clinics governed by this subdivision

1 and those performed in other settings. The cost of preparing the
2 reports shall be borne by the clinics that are required to submit
3 them to the Legislature pursuant to this paragraph.

4 ~~SEC. 6.~~

5 *SEC. 7.* Section 1212.5 is added to the Health and Safety Code,
6 to read:

7 ~~1212.5. (a) Commencing January 1, 2010, in addition to other~~
8 ~~licensing requirements of this chapter, any person, firm,~~
9 ~~association, partnership, or corporation seeking a license for a~~
10 ~~surgical clinic shall provide the department with documentation~~
11 ~~of satisfactory completion of the structural and building~~
12 ~~requirements set forth in Section 1226 of Title 24 of the California~~
13 ~~Code of Regulations, or compliance with the 2000 Medicare Life~~
14 ~~and Safety Code requirements.~~

15 ~~(b)~~

16 *1212.5. (a)* Commencing January 1, 2010, a surgical clinic
17 shall also meet all of the following standards:

18 ~~(1) Only those patients who have given full informed consent~~
19 ~~about the inherent risks of receiving surgery in facilities with~~
20 ~~limited post surgical rescue potential that would be available in a~~
21 ~~general acute care hospital shall receive services in the surgical~~
22 ~~clinic.~~

23 ~~(2)~~

24 *(1)* Comply with the conditions of coverage as set forth in
25 Subpart C of Part 416 of Title 42 of the Code of Federal
26 Regulations, as those conditions exist on January 1, 2008. The
27 conditions of coverage shall be conditions of providing services
28 regardless of the source of payment for those services.

29 ~~(3)~~

30 *(2)* Limit surgical procedures to those that comply with all of
31 the following:

32 *(A)* Do not require the presence of more than one surgeon during
33 the procedure.

34 *(B)* Are not expected to require a blood transfusion.

35 *(C)* Are not expected to require major or prolonged invasion of
36 body cavities.

37 *(D)* Are not expected to involve major blood vessels.

38 *(E)* Are not inherently life threatening.

39 *(F)* Are not emergency surgeries.

40 *(G)* Are not experimental surgeries.

1 (4)
2 (3) A preanesthesia evaluation, including an ASA Physical
3 Status Classification, shall be completed on all surgical anesthesia
4 patients. Surgical procedures shall not be performed on a patient
5 with severe systemic disease that is a constant threat to life (ASA
6 Classification 4) or on a moribund patient who is not expected to
7 survive for 24 hours without the operation (ASA Classification
8 5). A patient with severe systemic disease (ASA Classification 3)
9 shall have a presurgical consultation with a physician specialist
10 appropriate for the patient's severe systemic disease in order to
11 obtain medical clearance for surgery.

12 (5)
13 (4) Establish and implement policies and procedures compliant
14 with the conditions of coverage. The policies and procedures shall
15 comply with both of the following:

16 (A) The policies and procedures shall include, but need not be
17 limited to, all of the following:

18 (i) Surgical services, as provided by physicians, ~~dentists,~~ or
19 podiatrists.

20 (ii) Anesthesia services.

21 (iii) Nursing services.

22 (iv) Evaluation of quality assessment and performance
23 improvement.

24 (v) Infection control.

25 (vi) Pharmaceutical services.

26 (vii) Laboratory and radiology services.

27 (viii) Housekeeping services, including provisions for
28 maintenance of a safe, clean environment.

29 (ix) Patient health records, including provisions that shall be
30 developed with the assistance of a person skilled in record
31 maintenance and preservation.

32 (x) Personnel policies and procedures.

33 (B) The policies and procedures shall provide for appropriate
34 staffing ratios for all care provided to patients receiving general
35 anesthesia in compliance with both of the following:

36 (i) In each surgical room there shall be at least one registered
37 nurse assigned to the duties of the circulating nurse and a minimum
38 of one additional person serving as scrub assistant for each
39 patient-occupied operating room. The scrub assistant may be a
40 licensed nurse, an operating room technician, or other person who

1 has demonstrated current competence to the clinic as a scrub
2 assistant, but shall not be a physician or other licensed health
3 professional who is assisting in the performance of surgery.

4 (ii) The licensed nurse-to-patient ratio in a postanesthesia
5 recovery unit of the anesthesia service shall be one-to-two or fewer
6 at all times, regardless of the type of general anesthesia the patient
7 receives.

8 (b) *A clinic licensed pursuant to this section shall be subject to*
9 *the requirements of Section 1280.15.*

10 ~~SEC. 7.~~

11 *SEC. 8.* Section 1212.6 is added to the Health and Safety Code,
12 to read:

13 1212.6. Every clinic for which a license has been issued under
14 Section 1212.5 shall be subject to the reporting requirements
15 contained in Section 1279.1 and the penalties imposed under
16 Sections 1280.1, 1280.3, and 1280.4.

17 ~~SEC. 8.~~

18 *SEC. 9.* Section 1212.7 is added to the Health and Safety Code,
19 to read:

20 1212.7. It is the intent of the Legislature to provide funding
21 through an appropriation in the Budget Act or other measure to
22 the State Department of Public Health, for a loan for the support
23 the operations of the Licensing and Certification Program for
24 activities authorized by this chapter relating to the licensure of
25 surgical clinics. The loan shall be repaid with proceeds from fees
26 collected pursuant to Section 1266. *The department shall implement*
27 *the provisions of this chapter relating to the licensure of surgical*
28 *clinics to the extent resources are provided.*

29 ~~SEC. 9.~~

30 *SEC. 10.* Section 1248.1 of the Health and Safety Code is
31 amended to read:

32 1248.1. No association, corporation, firm, partnership, or person
33 shall operate, manage, conduct, or maintain an outpatient setting
34 in this state, unless the setting is one of the following:

35 (a) An ambulatory surgical center that is certified to participate
36 in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395
37 et seq.) of the federal Social Security Act.

38 (b) ~~Any~~ *A* clinic conducted, maintained, or operated by a
39 federally recognized Indian tribe or tribal organization, as defined

1 in Section 450 or 1601 of Title 25 of the United States Code, and
2 located on land recognized as tribal land by the federal government.

3 (c) ~~Any~~ A clinic directly conducted, maintained, or operated by
4 the United States or by any of its departments, officers, or agencies.

5 (d) ~~Any~~ A primary care clinic licensed under subdivision (a)
6 and ~~any~~ a surgical clinic licensed under subdivision (b) of Section
7 1204.

8 (e) ~~Any~~ A health facility licensed as a general acute care hospital
9 under Chapter 2 (commencing with Section 1250).

10 (f) ~~Any~~ An outpatient setting to the extent that it is used by a
11 dentist or physician and surgeon in compliance with Article 2.7
12 (commencing with Section 1646) or Article 2.8 (commencing with
13 Section 1647) of Chapter 4 of Division 2 of the Business and
14 Professions Code.

15 (g) An outpatient setting accredited by an accreditation agency
16 approved by the division pursuant to this chapter.

17 (h) A setting, including, but not limited to, a mobile van, in
18 which equipment is used to treat patients admitted to a facility
19 described in subdivision (a), (d), or (e), and in which the procedures
20 performed are staffed by the medical staff of, or other healthcare
21 practitioners with clinical privileges at, the facility and are subject
22 to the peer review process of the facility but which setting is not
23 a part of a facility described in subdivision (a), (d), or (e).

24 Nothing in this section shall relieve an association, corporation,
25 firm, partnership, or person from complying with all other
26 provisions of law that are otherwise applicable, including, but not
27 limited to, licensure as a primary care or specialty clinic as set
28 forth in Chapter 1 (commencing with Section 1200) of Division
29 2 of the Health and Safety Code. Surgical clinics shall be subject
30 to licensure regardless of any physician ownership interest.

31 ~~SEC. 10.~~

32 *SEC. 11.* No reimbursement is required by this act pursuant to
33 Section 6 of Article XIII B of the California Constitution because
34 the only costs that may be incurred by a local agency or school
35 district will be incurred because this act creates a new crime or
36 infraction, eliminates a crime or infraction, or changes the penalty
37 for a crime or infraction, within the meaning of Section 17556 of
38 the Government Code, or changes the definition of a crime within

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

O

AMENDED IN ASSEMBLY APRIL 21, 2009

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1094

Introduced by Assembly Member Conway

February 27, 2009

An act to amend Sections 1798.80, 1798.81, ~~and 1798.84~~ 1798.84, and 1983 of the Civil Code, relating to personal information.

LEGISLATIVE COUNSEL'S DIGEST

AB 1094, as amended, Conway. Disposal of personal information.

Existing law requires a business to take all reasonable steps to destroy, or arrange for the destruction of, a customer's records within its custody or control containing personal information that is no longer to be retained by the business by shredding, erasing, or otherwise modifying the personal information in those records to make it unreadable or undecipherable through any means. Existing law provides for specified civil remedies for a violation of these provisions.

This bill would, instead, require a business to take all reasonable steps to dispose, or arrange for the disposal, of an individual's records within its custody or control containing personal information when the records are no longer to be retained by the business by taking any of the actions described above. ~~A violation of this provision would be punishable as a misdemeanor. By creating a new crime, the bill would impose a state-mandated local program.~~ The bill would *exempt from these provisions information that is made available to the general public from federal, state, or local government records.* The bill would provide that a cause of action shall not lie against a business that comes into

possession of abandoned records containing personal information and that disposes of those records in accordance with these provisions. *The bill would set forth findings regarding records that end up in the possession of a storage company or commercial landlord, and would provide that it is the intent of the Legislature to create a safe harbor for such a record custodian who properly disposes of the records.*

~~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.~~

Existing law requires a landlord, if personal property remains on the premises after a tenancy has terminated and the premises have been vacated by the tenant, to give written notice to the tenant and to any other person the landlord reasonably believes to be the owner of the property, as specified.

This bill would provide that, if the property consists of records, the tenant shall be deemed to be the owner of the property.

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

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

- 1 SECTION 1. Section 1798.80 of the Civil Code is amended
- 2 to read:
- 3 1798.80. The following definitions apply to this title:
- 4 (a) "Business" means a sole proprietorship, partnership,
- 5 corporation, association, or other group, however organized and
- 6 whether or not organized to operate at a profit, including a financial
- 7 institution organized, chartered, or holding a license or
- 8 authorization certificate under the law of this state, any other state,
- 9 the United States, or of any other country, or the parent or the
- 10 subsidiary of a financial institution. The term includes an entity
- 11 that disposes of records.
- 12 (b) "Records" means any material, regardless of the physical
- 13 form, on which information is recorded or preserved by any means,
- 14 including in written or spoken words, graphically depicted, printed,
- 15 or electromagnetically transmitted. "Records" does not include
- 16 publicly available directories containing information an individual

1 has voluntarily consented to have publicly disseminated or listed,
2 such as name, address, or telephone number.

3 (c) "Customer" means an individual who provides personal
4 information to a business for the purpose of purchasing or leasing
5 a product or obtaining a service from the business.

6 (d) "Individual" means a natural person.

7 (e) "Personal information" means any information that identifies,
8 relates to, describes, or is capable of being associated with, a
9 particular individual, including, but not limited to, his or her name,
10 signature, social security number, physical characteristics or
11 description, address, telephone number, passport number, driver's
12 license or state identification card number, insurance policy
13 number, education, employment, employment history, bank account
14 number, credit card number, debit card number, or any other
15 financial information. "*Personal information*" does not include
16 publicly available information that is lawfully made available to
17 the general public from federal, state, or local government records.

18 SEC. 2. Section 1798.81 of the Civil Code is amended to read:

19 1798.81. A business shall take all reasonable steps to dispose,
20 or arrange for the disposal, of an individual's records within its
21 custody or control containing personal information when the
22 records are no longer to be retained by the business by (a)
23 shredding, (b) erasing, or (c) otherwise modifying the personal
24 information in those records to make it unreadable or
25 undecipherable through any means.

26 SEC. 3. Section 1798.84 of the Civil Code is amended to read:

27 1798.84. (a) Any waiver of a provision of this title is contrary
28 to public policy and is void and unenforceable.

29 (b) Any individual injured by a violation of this title may
30 institute a civil action to recover damages.

31 (c) In addition, for a willful, intentional, or reckless violation
32 of Section 1798.83, a customer may recover a civil penalty not to
33 exceed three thousand dollars (\$3,000) per violation; otherwise,
34 the customer may recover a civil penalty of up to five hundred
35 dollars (\$500) per violation for a violation of Section 1798.83.

36 (d) Unless the violation is willful, intentional, or reckless, a
37 business that is alleged to have not provided all the information
38 required by subdivision (a) of Section 1798.83, to have provided
39 inaccurate information, failed to provide any of the information
40 required by subdivision (a) of Section 1798.83, or failed to provide

1 information in the time period required by subdivision (b) of
2 Section 1798.83, may assert as a complete defense in any action
3 in law or equity that it thereafter provided regarding the information
4 that was alleged to be untimely, all the information, or accurate
5 information, to all customers who were provided incomplete or
6 inaccurate information, respectively, within 90 days of the date
7 the business knew that it had failed to provide the information,
8 timely information, all the information, or the accurate information,
9 respectively.

10 (e) Any business that violates, proposes to violate, or has
11 violated this title may be enjoined.

12 ~~(f) Every business, including any employee or agent thereof,
13 that knowingly disposes of records containing personal information
14 in violation of Section 1798.81 is guilty of a misdemeanor and
15 shall be punished, upon conviction, by a fine, by imprisonment in
16 the county jail not to exceed one year, or by both a fine and
17 imprisonment.~~

18 ~~(g)~~

19 (f) (1) A cause of action shall not lie against a business that
20 comes into possession of abandoned records containing personal
21 information and that disposes of those records in accordance with
22 Section 1798.81.

23 (2) *The Legislature finds and declares that, when records
24 containing personal information are abandoned by a business,
25 they often end up in the possession of a storage company or
26 commercial landlord. It is the intent of the Legislature in
27 paragraph (1) to create a safe harbor for such a record custodian
28 who properly disposes of the records in accordance with Section
29 1798.81.*

30 ~~(h)~~

31 (g) A prevailing plaintiff in any action commenced under
32 Section 1798.83 shall also be entitled to recover his or her
33 reasonable attorney's fees and costs.

34 ~~(i)~~

35 (h) The rights and remedies available under this section are
36 cumulative to each other and to any other rights and remedies
37 available under law.

38 ~~SEC. 4. No reimbursement is required by this act pursuant to
39 Section 6 of Article XIII B of the California Constitution because
40 the only costs that may be incurred by a local agency or school~~

1 ~~district will be incurred because this act creates a new crime or~~
2 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
3 ~~for a crime or infraction, within the meaning of Section 17556 of~~
4 ~~the Government Code, or changes the definition of a crime within~~
5 ~~the meaning of Section 6 of Article XIII B of the California~~
6 ~~Constitution.~~

7 *SEC. 4. Section 1983 of the Civil Code is amended to read:*

8 1983. (a) Where personal property remains on the premises
9 after a tenancy has terminated and the premises have been vacated
10 by the tenant, the landlord shall give written notice to ~~such the~~
11 tenant and to any other person the landlord reasonably believes to
12 be the owner of the property. *If the property consists of records,*
13 *the tenant shall be deemed to be the owner of the property.*

14 (b) The notice shall describe the property in a manner reasonably
15 adequate to permit the owner of the property to identify it. The
16 notice may describe all or a portion of the property, but the
17 limitation of liability provided by Section 1989 does not protect
18 the landlord from any liability arising from the disposition of
19 property not described in the notice except that a trunk, valise,
20 box, or other container which is locked, fastened, or tied in a
21 manner which deters immediate access to its contents may be
22 described as such without describing its contents. The notice shall
23 advise the person to be notified that reasonable costs of storage
24 may be charged before the property is returned, where the property
25 may be claimed, and the date before which the claim must be made.
26 The date specified in the notice shall be a date not less than 15
27 days after the notice is personally delivered or, if mailed, not less
28 than 18 days after the notice is deposited in the mail.

29 (c) The notice shall be personally delivered to the person to be
30 notified or sent by first-class mail, postage prepaid, to the person
31 to be notified at his *or her* last known address and, if there is reason
32 to believe that the notice sent to that address will not be received
33 by that person, also to ~~such any~~ other address, ~~if any,~~ known to
34 the landlord where ~~such the~~ person may reasonably be expected
35 to receive the notice. If the notice is sent by mail to the former
36 tenant, one copy shall be sent to the premises vacated by ~~such the~~
37 tenant.

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ASSEMBLY BILL

No. 1201

Introduced by Assembly Member V. Manuel Perez

February 27, 2009

An act to amend Section 1367.36 of the Health and Safety Code, and to add Sections 10123.56 and 12693.56 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1201, as introduced, V. Manuel Perez. Immunizations for children: reimbursement of physicians.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires every health care service plan or health insurer that covers hospital, medical, or surgical expenses on a group basis to provide certain preventative health care benefits for children, including immunizations. Existing law specifies the reimbursement rate with respect to immunizations that are not part of the current contract between a health care service plan or physician group.

This bill would require a health care service plan or health insurer that provides coverage for childhood and adolescent immunizations to reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine, as specified. The bill would prohibit a health care service plan contract or health insurance policy providing coverage for childhood or adolescent immunizations from imposing a deductible,

copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for related procedures. The bill would also prohibit those contracts or policies from containing a dollar limit provision for the administration of childhood and adolescent immunizations or including the cost of those immunizations in a dollar limit provision.

Existing law prohibits a risk-based contract between a health care service plan and a physician or physician group from including a provision requiring the physician or physician group to assume financial risk for the acquisition costs of required immunizations for children. Existing law prohibits a plan from requiring a physician or physician group to assume financial risk for immunizations that are not part of the current contract.

This bill would make those provisions apply to all contracts between plans and physicians or physician groups rather than just risk-based contracts. The bill would prohibit a plan from requiring a physician or physician group to assume financial risk for immunizations, whether or not those immunizations are part of the current contract. The bill would make other related changes.

Existing law prohibits a health care service plan from including the acquisition costs associated with required immunizations for children in the capitation rate of a physician who is individually capitated.

This bill would additionally prohibit a plan from including in that capitation rate the administration costs of those immunizations.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

Existing law creates the Healthy Families Program, administered by the Managed Risk Medical Insurance Board, to arrange for the provision of health, dental, and vision benefits to eligible children pursuant to a federal program, the State Children's Health Insurance Program.

This bill would require a health plan participating in that program to reimburse a physician or physician group for immunizations administered to program subscribers in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine, as specified.

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

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

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) Pediatric immunizations proved to be one of the most
4 successful, safe, and cost-effective public health interventions of
5 the 20th century. Worldwide, millions of childhood deaths are
6 prevented by vaccinations every year. Vaccine-preventable disease
7 levels are at or near record lows.

8 (b) Vaccines are among the most cost-effective components of
9 preventive medical care. In 2003, the Centers for Disease Control
10 estimated a direct cost savings of six dollars and thirty cents (\$6.30)
11 for every dollar spent on vaccinations. If societal costs are factored
12 in, the savings increase to eighteen dollars and forty cents (\$18.40)
13 per dollar spent.

14 (c) Due to increasing numbers of approved and recommended
15 life-saving vaccines, as well as increasing prices, pediatric vaccine
16 acquisition costs have increased dramatically in recent years and
17 could triple by the year 2020.

18 (d) Physicians typically face higher vaccine prices than large
19 public purchasers and usually lose money when they provide
20 immunizations due to under-reimbursement, which may discourage
21 physicians from purchasing adequate doses to meet the demand
22 in their practices. This trend could shift the burden of vaccine
23 financing to parents' out-of-pocket expenses or to local public
24 health clinics or other public programs.

25 (e) As small businesses, physicians face severe financial strain
26 when they continue to absorb the unreimbursed costs associated
27 with vaccine acquisition and administration. The purchase of
28 vaccines is the single most expensive part of a pediatric or family
29 practice. When providers are not adequately reimbursed to cover
30 the direct and indirect costs of providing immunizations, the
31 viability of their practice is threatened.

1 (f) Insured children and their families can face financial barriers
2 to immunization such as deductibles, copayments, and other
3 out-of-pocket expenses.

4 (g) Unvaccinated children can contract a dangerous or
5 life-threatening disease at any time in their lives. In order to
6 effectively protect the public health, it is imperative that we ensure
7 continued access to disease-preventing vaccines in order to achieve
8 maximum immunization for infants, children, and adolescents.

9 (h) Therefore, in order to maximize immunization rates to
10 protect individual children and the general population from existing
11 and emerging communicable diseases, it is the intent of the
12 Legislature to ensure that physicians are fully reimbursed for the
13 costs to acquire and administer recommended vaccines and that
14 out-of-pocket expenses do not deter parents from immunizing their
15 children.

16 SEC. 2. Section 1367.36 of the Health and Safety Code is
17 amended to read:

18 1367.36. (a) A ~~risk-based~~ contract between a health care
19 service plan and a physician or physician group that is issued,
20 amended, delivered, or renewed in this state on or after January
21 1, ~~2001~~ 2010, shall not include a provision that requires a physician
22 or a physician group to assume financial risk for the acquisition
23 costs of required immunizations for children as a condition of
24 accepting the ~~risk-based~~ contract. A physician or physician group
25 shall not be required to assume financial risk for immunizations
26 ~~that are not part of the current contract.~~

27 (b) *A health care service plan that provides coverage for*
28 *childhood and adolescent immunizations pursuant to Section*
29 *1367.3 or 1367.35 shall reimburse a physician or physician group*
30 *in an amount not less than the actual cost of acquiring the vaccine*
31 *plus the cost of administration of the vaccine. For purposes of this*
32 *subdivision, both of the following shall apply:*

33 (1) *The actual cost of acquiring the vaccine includes, but is not*
34 *limited to, the invoiced purchase price plus reasonable costs*
35 *associated with shipping, handling, insurance, and storage.*

36 (b)
37 (2) *The cost of administration of the vaccine shall be an amount*
38 *not less than that specified in the most current annual Medicare*
39 *physician fee schedule published pursuant to Section 1395w-4(b)(1)*
40 *of Title 42 of the United States Code.*

1 (c) Beginning January 1, ~~2001~~ 2010, with respect to
2 immunizations for children that are not part of the current contract
3 between a health care service plan and a physician or physician
4 group, the health care service plan shall reimburse a physician or
5 physician group at the lowest of the following, until the contract
6 is renegotiated: (1) the physician's actual acquisition cost, (2) the
7 "average wholesale price" as published in the Drug Topics Red
8 Book, or (3) the lowest acquisition cost through sources made
9 available to the physician by the health care service plan in an
10 amount not less than that specified in subdivision (b).
11 Reimbursements pursuant to this subdivision shall be made within
12 45 days of receipt by the plan of documents from the physician
13 demonstrating that the immunizations were performed, consistent
14 with Section 1371 or through an alternative funding mechanism
15 mutually agreed to by the health care service plan and the physician
16 or physician group. The alternative funding mechanism shall be
17 based on reimbursements consistent with this subdivision.

18 (e)

19 (d) Physicians and physician groups may assume financial risk
20 for providing required immunizations, if the immunizations have
21 experiential data that has been negotiated and agreed upon by the
22 health care service plan and the physician risk-bearing organization
23 or physician group. However, a health care service plan shall not
24 require a physician risk-bearing organization or physician group
25 to accept financial risk or impose additional risk on a physician
26 risk-bearing organization or physician group in violation of
27 subdivision (a).

28 (d)

29 (e) A health care service plan shall not include the acquisition
30 costs or administration costs associated with required
31 immunizations for children in the capitation rate of a physician
32 who is individually capitated.

33 (f) A health care service plan contract issued, amended, or
34 renewed on or after January 1, 2010, that provides coverage for
35 childhood and adolescent immunizations pursuant to Section
36 1367.3 or 1367.35 shall not do either of the following:

37 (1) Impose a deductible, copayment, coinsurance, or other
38 cost-sharing mechanism for the administration of a childhood or
39 adolescent immunization or for procedures related to that
40 administration.

1 (2) *Contain a dollar limit provision for the administration of*
2 *childhood and adolescent immunizations or include the cost of*
3 *those immunizations in a dollar limit provision of the contract.*

4 SEC. 3. Section 10123.56 is added to the Insurance Code, to
5 read:

6 10123.56. (a) A health insurer that provides coverage for
7 childhood and adolescent immunizations pursuant to Section
8 10123.5 or 10123.55 shall reimburse a physician or physician
9 group in an amount not less than the actual cost of acquiring the
10 vaccine plus the cost of administration of the vaccine. For purposes
11 of this subdivision, both of the following shall apply:

12 (1) The actual cost of acquiring the vaccine includes, but is not
13 limited to, the invoiced purchase price plus reasonable costs
14 associated with shipping, handling, insurance, and storage.

15 (2) The cost of administration of the vaccine shall be an amount
16 not less than that specified in the most current annual Medicare
17 physician fee schedule published pursuant to Section
18 1395w-4(b)(1) of Title 42 of the United States Code.

19 (b) A health insurance policy issued, amended, or renewed on
20 or after January 1, 2010, that provides coverage for childhood and
21 adolescent immunizations pursuant to Section 10123.5 or 10123.55
22 shall not do either of the following:

23 (1) Impose a deductible, copayment, coinsurance, or other
24 cost-sharing mechanism for the administration of a childhood or
25 adolescent immunization or for procedures related to that
26 administration.

27 (2) Contain a dollar limit provision for the administration of
28 childhood and adolescent immunizations or include the cost of
29 those immunizations in a dollar limit provision of the policy.

30 SEC. 4. Section 12693.56 is added to the Insurance Code, to
31 read:

32 12693.56. A participating health plan shall reimburse a
33 physician or physician group for immunizations administered to
34 a program subscriber in an amount not less than the actual cost of
35 acquiring the vaccine plus the cost of administration of the vaccine.
36 For purposes of this section, both of the following shall apply:

37 (a) The actual cost of acquiring the vaccine includes, but is not
38 limited to, the invoiced purchase price plus reasonable costs
39 associated with shipping, handling, insurance, and storage.

1 (b) The cost of administration of the vaccine shall be an amount
2 not less than that specified in the most current annual Medicare
3 physician fee schedule published pursuant to Section
4 1395w-4(b)(1) of Title 42 of the United States Code.

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

Attachment D-1

Summary of the Legislation and Regulation Committee Meeting held on April 16, 2009



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: April 16, 2009

LOCATION: Department of Consumer Affairs El Dorado Room
1625 North Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Andrea Zinder, Public Member, Chair
Kenneth Schell, PharmD
James Burgard, Public Member

BOARD MEMBERS

NOT PRESENT: Shirley Wheat, Public Member
Ryan Brooks, Public Member
Robert Swart, PharmD
Susan L. Ravnar, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Carolyn Klein, Legislation and Regulations Manager
Tessa Fraga, Staff Analyst

Call to Order

Chair Zinder called the meeting to order at 10:08 a.m.

A. REGULATIONS REPORT

1. Approved Regulations

Section 100 Changes

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms. Board staff was recently advised that these forms were approved by

the Office of Administrative Law. The revised forms are on the board's Web site. Additionally, a notice was provided in the upcoming issue of *The Script* advising readers of the change.

- a. Amendment of 16 CCR §1715 Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law; and related updates to Forms 17M-13 and 17M-14

Assistant Executive Officer Anne Sodergren provided that section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PICs. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the pharmacist-in-charge occurs. Ms. Sodergren advised that the new self-assessment forms are now on the board's website.

- b. Amendment of 16 CCR §1784 Self Assessment of a Wholesaler by the Designated Representative-in-Charge to Update for Changes in Pharmacy Law; and related updates to Form 17M-26

Ms. Sodergren provided that section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge (DRC) to complete this form to ensure compliance with pharmacy law. This self-assessment form is designed to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the inspection process more meaningful and provide relevant information to wholesalers and their DRC. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the designated representative-in-charge occurs. Ms. Sodergren advised that the self-assessment form is now available on the board's website.

2. Board Approved Regulations – Undergoing Administrative Review

- a. Proposed Adoption of 16 CCR §1760 – Disciplinary Guidelines

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency was concerned about the optional language relating to automatic revocation when a probationer fails to submit

cost recovery as mandated. As a result the matter was referred back to the board at the January 2009 Board Meeting.

During this meeting the board considered the option to withdraw the rulemaking and begin over, or to modify the language removing the specific term and notice the modification through a 15-day comment period. At the conclusion, the board directed staff to modify the text to remove the specific term / optional language discussed above and to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period. The board further stated that if, after the 15-day public comment period, no adverse comments are received, the Executive Officer is authorized to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to 16 CCR §1760 – Disciplinary Guidelines.

Ms. Sodergren provided that this rulemaking is currently undergoing review by the Office of Administrative Law.

b. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

Ms. Sodergren provided that the 15-day comment period is over and no additional comments were received. She indicated that board staff compiled the rulemaking and it is currently undergoing review by the department.

3. Board Approved Regulations – Previously Noticed

- a. Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. Based on the subcommittee's recommendation, at the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the recordkeeping requirements sterile products that are compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Ms. Sodergren provided that 15- day notice period is over. She stated that the board has received several comments in response to this 15-day notice period. Ms. Sodergren added that these comments will be provided to the board for further consideration at the April 2009 Board Meeting.

Public Comment:

John Grupps, representing UC Davis Medical Center, sought clarification regarding the comments that were received.

Ms. Sodergren provided that many of the comments that were received were outside of the scope of the change. She added that the comments that are within the scope of the 15-day change will be provided at the April Board Meeting. Ms. Sodergren indicated that after consideration the board will vote to adopt the changes, pursue another 15-day comment period, or withdraw the changes.

Mr. Grupps sought confirmation on whether the 15-day comment period was specific to the exemption.

Ms. Sodergren confirmed and reviewed the rulemaking and proposal process.

Discussion continued regarding the comment period and the issue of compounding.

There was no additional board or public comment.

4. Board Approved Regulations – Awaiting Notice

a. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Ms. Sodergren provided that board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

b. Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination/Confidentiality

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Ms. Sodergren provided that language has been approved by the board. She added that the board is awaiting notice by the end of this legislative year.

c. Title 16 CCR Section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation

agencies approved by the board. Since the inception of this statute, the board has approved two such agencies. At the July 2007 Board Meeting, the board voted to move this proposal.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Ms. Sodergren provided that language has been approved by the board. She added that the board is awaiting notice by the end of this legislative year.

5. Regulations Under Development

a. Title 16 CCR Section 1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

Ms. Sodergren provided that a subcommittee has been established and will be working with board staff and industry.

b. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending

committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Ms. Sodergren provided that language has not yet been developed.

B. LEGISLATIVE REPORT

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

- a. SB 819 (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).

Chair Zinder explained that, at the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

Committee Discussion:

Ms. Sodergren provided that SB 819 is scheduled for hearing and will most likely be a consent item.

Discussion continued regarding the status of SB 819.

There was no additional committee or public comment.

Changes based on recodification of B&PC §4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

- §733 – Dispensing Prescription Drugs and Devices
- §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Facilities
- §4040 – Prescription; Content Requirements
- §4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- §4060 – Controlled Substance; Prescription Required; Exceptions
- §4076 – Prescription Container; Requirements for Labeling
- §4111 – Restrictions on Prescriber Ownership
- §4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC §11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Changes

The following proposals were also approved as omnibus provisions for 2008.

- §4059.5 – Who may order Dangerous Drugs or Devices; Exceptions

A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

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

This section requires amendment to replace the term representative-in-charge with “designated representative-in-charge.”

- §4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

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

This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

- § 4362 – Entry Into Pharmacists Recovery Program

This section requires amendment to specify the administrative co-pay participants pay.

- H&SC §11165 – Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature

This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Omnibus Changes to Allow for the Use of Mobile Pharmacies

- §4062 – Furnishing Dangerous Drugs During an Emergency

This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

- §4110 – License Required; Temporary Permit Upon Transfer of Ownership

This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Omnibus Changes Specific to the PIC and DRC Requirements

Consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs. These changes were approved by the board and many were incorporated in SB 1779 as omnibus provisions. This bill was vetoed by the Governor. Board staff recommends that the board again consider including these changes as omnibus provisions in 2009.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed changes. The proposed language is following this memo.

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

This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

- §4161 – Non-Resident Wholesaler; Requirements

This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC 4043.

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

This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

- §4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

- §4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

- b. SB 820 (Senate Business, Professions & Economic Development Committee) –
New Omnibus Provisions

Ms. Sodergren provided that, late last year, board staff was advised that the Office of Examination Resources (OER) was being renamed to the Office of Professional Examination Resources. SB 820 (Senate Business, Professions & Economic Development Committee) make conforming changes throughout the Business and Professions Code to reflect this name change.

- §4200.3 – Exam Process; standards; development; reporting requirements
- §4200.4 – Retaking Examinations; Set Limits; Requirements

- c. SB 821 (Senate Business, Professions & Economic Development Committee) –
New Omnibus Provisions specific to PIC and DRC Requirements

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

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

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

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

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

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

- §4160 – Wholesaler Licenses

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

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

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

Committee Discussion:

Ms. Sodergren explained that, at the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions. These provisions are contained in SB 821 (Senate Business and Professions Committee).

Chair Zinder confirmed that the provisions are technical changes.

Ms. Herold provided that one provision will be added requiring all pharmacies in California to join the board's subscriber alert.

Public Comment:

Bryce Docherty, representing California Society of Health-System Pharmacists (CSHP), sought clarification regarding the subscriber alert provision.

Ms. Herold provided that the provision pertains to pharmacies and will place the burden on the pharmacist in charge (PIC) to register for the subscriber alert.

Cookie Quandt, representing Longs Drugs, confirmed that the provision pertains specifically to pharmacy sites.

Chair Zinder sought clarification regarding the number of pharmacies who currently subscribe to the subscriber alert.

Ms. Herold responded that there are methods to verify this number. She explained the importance of pharmacies receiving mail and notifications from the board.

Discussion continued regarding board notifications via mail and e-mail.

There was no additional committee or public comment.

- d. SB 470 (Corbett) – “Purpose” bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.

Chair Zinder provided that, at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the “condition” for which a medicine is prescribed, with the “purpose” for which the medicine is prescribed.

Committee Discussion:

Ms. Sodergren provided that Senator Corbett is authoring this bill for the board. This bill will amend Business and Professions Code sections 4040 and 4076 to include the “condition or purpose” for which a medicine is prescribed. (Senator Corbett authored SB 472, Chapter 470, and Statutes of 2007, requiring the board to standardize the prescription label to make them patient-centered.)

Ms. Sodergren indicated that board staff has been working to establish a broad base of support for this proposal. The California Medical Association recently submitted a letter advising the author’s office that it has taken a Support If Amended position and offered amendments. Senator Corbett’s office has advised CMA that they will be accepting the amendments offered.

Ms. Herold provided that board staff will continue to advocate for this proposal and will engage with stakeholders who may have concerns.

There was no additional committee or public comment.

- e. AB 977 (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8

At the October 2008 Board Meeting, the board vetoed to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Assembly Member Skinner is authoring this bill for the board. The bill will amend Business and Professions Code section 4052 and add 4052.8 to allow a pharmacist to administer immunizations as specified. As introduced, the bill would have allowed a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP), however with the approval of the board president, this proposal will be amended to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a prescriber protocol. The National Vital Statistics Report published by the U.S. Department of Health and Human Services reports that combined, influenza and pneumonia are the eighth leading cause of death in people of all ages, and the sixth leading cause of death in people over 65.

Board staff has been working with stakeholders to establish a broad base of support. Unfortunately, the California Medical Association (CMA) continues to oppose the bill, even with proposed amendments.

Committee Discussion:

Ms. Sodergren provided that, despite an amendment to only include influenza and pneumococcal vaccinations, the bill did not pass committee; however, was granted reconsideration.

Ms. Herold provided that if the bill is unsuccessful, the board is hoping that the profession will continue to work with the consumer advocates and the public health advocates to pursue this public health issue.

Discussion continued regarding access and administration of vaccinations.

There was no additional committee or public comment.

- f. AB 1071 (Emmerson) Pharmacy Fees. Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

Chair Zinder provided that, at the January 2009 Board Meeting, the board voted to pursue a statutory change increase to its fees.

Committee Discussion:

Ms. Sodergren provided that Assembly Member Emmerson is authorizing this proposal for the board. She stated that AB 1071 adjusts application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. Ms. Sodergren indicated that this bill also builds in a cap to increase future fees by no more than 30 percent.

Chair Zinder expressed concern regarding the increase for pharmacy technicians.

Ms. Sodergren responded that pharmacy technician fee will be increased from \$50 to \$80. She explained that this fee will not be increased to the actual cost to deliver the service.

Discussion continued regarding subsidies and fee increases.

There was no additional committee or public comment.

2. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction – For Committee Consideration

a. AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements

Ms. Sodergren provided that this bill would alter the requirements for licensure as a pharmacy technician as well as establish continuing education requirements as a condition of renewal. She indicated that the bill has been amended to remove the CE requirements.

Public Comments:

Bryce Docherty, representing California Society of Health-System Pharmacists (CSHP), provided that the minimum intent for the bill is to raise the minimum standard for licensure of pharmacy technicians to better protect Californian consumers. He discussed the high volume of pharmacy technicians and the need for adequate training. Mr. Docherty stated that the bill did not receive the requisite number of votes to pass out of the Assembly; but it has been granted reconsideration. He requested that the committee provide support for the bill.

Mr. Docherty reviewed the amended requirements for a pharmacy technician license.

Discussion continued regarding various amendments and requirements of the bill and the role of a pharmacy technician.

Cookie Quandt, representing Longs Drugs, sought clarification on whether § 4410 has been removed.

Ms. Sodergren confirmed.

Greg Lippe discussed the potential cost factor in licensing technicians at a higher level; thus, resulting in higher salaries and increasing costs for pharmacies.

Discussion continued regarding potential costs and standards.

James Burgard expressed concern regarding stronger qualified technicians with greater responsibilities.

Mr. Docherty responded that technician responsibilities are outlined in law.

There was no additional committee or public comment.

MOTION: To support AB 418.

M/S: JB/ KS

Approve: 2 Oppose: 1

b. AB 484 (Eng) Franchise Tax board: professional or occupational licenses

Ms. Sodergren provided that this bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity. The bill would require the Franchise Tax Board, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, as specified, to mail a preliminary notice of suspension to the licensee.

Committee Discussion:

Mr. Lippe expressed concern for the bill and recommended that it be opposed.

Ms. Sodergren provided that the bill failed in committee; but, has been granted reconsideration.

Chair Zinder questioned if the department has taken a position on this bill.

Marc Mason, representing the Department of Consumer Affairs, provided that the department has no official position.

There was no additional committee or public comment.

COMMITTEE RECOMMENDATION: none

- c. AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to electronically transmit data by 1/1/12

Ms. Sodergren provided that this bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission.

MOTION: To support AB 718.

M/S: JB/KS

Approve: 3 Oppose: 0

- d. AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid

Chair Zinder provided that this bill would replace various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services.

Committee Discussion:

Discussion continued regarding the list of the compendium guides and the intent of this bill.

There was no additional board or public comment.

MOTION: To oppose AB 830.

M/S: KS/ JB

Approve: 3 Oppose: 0

- e. AB 877 (Emmerson) (*Intent language*)Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice

Ms. Sodergren provided that this bill would declare the intent of the Legislature to enact legislation authorizing the Director of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice.

Ms. Sodergren reviewed the intended committee composition. She indicated that bill has been amended to include that the cost will be born by the regulatory agency.

Ms. Herold suggested that the committee provide a neutral recommendation.

MOTION: To take no position on AB 877

M/S: JB/KS

Approve: 3 Oppose: 0

- f. AB 931 (Fletcher) Emergency Supplies – Doses stored in an emergency supplies container

Chair Zinder provided that this bill would increase the number of oral dosage form and suppository dosage form drugs for storage within this container to limit to 48. She indicated that the current limit is 24. Chair Zinder stated that the bill is sponsored by the California Pharmacists Association (CPhA).

Ms. Herold provided that Department of Public Health is expected to oppose the bill.

COMMITTEE RECOMMENDATION: none

- g. AB 1310 (Hernandez) Specifies mandatory fields for initial and renewal application forms (various healing arts boards). Annual transmission of data to Health Care Workforce Clearinghouse (OSHPD)

Chair Zinder provided that this bill would require specified healing arts boards to add and label as “mandatory” specified fields on an application for initial licensure or a renewal form for applicants applying to those boards and would require the board to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse annually on or before January 1.

Committee Discussion:

Ms. Sodergren provided that existing law defines the required information an applicant of licensure or renewal must provide. She stated that the board does not currently collect several of the required elements including worksite information, number of hours worked, as well as race and ethnicity. Ms. Sodergren indicated that the board will require funding for additional staff as well as funding to purchase a database. She added that the board would require three full-time Office Technicians to collect and input specified data for all new and renewal applicants.

Ms. Herold provided that the Governor’s Office is encouraging the department to select additional information regarding “manpower shortages.”

Dr. Schell sought clarification on whether it is intended that the bill will be revenue neutral.

Carolyn Klein, Legislation and Regulations Manager, provided that the staff consultant representing the author has indicated a fee increase for licensees and minimal changes to the computer system in order to gather the additional information.

Discussion continued regarding implementation costs.

There was no additional committee or public comment.

MOTION: To take no position on AB 1310.

M/S: JB/KS

Approve: 3 Oppose: 0

h. AB 1370 (Solorio) "Best Before" date on a prescription label

Chair Zinder provided that this bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug of device.

Committee Discussion:

Ms. Herold provided that this bill is expected to be dropped by the author. She indicated that the Enforcement Committee will further evaluate the date and its implications.

Discussion continued regarding conditions impacting the date on the bottle.

There was no additional committee or public comment.

There was no position required.

i. SB 26 (Simitian) Home-Generated Pharmaceutical Waste

Chair Zinder provided that this bill would require the board to coordinate with other state agencies, local governments, drug manufactures, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. She stated that the bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps, waste, as defined.

Committee Discussion:

Ms. Herold reviewed comments provided to the California Integrated Waste Management Board (CIWMB). She indicated that Senator Simitain has agreed to take out provisions regarding the "common carrier."

There was no additional committee or public comment.

MOTION: To take no position on SB 26.

M/S: JB/ KS

Approve: 3 Oppose: 0

j. SB 43 (Alquist) Cultural and Linguistic Competency

Chair Zinder provided that this bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards.

Committee Discussion:

Ms. Sodergrén provided that this bill does not create a mandate, rather it is permissive. She indicated that the bill would allow the Office of Statewide Health Planning and Development (OSHDP) to obtain data for inclusion in the health care workforce clearinghouse and require that personally identifiable information be kept confidential.

Dr. Schell expressed concern regarding the protection of confidential information and potential disclosure costs.

There was no additional committee or public comment.

MOTION: To support SB 43.

M/S: KS/JB

Approve: 3 Oppose: 0

k. SB 364 (Florez) Intent language (as introduced). Penalties on a pharmacy that fails to safeguard controlled substances, as specified.

Ms. Sodergren provided that this bill would declare the intent of the Legislature to enact legislation authorizing the imposition of specified penalties on a pharmacy that fails to

safeguard controlled substances. She indicated that this bill has been amended and no longer pertains to pharmacy.

There was no position required.

I. SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus

Chair Zinder provided that this bill would require applicants for a license, and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

MOTION: To support SB 389.

M/S: KS/JB

Approve: 3 Oppose: 0

m. SB 484 (Wright) Ephedrine Products / Schedule V

Ms. Sodergren provided that this bill would add ephedrine and pseudoephedrine to California's Controlled Substances in Schedule V. She indicated that a prescription would be required before a consumer could purchase these substances.

Presentation to the Board:

Kent Shaw, representing the Department of Justice (DOJ), discussed the dramatic increase in methamphetamine labs in California. He explained that pseudoephedrine is the essential precursor for making methamphetamine. Mr. Shaw provided that pseudoephedrine purchased (smurfed) from retail outlets in California is the exclusive source of the precursor used by methamphetamine manufacturers. He indicated that the best way to combat the smurfing problem is to require a prescription for pseudoephedrine and only have it available from a pharmacy. He discussed that Oregon has successfully implemented such a regulation and the results have been dramatic.

Mr. Shaw encouraged the board's support for SB 484.

Committee Discussion:

Dr. Schell discussed possible impacts the bill may have on pharmacies and the potential for pharmacy errors.

Mr. Shaw provided that Oregon has no experienced such issues as a result of their bill.

Dr. Schell questioned if other precursors and methods for manufacture have been addressed.

Mr. Shaw responded that other methods are not as frequent and effective. He added that California's methamphetamine labs are much larger than the other states and stated that these labs have a greater production capacity than all of the other states combined.

Chair Zinder questioned if alternative products are available for people who are uninsured.

Dr. Schell responded that alternative products are available but they may not be as effective.

Discussion continued regarding the dispersion and use of pseudoephedrine.

Public Comment:

Cookie Quandt, representing Longs Drugs, provided that pharmacists are concerned about the smurfing issue and indicated that pharmacies are requiring a significant amount of time to deal with this issue. She stated that Longs is a proponent of making pseudoephedrine a scheduled drug. Ms. Quandt questioned if this issue would be reported to CURES and sought clarification on what role the board would play with this issue.

Mr. Shaw responded that there are tentative plans for monitoring. He indicated that DOJ will bear the burden for this action.

Discussion continued regarding smurfing and impact on pharmacists

Lynn Rolston, representing the California Pharmacists Association (CPhA), provided support to this initiative. She sought clarification on why the bill is seeking to add pseudoephedrine as a Schedule V drug as opposed to a Schedule IV drug that could be tracked by CURES.

Mr. Shaw responded that successfully requiring a prescription for this drug is the primary and most achievable challenge.

Ms. Herold discussed the purchase of pseudoephedrine via mail-order. She proposed the consideration for a sunset date on this provision for five years. Discussion continued regarding the possible impacts for the implementation of SB 484.

There was no additional committee or public comment

COMMITTEE RECOMMENDATION: none

- n. SB 599 (Negrete McLeod) Requirement for DCA Boards to post to board's Internet site within 10 days each accusation, statement of issues, or disciplinary action taken by the board

Chair Zinder provided this bill would require every board, as defined, to post each accusation, statement of issues, or disciplinary action taken by the board on that board's Internet Web site within 10 days of the filing date of the accusation or statement of issues, or the effective date of the disciplinary action.

Ms. Sodergren provided that this bill has been amended and is now specific to workforce development.

There was no position required.

- o. SB 638 (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements

Chair Zinder provided that this bill would redefine the sunset review process.

Ms. Sodergren provided that under existing law, all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence. She added that in the event the board becomes inoperative and is repealed, the board transforms into a bureau under the Department of Consumer Affairs. Ms. Sodergren indicated that this bill would redefine this process and would reconstitute any board that becomes inoperative or is repealed.

MOTION: To support AB 484.

M/S: KS/ JB

Approve: 3 Oppose: 0

p. SB 762 (Aanestad) Professions and Vocations; Healing Arts

Chair Zinder provided that this bill would also make it unlawful for a city, county, or city and county to prohibit a healing arts licensee from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee, but would prohibit construing this provision to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, as specified.

Committee Discussion:

The committee discussed the intent and focus of this bill in relation to pharmacy.

Mark Mason, representing the Department of Consumer Affairs, provided the department does not have a position on this bill.

There was no additional board or public comment.

COMMITTEE RECOMMENDATION: none

b. Other Legislation Introduced (Of Interest or for Information Only)

Chair Zinder acknowledged the following proposals that do not directly impact the board's jurisdiction but may be of interest.

- a. AB 832 (Jones) Clinic Licensing
- b. AB 1094 (Conway) Disposal of Personal Information
- c. AB 1201 (Perez) – Immunizations (physician reimbursement)
- d. SB 341 (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs

C. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA

No public comments were provided

The meeting was adjourned at 12:40 p.m.

Attachment E-1

Third Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

LEGISLATION AND REGULATION COMMITTEE

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

Outcome: Improve the health and safety of Californians.

<p>Objective 3.1</p> <p>Measure:</p>	<p>Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.</p> <p>100 percent successful enactment of promoted legislative changes.</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date. <p><i>Sept. 30, 2006:</i> Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</p> <p><i>June 2007:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</p> <p><i>July 2008:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</p> <p><i>Sept. 2008:</i> Governor signs SB 963 (Chapter 385, Statutes of 2008)</p> 2. Sponsor legislation to update pharmacy law. <p><i>Enacted - 1st Qtr. 08/09:</i> SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions</p> <p><i>Oct. 2007:</i> Board sponsors omnibus provisions for 2008. Four types of changes are discussed.</p> <ol style="list-style-type: none"> (1) Changes specific to the PIC and DRC requirements <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4161 – Nonresident wholesaler • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts (2) Changes to allow for the use of mobile pharmacies <ul style="list-style-type: none"> • Section 4062 – Furnishing Dangerous Drugs During an Emergency. • Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership. (3) General changes <ul style="list-style-type: none"> • Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions. • Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory • Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy. • Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee. • H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

Jan. 2008: *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.*

Board approved language for omnibus bill.

April 2008: *Some provisions of omnibus bill removed:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

Oct. 2008: *Governor vetoes SB 1779*

1st Qtr. 08/09: *Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change:*

(1) *Changes specific to the PIC and DRC requirements*

- *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*
- *Section 4036.5 – Pharmacist-in-Charge*
- *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*
- *Section 4329 – Nonpharmacists; Prohibited Acts*
- *Section 4330 – Proprietors; Prohibited Acts*

(2) *Changes to allow for the use of mobile pharmacies*

- *Section 4062 – Furnishing Dangerous Drugs During an Emergency.*
- *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.*

(3) *General changes*

- *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.*
- *Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*
- *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*
- *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*
H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

1st Qtr. 08/09: *Board seeks to introduce additional changes:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

New Provisions

- *4200.1 – Pharmacist Examination; Remedial Education*
- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

2nd Qtr. 08/09: Provisions contained in SB 821:

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*

New Provisions

- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.

Sept. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.
- Oct. 2007:** **Governor signs the following:**
AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.
SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.
- Governor vetoes the following:**
AB 249 (Eng) Healing Arts: Settlement Agreements.
AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.
AB 1025 (Bass) Professions and Vocations: Denial of Licensure.
SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.
- Oct. 2008:** **Governor signs the following:**
AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks
SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review
- Governor vetoes the following:**
AB 501 (Swanson) Pharmaceutical Devices
AB 865 (Davis) State Agencies
AB1574 (Plescia) Surgical Clinics: Licensure
- Jan. 2009:** *Legislation introduced affecting Pharmacy law:*
(New Session) *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.*
SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.

April 2009: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
 AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHDP)
 AB 1370 (Solorio) “Best Before” Date on a Prescription Label
 AB 1458 (Davis) Drugs: Adverse Effects Reporting
 SB 26 (Simitian) Home-Generated Pharmaceutical Waste
 SB 43 (Alquist) Cultural and Linguistic Competency
 SB 238 (Calderon) Medical Information
 SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
 SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts

7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.

March 2007: Licensing Committee considers and approves concept. More work is required.

June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.

Sept. 2007: Licensing Committee forwards to full board legislative proposal.

Oct. 2007: Board approved draft legislation.

Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.

Dec. 2007: Staff develop fact sheets and work with experts in immunizations.

Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.

April 2009: Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.

Apr. 2008: First public forum held in Fremont.

*May 2008: Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.*

June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.

July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.

Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.

Public Education Committee updated on the status of survey results.

Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.

9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.

Dec. 2008: Board receives findings of independent fee audit.

Jan. 2009: Board votes to pursue fee increase.

Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 258 1471 359">1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 369 1471 506">2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 516 1471 726">3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 737 1471 804">4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 814 1471 1325">5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Aug. 2006: Final changes to Disciplinary Guidelines being compiled by staff.</i> <i>Dec. 2006: Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.</i> <i>June 2007: Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.</i> <i>Sept. 2007: Enforcement Committee approves Disciplinary Guidelines and recommends board approval.</i> <i>Oct. 2007: Board approves Disciplinary Guidelines for 45-day comment period.</i> <i>Feb. 2008: Regulation released for 45 days of public comment.</i> <i>April 2008: Board adopts regulation.</i> <i>Sept. 2008: Rulemaking file submitted for review by the administration.</i> <i>Jan. 2009: Board pursues 15-day comment to eliminate an optional provision contained in the guidelines.</i> <i>March 2009: Rulemaking compiled and resubmitted for review by the administration.</i> <li data-bbox="370 1335 1471 1436">6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 1446 1471 1583">7. Exempt the address of records of interns from display on the board's website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> <li data-bbox="370 1593 1471 1799">8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i>

9. **Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).**
- Feb. 2007: Board notices regulation for 45 days comment period.*
- April 2007: Board considers comments submitted during public comment period and modifies text regulation to reflect comments.*
- May 2007: New section 1707.2 released for 45 days of public comment.*
- July 2007: Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.*
- Sept. 2007: File submitted to the Office of Administrative Law for review.*
- Oct. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Regulation changes takes effect.*
- Nov. 2007: Staff solicits design submissions from graphic designers.*
- Jan. 2008: Communication and Public Education Committee make recommendations on design submissions.*
- Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.*
10. **Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.**
- Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:*
- 1707 – Waiver of requirements for off-site storage of records*
- 1709.1 – Designation of pharmacist-in-charge*
- 1715 – Self-assessment of a pharmacy by the pharmacist-in-charge*
- 1717 – Pharmacy practice*
- 1746 – Emergency contraception*
- 1780.1 – Minimum standards for veterinary food-animal drug retailers*
- 1781 – Exemption certificate*
- 1787 – Authorization to distribute dialysis drugs and devices*
- 1790 – Assembling and packaging*
- 1793.8 – Technician check technician*
- Repeal section 1786 – Exemptions*
- March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*
11. **Increase fees to keep the board's contingency fund solvent and maintain operations.**
- Nov. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.*
- Jan. 1, 2008: New fees take effect.*

12. Secure regulatory standards for pharmacies that compound.

Dec. 2006: Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.

March 2007: Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.

May 2007: Licensing Committee holds detailed discussion on compounding regulations.

Sept. 2007: Licensing Committee forwards regulation proposal to the board for review.

Nov. 2007: Board releases language for the 45-day comment period.

Jan. 2008: Board held regulation hearing and considers written comments and oral testimony.

April 2008: Board votes to withdraw rulemaking.

Aug. 2008: Board releases new language for the 45-day comment period.

Oct. 2008: Board holds regulation hearing to elicit additional comments.

Jan. 2009: Board votes to pursue 15-day notice.

13. Establish an ethics course.

April 2007: Board establishes a subcommittee to examine the development of an ethics course.

Oct. 2007: Board votes to pursue regulation change to establish program components.

Sept. 2008: Board notices regulation for 45-day comment period.

Oct. 2008: Board votes to pursue 15-day comment period and, absent any negative comments, authorizes the Executive Officer to complete the rulemaking file.

March 2009: Rulemaking submitted for review by the administration.

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill.</p>