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

Legislation and Regulation Committee

Greg Lippe, Public Member, Chair
Ryan Brooks, Public Member
Robert Swart, PharmD
Stan Weisser, RPh
Shirley Wheat, Public Member

Part 2: LEGISLATION REPORT AND ACTION

A. Board Sponsored Legislation

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

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, Professions and Economic Development Committee) which was vetoed by the Governor (prior session).

The omnibus provisions included in SB 819 are 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.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed changes.

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.

Status: Staff reported at the July 8, 2009, Legislation and Regulation Committee that the measure passed Assembly policy committee and was referred to Assembly Appropriations.

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

Status: Staff reported that recent amendments to SB 820 moved the Board of Pharmacy’s omnibus provisions related to the renaming of the Department of Consumer Affairs Office of Professional Examination Resources (4200.3 and 4200.4) into SB 821.

As amended July 6, SB 820 no longer affects Pharmacy Law.

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

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.

Status: Staff reported that the measure was amended on July 6, 2009 to incorporate the Board of Pharmacy's omnibus provisions (previously found in SB 820) related to the renaming of the Office of Professional Examination Resources. SB 821 now makes conforming changes throughout the Business and Professions Code to reflect this name change.

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 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.

Status: Staff reported that the measure was scheduled to be heard July 8, 2009, in Assembly 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.

Status: This bill failed passage in the Assembly Business and Professions Committee and did not meet the deadline to be passed out of the house of origin.

6. **FOR INFORMATION** – 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, resulting in the (2/27/09) introduction of AB 1071.

Status: Staff reported that AB 1071, as introduced, passed policy and fiscal committees in the Assembly, and recently passed both policy and fiscal committees in the Senate.

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 583 (Hayashi) Health Care Practitioners / Disclosure of Education and Office Hours
Existing law (BPC 680) requires a health care practitioner to disclose his or her name, license on a name tag in 18-point type. AB 583 as amended 7/8/09 further requires a health care practitioner to provide their license type and the highest level of academic degree he or she holds on either a name tag, in writing to a patient as specified, or on a prominent display in his or her office. The measure provides specified exceptions for those licensed under BPC 2700 and makes additional requirements to those licensed under Chapter 5 or under the Osteopathic Act, and makes further requirements of physicians and surgeons who supervise locations outside of their primary office. The measure excepts from some of the requirements those who work in a facility licensed under HSC 1250 or in a clinical laboratory licensed under HSC 1265.

A bill analysis will be provided at the board meeting. This measure was not discussed at the Legislation and Regulation Committee meeting.

2. Possible Action AB 718 (Emmerson) Inland Empire Health Plan E-Prescribing Pilot Program (electronic transmission of prescriptions)

As amended 6/30/09, AB 718 removed amendments to Pharmacy Law and, instead, in the Welfare and Institutions Code, creates the Inland Empire Health Plan E-Prescribing Pilot, which is to be funded with funds made available by the Federal American Recovery and Reinvestment Act of 2009.

Following discussion of the bill and the board's stated support in general of e-prescribing, the committee voted to recommend that the Board "Support" of AB 718 as Amended 7/7/09.

Committee Recommendation: "Support" AB 718 as Amended 7/7/09

Bill Status: Amended (7/7) and passed out of Senate Business, Professions and Economic Development. Referred to Senate Appropriations.

3. Possible Action AB 830 (Cook) Drugs and devices

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

Ms. Herold provided an overview of the measure and discussed recent amendments that remove amendments to Pharmacy Law. The committee voted to recommend that the Board "Support" AB 830 as Amended 7/6/09. An updated bill analysis is included.

Committee Recommendation: "Support" AB 830 as Amended 7/6/09

Bill Status: Referred to Senate Committee on Health.

4. 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. The committee discussed the proposed expanded size of the e-kits, the time in which prescriptions are filled, and the use of the e-kits in STAT situations. Physicians determine what constitutes an "emergency" in a skilled nursing facility. Ms. Herold clarified that these e-kits are within the jurisdiction of the California Department of Public Health. The committee requested more information on the intent of the bill. The committee did not recommend a position on this measure.

Bill Status: In Senate Committee on Health. The committee has postponed hearings on this bill.

5. Possible Action 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, who petition for reinstatement of a revoked, surrendered or canceled license, 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.

The committee discussed how the agency receives fingerprint data, and Ms. Herold clarified how that data is secured. The committee voted to recommend that the board take a "Neutral" position on the bill.

Committee Recommendation: "Neutral" position on SB 389 as Amended 6/1/09
Bill Status: (7/7) Failed passage in ASM Public Safety. Reconsideration granted.

6. SB 484 (Wright) Ephedrine and pseudoephedrine

The current version of this bill (5/12/09) provides that transactions of specified ephedrine substances are to be reported to the Department of Justice. The bill also provides that any person obtaining a substance specified in H&S §11375.5(b) shall be guilty of a crime. Ms. Herold discussed that some drug manufacturers are offering a tracking system that would be funded by the manufacturers. The committee discussed inconsistencies in the language of this version. The committee did not establish a recommended position on this bill.

Bill Status: (6/30) Failed passage in ASM Public Safety. Reconsideration granted.

7. 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.

Bill Status: (7/2) Approved by the Governor and filed with the Secretary of State.
Chapter 16, Statutes of 2009

C. FOR INFORMATION AND POSSIBLE ACTION – Legislation that Failed Passage and May Become a 2-Year Bill

Attachment C-1

The committee was advised of various legislative measures that did not meet the deadline for passing out of the house of origin; thus, possible two-year bills. The Executive Officer specifically discussed SB 638, the measure that would extend the board's sunset provision. The committee discussion and recommended action are below.

1. **Possible Action** SB 638 (Negrete McLeod) Regulatory boards: operations (sunset)

This bill would redefine the sunset review process. The bill was held in Senate Rules and did not meet the deadline for bills to be passed out of the house of origin. Ms. Herold indicated that she has been working with the Senate Business, Professions and Economic Development committee to identify options to secure an extension of the board's sunset date. Following discussion, the committee voted to recommend that the board authorize the Executive Officer to have the Board of Pharmacy's sunset provisions addressed through a different legislative measure in order to extend the board's sunset date.

Committee Recommendation: Authorize the Executive Officer to take steps to have the Board of Pharmacy's sunset provision extended through another legislative measure.

2. SB 26 (Simitian) Drug Take Back

Ms. Herold advised the committee that SB 26 stalled in Senate Appropriations.

D. Other Legislation Introduced

1. AB 832 (Jones) Ambulatory Surgical Clinic Workgroup
2. AB 1094 (Conway) Disposal of Personal Information
3. AB 1201 (Perez) – Immunizations -- Physician Reimbursement

The committee did not discuss these items at its meeting, but board staff advised that an update on these measures would be provided at the board meeting.

E. Strategic Plan Update for the Legislation and Regulation Committee for 2009-10

Attachment E-1

The committee discussed the Strategic Plan Update for the Legislation and Regulation Committee and voted to approve the plan as submitted.

F. Summary of the Legislation and Regulation Committee Meeting Held on July 8, 2009

A summary of the meeting minutes will be provided at the meeting.

G. Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

Attachment G-1

Attachment G-1 reflects the updates to the Legislation/Regulation committee goals for 2008/09.

SB 819 (Senate Business, Professions and Economic Development)

AMENDED IN ASSEMBLY JUNE 22, 2009

AMENDED IN SENATE MAY 28, 2009

AMENDED IN SENATE MAY 5, 2009

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, 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, 8030.2, 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, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

1 into a formal agreement with the board to reimburse the board
2 within that one-year period for those unpaid costs.

3 ~~SEC. 43.~~

4 *SEC. 42.* Section 4022.5 of the Business and Professions Code
5 is amended to read:

6 4022.5. (a) "Designated representative" means an individual
7 to whom a license has been granted pursuant to Section 4053. A
8 pharmacist fulfilling the duties of Section 4053 shall not be
9 required to obtain a license as a designated representative.

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

17 ~~SEC. 44.~~

18 *SEC. 43.* Section 4027 of the Business and Professions Code
19 is amended to read:

20 4027. (a) As used in this chapter, the terms "skilled nursing
21 facility," "intermediate care facility," and other references to health
22 facilities shall be construed with respect to the definitions contained
23 in Article 1 (commencing with Section 1250) of Chapter 2 of
24 Division 2 of the Health and Safety Code.

25 (b) As used in Section 4052.1, "licensed health care facility"
26 means a facility licensed pursuant to Article 1 (commencing with
27 Section 1250) of Chapter 2 of Division 2 of the Health and Safety
28 Code or a facility, as defined in Section 1250 of the Health and
29 Safety Code, operated by a health care service plan licensed
30 pursuant to Chapter 2.2 (commencing with Section 1340) of
31 Division 2 of the Health and Safety Code.

32 (c) As used in Section 4052.2, "health care facility" means a
33 facility, other than a facility licensed under Division 2
34 (commencing with Section 1200) of the Health and Safety Code,
35 that is owned or operated by a health care service plan licensed
36 pursuant to Chapter 2.2 (commencing with Section 1340) of the
37 Health and Safety Code, or by an organization under common
38 ownership or control of the health care service plan; "licensed
39 home health agency" means a private or public organization
40 licensed by the State Department of Public Health pursuant to

1 Chapter 8 (commencing with Section 1725) of Division 2 of the
2 Health and Safety Code, as further defined in Section 1727 of the
3 Health and Safety Code; and “licensed clinic” means a clinic
4 licensed pursuant to Article 1 (commencing with Section 1200)
5 of Chapter 1 of Division 2 of the Health and Safety Code.

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

14 ~~SEC. 45.~~

15 *SEC. 44.* Section 4036.5 is added to the Business and
16 Professions Code, to read:

17 4036.5. “Pharmacist-in-charge” means a pharmacist proposed
18 by a pharmacy and approved by the board as the supervisor or
19 manager responsible for ensuring the pharmacy’s compliance with
20 all state and federal laws and regulations pertaining to the practice
21 of pharmacy.

22 ~~SEC. 46.~~

23 *SEC. 45.* Section 4040 of the Business and Professions Code
24 is amended to read:

25 4040. (a) “Prescription” means an oral, written, or electronic
26 transmission order that is both of the following:

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

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

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

32 (C) The date of issue.

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

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

39 (F) If in writing, signed by the prescriber issuing the order, or
40 the certified nurse-midwife, nurse practitioner, physician assistant,

1 or naturopathic doctor who issues a drug order pursuant to Section
2 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist
3 who issues a drug order pursuant to either Section 4052.1 or
4 4052.2.

5 (2) Issued by a physician, dentist, optometrist, podiatrist,
6 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,
7 if a drug order is issued pursuant to Section 2746.51, 2836.1,
8 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,
9 physician assistant, or naturopathic doctor licensed in this state,
10 or pursuant to either Section 4052.1 or 4052.2 by a pharmacist
11 licensed in this state.

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

24 (c) "Electronic transmission prescription" includes both image
25 and data prescriptions. "Electronic image transmission
26 prescription" means any prescription order for which a facsimile
27 of the order is received by a pharmacy from a licensed prescriber.
28 "Electronic data transmission prescription" means any prescription
29 order, other than an electronic image transmission prescription,
30 that is electronically transmitted from a licensed prescriber to a
31 pharmacy.

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

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

1 ~~SEC. 47.~~

2 ~~SEC. 46.~~ Section 4051 of the Business and Professions Code
3 is amended to read:

4 4051. (a) Except as otherwise provided in this chapter, it is
5 unlawful for any person to manufacture, compound, furnish, sell,
6 or dispense any dangerous drug or dangerous device, or to dispense
7 or compound any prescription pursuant to Section 4040 of a
8 prescriber unless he or she is a pharmacist under this chapter.

9 (b) Notwithstanding any other law, a pharmacist may authorize
10 the initiation of a prescription, pursuant to Section 4052.1, 4052.2,
11 or 4052.3, and otherwise provide clinical advice or information or
12 patient consultation if all of the following conditions are met:

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

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

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

20 ~~SEC. 48.~~

21 ~~SEC. 47.~~ Section 4059.5 of the Business and Professions Code
22 is amended to read:

23 4059.5. (a) Except as otherwise provided in this chapter,
24 dangerous drugs or dangerous devices may only be ordered by an
25 entity licensed by the board and shall be delivered to the licensed
26 premises and signed for and received by a pharmacist. Where a
27 licensee is permitted to operate through a designated representative,
28 the designated representative shall sign for and receive the delivery.

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

33 (c) Notwithstanding subdivisions (a) and (b), deliveries to a
34 hospital pharmacy may be made to a central receiving location
35 within the hospital. However, the dangerous drugs or dangerous
36 devices shall be delivered to the licensed pharmacy premises within
37 one working day following receipt by the hospital, and the
38 pharmacist on duty at that time shall immediately inventory the
39 dangerous drugs or dangerous devices.

1 (d) Notwithstanding any other provision of law, a dangerous
2 drug or dangerous device may be ordered by and provided to a
3 manufacturer, physician, dentist, podiatrist, optometrist,
4 veterinarian, naturopathic doctor pursuant to Section 3640.7, or
5 laboratory, or a physical therapist acting within the scope of his
6 or her license. A person or entity receiving delivery of a dangerous
7 drug or dangerous device, or a duly authorized representative of
8 the person or entity, shall sign for the receipt of the dangerous drug
9 or dangerous device.

10 (e) A dangerous drug or dangerous device shall not be
11 transferred, sold, or delivered to a person outside this state, whether
12 foreign or domestic, unless the transferor, seller, or deliverer does
13 so in compliance with the laws of this state and of the United States
14 and of the state or country to which the dangerous drugs or
15 dangerous devices are to be transferred, sold, or delivered.
16 Compliance with the laws of this state and the United States and
17 of the state or country to which the dangerous drugs or dangerous
18 devices are to be delivered shall include, but not be limited to,
19 determining that the recipient of the dangerous drugs or dangerous
20 devices is authorized by law to receive the dangerous drugs or
21 dangerous devices.

22 (f) Notwithstanding subdivision (a), a pharmacy may take
23 delivery of dangerous drugs and dangerous devices when the
24 pharmacy is closed and no pharmacist is on duty if all of the
25 following requirements are met:

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

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

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

34 (4) The pharmacy maintains written policies and procedures for
35 the delivery of dangerous drugs and dangerous devices to a secure
36 storage facility.

37 (5) The agent delivering dangerous drugs and dangerous devices
38 pursuant to this subdivision leaves documents indicating the name
39 and amount of each dangerous drug or dangerous device delivered
40 in the secure storage facility.

1 The pharmacy shall be responsible for the dangerous drugs and
2 dangerous devices delivered to the secure storage facility. The
3 pharmacy shall also be responsible for obtaining and maintaining
4 records relating to the delivery of dangerous drugs and dangerous
5 devices to a secure storage facility.

6 ~~SEC. 49.~~

7 *SEC. 48.* Section 4060 of the Business and Professions Code
8 is amended to read:

9 4060. No person shall possess any controlled substance, except
10 that furnished to a person upon the prescription of a physician,
11 dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
12 pursuant to Section 3640.7, or furnished pursuant to a drug order
13 issued by a certified nurse-midwife pursuant to Section 2746.51,
14 a nurse practitioner pursuant to Section 2836.1, a physician
15 assistant pursuant to Section 3502.1, a naturopathic doctor pursuant
16 to Section 3640.5, or a pharmacist pursuant to either Section 4052.1
17 or 4052.2. This section shall not apply to the possession of any
18 controlled substance by a manufacturer, wholesaler, pharmacy,
19 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian,
20 naturopathic doctor, certified nurse-midwife, nurse practitioner,
21 or physician assistant, when in stock in containers correctly labeled
22 with the name and address of the supplier or producer.

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

26 ~~SEC. 50.~~

27 *SEC. 49.* Section 4062 of the Business and Professions Code
28 is amended to read:

29 4062. (a) Notwithstanding Section 4059 or any other provision
30 of law, a pharmacist may, in good faith, furnish a dangerous drug
31 or dangerous device in reasonable quantities without a prescription
32 during a federal, state, or local emergency, to further the health
33 and safety of the public. A record containing the date, name, and
34 address of the person to whom the drug or device is furnished, and
35 the name, strength, and quantity of the drug or device furnished
36 shall be maintained. The pharmacist shall communicate this
37 information to the patient's attending physician as soon as possible.
38 Notwithstanding Section 4060 or any other provision of law, a
39 person may possess a dangerous drug or dangerous device
40 furnished without prescription pursuant to this section.

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

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

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

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

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

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

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

21 (6) The mobile pharmacy ceases the provision of services within
22 48 hours following the termination of the declared emergency.

23 ~~SEC. 51.~~

24 *SEC. 50.* Section 4076 of the Business and Professions Code
25 is amended to read:

26 4076. (a) A pharmacist shall not dispense any prescription
27 except in a container that meets the requirements of state and
28 federal law and is correctly labeled with all of the following:

29 (1) Except where the prescriber or the certified nurse-midwife
30 who functions pursuant to a standardized procedure or protocol
31 described in Section 2746.51, the nurse practitioner who functions
32 pursuant to a standardized procedure described in Section 2836.1,
33 or protocol, the physician assistant who functions pursuant to
34 Section 3502.1, the naturopathic doctor who functions pursuant
35 to a standardized procedure or protocol described in Section
36 3640.5, or the pharmacist who functions pursuant to a policy,
37 procedure, or protocol pursuant to either Section 4052.1 or 4052.2
38 orders otherwise, either the manufacturer's trade name of the drug
39 or the generic name and the name of the manufacturer. Commonly
40 used abbreviations may be used. Preparations containing two or

- 1 more active ingredients may be identified by the manufacturer's
2 trade name or the commonly used name or the principal active
3 ingredients.
- 4 (2) The directions for the use of the drug.
- 5 (3) The name of the patient or patients.
- 6 (4) The name of the prescriber or, if applicable, the name of the
7 certified nurse-midwife who functions pursuant to a standardized
8 procedure or protocol described in Section 2746.51, the nurse
9 practitioner who functions pursuant to a standardized procedure
10 described in Section 2836.1, or protocol, the physician assistant
11 who functions pursuant to Section 3502.1, the naturopathic doctor
12 who functions pursuant to a standardized procedure or protocol
13 described in Section 3640.5, or the pharmacist who functions
14 pursuant to a policy, procedure, or protocol pursuant to either
15 Section 4052.1 or 4052.2.
- 16 (5) The date of issue.
- 17 (6) The name and address of the pharmacy, and prescription
18 number or other means of identifying the prescription.
- 19 (7) The strength of the drug or drugs dispensed.
- 20 (8) The quantity of the drug or drugs dispensed.
- 21 (9) The expiration date of the effectiveness of the drug
22 dispensed.
- 23 (10) The condition for which the drug was prescribed if
24 requested by the patient and the condition is indicated on the
25 prescription.
- 26 (11) (A) Commencing January 1, 2006, the physical description
27 of the dispensed medication, including its color, shape, and any
28 identification code that appears on the tablets or capsules, except
29 as follows:
- 30 (i) Prescriptions dispensed by a veterinarian.
- 31 (ii) An exemption from the requirements of this paragraph shall
32 be granted to a new drug for the first 120 days that the drug is on
33 the market and for the 90 days during which the national reference
34 file has no description on file.
- 35 (iii) Dispensed medications for which no physical description
36 exists in any commercially available database.
- 37 (B) This paragraph applies to outpatient pharmacies only.
- 38 (C) The information required by this paragraph may be printed
39 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 Section 4052.1
23 or 4052.2.

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

34 ~~SEC. 52.~~

35 *SEC. 51.* Section 4081 of the Business and Professions Code
36 is amended to read:

37 4081. (a) All records of manufacture and of sale, acquisition,
38 or disposition of dangerous drugs or dangerous devices shall be
39 at all times during business hours open to inspection by authorized
40 officers of the law, and shall be preserved for at least three years

1 from the date of making. A current inventory shall be kept by every
2 manufacturer, wholesaler, pharmacy, veterinary food-animal drug
3 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
4 clinic, hospital, institution, or establishment holding a currently
5 valid and unrevoked certificate, license, permit, registration, or
6 exemption under Division 2 (commencing with Section 1200) of
7 the Health and Safety Code or under Part 4 (commencing with
8 Section 16000) of Division 9 of the Welfare and Institutions Code
9 who maintains a stock of dangerous drugs or dangerous devices.

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

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

21 ~~SEC. 53.~~

22 *SEC. 52.* Section 4110 of the Business and Professions Code
23 is amended to read:

24 4110. (a) No person shall conduct a pharmacy in the State of
25 California unless he or she has obtained a license from the board.
26 A license shall be required for each pharmacy owned or operated
27 by a specific person. A separate license shall be required for each
28 of the premises of any person operating a pharmacy in more than
29 one location. The license shall be renewed annually. The board
30 may, by regulation, determine the circumstances under which a
31 license may be transferred.

32 (b) The board may, at its discretion, issue a temporary permit,
33 when the ownership of a pharmacy is transferred from one person
34 to another, upon the conditions and for any periods of time as the
35 board determines to be in the public interest. A temporary permit
36 fee shall be established by the board at an amount not to exceed
37 the annual fee for renewal of a permit to conduct a pharmacy.
38 When needed to protect public safety, a temporary permit may be
39 issued for a period not to exceed 180 days, and may be issued
40 subject to terms and conditions the board deems necessary. If the

1 board determines a temporary permit was issued by mistake or
2 denies the application for a permanent license or registration, the
3 temporary license or registration shall terminate upon either
4 personal service of the notice of termination upon the permitholder
5 or service by certified mail, return receipt requested, at the
6 permitholder's address of record with the board, whichever comes
7 first. Neither for purposes of retaining a temporary permit nor for
8 purposes of any disciplinary or license denial proceeding before
9 the board shall the temporary permitholder be deemed to have a
10 vested property right or interest in the permit.

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

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

18 (2) The mobile pharmacy is under the control and management
19 of the pharmacist-in-charge of the pharmacy that was destroyed
20 or damaged.

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

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

25 (5) The pharmacy operating the mobile pharmacy provides the
26 board with records of the destruction or damage of the pharmacy
27 and an expected restoration date.

28 (6) Within three calendar days of restoration of the pharmacy
29 services, the board is provided with notice of the restoration of the
30 permanent pharmacy.

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

33 ~~SEC. 54.~~

34 *SEC. 53.* Section 4111 of the Business and Professions Code
35 is amended to read:

36 4111. (a) Except as otherwise provided in subdivision (b), (d),
37 or (e), the board shall not issue or renew a license to conduct a
38 pharmacy to any of the following:

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

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

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

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

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

12 (d) Subdivision (a) shall not preclude the issuance of a new or
13 renewal license for a pharmacy to be owned or owned and operated
14 by a person licensed on or before August 1, 1981, under the
15 Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2
16 commencing with Section 1340) of Division 2 of the Health and
17 Safety Code) and qualified on or before August 1, 1981, under
18 subsection (d) of Section 1310 of Title XIII of the federal Public
19 Health Service Act, as amended, whose ownership includes persons
20 defined pursuant to paragraphs (1) and (2) of subdivision (a).

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

25 ~~SEC. 55.~~

26 *SEC. 54.* Section 4126.5 of the Business and Professions Code
27 is amended to read:

28 4126.5. (a) A pharmacy may furnish dangerous drugs only to
29 the following:

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

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

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

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

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

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

5 (7) To another pharmacy under common control.

6 (b) Notwithstanding any other provision of law, a violation of
7 this section may subject the person or persons who committed the
8 violation to a fine not to exceed the amount specified in Section
9 125.9 for each occurrence pursuant to a citation issued by the
10 board.

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

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

20 ~~SEC. 56.~~

21 *SEC. 55.* Section 4161 of the Business and Professions Code
22 is amended to read:

23 4161. (a) A person located outside this state that (1) ships,
24 sells, mails, or delivers dangerous drugs or dangerous devices into
25 this state or (2) sells, brokers, or distributes dangerous drugs or
26 devices within this state shall be considered a nonresident
27 wholesaler.

28 (b) A nonresident wholesaler shall be licensed by the board
29 prior to shipping, selling, mailing, or delivering dangerous drugs
30 or dangerous devices to a site located in this state or selling,
31 brokering, or distributing dangerous drugs or devices within this
32 state.

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

39 (d) The following information shall be reported, in writing, to
40 the board at the time of initial application for licensure by a

- 1 nonresident wholesaler, on renewal of a nonresident wholesaler
2 license, or within 30 days of a change in that information:
- 3 (1) Its agent for service of process in this state.
 - 4 (2) Its principal corporate officers, as specified by the board, if
5 any.
 - 6 (3) Its general partners, as specified by the board, if any.
 - 7 (4) Its owners if the applicant is not a corporation or partnership.
 - 8 (e) A report containing the information in subdivision (d) shall
9 be made within 30 days of any change of ownership, office,
10 corporate officer, or partner.
 - 11 (f) A nonresident wholesaler shall comply with all directions
12 and requests for information from the regulatory or licensing
13 agency of the state in which it is licensed, as well as with all
14 requests for information made by the board.
 - 15 (g) A nonresident wholesaler shall maintain records of dangerous
16 drugs and dangerous devices sold, traded, or transferred to persons
17 in this state or within this state, so that the records are in a readily
18 retrievable form.
 - 19 (h) A nonresident wholesaler shall at all times maintain a valid,
20 unexpired license, permit, or registration to conduct the business
21 of the wholesaler in compliance with the laws of the state in which
22 it is a resident. An application for a nonresident wholesaler license
23 in this state shall include a license verification from the licensing
24 authority in the applicant's state of residence.
 - 25 (i) The board may not issue or renew a nonresident wholesaler
26 license until the nonresident wholesaler identifies a designated
27 representative-in-charge and notifies the board in writing of the
28 identity and license number of the designated
29 representative-in-charge.
 - 30 (j) The designated representative-in-charge shall be responsible
31 for the nonresident wholesaler's compliance with state and federal
32 laws governing wholesalers. A nonresident wholesaler shall
33 identify and notify the board of a new designated
34 representative-in-charge within 30 days of the date that the prior
35 designated representative-in-charge ceases to be the designated
36 representative-in-charge.
 - 37 (k) The board may issue a temporary license, upon conditions
38 and for periods of time as the board determines to be in the public
39 interest. A temporary license fee shall be five hundred fifty dollars
40 (\$550) or another amount established by the board not to exceed

1 the annual fee for renewal of a license to compound injectable
2 sterile drug products. When needed to protect public safety, a
3 temporary license may be issued for a period not to exceed 180
4 days, subject to terms and conditions that the board deems
5 necessary. If the board determines that a temporary license was
6 issued by mistake or denies the application for a permanent license,
7 the temporary license shall terminate upon either personal service
8 of the notice of termination upon the licenseholder or service by
9 certified mail, return receipt requested, at the licenseholder's
10 address of record with the board, whichever occurs first. Neither
11 for purposes of retaining a temporary license, nor for purposes of
12 any disciplinary or license denial proceeding before the board,
13 shall the temporary licenseholder be deemed to have a vested
14 property right or interest in the license.

15 (I) The registration fee shall be the fee specified in subdivision
16 (f) of Section 4400.

17 ~~SEC. 57.~~

18 *SEC. 56.* Section 4174 of the Business and Professions Code
19 is amended to read:

20 4174. Notwithstanding any other provision of law, a pharmacist
21 may dispense drugs or devices upon the drug order of a nurse
22 practitioner functioning pursuant to Section 2836.1 or a certified
23 nurse-midwife functioning pursuant to Section 2746.51, a drug
24 order of a physician assistant functioning pursuant to Section
25 3502.1 or a naturopathic doctor functioning pursuant to Section
26 3640.5, or the order of a pharmacist acting under Section 4052.1,
27 4052.2, or 4052.3.

28 ~~SEC. 58.~~

29 *SEC. 57.* Section 4231 of the Business and Professions Code
30 is amended to read:

31 4231. (a) The board shall not renew a pharmacist license unless
32 the applicant submits proof satisfactory to the board that he or she
33 has successfully completed 30 hours of approved courses of
34 continuing pharmacy education during the two years preceding
35 the application for renewal.

36 (b) Notwithstanding subdivision (a), the board shall not require
37 completion of continuing education for the first renewal of a
38 pharmacist license.

39 (c) If an applicant for renewal of a pharmacist license submits
40 the renewal application and payment of the renewal fee but does

1 not submit proof satisfactory to the board that the licensee has
2 completed 30 hours of continuing pharmacy education, the board
3 shall not renew the license and shall issue the applicant an inactive
4 pharmacist license. A licensee with an inactive pharmacist license
5 issued pursuant to this section may obtain an active pharmacist
6 license by paying the renewal fees due and submitting satisfactory
7 proof to the board that the licensee has completed 30 hours of
8 continuing pharmacy education.

9 (d) If, as part of an investigation or audit conducted by the board,
10 a pharmacist fails to provide documentation substantiating the
11 completion of continuing education as required in subdivision (a),
12 the board shall cancel the active pharmacist license and issue an
13 inactive pharmacist license in its place. A licensee with an inactive
14 pharmacist license issued pursuant to this section may obtain an
15 active pharmacist license by paying the renewal fees due and
16 submitting satisfactory proof to the board that the licensee has
17 completed 30 hours of continuing pharmacy education.

18 ~~SEC. 59.~~

19 *SEC. 58.* Section 4301 of the Business and Professions Code
20 is amended to read:

21 4301. The board shall take action against any holder of a license
22 who is guilty of unprofessional conduct or whose license has been
23 procured by fraud or misrepresentation or issued by mistake.
24 Unprofessional conduct shall include, but is not limited to, any of
25 the following:

26 (a) Gross immorality.

27 (b) Incompetence.

28 (c) Gross negligence.

29 (d) The clearly excessive furnishing of controlled substances
30 in violation of subdivision (a) of Section 11153 of the Health and
31 Safety Code.

32 (e) The clearly excessive furnishing of controlled substances in
33 violation of subdivision (a) of Section 11153.5 of the Health and
34 Safety Code. Factors to be considered in determining whether the
35 furnishing of controlled substances is clearly excessive shall
36 include, but not be limited to, the amount of controlled substances
37 furnished, the previous ordering pattern of the customer (including
38 size and frequency of orders), the type and size of the customer,
39 and where and to whom the customer distributes its product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 ~~SEC. 60.~~

17 *SEC. 59.* Section 4305 of the Business and Professions Code
18 is amended to read:

19 4305. (a) Failure by any pharmacist to notify the board in
20 writing that he or she has ceased to act as the pharmacist-in-charge
21 of a pharmacy, or by any pharmacy to notify the board in writing
22 that a pharmacist-in-charge is no longer acting in that capacity,
23 within the 30-day period specified in Sections 4101 and 4113 shall
24 constitute grounds for disciplinary action.

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

28 (c) Any person who has obtained a license to conduct a
29 pharmacy, who willfully fails to timely notify the board that the
30 pharmacist-in-charge of the pharmacy has ceased to act in that
31 capacity, and who continues to permit the compounding or
32 dispensing of prescriptions, or the furnishing of drugs or poisons,
33 in his or her pharmacy, except by a pharmacist subject to the
34 supervision and management of a responsible pharmacist-in-charge,
35 shall be subject to summary suspension or revocation of his or her
36 license to conduct a pharmacy.

37 ~~SEC. 61.~~

38 *SEC. 60.* Section 4329 of the Business and Professions Code
39 is amended to read:

1 4329. Any nonpharmacist who takes charge of or acts as
2 supervisor, manager, or pharmacist-in-charge of any pharmacy,
3 or who compounds or dispenses a prescription or furnishes
4 dangerous drugs except as otherwise provided in this chapter, is
5 guilty of a misdemeanor.

6 ~~SEC. 62.~~

7 *SEC. 61.* Section 4330 of the Business and Professions Code
8 is amended to read:

9 4330. (a) Any person who has obtained a license to conduct
10 a pharmacy, who fails to place in charge of the pharmacy a
11 pharmacist, or any person, who by himself or herself, or by any
12 other person, permits the compounding or dispensing of
13 prescriptions, or the furnishing of dangerous drugs, in his or her
14 pharmacy, except by a pharmacist, or as otherwise provided in this
15 chapter, is guilty of a misdemeanor.

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

20 ~~SEC. 63.~~

21 *SEC. 62.* Section 4857 of the Business and Professions Code
22 is amended to read:

23 4857. (a) A veterinarian licensed under the provisions of this
24 chapter shall not disclose any information concerning an animal
25 receiving veterinary services, the client responsible for the animal
26 receiving veterinary services, or the veterinary care provided to
27 an animal, except under any one of the following circumstances:

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

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

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

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

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

AMENDED IN ASSEMBLY JULY 6, 2009
AMENDED IN ASSEMBLY JUNE 15, 2009
AMENDED IN SENATE MAY 20, 2009
AMENDED IN SENATE APRIL 30, 2009
AMENDED IN SENATE APRIL 16, 2009

SENATE BILL

No. 821

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

March 10, 2009

An act to amend Sections ~~805~~, 139, 146, 805, 1632.5, 1634.2, 2493, 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, 4200.3, 4200.4, 4510.1, 4933, 4938, 4980.45, 4980.48, 4982, 4982.2, 4989.22, 4989.54, 4992.1, 4992.3, 4996.23, 4996.28, 4996.5, ~~and 4999.2~~ 4999.2, 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 Sections 2532.25, 2570.17, 4013, 4146, 4989.49, 4992.2, ~~and 4996.24~~ 4996.24, 5515.5, 7044.01, and 7507.115 to, ~~and to repeal Sections 821.5 and 821.6~~ 821.5, 821.6, and 6763.1 of, and to repeal and add Section 7108.5 of, of, the Business and Professions Code, to amend ~~Section~~ Sections 44014.2, 44017.3, 44072.1, 44072.2, 44095, and 123105 of the Health and Safety Code, to amend Sections 28, 5201, and 24603 of

1 (2) The name and address of the licensee's current employer or
2 employers.

3 (b) The licensee shall cooperate in furnishing additional
4 information as requested by the board. If the licensee fails to
5 provide the requested information within 30 days, the license shall
6 be made inactive until the information is received.

7 ~~SEC. 32.~~

8 *SEC. 37.* Section 4013 is added to the Business and Professions
9 Code, to read:

10 4013. (a) Any facility licensed by the board shall join the
11 board's e-mail notification list within 60 days of obtaining a license
12 or at the time of license renewal.

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

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

17 ~~SEC. 33.~~

18 *SEC. 38.* Section 4101 of the Business and Professions Code
19 is amended to read:

20 4101. (a) A pharmacist may take charge of and act as the
21 pharmacist-in-charge of a pharmacy upon application by the
22 pharmacy and approval by the board. Any pharmacist-in-charge
23 who ceases to act as the pharmacist-in-charge of the pharmacy
24 shall notify the board in writing within 30 days of the date of that
25 change in status.

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

34 ~~SEC. 34.~~

35 *SEC. 39.* Section 4112 of the Business and Professions Code
36 is amended to read:

37 4112. (a) Any pharmacy located outside this state that ships,
38 mails, or delivers, in any manner, controlled substances, dangerous
39 drugs, or dangerous devices into this state shall be considered a
40 nonresident pharmacy.

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

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

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

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

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

36 (g) The board shall adopt regulations that apply the same
37 requirements or standards for oral consultation to a nonresident
38 pharmacy that operates pursuant to this section and ships, mails,
39 or delivers any controlled substances, dangerous drugs, or
40 dangerous devices to residents of this state, as are applied to an

1 in-state pharmacy that operates pursuant to Section 4037 when the
2 pharmacy ships, mails, or delivers any controlled substances,
3 dangerous drugs, or dangerous devices to residents of this state.
4 The board shall not adopt any regulations that require face-to-face
5 consultation for a prescription that is shipped, mailed, or delivered
6 to the patient. The regulations adopted pursuant to this subdivision
7 shall not result in any unnecessary delay in patients receiving their
8 medication.

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

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

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

18 ~~SEC. 35.~~

19 *SEC. 40.* Section 4113 of the Business and Professions Code
20 is amended to read:

21 4113. (a) Every pharmacy shall designate a
22 pharmacist-in-charge and, within 30 days thereof, shall notify the
23 board in writing of the identity and license number of that
24 pharmacist and the date he or she was designated.

25 (b) The proposed pharmacist-in-charge shall be subject to
26 approval by the board. The board shall not issue or renew a
27 pharmacy license without identification of an approved
28 pharmacist-in-charge for the pharmacy.

29 (c) The pharmacist-in-charge shall be responsible for a
30 pharmacy's compliance with all state and federal laws and
31 regulations pertaining to the practice of pharmacy.

32 (d) Every pharmacy shall notify the board in writing, on a form
33 designed by the board, within 30 days of the date when a
34 pharmacist-in-charge ceases to act as the pharmacist-in-charge,
35 and shall on the same form propose another pharmacist to take
36 over as the pharmacist-in-charge. The proposed replacement
37 pharmacist-in-charge shall be subject to approval by the board. If
38 disapproved, the pharmacy shall propose another replacement
39 within 15 days of the date of disapproval and shall continue to

1 name proposed replacements until a pharmacist-in-charge is
2 approved by the board.

3 (e) If a pharmacy is unable, in the exercise of reasonable
4 diligence, to identify within 30 days a permanent replacement
5 pharmacist-in-charge to propose to the board on the notification
6 form, the pharmacy may instead provide on that form the name of
7 any pharmacist who is an employee, officer, or administrator of
8 the pharmacy or the entity that owns the pharmacy and who is
9 actively involved in the management of the pharmacy on a daily
10 basis, to act as the interim pharmacist-in-charge for a period not
11 to exceed 120 days. The pharmacy, or the entity that owns the
12 pharmacy, shall be prepared during normal business hours to
13 provide a representative of the board with the name of the interim
14 pharmacist-in-charge with documentation of the active involvement
15 of the interim pharmacist-in-charge in the daily management of
16 the pharmacy, and with documentation of the pharmacy's good
17 faith efforts prior to naming the interim pharmacist-in-charge to
18 obtain a permanent pharmacist-in-charge. By no later than 120
19 days following the identification of the interim
20 pharmacist-in-charge, the pharmacy shall propose to the board the
21 name of a pharmacist to serve as the permanent
22 pharmacist-in-charge. The proposed permanent
23 pharmacist-in-charge shall be subject to approval by the board. If
24 disapproved, the pharmacy shall propose another replacement
25 within 15 days of the date of disapproval, and shall continue to
26 name proposed replacements until a pharmacist-in-charge is
27 approved by the board.

28 ~~SEC. 36.~~

29 *SEC. 41.* Section 4146 is added to the Business and Professions
30 Code, to read:

31 4146. A pharmacy may accept the return of needles and
32 syringes from the public if contained in a sharps container, as
33 defined in Section 117750 of the Health and Safety Code.

34 ~~SEC. 37.~~

35 *SEC. 42.* Section 4160 of the Business and Professions Code
36 is amended to read:

37 4160. (a) A person may not act as a wholesaler of any
38 dangerous drug or dangerous device unless he or she has obtained
39 a license from the board.

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

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

6 (d) Every wholesaler shall be supervised or managed by a
7 designated representative-in-charge. The designated
8 representative-in-charge shall be responsible for the wholesaler's
9 compliance with state and federal laws governing wholesalers. As
10 part of its initial application for a license, and for each renewal,
11 each wholesaler shall, on a form designed by the board, provide
12 identifying information and the California license number for a
13 designated representative or pharmacist proposed to serve as the
14 designated representative-in-charge. The proposed designated
15 representative-in-charge shall be subject to approval by the board.
16 The board shall not issue or renew a wholesaler license without
17 identification of an approved designated representative-in-charge
18 for the wholesaler.

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

30 (f) A drug manufacturer premises licensed by the Food and
31 Drug Administration or licensed pursuant to Section 111615 of
32 the Health and Safety Code that only distributes dangerous drugs
33 and dangerous devices of its own manufacture is exempt from this
34 section and Section 4161.

35 (g) The board may issue a temporary license, upon conditions
36 and for periods of time as the board determines to be in the public
37 interest. A temporary license fee shall be five hundred fifty dollars
38 (\$550) or another amount established by the board not to exceed
39 the annual fee for renewal of a license to compound injectable
40 sterile drug products. When needed to protect public safety, a

1 temporary license may be issued for a period not to exceed 180
2 days, subject to terms and conditions that the board deems
3 necessary. If the board determines that a temporary license was
4 issued by mistake or denies the application for a permanent license,
5 the temporary license shall terminate upon either personal service
6 of the notice of termination upon the licenseholder or service by
7 certified mail, return receipt requested, at the licenseholder's
8 address of record with the board, whichever occurs first. Neither
9 for purposes of retaining a temporary license, nor for purposes of
10 any disciplinary or license denial proceeding before the board,
11 shall the temporary licenseholder be deemed to have a vested
12 property right or interest in the license.

13 ~~SEC. 38.~~

14 *SEC. 43.* Section 4196 of the Business and Professions Code
15 is amended to read:

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

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

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

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

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

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

31 *SEC. 44. Section 4200.3 of the Business and Professions Code*
32 *is amended to read:*

33 4200.3. (a) The examination process shall be regularly
34 reviewed pursuant to Section 139.

35 (b) The examination process shall meet the standards and
36 guidelines set forth in the Standards for Educational and
37 Psychological Testing and the Federal Uniform Guidelines for
38 Employee Selection Procedures. The board shall work with the
39 Office of *Professional Examination-Resources Services* of the
40 department or with an equivalent organization who shall certify

1 at minimum once every five years that the examination process
2 meets these national testing standards. If the department determines
3 that the examination process fails to meet these standards, the
4 board shall terminate its use of the North American Pharmacy
5 Licensure Examination and shall use only the written and practical
6 examination developed by the board.

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

9 (d) The board shall work with the Office of *Professional*
10 ~~Examination-Resources Services~~ or with an equivalent organization
11 to develop the state jurisprudence examination to ensure that
12 applicants for licensure are evaluated on their knowledge of
13 applicable state laws and regulations.

14 (e) The board shall annually publish the pass and fail rates for
15 the pharmacist's licensure examination administered pursuant to
16 Section 4200, including a comparison of historical pass and fail
17 rates before utilization of the North American Pharmacist Licensure
18 Examination.

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

27 *SEC. 45. Section 4200.4 of the Business and Professions Code*
28 *is amended to read:*

29 4200.4. An applicant who fails the national examination may
30 not retake the examination for at least 90 days or for a period
31 established by regulations adopted by the board in consultation
32 with the Office of *Professional Examination-Resources Services*
33 of the department.

34 ~~SEC. 39.~~

35 *SEC. 46. Section 4510.1 of the Business and Professions Code*
36 *is amended to read:*

37 4510.1. An applicant for license by examination shall submit
38 a written application in the form prescribed by the board. Provided
39 that the application for licensure is received by the board no later
40 than four months after completion of a board accredited psychiatric

1 technician program and approval of the application, the board may
2 issue an interim permit authorizing the applicant to practice all
3 skills included in the permittee's basic course of study, pending
4 the results of the first licensing examination, or for a period of nine
5 months, whichever occurs first.

6 A permittee shall function under the supervision of a licensed
7 psychiatric technician or a registered nurse, who shall be present
8 and available on the premises during the time the permittee is
9 rendering professional services. The permittee may perform any
10 function taught in the permittee's basic psychiatric technician
11 program.

12 If the applicant passes the examination, the interim permit shall
13 remain in effect until an initial license is issued by the board or
14 for a maximum period of six months after passing the examination,
15 whichever occurs first. If the applicant fails the examination, the
16 interim permit shall terminate upon notice by certified mail, return
17 receipt requested, or if the applicant fails to receive the notice,
18 upon the date specified in the interim permit, whichever occurs
19 first. An interim permittee shall not use any title or designation
20 other than psychiatric technician interim permittee or "P.T.I.P."

21 ~~SEC. 40.~~

22 *SEC. 47.* Section 4933 of the Business and Professions Code
23 is amended to read:

24 4933. (a) The board shall administer this chapter.

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

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

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

35 *SEC. 48.* Section 4938 of the Business and Professions Code
36 is amended to read:

37 4938. The board shall issue a license to practice acupuncture
38 to any person who makes an application and meets the following
39 requirements:

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

SB 470 (Corbett) Prescription Labeling

AMENDED IN SENATE APRIL 30, 2009

AMENDED IN SENATE APRIL 27, 2009

SENATE BILL

No. 470

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 amended, Corbett. Prescriptions.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and provides that a knowing violation of the law is a crime. Existing law requires a prescription, as defined, to include a legible, clear notice of 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 that is correctly labeled to include, 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 instead require that every prescription include a legible, clear notice of the condition or purpose for which the drug is prescribed, ~~and would delete the requirement that a patient request the inclusion of that information if requested by the patient.~~ The bill would also require that every prescription container be correctly labeled to include that information if so ~~included~~ *indicated* on the prescription; ~~and would provide a process for inclusion of that information on the label if it is not included on the prescription and is requested by the patient.~~

By revising these requirements, 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 or 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,

1 or pursuant to either subparagraph (D) of paragraph (4) of, or
2 clause (iv) of subparagraph (A) of paragraph (5) of, subdivision
3 (a) of Section 4052 by a pharmacist licensed in this state.

4 (b) Notwithstanding subdivision (a), a written order of the
5 prescriber for a dangerous drug, except for any Schedule II
6 controlled substance, that contains at least the name and signature
7 of the prescriber, the name and address of the patient in a manner
8 consistent with paragraph (3) of subdivision (b) of Section 11164
9 of the Health and Safety Code, the name and quantity of the drug
10 prescribed, directions for use, and the date of issue may be treated
11 as a prescription by the dispensing pharmacist as long as any
12 additional information required by subdivision (a) is readily
13 retrievable in the pharmacy. In the event of a conflict between this
14 subdivision and Section 11164 of the Health and Safety Code,
15 Section 11164 of the Health and Safety Code shall prevail.

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

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

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

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

33 4076. (a) A pharmacist shall not dispense any prescription
34 except in a container that meets the requirements of state and
35 federal law and is correctly labeled with all of the following:

36 (1) Except where the prescriber or the certified nurse-midwife
37 who functions pursuant to a standardized procedure or protocol
38 described in Section 2746.51, the nurse practitioner who functions
39 pursuant to a standardized procedure described in Section 2836.1,
40 or protocol, the physician assistant who functions pursuant to

1 Section 3502.1, the naturopathic doctor who functions pursuant
2 to a standardized procedure or protocol described in Section
3 3640.5, or the pharmacist who functions pursuant to a policy,
4 procedure, or protocol pursuant to either subparagraph (D) of
5 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
6 (5) of, subdivision (a) of Section 4052 orders otherwise, either the
7 manufacturer's trade name of the drug or the generic name and
8 the name of the manufacturer. Commonly used abbreviations may
9 be used. Preparations containing two or more active ingredients
10 may be identified by the manufacturer's trade name or the
11 commonly used name or the principal active ingredients.

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

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

14 (4) The name of the prescriber or, if applicable, the name of the
15 certified nurse-midwife who functions pursuant to a standardized
16 procedure or protocol described in Section 2746.51, the nurse
17 practitioner who functions pursuant to a standardized procedure
18 described in Section 2836.1, or protocol, the physician assistant
19 who functions pursuant to Section 3502.1, the naturopathic doctor
20 who functions pursuant to a standardized procedure or protocol
21 described in Section 3640.5, or the pharmacist who functions
22 pursuant to a policy, procedure, or protocol pursuant to either
23 subparagraph (D) of paragraph (4) of, or clause (iv) of
24 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
25 4052.

26 (5) The date of issue.

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

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

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

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

33 (10) The condition or purpose for which the drug was prescribed
34 if the condition or purpose is indicated on the prescription. If the
35 patient requests the condition or purpose on the container label
36 but it is not included on the prescription, the pharmacist may
37 include this information only after consulting with the prescriber.
38 The consultation may be conducted orally or electronically.
39 *prescription.*

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

5 (i) Prescriptions dispensed by a veterinarian.

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

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

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

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

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

18 (b) If a pharmacist dispenses a prescribed drug by means of a
19 unit dose medication system, as defined by administrative
20 regulation, for a patient in a skilled nursing, intermediate care, or
21 other health care facility, the requirements of this section will be
22 satisfied if the unit dose medication system contains the
23 aforementioned information or the information is otherwise readily
24 available at the time of drug administration.

25 (c) If a pharmacist dispenses a dangerous drug or device in a
26 facility licensed pursuant to Section 1250 of the Health and Safety
27 Code, it is not necessary to include on individual unit dose
28 containers for a specific patient, the name of the certified
29 nurse-midwife who functions pursuant to a standardized procedure
30 or protocol described in Section 2746.51, the nurse practitioner
31 who functions pursuant to a standardized procedure described in
32 Section 2836.1, or protocol, the physician assistant who functions
33 pursuant to Section 3502.1, the naturopathic doctor who functions
34 pursuant to a standardized procedure or protocol described in
35 Section 3640.5, or the pharmacist who functions pursuant to a
36 policy, procedure, or protocol pursuant to either subparagraph (D)
37 of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
38 (5) of, subdivision (a) of Section 4052.

39 (d) If a pharmacist dispenses a prescription drug for use in a
40 facility licensed pursuant to Section 1250 of the Health and Safety

1 Code, it is not necessary to include the information required in
2 paragraph (11) of subdivision (a) when the prescription drug is
3 administered to a patient by a person licensed under the Medical
4 Practice Act (Chapter 5 (commencing with Section 2000)), the
5 Nursing Practice Act (Chapter 6 (commencing with Section 2700)),
6 or the Vocational Nursing Practice Act (Chapter 6.5 (commencing
7 with Section 2840)), who is acting within his or her scope of
8 practice.

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

AB 977 (Skinner) Pharmacies: Immunization Administration

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 977

Introduced by Assembly Member Skinner

February 26, 2009

~~An act to 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. protocols with physicians.~~

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy.

This bill would request the California Pharmacists Association to provide information to specified legislative committees on the status of immunization protocols between independent pharmacists and physicians.

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

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

1 SECTION 1. The California Pharmacists Association is hereby
 2 requested to provide information to the respective chairpersons
 3 of the Committees on Business and Professions and Health of the
 4 Assembly and of the Committees on Business, Professions and
 5 Economic Development and Health of the Senate on the status of
 6 immunization protocols between independent pharmacists and
 7 physicians.

8 SECTION 1. The Legislature finds and declares all of the
 9 following:

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

4 ~~(b) The National Vital Statistics Report published by HHS~~
5 ~~reports that influenza and pneumonia combined are the eighth~~
6 ~~leading cause of death in people of all ages, and the sixth leading~~
7 ~~cause of death in people over 65 years of age.~~

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

11 ~~(d) According to the California Health Care Foundation,~~
12 ~~6,600,000 Californians are uninsured and may not have access to~~
13 ~~immunizations.~~

14 ~~(e) Pharmacists represent the third largest health professional~~
15 ~~group in the United States and are on the front line of preventative~~
16 ~~care.~~

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

19 ~~(g) Therefore, in order to achieve greater access to immunization~~
20 ~~and to protect Californians, it is the intent of the Legislature to~~
21 ~~provide greater access to lifesaving vaccinations and to ensure that~~
22 ~~pharmacists may independently administer influenza and~~
23 ~~pneumonia vaccinations.~~

24 ~~SEC. 2. Section 4052 of the Business and Professions Code is~~
25 ~~amended to read:~~

26 ~~4052. (a) Notwithstanding any other provision of law, a~~
27 ~~pharmacist may:~~

28 ~~(1) Furnish a reasonable quantity of compounded drug product~~
29 ~~to a prescriber for office use by the prescriber.~~

30 ~~(2) Transmit a valid prescription to another pharmacist.~~

31 ~~(3) Administer, orally or topically, drugs and biologicals~~
32 ~~pursuant to a prescriber's order.~~

33 ~~(4) Perform procedures or functions in a licensed health care~~
34 ~~facility as authorized by Section 4052.1.~~

35 ~~(5) Perform procedures or functions as part of the care provided~~
36 ~~by a health care facility, a licensed home health agency, a licensed~~
37 ~~clinic in which there is a physician oversight, a provider who~~
38 ~~contracts with a licensed health care service plan with regard to~~
39 ~~the care or services provided to the enrollees of that health care~~
40 ~~service plan, or a physician, as authorized by Section 4052.2.~~

1 ~~(6) Manufacture, measure, fit to the patient, or sell and repair~~
2 ~~dangerous devices or furnish instructions to the patient or the~~
3 ~~patient's representative concerning the use of those devices.~~

4 ~~(7) Provide consultation to patients and professional information,~~
5 ~~including clinical or pharmacological information, advice, or~~
6 ~~consultation to other health care professionals.~~

7 ~~(8) Furnish emergency contraception drug therapy as authorized~~
8 ~~by Section 4052.3.~~

9 ~~(9) Administer or initiate and administer immunizations pursuant~~
10 ~~to Section 4052.8.~~

11 ~~(b) A pharmacist who is authorized to issue an order to initiate~~
12 ~~or adjust a controlled substance therapy pursuant to this section~~
13 ~~shall personally register with the federal Drug Enforcement~~
14 ~~Administration.~~

15 ~~(c) Nothing in this section shall affect the requirements of~~
16 ~~existing law relating to maintaining the confidentiality of medical~~
17 ~~records.~~

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

20 ~~SEC. 3. Section 4052.8 is added to the Business and Professions~~
21 ~~Code, to read:~~

22 ~~4052.8. (a) A pharmacist may do either of the following:~~

23 ~~(1) Administer any immunization pursuant to a protocol with a~~
24 ~~prescriber.~~

25 ~~(2) Initiate and administer influenza or pneumococcal~~
26 ~~immunizations to any person seven years of age or older.~~

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

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

38 ~~(2) If a pharmacist fails to satisfy this requirement, he or she~~
39 ~~shall, in addition to any other applicable disciplinary action, retake~~
40 ~~the training identified in subdivision (b) and also complete the~~

1 ~~three hours of immunization-related continuing education~~
2 ~~coursework described in paragraph (1) prior to initiating and~~
3 ~~administering any further immunizations.~~

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

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

10 ~~(e) A pharmacist shall obtain the consent of a parent or guardian~~
11 ~~before administering an immunization to a patient under 18 years~~
12 ~~of age.~~

13 ~~(f) At the time of administration of an immunization, the~~
14 ~~pharmacist shall do all of the following:~~

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

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

22 ~~(3) Provide documentation of administration of the~~
23 ~~immunization to the California Immunization Registry (CAIR).~~

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

31 ~~(1) Ten years from the date of administration.~~

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

34 ~~(h) Any pharmacist initiating and administering vaccines may~~
35 ~~initiate and administer epinephrine by injection for severe allergic~~
36 ~~reactions.~~

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

1 ~~(j) Upon receipt of a vaccine as authorized by this section, a~~
2 ~~pharmacist is responsible for assuring that proper vaccine~~
3 ~~temperatures are maintained during subsequent storage and~~
4 ~~handling to preserve the potency of the vaccine.~~

5 SEC. 4. 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.

14

15

16 CORRECTIONS: _____

17 Digest—Page 2—Vote key line.

18 _____

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~~ *license* ~~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

AMENDED IN SENATE JULY 8, 2009

AMENDED IN SENATE JUNE 22, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 583

Introduced by Assembly Member Hayashi

February 25, 2009

An act to amend Section 680 of the Business and Professions Code, relating to health care practitioners.

LEGISLATIVE COUNSEL'S DIGEST

AB 583, as amended, Hayashi. Health care practitioners: disclosure of education and office hours.

Existing law requires a health care practitioner to disclose, while working, his or her name and practitioner's license status on a name tag in at least 18-point type or to prominently display his or her license in his or her office, except as specified.

This bill would require each of those health care practitioners to also display the type of license and, except for nurses, the highest level of academic degree he or she holds either on a name tag in at least 18-point type, in his or her office, or in writing given to patients. The bill would require a physician and surgeon, osteopathic physician and surgeon, and doctor of podiatric medicine who is certified in a medical specialty, as specified, to disclose the name of the certifying board or association either on a name tag in at least 18-point type, in writing given to the patient on the patient's first office visit, or in his or her office. The bill would require a physician and surgeon who supervises an office in addition to his or her primary practice location to conspicuously post in each office a schedule of the regular hours when he or she will be

present in that office and the office hours during which he or she will not be present. The bill would also require an office that is part of a group practice with more than one physician and surgeon to post a current schedule of the hours when a physician and surgeon is present. The bill would exempt health care practitioners working in certain licensed laboratories and health care facilities, as specified, from the requirements to disclose license type, highest level of academic degree, and name of certifying board or association providing certification in the practitioner's specialty or subspecialty.

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 680 of the Business and Professions Code
2 is amended to read:
3 680. (a) (1) Except as otherwise provided in this section, a
4 health care practitioner shall disclose, while working, his or her
5 name, practitioner's license status, license type, as granted by this
6 state, and the highest level of academic degree he or she holds, by
7 one of the following methods:
8 (A) On a name tag in at least 18-point type.
9 (B) In writing to a patient at the ~~patient's~~ *patient's* initial office
10 visit.
11 (C) In a prominent display in his or her office.
12 (2) If a health care practitioner or a licensed clinical social
13 worker is working in a psychiatric setting or in a setting that is not
14 licensed by the state, the employing entity or agency shall have
15 the discretion to make an exception from the name tag requirement
16 for individual safety or therapeutic concerns.
17 (3) (A) In the interest of public safety and consumer awareness,
18 it shall be unlawful for any person to use the title "nurse" in
19 reference to himself or herself in any capacity, except for an
20 individual who is a registered nurse or a licensed vocational nurse,
21 or as otherwise provided in Section 2800. Nothing in this section
22 shall be deemed to prohibit a certified nurse assistant from using
23 his or her title.
24 (B) An individual licensed under Chapter 6 (commencing with
25 Section 2700) is not required to disclose the highest level of
26 academic degree he or she holds.

1 (b) Facilities licensed by the State Department of Social
2 Services, the State Department of Mental Health, or the State
3 Department of Public Health shall develop and implement policies
4 to ensure that health care practitioners providing care in those
5 facilities are in compliance with subdivision (a). The State
6 Department of Social Services, the State Department of Mental
7 Health, and the State Department of Public Health shall verify
8 through periodic inspections that the policies required pursuant to
9 subdivision (a) have been developed and implemented by the
10 respective licensed facilities.

11 (c) For purposes of this article, "health care practitioner" means
12 any person who engages in acts that are the subject of licensure
13 or regulation under this division or under any initiative act referred
14 to in this division.

15 (d) An individual licensed under Chapter 5 (commencing with
16 Section 2000) or under the Osteopathic Act, who is certified by
17 (1) an American Board of Medical Specialties member board, (2)
18 a board or association with equivalent requirements approved by
19 that person's medical licensing authority, or (3) a board or
20 association with an Accreditation Council for Graduate Medical
21 Education approved postgraduate training program that provides
22 complete training in that specialty or subspecialty, shall disclose
23 the name of the board or association by one of the following
24 methods:

25 (1) On a name tag in at least 18-point type.

26 (2) In writing to a patient at the patient's initial office visit.

27 (3) In a prominent display in his or her office.

28 (e) A physician and surgeon who supervises an office in addition
29 to his or her primary practice location shall prominently display
30 in each of those offices a current schedule of the regular hours
31 when he or she is present in the respective office, and the hours
32 during which each office is open and he or she is not present. If
33 the office is a part of a group practice with more than one physician
34 and surgeon, the office shall post a current schedule of the hours
35 when a physician and surgeon is present in the office.

36 (f) Subdivisions (d) and (e) shall not apply to a health care
37 practitioner working in a facility licensed under Section 1250 of

- 1 the Health and Safety Code or in a clinical laboratory licensed
- 2 under Section 1265.

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AMENDED IN SENATE JULY 8, 2009
AMENDED IN SENATE JUNE 30, 2009
AMENDED IN SENATE JUNE 16, 2009
AMENDED IN SENATE MAY 27, 2009
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
(Coauthor: Senator Negrete McLeod)

February 26, 2009

An act to add and repeal Section 14087.521 of the Welfare and Institutions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 718, as amended, Emmerson. Inland Empire Health Plan E-Prescribing Pilot Program.

Existing law establishes the Medi-Cal program, administered by the State Department of Health Care Services, under which basic health care services are provided to qualified low-income persons. Existing law authorizes the California Medical Assistance Commission to negotiate exclusive contracts with any county that seeks to provide, or arrange for the provision of health care services provided under the Medi-Cal program. Existing law authorizes the Board of Supervisors of San Bernardino County to, by ordinance, establish a commission to

negotiate the above-described exclusive contract and to arrange for the supervision of certain health care services.

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.

This bill would, until January 1, 2013, create the Inland Empire Health Plan E-Prescribing Pilot Program and would require the program to promote health care quality and the exchange of health care information and to include specified components, including electronic prescribing, as defined. The bill would require the Inland Empire Health Plan, a joint powers agency, to select, through a competitive bid process, an entity whose product has specified certification to administer the program and would require this entity to submit a report to the Legislature, by January 1, 2012, regarding the goals and results of the program and whether the program should be extended, as specified. *The bill would provide that a physician who contracts with the Inland Empire Health Plan shall not be required to participate in the pilot program.* The bill would provide that the above-described provisions shall be funded by funds made available by the federal American Recovery and Reinvestment Act of 2009. By imposing a new requirement on a joint powers agency, 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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

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 14087.521 is added to the Welfare and
- 2 Institutions Code, to read:
- 3 14087.521. (a) The Inland Empire Health Plan E-Prescribing
- 4 Pilot Program is hereby created. For purposes of this section,

1 “program” means the Inland Empire Health Plan E-Prescribing
2 Pilot Program.

3 (b) The program shall be administered by an entity whose
4 product has been certified by the Certification Commission for
5 Health Information Technology *or another certifying entity*
6 *authorized by the federal Department of Health and Human*
7 *Services*, either as a stand-alone electronic prescribing product or
8 service or as part of an electronic health record product or service.
9 This entity shall be selected by the Inland Empire Health Plan
10 through a competitive bid process.

11 (c) The program shall promote health care quality and the
12 exchange of health care information consistent with applicable
13 law, including, but not limited to, applicable state and federal
14 confidentiality and data security requirements and applicable state
15 record retention and reporting requirements. The program shall
16 include all of the following components:

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

19 (2) Current payer formulary information.

20 (3) Appropriate alternatives, when needed, to support
21 cost-effective prescribing at the point of care, except that nothing
22 in this section shall be construed to authorize the program to
23 establish a drug formulary.

24 (4) Drug compendia approved by the federal Centers for
25 Medicare and Medicaid Services.

26 (5) Electronic prescribing consistent with applicable state and
27 federal law.

28 (6) Patient drug history.

29 (d) (1) Electronic prescribing pursuant to the program shall not
30 interfere with a patient’s existing freedom to choose a pharmacy
31 and shall not interfere with the prescribing decision at the point of
32 care.

33 (2) *A physician who contracts with the Inland Empire Health*
34 *Plan shall not be required to participate in the pilot program.*

35 (e) The entity administering the program shall, on or before
36 January 1, 2012, submit a report to the Legislature on the goals
37 and results of the program and whether the program should be
38 extended. This report shall include quantifiable data on all of the
39 following:

- 1 (1) The number of prescribers enrolled in the program who use
2 electronic prescribing.
- 3 (2) The number of pharmacies participating in the program.
- 4 (3) The number and percentage of prescriptions sent
5 electronically as a percentage of the overall number of prescriptions
6 reimbursed by the plan.
- 7 (4) Expenditures on the program.
- 8 (5) Data on whether and to what extent the program achieved
9 the following goals:
- 10 (A) Reduced medication errors.
- 11 (B) Reduced prescription fraud.
- 12 (C) Reduced health care costs, including, but not limited to,
13 inpatient hospitalization, by reducing medication errors, increasing
14 patient medication compliance, and identifying medication
15 contraindications.
- 16 (f) For purposes of this section, “electronic prescribing” shall
17 have the same meaning as “electronic data transmission
18 prescription” as defined in subdivision (c) of Section 4040 of the
19 Business and Professions Code.
- 20 (g) This section shall be funded by funds made available by the
21 federal American Recovery and Reinvestment Act of 2009 (Public
22 Law 111-5).
- 23 (h) This section shall remain in effect only until January 1, 2013,
24 and as of that date is repealed, unless a later enacted statute, that
25 is enacted before January 1, 2013, deletes or extends that date.
- 26 SEC. 2. If the Commission on State Mandates determines that
27 this act contains costs mandated by the state, reimbursement to
28 local agencies and school districts for those costs shall be made
29 pursuant to Part 7 (commencing with Section 17500) of Division
30 4 of Title 2 of the Government Code.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 718

VERSION: As amended: ~~May 27, 2009~~
~~June 16, 2009~~
June 30, 2009

AUTHOR: Emmerson

SPONSOR: Reed Elsevier, Inc.

Board Position: None

SUBJECT: 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:

State legislative intent to create

Add Section 4071.2 to the Business and Professions Code:

Adds Section 14087.521 to the Welfare and Institutions Code:

Until January 1, 2013, create the Inland Empire Health Plan E-Prescribing Pilot which must meet all of the following requirements:

- Be administered by an entity with certification from the Certification Commission for Healthcare Information, either as a stand-alone electronic prescribing product or service as part of an electronic health record product or service. The program shall be selected through a competitive bid process,
- Requires that the pilot program promote health care quality and the exchange of health information and include the following specific components.
 - Integrated clinical decisions alerts,
 - Current payer formulary information,
 - Appropriate alternatives as specified,
 - Drug compendia approved by the Centers for Medicare and Medicaid Services, and
 - Electronic prescribing,
 - Patient drug history
- That electronic prescribing shall not interfere with a patient's existing freedom to choose a pharmacy and shall not interfere with the prescribing decision at the point of care,
- Submission of a report to the Legislature on or before 1/1/12 the goals and results of the program, as well as specified quantifiable data.
- Incorporates by reference the definition of "electronic prescribing" as defined in B&P 4040(c)

- That the pilot program be funded by funds made available by the Federal American Recovery and Reinvestment Act of 2009, and that
- Violation of this section shall not be a crime.

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. Further, the sponsor states that e-prescribing can help ensure that patients with multiple physicians are not being over prescribed or taking medications that are contradictory in nature and can ensure that only Medi-Cal approved medications are prescribed as a physician will be immediately notified if the medication is not on the formulary.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

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.

On April 16, 2009, the Legislation and Regulation Committee recommended a 'support' position on an earlier version of the bill. The Board did not take a position on the bill at its 4/30/09 board meeting.

SUPPORT/OPPOSITION:

Reed Elsevier, Inc.

HISTORY:

June 30 From committee chair, with author's amendments: Amend and re-refer to committee. Read second time, amended, and re-referred to Com. on B.P.&E.D.

June 26 From committee: Do pass, and re-refer to Com. on BP&ED. Re-referred (Ayes 11. Noes 0.) (June 25).

June 22 In committee. Hearing postponed by committee.

June 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH

June 11 In committee: Set, first hearing. Hearing canceled at the request of author.

June 4 Re-referred to Coms. On HEALTH and BP&ED

Bill Analysis: AB 718 as Amended 6/30/09

Page 3

- May 27 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on RLS.
- May 21 Referred to Com. on RLS.
- May 11 In Senate. Read first time. To Com. on RLS. For Assignment
- May 11 Read third time, passed, and to Senate. (Ayes 78. Noes 0.)
- Apr. 30 Read second time. To Consent Calendar.
- 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 SENATE JULY 6, 2009
AMENDED IN ASSEMBLY APRIL 23, 2009
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 Insurance 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 compendiums and compendia, including the United States Pharmacopoeia, ~~in various licensure, health care, and social services provisions for purposes of the Knox-Keene Health Care Service Plan Act of 1975, disability insurance, and for Medi-Cal.~~

This bill would replace these references with a compendium approved by the federal Centers for Medicare and Medicaid Services ~~references~~

to a specified compendia, as 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 Pharmacopocia.

This bill would replace the above drug compendium's with a compendium 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: yes-no.

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 a compendium or supplement thereof approved by the federal~~
- 6 ~~Centers for Medicare and Medicaid Services, except substances~~
- 7 ~~covered by subdivision (a) of Section 4052 and Section 4057.~~
- 8 SEC. 2. ~~Section 4025 of the Business and Professions Code is~~
- 9 ~~amended to read:~~
- 10 4025. "Drug" means any of the following:
- 11 (a) ~~Articles recognized in a compendium or supplement thereof~~
- 12 ~~approved by the federal Centers for Medicare and Medicaid~~
- 13 ~~Services.~~
- 14 (b) ~~Articles intended for use in the diagnosis, cure, mitigation,~~
- 15 ~~treatment, or prevention of disease in humans or other animals.~~
- 16 (c) ~~Articles (other than food) intended to affect the structure or~~
- 17 ~~any function of the body of humans or other animals.~~
- 18 (d) ~~Articles intended for use as a component of any article~~
- 19 ~~specified in subdivision (a), (b), or (c).~~

1 ~~SEC. 3. Section 4053 of the Business and Professions Code is~~
2 ~~amended to read:~~

3 ~~4053. (a) Notwithstanding Section 4051, the board may issue~~
4 ~~a license as a designated representative to provide sufficient and~~
5 ~~qualified supervision in a wholesaler or veterinary food-animal~~
6 ~~drug retailer. The designated representative shall protect the public~~
7 ~~health and safety in the handling, storage, and shipment of~~
8 ~~dangerous drugs and dangerous devices in the wholesaler or~~
9 ~~veterinary food-animal drug retailer.~~

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

13 ~~(1) He or she shall be a high school graduate or possess a general~~
14 ~~education development equivalent.~~

15 ~~(2) He or she shall have a minimum of one year of paid work~~
16 ~~experience, in the past three years, related to the distribution or~~
17 ~~dispensing of dangerous drugs or dangerous devices or meet all~~
18 ~~of the prerequisites to take the examination required for licensure~~
19 ~~as a pharmacist by the board.~~

20 ~~(3) He or she shall complete a training program approved by~~
21 ~~the board that, at a minimum, addresses each of the following~~
22 ~~subjects:~~

23 ~~(A) Knowledge and understanding of California law and federal~~
24 ~~law relating to the distribution of dangerous drugs and dangerous~~
25 ~~devices.~~

26 ~~(B) Knowledge and understanding of California law and federal~~
27 ~~law relating to the distribution of controlled substances.~~

28 ~~(C) Knowledge and understanding of quality control systems.~~

29 ~~(D) Knowledge and understanding of the standards relating to~~
30 ~~the safe storage and handling of drugs in a compendium approved~~
31 ~~by the federal Centers for Medicare and Medicaid Services.~~

32 ~~(E) Knowledge and understanding of prescription terminology,~~
33 ~~abbreviations, dosages and format.~~

34 ~~(4) The board may, by regulation, require training programs to~~
35 ~~include additional material.~~

36 ~~(5) The board may not issue a license as a designated~~
37 ~~representative until the applicant provides proof of completion of~~
38 ~~the required training to the board.~~

1 ~~(e) The veterinary food-animal drug retailer or wholesaler shall~~
2 ~~not operate without a pharmacist or a designated representative~~
3 ~~on its premises.~~

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

6 ~~(e) Section 4051 shall not apply to any laboratory licensed under~~
7 ~~Section 351 of Title III of the Public Health Service Act (Public~~
8 ~~Law 78-410).~~

9 ~~SEC. 4. Section 4342 of the Business and Professions Code is~~
10 ~~amended to read:~~

11 ~~4342. (a) The board may institute any action or actions as may~~
12 ~~be provided by law and that, in its discretion, are necessary, to~~
13 ~~prevent the sale of pharmaceutical preparations and drugs that do~~
14 ~~not conform to the standard and tests as to quality and strength,~~
15 ~~provided in the latest edition of a compendium approved by the~~
16 ~~federal Centers for Medicare and Medicaid Services or that violate~~
17 ~~any provision of the Sherman Food, Drug and Cosmetic Law (Part~~
18 ~~5 (commencing with Section 109875) of Division 104 of the Health~~
19 ~~and Safety Code).~~

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

23 ~~SEC. 5:~~

24 ~~SECTION 1. Section 1367.21 of the Health and Safety Code~~
25 ~~is amended to read:~~

26 ~~1367.21. (a) No health care service plan contract which covers~~
27 ~~prescription drug benefits shall be issued, amended, delivered, or~~
28 ~~renewed in this state if the plan limits or excludes coverage for a~~
29 ~~drug on the basis that the drug is prescribed for a use that is~~
30 ~~different from the use for which that drug has been approved for~~
31 ~~marketing by the federal Food and Drug Administration (FDA),~~
32 ~~provided that all of the following conditions have been met:~~

33 ~~(1) The drug is approved by the FDA.~~

34 ~~(2) (A) The drug is prescribed by a participating licensed health~~
35 ~~care professional for the treatment of a life-threatening condition;~~
36 ~~or~~

37 ~~(B) The drug is prescribed by a participating licensed health~~
38 ~~care professional for the treatment of a chronic and seriously~~
39 ~~debilitating condition, the drug is medically necessary to treat that~~
40 ~~condition, and the drug is on the plan formulary. If the drug is not~~

1 on the plan formulary, the participating subscriber's request shall
2 be considered pursuant to the process required by Section 1367.24.

3 (3) The drug has been recognized for treatment of that condition
4 by either of the following:

5 ~~(A) A compendium approved by the federal Centers for~~
6 ~~Medicare and Medicaid Services, by one of the following~~
7 ~~compendia, as approved by the federal Centers for Medicare and~~
8 ~~Medicaid Services:~~

9 (A) *The American Hospital Formulary Service's Drug*
10 *Information.*

11 (B) *The Elsevier Gold Standard's Clinical Pharmacology.*

12 (C) *The National Comprehensive Cancer Network Drug and*
13 *Biologics Compendium.*

14 (D) *The Thomson Micromedex DrugDex.*

15 ~~(B)~~

16 (E) Two articles from major peer reviewed medical journals
17 that present data supporting the proposed off-label use or uses as
18 generally safe and effective unless there is clear and convincing
19 contradictory evidence presented in a major peer reviewed medical
20 journal.

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

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

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

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

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

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

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

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

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

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

14 ~~SEC. 6.~~

15 *SEC. 2.* Section 1370.4 of the Health and Safety Code is
16 amended to read:

17 1370.4. (a) Every health care service plan shall provide an
18 external, independent review process to examine the plan's
19 coverage decisions regarding experimental or investigational
20 therapies for individual enrollees who meet all of the following
21 criteria:

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

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

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

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

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

32 (2) The enrollee's physician certifies that the enrollee has a
33 condition, as defined in paragraph (1), for which standard therapies
34 have not been effective in improving the condition of the enrollee,
35 for which standard therapies would not be medically appropriate
36 for the enrollee, or for which there is no more beneficial standard
37 therapy covered by the plan than the therapy proposed pursuant
38 to paragraph (3).

39 (3) Either (A) the enrollee's physician, who is under contract
40 with or employed by the plan, has recommended a drug, device,

1 procedure, or other therapy that the physician certifies in writing
2 is likely to be more beneficial to the enrollee than any available
3 standard therapies, or (B) the enrollee, or the enrollee's physician
4 who is a licensed, board-certified or board-eligible physician
5 qualified to practice in the area of practice appropriate to treat the
6 enrollee's condition, has requested a therapy that, based on two
7 documents from the medical and scientific evidence, as defined
8 in subdivision (d), is likely to be more beneficial for the enrollee
9 than any available standard therapy. The physician certification
10 pursuant to this subdivision shall include a statement of the
11 evidence relied upon by the physician in certifying his or her
12 recommendation. Nothing in this subdivision shall be construed
13 to require the plan to pay for the services of a nonparticipating
14 physician provided pursuant to this subdivision, that are not
15 otherwise covered pursuant to the plan contract.

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

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

23 (b) The plan's decision to delay, deny, or modify experimental
24 or investigational therapies shall be subject to the independent
25 medical review process under Article 5.55 (commencing with
26 Section 1374.30) except that, in lieu of the information specified
27 in subdivision (b) of Section 1374.33, an independent medical
28 reviewer shall base his or her determination on relevant medical
29 and scientific evidence, including, but not limited to, the medical
30 and scientific evidence defined in subdivision (d).

31 (c) The independent medical review process shall also meet the
32 following criteria:

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

36 (2) If the enrollee's physician determines that the proposed
37 therapy would be significantly less effective if not promptly
38 initiated, the analyses and recommendations of the experts on the
39 panel shall be rendered within seven days of the request for
40 expedited review. At the request of the expert, the deadline shall

1 be extended by up to three days for a delay in providing the
2 documents required. The timeframes specified in this paragraph
3 shall be in addition to any otherwise applicable timeframes
4 contained in subdivision (c) of Section 1374.33.

5 (3) Each expert's analysis and recommendation shall be in
6 written form and state the reasons the requested therapy is or is
7 not likely to be more beneficial for the enrollee than any available
8 standard therapy, and the reasons that the expert recommends that
9 the therapy should or should not be provided by the plan, citing
10 the enrollee's specific medical condition, the relevant documents
11 provided, and the relevant medical and scientific evidence,
12 including, but not limited to, the medical and scientific evidence
13 as defined in subdivision (d), to support the expert's
14 recommendation.

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

18 (d) For the purposes of subdivision (b), "medical and scientific
19 evidence" means the following sources:

20 (1) Peer-reviewed scientific studies published in or accepted
21 for publication by medical journals that meet nationally recognized
22 requirements for scientific manuscripts and that submit most of
23 their published articles for review by experts who are not part of
24 the editorial staff.

25 (2) Peer-reviewed literature, biomedical compendia, and other
26 medical literature that meet the criteria of the National Institutes
27 of Health's National Library of Medicine for indexing in Index
28 Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS
29 database of Health Services Technology Assessment Research
30 (HSTAR).

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

34 ~~(4) A compendium approved by the federal Centers for Medicare
35 and Medicaid Services.~~

36 (4) *The following standard reference compendia, as approved*
37 *by the federal Centers for Medicare and Medicaid Services: the*
38 *American Hospital Formulary Service's Drug Information, the*
39 *American Dental Association Accepted Dental Therapeutics, the*
40 *Elsevier Gold Standard's Clinical Pharmacology, the National*

1 *Comprehensive Cancer Network Drug and Biologics Compendium,*
2 *and the Thomson Micromedex DrugDex.*

3 (5) Findings, studies, or research conducted by or under the
4 auspices of federal government agencies and nationally recognized
5 federal research institutes, including the Federal Agency for Health
6 Care Policy and Research, National Institutes of Health, National
7 Cancer Institute, National Academy of Sciences, Health Care
8 Financing Administration, Congressional Office of Technology
9 Assessment, and any national board recognized by the National
10 Institutes of Health for the purpose of evaluating the medical value
11 of health services.

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

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

16 ~~SEC. 7. Section 11014 of the Health and Safety Code is~~
17 ~~amended to read:~~

18 ~~11014. "Drug" means (a) substances recognized as drugs in a~~
19 ~~compendium approved by the federal Centers for Medicare and~~
20 ~~Medicaid Services; (b) substances intended for use in the diagnosis,~~
21 ~~cure, mitigation, treatment, or prevention of disease in man or~~
22 ~~animals; (c) substances (other than food) intended to affect the~~
23 ~~structure or any function of the body of man or animals; and (d)~~
24 ~~substances intended for use as a component of any article specified~~
25 ~~in subdivision (a), (b), or (c) of this section. It does not include~~
26 ~~devices or their components, parts, or accessories.~~

27 ~~SEC. 8. Section 109920 of the Health and Safety Code is~~
28 ~~amended to read:~~

29 ~~109920. "Device" means any instrument, apparatus, implement,~~
30 ~~machine, contrivance, implant, in vitro reagent, or other similar~~
31 ~~or related article, including any component, part, or accessory, that~~
32 ~~is any of the following:~~

33 ~~(a) Recognized in a compendium or supplement thereof~~
34 ~~approved by the federal Centers for Medicare and Medicaid~~
35 ~~Services.~~

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

39 ~~(c) Intended to affect the structure or any function of the body~~
40 ~~of humans or any other animal and that does not achieve any of~~

1 its principal intended purposes through chemical action within or
2 on the body of humans or other animals and that is not dependent
3 upon being metabolized for the achievement of any of its principal
4 intended purposes:

5 ~~SEC. 9. Section 109985 of the Health and Safety Code is~~
6 ~~amended to read:~~

7 ~~109985. "Official compendium" means a compendium or~~
8 ~~supplement thereof approved by the federal Centers for Medicare~~
9 ~~and Medicaid Services.~~

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

12 ~~111225. As used in this chapter, with respect to a drug or drug~~
13 ~~ingredient, "established name" means either of the following:~~

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

16 ~~(b) If there is no designated name and the drug or ingredient is~~
17 ~~an article recognized in a compendium approved by the federal~~
18 ~~Centers for Medicare and Medicaid Services, then the official title~~
19 ~~in the compendia is the established name.~~

20 ~~If neither subdivision (a) or (b) of this section applies, the~~
21 ~~common or usual name, if any, of the drug or of the ingredient is~~
22 ~~the established name. When an article is recognized in a~~
23 ~~compendium approved by the federal Centers for Medicare and~~
24 ~~Medicaid Services and in the Homeopathic Pharmacopoeia under~~
25 ~~different official titles, the official title used in the approved~~
26 ~~compendium shall apply unless it is labeled and offered for sale~~
27 ~~as a homeopathic drug. If it is labeled and offered for sale as a~~
28 ~~homeopathic drug, the official title used in the Homeopathic~~
29 ~~Pharmacopoeia shall apply.~~

30 ~~SEC. 11. Section 111235 of the Health and Safety Code is~~
31 ~~amended to read:~~

32 ~~111235. Whenever a drug is recognized in both a compendium~~
33 ~~approved by the federal Centers for Medicare and Medicaid~~
34 ~~Services and the Homeopathic Pharmacopoeia of the United States,~~
35 ~~it shall be subject to the requirements of the approved compendium~~
36 ~~unless it is labeled and offered for sale as a homeopathic drug. If~~
37 ~~it is labeled and offered for sale as a homeopathic drug, it shall be~~
38 ~~subject to the Homeopathic Pharmacopoeia of the United States~~
39 ~~and not to those of the approved compendium.~~

1 SEC. 12. Section 111656.4 of the Health and Safety Code is
2 amended to read:

3 ~~111656.4. Section 4051 of the Business and Professions Code~~
4 ~~shall not prohibit a home medical device retail facility from selling~~
5 ~~or dispensing prescription devices if the department finds that~~
6 ~~sufficient qualified supervision is employed by the home medical~~
7 ~~device retail facility to adequately safeguard and protect the public~~
8 ~~health. Each person applying to the department for this exemption~~
9 ~~shall meet the following requirements to obtain and maintain the~~
10 ~~exemption:~~

11 ~~(a) A licensed pharmacist or an exemptee who meets the~~
12 ~~requirements set forth in paragraphs (1) to (5), inclusive, and whose~~
13 ~~license of exemption is currently valid, shall be in charge of the~~
14 ~~home medical device retail facility.~~

15 ~~(1) He or she shall be a high school graduate or possess a general~~
16 ~~education development equivalent.~~

17 ~~(2) He or she shall have a minimum of one year of paid work~~
18 ~~experience related to the distribution or dispensing of dangerous~~
19 ~~drugs or dangerous devices.~~

20 ~~(3) He or she shall complete a training program that addresses~~
21 ~~each of the following subjects that are applicable to his or her~~
22 ~~duties:~~

23 ~~(A) Knowledge and understanding of state and federal laws~~
24 ~~relating to the distribution of dangerous drugs and dangerous~~
25 ~~devices.~~

26 ~~(B) Knowledge and understanding of state and federal laws~~
27 ~~relating the distribution of controlled substances.~~

28 ~~(C) Knowledge and understanding of quality control systems.~~

29 ~~(D) Knowledge and understanding of the standards relating to~~
30 ~~the safe storage and handling of drugs in a compendium approved~~
31 ~~by the federal Centers for Medicare and Medicaid Services.~~

32 ~~(E) Knowledge and understanding relating to the safe storage~~
33 ~~and handling of home medical devices.~~

34 ~~(F) Knowledge and understanding of prescription terminology,~~
35 ~~abbreviations, and format.~~

36 ~~(4) The department may, by regulation, require training~~
37 ~~programs that include additional material.~~

38 ~~(5) The department shall not issue an exemptee a license until~~
39 ~~the applicant provides proof of completion of the required training~~

1 ~~that the department determines is adequate to fulfill these~~
2 ~~requirements.~~

3 ~~(b) The licensed pharmacist or exemptee shall be on the premises~~
4 ~~at all times that prescription devices are available for sale or fitting~~
5 ~~unless the prescription devices are stored separately from other~~
6 ~~merchandise and are under the exclusive control of the licensed~~
7 ~~pharmacist or exemptee. A licensed pharmacist or an exemptee~~
8 ~~need not be present in the warehouse facility of a home medical~~
9 ~~device retail facility unless the department establishes that~~
10 ~~requirement by regulation based upon the need to protect the~~
11 ~~public.~~

12 ~~(c) The department may require an exemptee to complete a~~
13 ~~designated number of hours of coursework in department-approved~~
14 ~~courses of home health education in the disposition of any~~
15 ~~disciplinary action taken against the exemptee.~~

16 ~~(d) Each premises maintained by a home medical device retail~~
17 ~~facility shall have a license issued by the department and shall~~
18 ~~have a licensed pharmacist or exemptee on the premises if~~
19 ~~prescription devices are furnished, sold, or dispensed.~~

20 ~~(e) A home medical device retail facility may establish locked~~
21 ~~storage (a lock box or locked area) for emergency or after working~~
22 ~~hours furnishing of prescription devices. Locked storage may be~~
23 ~~installed or placed in a service vehicle of the home medical device~~
24 ~~retail facility for emergency or after hours service to patients having~~
25 ~~prescriptions for prescription devices.~~

26 ~~(f) The department may by regulation authorize a licensed~~
27 ~~pharmacist or exemptee to direct an employee of the home medical~~
28 ~~device retail facility who operates the service vehicle equipped~~
29 ~~with locked storage described in subdivision (e) to deliver a~~
30 ~~prescription device from the locked storage to patients having~~
31 ~~prescriptions for prescription devices. These regulations shall~~
32 ~~establish inventory requirements for the locked storage by a~~
33 ~~licensed pharmacist or exemptee to take place shortly after a~~
34 ~~prescription device has been delivered from the locked storage to~~
35 ~~a patient.~~

36 ~~SEC. 13. Section 150204 of the Health and Safety Code is~~
37 ~~amended to read:~~

38 ~~150204. (a) A county may establish, by ordinance, a repository~~
39 ~~and distribution program for purposes of this division. Only~~
40 ~~pharmacies that are county-owned or that contract with the county~~

1 pursuant to this division may participate in this program to dispense
2 medication donated to the drug repository and distribution program.

3 (b) A county that elects to establish a repository and distribution
4 program pursuant to this division shall establish procedures for,
5 at a minimum, all of the following:

6 (1) Establishing eligibility for medically indigent patients who
7 may participate in the program.

8 (2) Ensuring that patients eligible for the program shall not be
9 charged for any medications provided under the program.

10 (3) Developing a formulary of medications appropriate for the
11 repository and distribution program.

12 (4) Ensuring proper safety and management of any medications
13 collected by and maintained under the authority of a county-owned
14 or county-contracted, licensed pharmacy.

15 (5) Ensuring the privacy of individuals for whom the medication
16 was originally prescribed.

17 (c) Any medication donated to the repository and distribution
18 program shall comply with the requirements specified in this
19 division. Medication donated to the repository and distribution
20 program shall meet all of the following criteria:

21 (1) The medication shall not be a controlled substance.

22 (2) The medication shall not have been adulterated, misbranded,
23 or stored under conditions contrary to standards set by a
24 compendium approved by the federal Centers for Medicare and
25 Medicaid Services or the product manufacturer.

26 (3) The medication shall not have been in the possession of a
27 patient or any individual member of the public, and in the case of
28 medications donated by a skilled nursing facility, shall have been
29 under the control of staff of the skilled nursing facility.

30 (d) Only medication that is donated in unopened, tamper-evident
31 packaging or modified unit dose containers that meet standards in
32 a compendium approved by the federal Centers for Medicare and
33 Medicaid Services is eligible for donation to the repository and
34 distribution program, provided lot numbers and expiration dates
35 are affixed. Medication donated in opened containers shall not be
36 dispensed by the repository and distribution program.

37 (e) A pharmacist shall use his or her professional judgment in
38 determining whether donated medication meets the standards of
39 this division before accepting or dispensing any medication under
40 the repository and distribution program.

1 ~~(f) A pharmacist shall adhere to standard pharmacy practices,~~
2 ~~as required by state and federal law, when dispensing all~~
3 ~~medications.~~

4 ~~(g) Medication that is donated to the repository and distribution~~
5 ~~program shall be handled in any of the following ways:~~

6 ~~(1) Dispensed to an eligible patient.~~

7 ~~(2) Destroyed.~~

8 ~~(3) Returned to a reverse distributor.~~

9 ~~(h) Medication that is donated to the repository and distribution~~
10 ~~program that does not meet the requirements of this division shall~~
11 ~~not be distributed under this program and shall be either destroyed~~
12 ~~or returned to a reverse distributor. This medication shall not be~~
13 ~~sold, dispensed, or otherwise transferred to any other entity.~~

14 ~~(i) Medication donated to the repository and distribution program~~
15 ~~shall be maintained in the donated packaging units until dispensed~~
16 ~~to an eligible patient under this program, who presents a valid~~
17 ~~prescription. When dispensed to an eligible patient under this~~
18 ~~program, the medication shall be in a new and properly labeled~~
19 ~~container, specific to the eligible patient and ensuring the privacy~~
20 ~~of the individuals for whom the medication was initially dispensed.~~
21 ~~Expired medication shall not be dispensed.~~

22 ~~(j) Medication donated to the repository and distribution program~~
23 ~~shall be segregated from the pharmacy's other drug stock by~~
24 ~~physical means, for purposes including, but not limited to,~~
25 ~~inventory, accounting, and inspection.~~

26 ~~(k) The pharmacy shall keep complete records of the acquisition~~
27 ~~and disposition of medication donated to and dispensed under the~~
28 ~~repository and distribution program. These records shall be kept~~
29 ~~separate from the pharmacy's other acquisition and disposition~~
30 ~~records and shall conform to the Pharmacy Law (Chapter 9~~
31 ~~(commencing with Section 4000) of Division 2 of the Business~~
32 ~~and Professions Code), including being readily retrievable.~~

33 ~~(l) Local and county protocols established pursuant to this~~
34 ~~division shall conform to the Pharmacy Law regarding packaging,~~
35 ~~transporting, storing, and dispensing all medications.~~

36 ~~(m) County protocols established for packaging, transporting,~~
37 ~~storing, and dispensing medications that require refrigeration,~~
38 ~~including, but not limited to, any biological product as defined in~~
39 ~~Section 351 of the Public Health and Service Act (42 U.S.C. Sec.~~
40 ~~262), an intravenously injected drug, or an infused drug, include~~

1 specific procedures to ensure that these medications are packaged,
2 transported, stored, and dispensed at their appropriate temperatures
3 and in accordance with standards in a compendium approved by
4 the federal Centers for Medicare and Medicaid Services and the
5 Pharmacy Law.

6 (n) Notwithstanding any other provision of law, a participating
7 county-owned or county-contracted pharmacy shall follow the
8 same procedural drug pedigree requirements for donated drugs as
9 it would follow for drugs purchased from a wholesaler or directly
10 from a drug manufacturer.

11 ~~SEC. 14.~~

12 *SEC. 3.* Section 10123.195 of the Insurance Code is amended
13 to read:

14 10123.195. (a) No group or individual disability insurance
15 policy issued, delivered, or renewed in this state or certificate of
16 group disability insurance issued, delivered, or renewed in this
17 state pursuant to a master group policy issued, delivered, or
18 renewed in another state that, as a provision of hospital, medical,
19 or surgical services, directly or indirectly covers prescription drugs
20 shall limit or exclude coverage for a drug on the basis that the drug
21 is prescribed for a use that is different from the use for which that
22 drug has been approved for marketing by the federal Food and
23 Drug Administration (FDA), provided that all of the following
24 conditions have been met:

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

26 (2) (A) The drug is prescribed by a contracting licensed health
27 care professional for the treatment of a life-threatening condition;
28 or

29 (B) The drug is prescribed by a contracting licensed health care
30 professional for the treatment of a chronic and seriously debilitating
31 condition, the drug is medically necessary to treat that condition,
32 and the drug is on the insurer's formulary, if any.

33 (3) The drug has been recognized for treatment of that condition
34 by either of the following:

35 ~~(A) A compendium approved by the federal Centers for~~
36 ~~Medicare and Medicaid Services.~~ *by one of the following*
37 *compendia, as approved by the federal Centers for Medicare and*
38 *Medicaid Services:*

39 (A) *The American Hospital Formulary Service's Drug*
40 *Information.*

- 1 (B) *The Elsevier Gold Standard's Clinical Pharmacology.*
2 (C) *The National Comprehensive Cancer Network Drug and*
3 *Biologics Compendium.*
4 (D) *The Thomson Micromedex DrugDex.*
5 ~~(B)~~
6 (E) Two articles from major peer reviewed medical journals
7 that present data supporting the proposed off-label use or uses as
8 generally safe and effective unless there is clear and convincing
9 contradictory evidence presented in a major peer reviewed medical
10 journal.
- 11 (b) It shall be the responsibility of the contracting prescriber to
12 submit to the insurer documentation supporting compliance with
13 the requirements of subdivision (a), if requested by the insurer.
- 14 (c) Any coverage required by this section shall also include
15 medically necessary services associated with the administration
16 of a drug subject to the conditions of the contract.
- 17 (d) For purposes of this section, "life-threatening" means either
18 or both of the following:
- 19 (1) Diseases or conditions where the likelihood of death is high
20 unless the course of the disease is interrupted.
- 21 (2) Diseases or conditions with potentially fatal outcomes, where
22 the end point of clinical intervention is survival.
- 23 (e) For purposes of this section, "chronic and seriously
24 debilitating" means diseases or conditions that require ongoing
25 treatment to maintain remission or prevent deterioration and cause
26 significant long-term morbidity.
- 27 (f) The provision of drugs and services when required by this
28 section shall not, in itself, give rise to liability on the part of the
29 insurer.
- 30 (g) This section shall not apply to a policy of disability insurance
31 that covers hospital, medical, or surgical expenses which is issued
32 outside of California to an employer whose principal place of
33 business is located outside of California.
- 34 (h) Nothing in this section shall be construed to prohibit the use
35 of a formulary, copayment, technology assessment panel, or similar
36 mechanism as a means for appropriately controlling the utilization
37 of a drug that is prescribed for a use that is different from the use
38 for which that drug has been approved for marketing by the FDA.
- 39 (i) If an insurer denies coverage pursuant to this section on the
40 basis that its use is experimental or investigational, that decision

1 is subject to review under the Independent Medical Review System
2 of Article 3.5 (commencing with Section 10169).

3 (j) This section is not applicable to vision-only, dental-only,
4 Medicare or Champus supplement, disability income, long-term
5 care, accident-only, specified disease or hospital confinement
6 indemnity insurance.

7 ~~SEC. 15.~~

8 *SEC. 4.* Section 10145.3 of the Insurance Code is amended to
9 read:

10 10145.3. (a) Every disability insurer that covers hospital,
11 medical, or surgical benefits shall provide an external, independent
12 review process to examine the insurer's coverage decisions
13 regarding experimental or investigational therapies for individual
14 insureds who meet all of the following criteria:

15 (1) (A) The insured has a life-threatening or seriously
16 debilitating condition.

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

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

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

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

25 (2) The insured's physician certifies that the insured has a
26 condition, as defined in paragraph (1), for which standard therapies
27 have not been effective in improving the condition of the insured,
28 for which standard therapies would not be medically appropriate
29 for the insured, or for which there is no more beneficial standard
30 therapy covered by the insurer than the therapy proposed pursuant
31 to paragraph (3).

32 (3) Either (A) the insured's contracting physician has
33 recommended a drug, device, procedure, or other therapy that the
34 physician certifies in writing is likely to be more beneficial to the
35 insured than any available standard therapies, or (B) the insured,
36 or the insured's physician who is a licensed, board-certified or
37 board-eligible physician qualified to practice in the area of practice
38 appropriate to treat the insured's condition, has requested a therapy
39 that, based on two documents from the medical and scientific
40 evidence, as defined in subdivision (d), is likely to be more

1 beneficial for the insured than any available standard therapy. The
2 physician certification pursuant to this subdivision shall include a
3 statement of the evidence relied upon by the physician in certifying
4 his or her recommendation. Nothing in this subdivision shall be
5 construed to require the insurer to pay for the services of a
6 noncontracting physician, provided pursuant to this subdivision,
7 that are not otherwise covered pursuant to the contract.

8 (4) The insured has been denied coverage by the insurer for a
9 drug, device, procedure, or other therapy recommended or
10 requested pursuant to paragraph (3), unless coverage for the
11 specific therapy has been excluded by the insurer's contract.

12 (5) The specific drug, device, procedure, or other therapy
13 recommended pursuant to paragraph (3) would be a covered service
14 except for the insurer's determination that the therapy is
15 experimental or under investigation.

16 (b) The insurer's decision to deny, delay, or modify experimental
17 or investigational therapies shall be subject to the independent
18 medical review process established under Article 3.5 (commencing
19 with Section 10169) of Chapter 1 of Part 2 of Division 2, except
20 that in lieu of the information specified in subdivision (b) of
21 Section 10169.3, an independent medical reviewer shall base his
22 or her determination on relevant medical and scientific evidence,
23 including, but not limited to, the medical and scientific evidence
24 defined in subdivision (d).

25 (c) The independent medical review process shall also meet the
26 following criteria:

27 (1) The insurer shall notify eligible insureds in writing of the
28 opportunity to request the external independent review within five
29 business days of the decision to deny coverage.

30 (2) If the insured's physician determines that the proposed
31 therapy would be significantly less effective if not promptly
32 initiated, the analyses and recommendations of the experts on the
33 panel shall be rendered within seven days of the request for
34 expedited review. At the request of the expert, the deadline shall
35 be extended by up to three days for a delay in providing the
36 documents required. The timeframes specified in this paragraph
37 shall be in addition to any otherwise applicable timeframes
38 contained in subdivision (c) of Section 10169.3.

39 (3) Each expert's analysis and recommendation shall be in
40 written form and state the reasons the requested therapy is or is

1 not likely to be more beneficial for the insured than any available
2 standard therapy, and the reasons that the expert recommends that
3 the therapy should or should not be covered by the insurer, citing
4 the insured's specific medical condition, the relevant documents,
5 and the relevant medical and scientific evidence, including, but
6 not limited to, the medical and scientific evidence as defined in
7 subdivision (d), to support the expert's recommendation.

8 (4) Coverage for the services required under this section shall
9 be provided subject to the terms and conditions generally applicable
10 to other benefits under the contract.

11 (d) For the purposes of subdivision (b), "medical and scientific
12 evidence" means the following sources:

13 (1) Peer-reviewed scientific studies published in or accepted
14 for publication by medical journals that meet nationally recognized
15 requirements for scientific manuscripts and that submit most of
16 their published articles for review by experts who are not part of
17 the editorial staff.

18 (2) Peer-reviewed literature, biomedical compendia and other
19 medical literature that meet the criteria of the National Institutes
20 of Health's National Library of Medicine for indexing in Index
21 Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS
22 database of Health Services Technology Assessment Research
23 (HSTAR).

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

27 ~~(4) A compendium approved by the federal Centers for Medicare
28 and Medicaid Services:~~

29 *(4) The following standard reference compendia, as approved
30 by the federal Centers for Medicare and Medicaid Services: the
31 American Hospital Formulary Service's Drug Information, the
32 American Dental Association Accepted Dental Therapeutics, the
33 Elsevier Gold Standard's Clinical Pharmacology, the National
34 Comprehensive Cancer Network Drug and Biologics Compendium,
35 and the Thomson Micromedex DrugDex.*

36 (5) Findings, studies, or research conducted by or under the
37 auspices of federal government agencies and nationally recognized
38 federal research institutes, including the Federal Agency for Health
39 Care Policy and Research, National Institutes of Health, National
40 Cancer Institute, National Academy of Sciences, Health Care

1 Financing Administration, Congressional Office of Technology
2 Assessment, and any national board recognized by the National
3 Institutes of Health for the purpose of evaluating the medical value
4 of health services.

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

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

9 ~~SEC. 16. Section 383 of the Penal Code is amended to read:~~

10 ~~383. Every person who knowingly sells, or keeps or offers for~~
11 ~~sale, or otherwise disposes of any article of food, drink, drug, or~~
12 ~~medicine, knowing that the same is adulterated or has become~~
13 ~~tainted, decayed, spoiled, or otherwise unwholesome or unfit to~~
14 ~~be eaten or drunk, with intent to permit the same to be eaten or~~
15 ~~drunk, is guilty of a misdemeanor, and must be fined not exceeding~~
16 ~~one thousand dollars (\$1,000), or imprisoned in the county jail not~~
17 ~~exceeding six months, or both, and may, in the discretion of the~~
18 ~~court, be adjudged to pay, in addition, all the necessary expenses,~~
19 ~~not exceeding one thousand dollars (\$1,000), incurred in inspecting~~
20 ~~and analyzing these articles. The term "drug," as used herein,~~
21 ~~includes all medicines for internal or external use, antiseptics,~~
22 ~~disinfectants, and cosmetics. The term "food," as used herein,~~
23 ~~includes all articles used for food or drink by man, whether simple,~~
24 ~~mixed, or compound. Any article is deemed to be adulterated within~~
25 ~~the meaning of this section:~~

26 ~~(a) In case of drugs: (1) if, when sold under or by a name~~
27 ~~recognized in a compendium approved by the federal Centers of~~
28 ~~Medicare and Medicaid Services, it differs materially from the~~
29 ~~standard of strength, quality, or purity laid down therein; (2) if,~~
30 ~~when sold under or by a name not recognized in a compendium~~
31 ~~approved by the federal Centers of Medicare and Medicaid~~
32 ~~Services, but which is found in some other pharmacopocia or other~~
33 ~~standard work on materia medica, it differs materially from the~~
34 ~~standard of strength, quality, or purity laid down in such work;~~
35 ~~(3) if its strength, quality, or purity falls below the professed~~
36 ~~standard under which it is sold.~~

37 ~~(b) In the case of food: (1) if any substance or substances have~~
38 ~~been mixed with it, so as to lower or depreciate, or injuriously~~
39 ~~affect its quality, strength, or purity; (2) if any inferior or cheaper~~
40 ~~substance or substances have been substituted wholly or in part~~

1 for it; (3) if any valuable or necessary constituent or ingredient
2 has been wholly or in part abstracted from it; (4) if it is an
3 imitation of, or is sold under the name of, another article; (5) if it
4 consists wholly, or in part, of a diseased, decomposed, putrid,
5 infected, tainted, or rotten animal or vegetable substance or article,
6 whether manufactured or not; or in the case of milk, if it is the
7 produce of a diseased animal; (6) if it is colored, coated, polished,
8 or powdered, whereby damage or inferiority is concealed, or if by
9 any means it is made to appear better or of greater value than it
10 really is; (7) if it contains any added substance or ingredient which
11 is poisonous or injurious to health.

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 a compendium or supplement thereof
23 approved by the federal Centers for Medicare and Medicaid
24 Services.

25 (2) Articles intended for use in the diagnosis, cure, mitigation,
26 treatment, or prevention of disease in humans or other animals.

27 (3) Articles, excluding food, intended to affect the structure or
28 function of the body of humans or other animals.

29 (4) Articles intended for use as a component of an article
30 specified in paragraph (1), (2), or (3).

31 (c) "Participant" means any entity which the board deems
32 appropriate for implementing and evaluating a model program and
33 which chooses to participate, including, but not limited to,
34 governmental entities, pharmacies, veterinarians, clinics, and other
35 medical settings.

36 (d) "Sale" includes, but is not limited to, transactions conducted
37 through sales outlets, catalogs, or the Internet, or any other similar
38 electronic means, but does not include a sale that is a wholesale
39 transaction with a distributor or retailer.

1 ~~SEC. 18.~~

2 ~~SEC. 5.~~ Section 14105.43 of the Welfare and Institutions Code
3 is amended to read:

4 14105.43. (a) (1) Notwithstanding other provisions of this
5 chapter, any drug which is approved by the federal Food and Drug
6 Administration for use in the treatment of acquired
7 immunodeficiency syndrome (AIDS) or an AIDS-related condition
8 shall be deemed to be approved for addition to the Medi-Cal list
9 of contract drugs only for the purpose of treating AIDS or an
10 AIDS-related condition, for the period prior to the completion of
11 the procedures established pursuant to Section 14105.33.

12 (2) (A) In addition to any drug that is deemed to be approved
13 pursuant to paragraph (1), any drug that meets any of the following
14 criteria shall be a Medi-Cal benefit, subject to utilization controls:

15 (i) Any vaccine to protect against human immunodeficiency
16 virus (HIV) infection.

17 (ii) Any antiviral agent, immune modulator, or other agent to
18 be administered to persons who have been infected with human
19 immunodeficiency virus to counteract the effects of that infection.

20 (iii) Any drug or biologic used to treat opportunistic infections
21 associated with acquired immune deficiency syndrome, that have
22 been found to be medically accepted indications and that has either
23 been approved by the federal Food and Drug Administration or
24 recognized for that use in either of the following:

25 ~~(I) A compendium approved by the federal Centers for Medicare~~
26 ~~and Medicaid Services; recognized for that use in one of the~~
27 ~~following compendia, as approved by the federal Centers for~~
28 ~~Medicare and Medicaid Services:~~

29 (I) *The American Hospital Formulary Service's Drug*
30 *Information.*

31 (II) *The Elsevier Gold Standard's Clinical Pharmacology.*

32 (III) *The National Comprehensive Cancer Network Drug and*
33 *Biologics Compendium.*

34 (IV) *The Thomson Micromedex DrugDex.*

35 ~~(H)~~

36 (V) Two articles from peer reviewed medical journals that
37 present data supporting the proposed use or uses as generally safe
38 and effective.

1 (iv) Any drug or biologic used to treat the chemotherapy-induced
2 suppression of the human immune system resulting from the
3 treatment of acquired immune deficiency syndrome.

4 (3) The department shall add any drug deemed to be approved
5 pursuant to paragraph (1) to the Medi-Cal list of contract drugs or
6 allow the provision of the drug as a Medi-Cal benefit, subject to
7 utilization controls, pursuant to paragraph (2), only if the
8 manufacturer of the drug has executed a contract with the Centers
9 for Medicare and Medicaid Services which provides for rebates
10 in accordance with Section 1396r-8 of Title 42 of the United States
11 Code.

12 (b) Any drug deemed to be approved pursuant to paragraph (1)
13 of subdivision (a) shall be immediately added to the Medi-Cal list
14 of contract drugs, and shall be exempt from the contract
15 requirements of Section 14105.33.

16 (c) If it is determined pursuant to subdivision (c) of Section
17 14105.39 that a drug to which subdivision (a) applies should not
18 be placed on the Medi-Cal list of contract drugs, that drug shall
19 no longer be deemed to be approved for addition to the list of
20 contract drugs pursuant to subdivision (a).

21 ~~SEC. 19.~~

22 *SEC. 6.* Section 14133.2 of the Welfare and Institutions Code
23 is amended to read:

24 14133.2. (a) The director shall include in the Medi-Cal list of
25 contract drugs any drug approved for the treatment of cancer by
26 the federal Food and Drug Administration, so long as the
27 manufacturer has executed a contract with the Health Care
28 Financing Administration which provides for rebates in accordance
29 with Section 1396r-8 of Title 42 of the United States Code. These
30 drugs shall be exempt from the contract requirements of Section
31 14105.33.

32 (b) In addition to any drug added to the list of contract drugs
33 pursuant to subdivision (a), any drug that meets either of the
34 following criteria and for which the manufacturer has executed a
35 contract with the Health Care Financing Administration that
36 provides for rebates in accordance with Section 1396r-8 of Title
37 42 of the United States Code, shall be a Medi-Cal benefit, subject
38 to utilization controls, unless the contract requirements of Section
39 14105.33 have been complied with:

1 (1) Any drug approved by the federal Food and Drug
2 Administration for treatment of opportunistic infections associated
3 with cancer.

4 (2) Any drug or biologic used in an anticancer chemotherapeutic
5 regimen for a medically accepted indication, which has either been
6 approved by the federal Food and Drug Administration, or
7 recognized for that use in either of the following:

8 ~~(A) A compendium approved by the federal Centers for~~
9 ~~Medicare and Medicaid Services, recognized for that use in one~~
10 ~~of the following compendia, as approved by the federal Centers~~
11 ~~for Medicare and Medicaid Services:~~

12 (A) *The American Hospital Formulary Service's Drug*
13 *Information.*

14 (B) *The Elsevier Gold Standard's Clinical Pharmacology.*

15 (C) *The National Comprehensive Cancer Network Drug and*
16 *Biologics Compendium.*

17 (D) *The Thomson Micromedex DrugDex.*

18 ~~(B)~~

19 (E) Two articles from peer reviewed medical journals that
20 present data supporting the proposed use or uses as generally safe
21 and effective.

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

AMENDED IN SENATE JUNE 17, 2009
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 storage container limit to 48, *as specified*.
The bill would also increase the authorized dosage amount available to a skilled nursing facility or intermediate care facility.

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 48. The State Department of Public Health may
9 limit the number of doses of each drug available to not more than
10 ~~four~~ 16 doses of any separate drug dosage form in each emergency
11 supply.

12 (b) *Not more than four of the 48 oral form or suppository form*
13 *drugs secured for storage in the emergency supplies container*
14 *shall be psychotherapeutic drugs, except that the department may*
15 *grant a program flexibility request to the facility to increase the*
16 *number of psychotherapeutic drugs in the emergency supplies*
17 *container to not more than 10 if the facility can demonstrate the*
18 *necessity for an increased number of drugs based on the needs of*
19 *the patient population at the facility. In addition, the four oral*
20 *form or suppository form psychotherapeutic drug limit shall not*
21 *apply to a special treatment program service unit distinct part, as*
22 *defined in Section 1276.9. The department shall limit the number*
23 *of doses of psychotherapeutic drugs available to not more than*
24 *four doses in each emergency supply. Nothing in this section shall*
25 *alter or diminish informed consent requirements, including, but*
26 *not limited to, the requirements of Section 1418.9.*

27 ~~(b)~~
28 (c) Any limitations established pursuant to ~~subdivision (a)~~
29 ~~subdivisions (a) and (b)~~ on the number and quantity of oral dosage
30 or suppository form drugs provided by a pharmacy to a health
31 facility licensed pursuant to subdivision (c), (d), or both (c) and
32 (d), of Section 1250 for storage in a secured emergency supplies

- 1 container shall not apply to an automated drug delivery system,
- 2 as defined in Section 1261.6, when a pharmacist controls access
- 3 to the drugs.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 931

VERSION: Amended ~~March 26, 2009~~
Amended June 17, 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 emergency kit at specified facilities to from 24 to 48.
2. Provide that CDPH may limit to 16 (currently, four) the number of doses of each drug available in each emergency supply.
3. Provide for limitations and exceptions to psychotherapeutic drugs in an emergency supplies container, as specified.

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.

At its April 16, 2009, meeting, the Legislation and Regulation Committee did not recommend a position on this bill; likewise, the board did not take a position on this measure at its April 30th board meeting.

PROPOSERS

California Pharmacists Association

OPPOSITION

None of file.

HISTORY:

July 1 In committee: Hearing postponed by committee.
June 26 In committee: Hearing postponed by committee.
June 22 In committee: Hearing postponed by committee.

- June 17 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
- June 11 In committee: Hearing postponed by committee.
- May 21 Referred to Com. on HEALTH.
- May 14 In Senate. Read first time. To Com. on RLS. for assignment.
- May 14 Read third time, passed, and to Senate. (Ayes 74. Noes 0. Page 1445.)
- May 7 Read second time. To third reading.
- May 6 From committee: Do pass. (Ayes 19. Noes 0.) (May 5).
- 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 SENATE JUNE 1, 2009

AMENDED IN SENATE MAY 5, 2009

SENATE BILL

No. 389

Introduced by Senator Negrete McLeod

February 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 amended, 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 Fiduciaries Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require *new* applicants for a license ~~and~~, *and petitioners for reinstatement of a revoked, surrendered, or canceled license, to successfully complete a state and federal level criminal record information search. The bill would also require, 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 *the process necessary* for a state and federal level criminal offender record information search, as specified. The bill would require licensees *applying for license renewal* 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, *or any member of the personnel of record of the licensee*, has been convicted, as defined, of a felony or misdemeanor since ~~his or her~~ *the* last renewal, or if this is the licensee's first renewal, since the initial license was issued. *The bill would provide that the Contractors' State License Board shall implement the provisions pertaining to renewal licenses on a specified schedule, after an appropriation is made for this purpose, utilizing its applicable fees.*

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 *or a petitioner for reinstatement of a revoked, surrendered, or*
- 6 *canceled license* to furnish to the agency a full set of fingerprints
- 7 for purposes of conducting criminal history record checks and
- 8 shall require the applicant *or petitioner* to successfully complete
- 9 a state and federal level criminal offender record information search
- 10 conducted through the Department of Justice as provided in
- 11 subdivision (c) or as otherwise provided in this code.
- 12 (b) Subdivision (a) applies to the following:
- 13 (1) California Board of Accountancy.
- 14 (2) State Athletic Commission.
- 15 (3) Board of Behavioral Sciences.
- 16 (4) Court Reporters Board of California.
- 17 (5) State Board of Guide Dogs for the Blind.
- 18 (6) California State Board of Pharmacy.
- 19 (7) Board of Registered Nursing.
- 20 (8) Veterinary Medical Board.

- 1 (9) Registered Veterinary Technician Committee.
- 2 (10) Board of Vocational Nursing and Psychiatric Technicians.
- 3 (11) Respiratory Care Board of California.
- 4 (12) Hearing Aid Dispensers Bureau.
- 5 (13) Physical Therapy Board of California.
- 6 (14) Physician Assistant Committee of the Medical Board of
- 7 California.
- 8 (15) Speech-Language Pathology and Audiology Board.
- 9 (16) Medical Board of California.
- 10 (17) State Board of Optometry.
- 11 (18) Acupuncture Board.
- 12 (19) Cemetery and Funeral Bureau.
- 13 (20) Bureau of Security and Investigative Services.
- 14 (21) Division of Investigation.
- 15 (22) Board of Psychology.
- 16 (23) California Board of Occupational Therapy.
- 17 (24) Structural Pest Control Board.
- 18 (25) Contractors' State License Board.
- 19 (26) Bureau of Naturopathic Medicine.
- 20 (27) Dental Board of California.
- 21 (28) Dental Hygiene Committee of California.
- 22 (29) Professional Fiduciaries Bureau.
- 23 (30) California Board of Podiatric Medicine.
- 24 (31) Osteopathic Medical Board of California.
- 25 (32) State Board of Chiropractic Examiners.

26 (c) Except as otherwise provided in this code, each agency listed
27 in subdivision (b) shall direct applicants for a license *or a petitioner*
28 *for reinstatement of a revoked, surrendered, or canceled license*
29 to submit to the Department of Justice fingerprint images and
30 related information required by the Department of Justice for the
31 purpose of obtaining information as to the existence and content
32 of a record of state or federal convictions and state or federal arrests
33 and also information as to the existence and content of a record of
34 state or federal arrests for which the Department of Justice
35 establishes that the person is free on bail or on his or her
36 recognizance pending trial or appeal. The Department of Justice
37 shall forward the fingerprint images and related information
38 received to the Federal Bureau of Investigation and request federal
39 criminal history information. The Department of Justice shall
40 compile and disseminate state and federal responses to the agency

1 pursuant to subdivision (p) of Section 11105 of the Penal Code.
2 The agency shall request from the Department of Justice
3 subsequent arrest notification service, pursuant to Section 11105.2
4 of the Penal Code, for each person who submitted information
5 pursuant to this subdivision. The Department of Justice shall charge
6 a fee sufficient to cover the cost of processing the request described
7 in this section.

8 SEC. 2. Section 144.5 is added to the Business and Professions
9 Code, to read:

10 144.5. (a) Notwithstanding any other provision of law, an
11 agency designated in subdivision (b) of Section 144 shall require
12 a licensee who has not previously submitted fingerprints or for
13 whom a record of the submission of fingerprints no longer exists
14 to, as a condition of license renewal, ~~successfully complete~~
15 *complete the process necessary for* a state and federal level criminal
16 offender record information search *to be* conducted through the
17 Department of Justice as provided in subdivision (d).

18 ~~(b) (1) A licensee described in subdivision (a) shall, as a~~
19 ~~condition of license renewal, certify on the renewal application~~
20 ~~that he or she has successfully completed a state and federal level~~
21 ~~criminal offender record information search pursuant to subdivision~~
22 ~~(d).~~

23 ~~(2) The licensee shall retain for at least three years, as evidence~~
24 ~~of the certification made pursuant to paragraph (1), either a receipt~~
25 ~~showing that he or she has electronically transmitted his or her~~
26 ~~fingerprint images to the Department of Justice or, for those~~
27 ~~licensees who did not use an electronic fingerprinting system, a~~
28 ~~receipt evidencing that the licensee's fingerprints were taken.~~

29 ~~(b) (1) As a condition of license renewal, a licensee described~~
30 ~~in subdivision (a) shall complete the process necessary for a state~~
31 ~~and federal level criminal offender record information search to~~
32 ~~be conducted as provided in subdivision (d).~~

33 ~~(2) No license of a licensee described in subdivision (a) shall~~
34 ~~be renewed until certification by the licensee is received by the~~
35 ~~agency verifying that the licensee has complied with this~~
36 ~~subdivision. The certification shall be made on a form provided~~
37 ~~by the agency not later than the renewal date of the license.~~

38 ~~(3) As evidence of the certification made pursuant to paragraph~~
39 ~~(2), the licensee shall retain either of the following for at least~~
40 ~~three years:~~

1 (A) *The receipt showing that the fingerprint images required*
2 *by this section were electronically transmitted to the Department*
3 *of Justice.*

4 (B) *For those licensees who did not use an electronic*
5 *fingerprinting system, the receipt evidencing that the fingerprint*
6 *images required by this section were taken.*

7 (c) Failure to provide the certification required by subdivision
8 (b) renders an application for *license* renewal incomplete. An
9 agency shall not renew the license until a complete application is
10 submitted.

11 (d) Each agency listed in subdivision (b) of Section 144 shall
12 direct licensees described in subdivision (a) to submit to the
13 Department of Justice fingerprint images and related information
14 required by the Department of Justice for the purpose of obtaining
15 information as to the existence and content of a record of state or
16 federal convictions and state or federal arrests and also information
17 as to the existence and content of a record of state or federal arrests
18 for which the Department of Justice establishes that the person is
19 free on bail or on his or her recognizance pending trial or appeal.
20 The Department of Justice shall forward the fingerprint images
21 and related information received to the Federal Bureau of
22 Investigation and request federal criminal history information. The
23 Department of Justice shall compile and disseminate state and
24 federal responses to the agency pursuant to subdivision (p) of
25 Section 11105 of the Penal Code. The agency shall request from
26 the Department of Justice subsequent arrest notification service,
27 pursuant to Section 11105.2 of the Penal Code, for each person
28 who submitted information pursuant to this subdivision. The
29 Department of Justice shall charge a fee sufficient to cover the
30 cost of processing the request described in this section.

31 (e) An agency may waive the requirements of this section if the
32 license is inactive or retired, or if the licensee is actively serving
33 in the military. The agency ~~may~~ shall not activate an inactive
34 license or return a retired license to full licensure status for a
35 licensee described in subdivision (a) until the licensee has
36 successfully completed a state and federal level criminal offender
37 record information search pursuant to subdivision (d).

38 ~~(f) With respect to licensees that are business entities, each~~
39 ~~agency listed in subdivision (b) of Section 144 shall, by regulation,~~
40 ~~determine which owners, officers, directors, shareholders,~~

1 ~~members, agents, employees, or other natural persons who are~~
2 ~~representatives of the business entity are required to submit~~
3 ~~fingerprint images to the Department of Justice and disclose the~~
4 ~~information on its renewal forms, as required by this section.~~

5 ~~(g)~~

6 ~~(f) A licensee who falsely certifies completion of a state and~~
7 ~~federal level criminal record information search under subdivision~~
8 ~~(b) may be subject to disciplinary action by his or her licensing~~
9 ~~agency. (b) shall be subject to disciplinary action.~~

10 ~~(g) (1) As it relates to the Contractors' State License Board,~~
11 ~~the provisions of this section shall become operative on the date~~
12 ~~on which an appropriation is made in the annual Budget Act to~~
13 ~~fund the activities of the Contractors' State License Board to~~
14 ~~accommodate a criminal history record check pursuant to this~~
15 ~~section. If this section becomes operative with respect to the~~
16 ~~Contractors' State License Board on or before July 1, 2012, the~~
17 ~~Contractors' State License Board shall implement this section~~
18 ~~according to the following schedule, and shall utilize the fees under~~
19 ~~its fee cap accordingly:~~

20 ~~(A) For licenses initially issued between January 1, 2000, and~~
21 ~~December 31, 2005, inclusive, the certification required under~~
22 ~~subdivision (b) shall be submitted during the license renewal period~~
23 ~~that commences on January 1, 2013.~~

24 ~~(B) For licenses initially issued between January 1, 1990, and~~
25 ~~December 31, 1999, inclusive, the certification required under~~
26 ~~subdivision (b) shall be submitted during the license renewal period~~
27 ~~that commences on January 1, 2015.~~

28 ~~(C) For licenses initially issued prior to January 1, 1990, the~~
29 ~~certification required under subdivision (b) shall be submitted~~
30 ~~during the license renewal period that commences on January 1,~~
31 ~~2017.~~

32 ~~(2) If this section becomes operative with respect to the~~
33 ~~Contractors' State License Board after July 1, 2012, the license~~
34 ~~renewal period commencement dates specified in subparagraphs~~
35 ~~(A), (B), and (C) of paragraph (1) shall be delayed one year at a~~
36 ~~time until this section becomes operative with respect to the~~
37 ~~Contractors' State License Board.~~

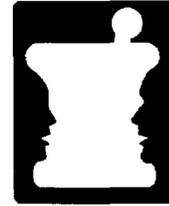
38 ~~(h) This section shall become operative on January 1, 2011.~~

39 SEC. 3. Section 144.6 is added to the Business and Professions
40 Code, to read:

1 144.6. (a) An agency described in subdivision (b) of Section
2 144 shall require a licensee, as a condition of license renewal, to
3 ~~notify the board on the license renewal form if he or she has been~~
4 *notify the agency on the license renewal form if he or she, or any*
5 *member of the personnel of record of the licensee, has been*
6 convicted, as defined in Section 490, of a felony or misdemeanor
7 ~~since his or her last renewal, or if this is the licensee's first renewal,~~
8 ~~since the initial license was issued.~~ *since the license was last*
9 *renewed, or since the license was initially issued if it has not been*
10 *previously renewed.*

11 (b) The reporting requirement imposed under this section shall
12 apply in addition to any other reporting requirement imposed under
13 this code.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 389

VERSION: As Amended June 1, 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.
3. Specifies the information to be disseminated by the Department of Justice as to the existence and content of a record of state or federal convictions and arrests, as specified. (PC 11105(p))
4. Authorizes the Department of Justice to distribute subsequent arrest notifications, as specified.

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 *an* applicant for a license *or petitions for reinstatement of a revoked, surrendered, or canceled 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, which will be disseminated pursuant to statutory authorization by DOJ.
4. Require each agency to request subsequent arrest notification service from DOJ for each person for whom fingerprint images were submitted.
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 *or those who petition for reinstatement of a revoked, surrendered or canceled license*, 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 *or issuing a reinstatement of a revoked, surrendered, or canceled license* until *the the agency has received certification by the applicant that the renewal application* is complete.
8. Allow an agency to waive this requirement if the license is inactive, retired or if the licensee is actively serving in the military; however, the agency shall not activate a license until the criminal record information search, as specified, 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~~ **shall 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, *or since the initial licensure if the license has not previously been renewed.*
12. Provides that certain provisions of the bill related to the State Contractors License Board become operative on a date specified, and at such time that an appropriation is made to fund the criminal history requirements contained within the measure.

AUTHOR'S INTENT:

To require fingerprint background checks on all applicants and licensees within the Department of Consumer Affairs.

FISCAL IMPACT:

Up to 2001, the board fingerprinted its licensees for state-level criminal history only. SB 389 requires that a federal-level criminal history check be on file for specified licensees. The board anticipates that approximately 80,000 current licensees will need to be re-printed to satisfy the requirements of this measure.

The board anticipates that the addition of the following staff will be required to implement the fingerprint requirements contained in the June 1, 2009, version of SB 389:

- One, two-year limited term AGPA to lead implementation of these requirements;
- One, two-year limited term SSA to analyze received criminal history results;
- Two, two-year limited term Office Technicians to process the incoming fingerprint results;
- One, full-time, permanent Management Services Technician to handle all renewal-related holds that result from this proposal; and
- One, full-time, permanent SSA to complete investigations on the subsequent arrest notifications received as a result of this proposal.

Further, the board 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 approximately 80,000 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 of licensees currently on file

and the level of services provided for each. 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 its public meeting held April 30, 2009, the Board of Pharmacy established a "Support" position on the bill, as Introduced (2/26/09).

SUPPORT/OPPOSITION:

Support [Per the Senate Floor Analysis dated 6/1/09]

California Association of Nurse Practitioners
California Board of Accountancy
California Chiropractic Association
Medical Board of California

Oppose (prior version) [Per the Senate Floor Analysis dated 6/1/09]

California Chapter of the American Fence Contractors Association
California Fence Contractors Association
Engineering and Utility Contractors Association
Engineering Contractors Association
Flasher/Barricade Association
Golden State Builders Exchanges
Marin Builders Association
California Medical Association
Southern California Contractors Association
Construction Industry Legislative Council

HISTORY:

2009

June 18 To Coms. on B. & P. and PUB. S.
June 3 In Assembly. Read first time. Held at Desk.
June 3 Read third time. Passed. (Ayes 37. Noes 1. Page 1178.) To Assembly.
June 1 From committee: Do pass as amended. (Ayes 12. Noes 0. Page 1070.) Read second time. Amended. To third reading.
May 22 Set for hearing May 28. (Suspense - for vote only.)
May 18 Placed on APPR suspense file.
May 8 Set for hearing May 18.
May 5 Read second time. Amended. Re-referred to Com. on APPR.
May 4 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 0. Page 705.)
Apr. 24 Set for hearing April 28.
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.

AMENDED IN SENATE MAY 12, 2009

AMENDED IN SENATE MAY 5, 2009

SENATE BILL

No. 484

**Introduced by Senator Wright
(Coauthor: Senator Florez)**

February 26, 2009

An act to amend Sections ~~11058, 11100, 11100~~ and 11106 of, and to add Section 11375.5 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as amended, 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 provide, in addition, that any person who obtains any of these ephedrine,~~

pseudoephedrine, and specified related drugs without a prescription, as specified, shall be guilty of an infraction or a misdemeanor. The bill would make conforming changes to related provisions. By creating new crimes or revising the penalties for existing crimes involving ephedrine, pseudoephedrine, and specified related drugs, this bill would impose a state-mandated local program.

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

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

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

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

1 ~~SECTION 1. Section 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 diphenoxyate and not less~~
23 ~~than 25 micrograms of atropine sulfate per dosage unit.~~

1 (5) Not more than 100 milligrams of opium per 100 milliliters
2 or per 100 grams:

3 (6) Not more than 0.5 milligram of difenoxin and not less than
4 25 micrograms of atropine sulfate per dosage unit.

5 (d) Buprenorphine.

6 (e) Products ~~containing ephedrine, pseudoephedrine,~~
7 ~~norpseudoephedrine, phenylpropanolamine, N-methylephedrine,~~
8 ~~N-ethylephedrine, N-methylpseudoephedrine,~~
9 ~~N-ethylpseudoephedrine, chloroephedrine, or~~
10 ~~chloropseudoephedrine, except for pediatric liquid forms as~~
11 ~~specified in subdivision (h) of Section 11100.~~

12 SEC. 2.

13 SECTION 1. Section 11100 of the Health and Safety Code is
14 amended to read:

15 11100. (a) Any manufacturer ~~or wholesaler, wholesaler,~~
16 ~~retailer, or other person or entity~~ in this state that sells, transfers,
17 or otherwise furnishes any of the following substances to any
18 person or entity in this state or any other state shall submit a report
19 to the Department of Justice of all of those transactions:

- 20 (1) Phenyl-2-propanone.
- 21 (2) Methylamine.
- 22 (3) Ethylamine.
- 23 (4) D-lysergic acid.
- 24 (5) Ergotamine tartrate.
- 25 (6) Diethyl malonate.
- 26 (7) Malonic acid.
- 27 (8) Ethyl malonate.
- 28 (9) Barbituric acid.
- 29 (10) Piperidine.
- 30 (11) N-acetylanthranilic acid.
- 31 (12) Pyrrolidine.
- 32 (13) Phenylacetic acid.
- 33 (14) Anthranilic acid.
- 34 (15) Morpholine.
- 35 (16) *Ephedrine.*
- 36 (17) *Pseudoephedrine.*
- 37 (18) *Norpseudoephedrine.*
- 38 (19) *Phenylpropanolamine.*
- 39 (20) Propionic anhydride.
- 40 (21) Isosafrole.

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

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

17 (B) For the purposes of this paragraph, "proper identification"
18 for in-state or out-of-state purchasers includes two or more of the
19 following: federal tax identification number; seller's permit
20 identification number; city or county business license number;
21 license issued by the California Department of Health Services;
22 registration number issued by the Federal Drug Enforcement
23 Administration; precursor business permit number issued by the
24 Bureau of Narcotic Enforcement of the California Department of
25 Justice; driver's license; or other identification issued by a state.

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

36 (B) The department may authorize the submission of the
37 notification on a monthly basis with respect to repeated, regular
38 transactions between an exporter and an importer involving a
39 substance specified in subdivision (a), if the department determines
40 that a pattern of regular supply of the substance exists between the

1 exporter and importer and that the importer has established a record
2 of utilization of the substance for lawful purposes.

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

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

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

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

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

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

39 (3)

1 (4) Any analytical research facility that is registered with the
2 federal Drug Enforcement Administration of the United States
3 Department of Justice.

4 ~~(4)~~

5 (5) A state-licensed health care facility that administers or
6 furnishes a substance to its patients.

7 ~~(5)~~

8 (6) Any sale, transfer, furnishing, or receipt of a product
9 specified in ~~subdivision (e) of Section 11058~~ *Section 11375.5*
10 pursuant to prescription shall not be subject to the reporting or
11 permitting requirements of this section, unless a product is
12 subsequently removed from exemption pursuant to Section 814
13 of Title 21 of the United States Code, in which case the product
14 shall similarly no longer be exempt from any state reporting or
15 permitting requirement unless otherwise reinstated pursuant to
16 subdivision (d) or (e) of Section 814 of Title 21 of the United States
17 Code as an exempt product.

18 ~~(6)~~

19 (7) The sale, transfer, furnishing, or receipt of any betadine or
20 povidone solution with an iodine content not exceeding 1 percent
21 in containers of eight ounces or less, or any tincture of iodine not
22 exceeding 2 percent in containers of one ounce or less, that is sold
23 over the counter.

24 ~~(7)~~

25 (8) Any transfer of a substance specified in subdivision (a) for
26 purposes of lawful disposal as waste.

27 (f) (1) Any person specified in subdivision (a) or (d) who does
28 not submit a report as required by that subdivision or who
29 knowingly submits a report with false or fictitious information
30 shall be punished by imprisonment in a county jail not exceeding
31 six months, by a fine not exceeding five thousand dollars (\$5,000),
32 or by both the fine and imprisonment.

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

39 (g) (1) ~~Except as otherwise provided, it~~ *It* is unlawful for any
40 manufacturer ~~or wholesaler, wholesaler, retailer, or other person~~

1 *or entity in this state* to sell, transfer, or otherwise furnish a
2 substance specified in subdivision (a) to a person under 18 years
3 of age.

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

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

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

14 (h) For the purposes of this article, the following terms have
15 the following meanings:

16 (1) "Drug store" is any entity described in Code 5912 of the
17 Standard Industrial Classification (SIC) Manual published by the
18 United States Office of Management and Budget, 1987 edition.

19 (2) "General merchandise store" is any entity described in Codes
20 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial
21 Classification (SIC) Manual published by the United States Office
22 of Management and Budget, 1987 edition.

23 (3) "Grocery store" is any entity described in Code 5411 of the
24 Standard Industrial Classification (SIC) Manual published by the
25 United States Office of Management and Budget, 1987 edition.

26 (4) "Pediatric liquid" means a nonencapsulated liquid whose
27 unit measure according to product labeling is stated in milligrams,
28 ounces, or other similar measure. In no instance shall the dosage
29 units exceed 15 milligrams of any product specified in ~~subdivision~~
30 ~~(e) of Section 11058 per five~~ *Section 11375.5 per five* milliliters
31 of liquid product, except for liquid products primarily intended
32 for administration to children under two years of age for which
33 the recommended dosage unit does not exceed two milliliters and
34 the total package content does not exceed one fluid ounce.

35 (5) "Retail distributor" means a grocery store, general
36 merchandise store, drugstore, or other related entity, the activities
37 of which, ~~as include being~~ a distributor of any product specified
38 in ~~subdivision (e) of Section 11058 are limited to the sale of those~~
39 ~~products~~ *Section 11375.5* upon prescription only, except for
40 pediatric liquids, either directly to walk-in customers or in

1 face-to-face transactions by direct sales. "Retail distributor"
2 includes an entity that makes a direct sale, but does not include
3 the parent company of that entity if the company is not involved
4 in direct sales regulated by this article.

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

10 ~~SEC. 3.~~

11 *SEC. 2.* Section 11106 of the Health and Safety Code is
12 amended to read:

13 11106. (a) (1) (A) Any ~~manufacturer or wholesaler,~~
14 *wholesaler, retailer, or other person or entity* in this state that
15 sells, transfers, or otherwise furnishes any substance specified in
16 subdivision (a) of Section 11100 to a person or business entity in
17 this state or any other state or who obtains from a source outside
18 of the state any substance specified in subdivision (a) of Section
19 11100 shall submit an application to, and obtain a permit for the
20 conduct of that business from, the Department of Justice. For any
21 substance added to the list set forth in subdivision (a) of Section
22 11100 on or after January 1, 2002, the Department of Justice may
23 postpone the effective date of the requirement for a permit for a
24 period not to exceed six months from the listing date of the
25 substance.

26 (B) An intracompany transfer does not require a permit if the
27 transferor is a permittee. Transfers between company partners or
28 between a company and an analytical laboratory do not require a
29 permit if the transferor is a permittee and a report as to the nature
30 and extent of the transfer is made to the Department of Justice
31 pursuant to Section 11100 or 11100.1.

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

1 State Board of Pharmacy that administers or furnishes a substance
2 to a patient; or any analytical research facility that is registered
3 with the federal Drug Enforcement Administration of the United
4 States Department of Justice.

5 (D) This paragraph shall not apply to the sale, transfer,
6 furnishing, or receipt of any betadine or povidone solution with
7 an iodine content not exceeding 1 percent in containers of eight
8 ounces or less, or any tincture of iodine not exceeding 2 percent
9 in containers of one ounce or less, that is sold over the counter.

10 (2) A permit shall be required for the sale, transfer, furnishing,
11 or obtaining of preparations in solid or liquid dosage form
12 containing any product as specified in ~~subdivision (e) of Section~~
13 ~~11058. Section 11375.5.~~

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

28 (2) The requirement for the specific purpose for the use, sale,
29 or transfer of those substances specified in subdivision (a) of
30 Section 11100 does not require applicants or permittees to reveal
31 their chemical processes that are typically considered trade secrets
32 and proprietary business information.

33 (c) Applicants and permittees shall authorize the department,
34 or any of its duly authorized representatives, as a condition of
35 being permitted, to make any examination of the books and records
36 of any applicant, permittee, or other person, or visit and inspect
37 the business premises of any applicant or permittee during normal
38 business hours, as deemed necessary to enforce this chapter.

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

4 (1) Materially falsifying an application for a permit or an
5 application for the renewal of a permit.

6 (2) If any individual owner, manager, agent, representative, or
7 employee for the applicant who has direct access, management,
8 or control for any substance listed under subdivision (a) of Section
9 11100, is or has been convicted of a misdemeanor or felony relating
10 to any of the substances listed under subdivision (a) of Section
11 11100, any misdemeanor drug-related offense, or any felony under
12 the laws of this state or the United States.

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

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

17 (5) Failure to provide the department, or any duly authorized
18 federal or state official, with access to any place for which a permit
19 has been issued, or for which an application for a permit has been
20 submitted, in the course of conducting a site investigation,
21 inspection, or audit; or failure to promptly produce for the official
22 conducting the site investigation, inspection, or audit any book,
23 record, or document requested by the official.

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

27 (7) Commission of any act which would demonstrate actual or
28 potential unfitness to hold a permit in light of the public safety and
29 welfare, which act is substantially related to the qualifications,
30 functions, or duties of a permit holder.

31 (8) If any individual owner, manager, agent, representative, or
32 employee for the applicant who has direct access, management,
33 or control for any substance listed under subdivision (a) of Section
34 11100, willfully violates or has been convicted of violating, any
35 federal, state, or local criminal statute, rule, or ordinance regulating
36 the manufacture, maintenance, disposal, sale, transfer, or furnishing
37 of any of those substances.

38 (e) Notwithstanding any other provision of law, an investigation
39 of an individual applicant's qualifications, or the qualifications of
40 an applicant's owner, manager, agent, representative, or employee

1 who has direct access, management, or control of any substance
2 listed under subdivision (a) of Section 11100, for a permit may
3 include review of his or her summary criminal history information
4 pursuant to Sections 11105 and 13300 of the Penal Code, including,
5 but not limited to, records of convictions, regardless of whether
6 those convictions have been expunged pursuant to Section 1203.4
7 of the Penal Code, and any arrests pending adjudication.

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

11 (g) The department may grant permits on forms prescribed by
12 it, which shall be effective for not more than one year from the
13 date of issuance and which shall not be transferable. Applications
14 and permits shall be uniform throughout the state, on forms
15 prescribed by the department.

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

19 (i) A permit granted pursuant to this article may be renewed
20 one year from the date of issuance, and annually thereafter,
21 following the timely filing of a complete renewal application with
22 all supporting documents, the payment of a permit renewal fee not
23 to exceed the application processing costs of the department, and
24 a review of the application by the department.

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

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

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

33 (l) (1) An applicant, or an applicant's employees who have
34 direct access, management, or control of any substance listed under
35 subdivision (a) of Section 11100, for an initial permit shall submit
36 with the application one set of 10-print fingerprints for each
37 individual acting in the capacity of an owner, manager, agent, or
38 representative for the applicant, unless the applicant's employees
39 are exempted from this requirement by the Department of Justice.

1 These exemptions may only be obtained upon the written request
2 of the applicant.

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

8 ~~SEC. 4.~~

9 *SEC. 3.* Section 11375.5 is added to the Health and Safety
10 Code, to read:

11 ~~11375.5. (a) As to the substances specified in subdivision (c),~~
12 ~~this section, but not Sections 11377, 11378, 11379, and 11380,~~
13 ~~shall apply.~~

14 ~~(b) Any person who obtains any controlled substance specified~~
15 ~~in subdivision (c)~~

16 *11375.5. (a) Any person who obtains any substance specified*
17 *in subdivision (b), unless upon the prescription of a physician,*
18 *dentist, podiatrist, or veterinarian, licensed to practice in this state,*
19 *shall be guilty of an infraction or a misdemeanor.*

20 ~~(e)~~

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

28 ~~(d)~~

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

31 ~~SEC. 5.~~

32 *SEC. 4.* 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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 484

**VERSION: ~~Introduced February 26, 2009~~
Amended 5/12/09**

AUTHOR: Wright

SPONSOR: Attorney General's Office

SUBJECT: Ephedrine and Pseudoephedrine

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 to the list of substances contained in H&S §11100 specified ephedrine substances, transactions of which are required to be reported to DOJ (CURES).

Exempts from the reporting requirement any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers or otherwise furnishes a substance to a licensed pharmacy, physician, etc., provided that records of 'suspicious sales or transfers' be reported.

Provide that any person obtaining a substance specified in H&S §11375.5(b) (i.e., material, compound, mixture, or preparation containing ephedrine, as specified) unless upon the prescription of a physician, dentist, podiatrist, or veterinarian, as specified, shall be guilty of an infraction or a misdemeanor.

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.

COMMENTS:

Previous versions of SB 484 classified specified ephedrine substances as a schedule V drug, with an anticipated significant fiscal impact to the board (inspections). Currently the law requires pharmacies, retailers, manufacturers and wholesalers to report the sales of such products to the Department of Justice. Additionally, this proposal (in H&S §11375.5(a)) specifies that any person who obtains specified substances (including ephedrine) without a prescription shall be guilty of an infraction or a misdemeanor.

The bill *may have* died in ASM Public Safety on Tuesday (6/30). Opponents to the measure have prepared an alternative (not yet in print).

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.

While the Committee did not take a position on this bill, the Board at its 4/30/09 meeting voted to support the measure.

HISTORY:

- June 15 To Com. on PUB. S.
- June 2 In Assembly. Read first time. Held at Desk.
- June 2 Read third time. Passed. (Ayes 22. Noes 10. Page 1146.) To Assembly.
- May 28 From committee: Do pass. (Ayes 7. Noes 5. Page 1072.) Read second time. To third reading.
- May 28 Joint Rule 62(a) file notice suspended. (Page 1036.) Set for hearing May 28. (Suspense - for vote only.)
- May 26 Placed on APPR suspense file.
- May 19 Set for hearing May 26.
- May 14 Set, first hearing. Hearing canceled at the request of author.
- May 12 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on APPR.
- May 8 Set for hearing May 18.
- May 5 Read second time. Amended. Re-referred to Com. on APPR.

Bill Analysis: SB 484 as Amended May 12, 2009

Page 3

- May 4 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 6. Noes 1. Page 705.)
- Apr. 13 Set for hearing April 28.
- 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.

Senate Bill No. 762

CHAPTER 16

An act to amend Section 460 of the Business and Professions Code, relating to professions and vocations.

[Approved by Governor July 2, 2009. Filed with Secretary of State July 2, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

SB 762, 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 in effect prior to January 1, 2010, as specified, or to prohibit the adoption or enforcement of a local ordinance governing zoning, business licensing, or reasonable health and safety requirements, as specified.

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

SECTION 1. Section 460 of the Business and Professions Code is amended to read:

460. (a) No city or county shall prohibit a person or group of persons, authorized by one of the agencies in the Department of Consumer Affairs by a license, certificate, or other such means to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

(b) No city, county, or city and county shall prohibit a healing arts professional licensed with the state under Division 2 (commencing with Section 500) from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee.

(1) This subdivision shall not be construed to prohibit the enforcement of a local ordinance in effect prior to January 1, 2010, related to any act or procedure that falls within the professionally recognized scope of practice of a healing arts professional licensed under Division 2 (commencing with Section 500).

(2) This subdivision shall not be construed to prevent a city, county, or city and county from adopting or enforcing any local ordinance governing zoning, business licensing, or reasonable health and safety requirements for establishments or businesses of a healing arts professional licensed under Division 2 (commencing with Section 500).

(c) Nothing in this section shall 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 purpose of covering the cost of regulation.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 762

VERSION: ~~Introduced: February 27, 2009~~
Amended May 5, 2009

AUTHOR: Aanestad

SPONSOR:

RECOMMENDED POSITION: NONE

SUBJECT: Professions and Vocations: healing arts

THIS BILL WAS ENROLLED AND TO THE GOVERNOR ON JUNE 29, 2009

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.
4. Specifies that the provisions of the bill shall not be construed to prevent a city, county, or city and county from adopting or enforcing any local ordinance governing zoning, business licensing, or reasonable health and safety requirements for establishments or businesses of a healing arts professional licensed under Division 2.

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:

The Board voted to "Support" the introduced (2/27/09) version of this measure. Following the recent (5/5) amendment, the board's Executive Officer provided the author with a letter of support on the measure.

HISTORY:

June 29 Enrolled. To Governor at 4:30 p.m.
June 25 In Senate. To enrollment.
June 25 Read third time. Passed. (Ayes 59. Noes 6. Page 2260.) To Senate.
June 17 Read second time. To third reading.
June 16 From committee: Do pass. (Ayes 9. Noes 0.) (Hearing date: June 16.)
May 28 To Com. on B. & P.
May 14 In Assembly. Read first time. Held at Desk.
May 14 Read third time. Passed. (Ayes 31. Noes 6. Page 887.) To Assembly.
May 5 Read second time. Amended. To third reading.
May 4 From committee: Do pass as amended. (Ayes 7. Noes 3. Page 676.)
Apr. 13 Set for hearing April 27.
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.

Other Legislation Introduced
Copy of bills

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 ~~(c) 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~~ *Every entity that is named*
9 *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'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.

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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.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes
Tasks:	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date. 2. Sponsor legislation to update pharmacy law. 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. 4. Secure statutory standards for pharmacies that compound medications. 5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. 6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction. 7. <u>Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</u> 8. <u>Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.</u> 9. <u>Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.</u>

<p>Objective 3.2</p>	<p>Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board’s mission.</p>
<p>Measure:</p>	<p>Percentage successful enactment of promoted regulatory changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)) 3. Make technical changes in pharmacy regulations to keep the code updated <ul style="list-style-type: none"> Section 1706.2 criteria for abandonment of files Section 1775.4 contested citations Section 1709.1 designation of pharmacist-in-charge Section 1780 standards for wholesalers Section 1780.1 standards for veterinary food animal drug retailers Section 1781 Designated Representative certificate Section 1786 Designated Representative 4. Notice of posting regarding electronic files (section 1717.2) 5. Disciplinary guidelines revision and update (section 1760) 6. Self-assessment of a wholesaler by the designated representative section (1784) 7. Exempt the address of records of interns from display on the board’s Web site (section 1727.1) 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2) 10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current. 11. Increase fees to keep the board’s contingency fund solvent and maintain operations. 12. <u>Secure regulatory standards for pharmacies that compound.</u> 13. <u>Establish an ethics course.</u>
<p>Objective 3.3</p>	<p>Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.</p>
<p>Measure:</p>	<p>Number of areas of pharmacy law reviewed</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Initiate review of the pharmacist-in-charge requirement.

**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.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<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.

	<p>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 (OSHPD) AB 1370 (Solorio) “Best Before” Date on a Prescription Label AB 1458 (Davis) Drugs: Adverse Effects Reporting SB 26 (Simitian) Home-Generated Pharmaceutical Waste SB 43 (Alquist) Cultural and Linguistic Competency SB 238 (Calderon) Medical Information SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>June 2009: AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD) SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts</p>
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- 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.
- May 2009:* Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols.
- 8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.**
- Oct. 2007:* Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
- Apr. 2008:* First public forum held in Fremont.
- May 2008:* Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.
- June 2008:* Staff attends community events, interview attendees about prescription label and distribute surveys.
- July 2008:* Staff attends community events, interview attendees about prescription label and distribute surveys.
- Oct. 2008:* Staff continues to attend community events, interview attendees about prescription label and distribute surveys.
Public Education Committee updated on the status of survey results.
- Feb. 2009:* Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.
- May 2009:* Bill passes out of the Senate
- 9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.**
- Dec. 2008:* Board receives findings of independent fee audit.
- Jan. 2009:* Board votes to pursue fee increase.
- Feb. 2009:* Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.
- June 2009:* Bill passes out of the Assembly

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="370 254 1484 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="370 359 1484 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="370 506 1484 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="370 726 1484 800">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="370 800 1484 1398">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> <i>May 2009: Regulation takes effect.</i> <li data-bbox="370 1398 1484 1472">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 1472 1484 1619">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 1619 1484 1843">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.

April 2009: Board releases second 15-day comment period.

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>