California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
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www.pharmacy.ca.gov

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

Contact Person: Virginia Herold
(916) 574-7911

NOTICE OF MEETING and AGENDA

LEGISLATION AND REGULATION COMMITTEE

Date: **April 16, 2009**
Time: **10:00 a.m. – 1:00 p.m.**
Location: **Department of Consumer Affairs Hearing Room**
1625 North Market Blvd.
Sacramento, CA 95834

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tessa Fraga at (916) 574-7912, at least five working days prior to the meeting.

Opportunities are provided to the public to address the committee on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of continuing education (CE), in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order **10:00 a.m.**

A. REGULATIONS REPORT

1. **Approved Regulations**
   Section 100 Changes
   a. Amendment of 16 CCR §1715 Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law; and related updates to Forms 17M-13 and 17M-14
   b. Amendment of 16 CCR §1784 Self Assessment of a Wholesaler by the Designated Representative-in-Charge to Update for Changes in Pharmacy Law; and related updates to Form 17M-26

2. **Board Approved Regulations – Undergoing Administrative Review**
   a. Proposed Adoption of 16 CCR §1760 – Disciplinary Guidelines
   b. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

3. **Board Approved Regulations – Previously Noticed**
   a. Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

4. **Board Approved Regulations – Awaiting Notice**
   a. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer
   b. Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality
   c. Title 16 CCR Section 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

5. **Regulations Under Development**
   a. Title 16 CCR Section 1780 – Update the USP Standards Reference Material
   b. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

B. LEGISLATIVE REPORT

1. **Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction**
   a. **SB 819** (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).
      - <u>Changes based on recodification of B&PC §4052</u>
        - §733 – Dispensing Prescription Drugs and Devices
        - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Facilities
        - §4040 – Prescription; Content Requirements
        - §4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
        - §4060 – Controlled Substance; Prescription Required; Exceptions
        - §4076 – Prescription Container; Requirements for Labeling
        - §4111 – Restrictions on Prescriber Ownership
        - §4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
        - H&SC §11150 – Persons Authorized to Write or Issue a Prescription
      - <u>General Omnibus Changes</u>
        - §4059.5 – Who may order Dangerous Drugs or Devices; Exceptions
        - §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records; Current Inventory
        - §4126.5 – Furnishing Dangerous Drugs by Pharmacy

- §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
- §4301 – Unprofessional Conduct
- H&SC §11165 – Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature

- Omnibus Changes to Allow for the Use of Mobile Pharmacies
  - §4062 – Furnishing Dangerous Drugs During an Emergency
  - §4110 – License Required; Temporary Permit Upon Transfer of Ownership
- Omnibus Changes Specific to the PIC and DRC Requirements
  - §4022.5 – Designated Representative; Designated Representative-in-Charge
  - §4161 – Non-Resident Wholesaler; Requirements
  - §4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
  - §4329 – Nonpharmacists; Prohibited Acts
  - §4330 – Proprietors; Prohibited Acts

b. **SB 820** (Senate Business, Professions & Economic Development Committee) – New Omnibus Provisions
   - §4200.3 – Exam Process; standards; development; reporting requirements
   - §4200.4 – Retaking Examinations; Set Limits; Requirements

c. **SB 821** (Senate Business, Professions & Economic Development Committee) – New Omnibus Provisions specific to PIC and DRC Requirements
   - §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board
   - §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
   - §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
   - §4160 – Wholesaler Licenses
   - §4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed or Repacked

d. **SB 470** (Corbett) – "Purpose" bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.

e. **AB 977** (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8

f. **AB 1071** (Emmerson) Pharmacy Fees. Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

2. **Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction – For Committee Consideration**
   a. **AB 418** (Emmerson) Pharmacy Technicians – Education and CE Requirements
   b. **AB 484** (Eng) Licensees not in compliance with judgment or order; enforcement; action on a license
   c. **AB 718** (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to electronically transmit data by 1/1/12

d. **AB 830** (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia recognized by the Centers of Medicare and Medicaid
e. **AB 877** (Emmerson) (*Intent language*)Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
f. **AB 931** (Fletcher) Emergency Supplies – Doses stored in an emergency supplies **container**
g. **AB 1310** (Hernandez) Specifies mandatory fields for initial and renewal application forms (various healing arts boards). Annual transmission of data to Health Care Workforce Clearinghouse (OSHPD)
h. **AB 1370** (Solorio) "Best Before" date on a prescription label
i. **SB 26** (Simitian) Home-Generated Pharmaceutical Waste
j. **SB 43** (Alquist) Cultural and Linguistic Competency
k. **SB 364** (Florez) Intent language (as introduced). Penalties on a pharmacy that fails to safeguard controlled substances, as specified.
l. **SB 389** (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
m. **SB 484** (Wright) Ephedrine Products / Schedule V
n. **SB 599** (Negrete McLeod) Requirement for DCA Boards to post to board's Internet site within 10 days each accusation, statement of issues, or disciplinary action taken by the board
o. **SB 638** (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements
p. **SB 762** (Aanestad) Professions and Vocations; Healing Arts

3. **Other Legislation Introduced (Of Interest or for Information Only)**
   a. AB 832 (Jones) Clinic Licensing
   b. AB 1094 (Conway) Disposal of Personal Information
   c. AB 1201 (Perez) – Immunizations (physician reimbursement)
   d. SB 341 (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs

C. Public Comment for Items Not On the Agenda*

*(Note: The committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment

Committee materials will be available on the board's Web site by April 10, 2009

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

To: Legislation and Regulation Committee

From: Staff

Subject: Approved Regulations

a. Amend 16 CCR §1715 – Self Assessment Forms for Community and Inpatient Pharmacies (Forms 17M-13 and 17M-14)

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PIC. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the pharmacist-in-charge occurs.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms. Board staff was recently advised that these forms were approved by the Office of Administrative Law. The revised forms are on the board's Web site. Additionally, a notice was provided in the upcoming issue of *The Script* advising readers of the change.

b. Amend 16 CCR §1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge (Form 17M-26)

Section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge (DRC) to complete this form to ensure compliance with pharmacy law. This self-assessment form is designed to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the inspection process more meaningful and provide relevant information to wholesalers and their DRC. The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the designated representative-in-charge occurs.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update this form as well. Board staff was recently advised that it was approved by the Office of Administrative Law. The revised form is on the board's Web site. Additionally, a notice was provided in the upcoming issue of *The Script* advising readers of the change.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Undergoing Administrative Review

a. Proposed Amendment to 16 CCR §1760 – Disciplinary Guidelines

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency is concerned about the optional language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. As a result the matter was referred back to the board at the January 2009 Board Meeting.

During this meeting the board considered the option to withdraw the rulemaking and begin over, or to modify the language removing the specific term and notice the modification through a 15-day comment period. At the conclusion, the board directed staff to modify the text to remove the specific term / optional language discussed above and to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period. The board further stated that if, after the 15-day public comment period, no adverse comments are received, the Executive Officer is authorized to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to 16 CCR §1760 – Disciplinary Guidelines.

This rulemaking is currently undergoing review by the Office of Administrative Law.

b. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the

proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. Board staff compiled the rulemaking and it is currently undergoing review by the department.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Previously Noticed

Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. Based on the subcommittee's recommendation, at the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the recordkeeping requirements sterile products that are compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. The board has received several comments in response to this 15-day notice period. These comments will be provided to the board for further consideration at the April 2009 Board Meeting.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

a. Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

A copy of the draft language and form is provided, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

b. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Following is a copy of the language as approved by the board.

c. Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on

Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies. At the July 2007 Board Meeting, the board voted to move this proposal.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Following is a copy of the language as approved by the board.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Under Development

a. Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell and Committee Chair Bob Graul are serving in the subcommittee and will be working with board staff and industry.

b. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a

committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

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STATE AND CONSUMER SERVICES AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: April 10, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Reintroduction of 2008 Omnibus Provisions

At the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor. These provisions are now included in SB 819 (Senate Business and Professions Committee.)

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. 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.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

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

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

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

Consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs. These changes were approved by the board and many were incorporated in SB 1779 as omnibus provisions. This bill was vetoed by the Governor. Board staff recommends that the board again consider including these changes as omnibus provisions in 2009.

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

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
  This section requires amendment to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

- Section 4036.5 – Pharmacist-in-Charge
  A new section is needed to define the term "pharmacist-in-charge" as well as the responsibilities 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.

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.

- Section 4362 – Entry Into Pharmacists Recovery Program
  This section requires amendment to specify the administrative co-pay participants pay.

- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
  This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Omnibus 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 Facililty – 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

A copy of the bill is provided in Attachment ??.

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Date: April 10, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Omnibus Provisions for 2009 – SB 820

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

A copy of this bill is provided in Attachment 4.

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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: April 10, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Omnibus Provisions for 2009 – SB 821

At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions. These provisions are contained in SB 821 (Senate Business and Professions Committee).

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.

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.

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.

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.

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

A copy of the bill is provided in Attachment 5.

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

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Sponsored by the Board of Pharmacy
Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a medicine is prescribed, with the "purpose" for which the medicine is prescribed.

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

Board staff has been working to establish a broad base of support for this proposal. The California Medical Association recently submitted a letter advising the author's office that it has taken a Support If Amended position and offered amendments. Senator Corbett's office has advised CMA that they will be accepting the amendments offered.

Attachment 6 contains a copy of the bill in its current form as well as the letter from CMA (which includes the amendments.)

Board staff will continue to advocate for this proposal and will engage with stakeholders who may have concerns.

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To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Sponsored by the Board of Pharmacy
Immunization Proposal – Amendment to Business and Professions Code Section 4052 and Section 4052.8 – AB 977 (Skinner)

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.

Attachment 7 contains a copy of the bill in its current form, the proposed amendments as well as a recent article from the Sacramento Bee that reports survey results from Families USA and a UC Study, that highlight the number of Californians that do not have health coverage.

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To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Sponsored by the Board of Pharmacy
Pharmacy Fees – AB 1071 (Emmerson)

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

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

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

Attachment 8 contains a copy of the bill.

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

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

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Several Legislative proposals were introduced this year that impact the practice of pharmacy or the board's jurisdiction. Attachment 9 contains copies of these bills as well as staff analysis. It is anticipated that several of these bills will be amended before the end of the month during committee hearings. Board staff will update the committee of any changes during the meeting.

a. AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
This bill would alter the requirements for licensure as a pharmacy technician as well as establish continuing education requirements as a condition of renewal.

b. AB 484 (Eng) Franchise Tax Board: professional or occupational licenses
This bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity. The bill would also require the Franchise Tax Board, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, as specified, to mail a preliminary notice of suspension to the licensee.

c. AB 718 (Emmerson) Prescription drugs: electronic transmissions
This bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission.

d. AB 830 (Cook) Drugs and devices
This bill would replace various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services.

e. AB 877 (Emmerson) Healing arts
This bill would declare the intent of the Legislature to enact legislation authorizing the Director of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice.

f. 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.

g. AB 1310 (Hernandez) Healing arts: database.
This bill would require specified healing arts boards to add and label as "mandatory" specified fields on an application for initial licensure or a renewal form for applicants applying to those boards and would require the board to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse annually on or before January 1.

h. AB 1370 (Solorio) Drugs and devices: labeling: expiration date: best before date.
This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device.

i. SB 26 (Simitian) Home Generated Pharmaceutical Waste
This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

i. SB 43 (Alquist) Health professions.
This bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards.

k. SB 364 (Florez) Pharmacies.
This bill would declare the intent of the Legislature to enact legislation authorizing the imposition of specified penalties on a pharmacy that fails to safeguard controlled substances.

l. SB 389 (Negrete McLeod) Professions and vocations.
The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

m. SB 484 (Wright) Ephedrine and pseudoephedrine.
This bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription.

n. SB 599 (Negrete McLeod) Licensing boards: disciplinary actions.
This bill would require every board, as defined, to post each accusation, statement of issues, or disciplinary action taken by the board on that board's Internet Web site within 10 days of the filing date of the accusation or statement of issues, or the effective date of the disciplinary action.

o. SB 638 (Negrete McLeod) Regulatory boards: operations.
This bill would redefine the sunset review process.

p. 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.

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

To: Legislation and Regulation Committee

From: Staff

Subject: Other Legislation Introduced

In addition to the legislation that board staff are tracking and submitted to the committee for consideration, there are other proposals that do not directly impact our jurisdiction but may be of interest to the board. Copies of these bills are included in Attachment 10.

AB 832 (Jones) Clinic Licensing
AB 1094 (Conway) Disposal of Personal Information
AB 1301 (Perez) Immunizations (physician reimbursement)
SB 341 (DeSaulnier) California Department of Public Health

Attachment 1

Board Approved Regulations Awaiting Notice

Title 16 CCR Sections 1721 and 1723.1
Dishonest Conduct During a Pharmacist's
Licensure Examination / Confidentiality

Board of Pharmacy
Specific Language

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

Attachment 2

Board Approved Regulations Awaiting Notice

Title 16 CCR Section 1751.9
Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Board of Pharmacy
Specific Language to Add Section 1751.9

Add Section 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
   (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
   (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
   (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
   (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
   (5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an

approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Attachment 3

SB 819
(Senate Business, Professions & Economic Development Committee)

Omnibus Provisions
(Formerly contained in the enrolled version of SB 1779 [2008], vetoed)

SENATE BILL No. 819

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

March 10, 2009

An act to amend Sections 27, 101, 128.5, 144, 146, 149, 683, 733, 800, 801, 801.01, 803, 2089.5, 2096, 2102, 2107, 2135, 2168.4, 2175, 2221, 2307, 2335, 2486, 2488, 2570.5, 2570.6, 2570.7, 2570.185, 2760.1, 3503, 3517, 3518, 3625, 3633.1, 3635, 3636, 3685, 3750.5, 3753.5, 3773, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, 4161, 4174, 4231, 4301, 4305, 4329, 4330, 4857, 4980.30, 4980.43, 4996.2, 4996.17, 4996.18, 5801, 6534, 6536, 6561, 7616, 7629, 8740, and 8746 of, to add Sections 2169, 2570.36, 4036.5, 4980.04, 4990.09, 5515.5, and 9855.15 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, 4996.21, and 6761 of, the Business and Professions Code, to amend Section 8659 of the Government Code, to amend Sections 8778.5, 11150, and 11165 of the Health and Safety Code, and to amend Section 14132.100 of the Welfare and Institutions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

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

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

Existing law requires certain boards and bureaus to disclose on the Internet information on licensees.

This bill would require the Cemetery and Funeral Bureau to disclose on the Internet information on specified licensees.

(2) Under existing law, if, upon investigation, a specified state regulatory agency has probable cause to believe that a person is advertising in a telephone directory with respect to the offering or performance of services, without being properly licensed by or registered with that agency, the agency is authorized to issue a specified citation.

This bill would add the Physical Therapy Board of California to those authorized agencies.

Existing law requires specified licensure boards to report to the State Department of Health Care Services the name and license number of a person whose license has been revoked, suspended, surrendered, made inactive, or otherwise restricted, and requires specified licensure boards to create and maintain a central file of the names of all persons who hold a license from the board, and to prescribe and promulgate written complaint forms, as specified.

This bill would also subject the California Board of Occupational Therapy to these requirements, and would subject the Acupuncture Board to the requirement to create and maintain a central file of the names of its licensees and to prescribe and promulgate written complaint forms, as specified.

Existing law requires specified healing arts licensees, insurers providing professional liability insurance to those licensees, and governmental agencies that self-insure those licensees to report settlements over $30,000 to the licensee's board if the settlement is for damages for death or personal injury caused by or is based on the licensee's alleged negligence, error, or omission in practice, or his or her rendering unauthorized professional services.

This bill would instead require that report if the settlement is based on the licensee's alleged negligence, error, or omission in practice in California or rendering unauthorized professional services in California.

(3) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. The act requires each applicant for a physician and surgeon's license to meet specified training and examinations requirements, authorizes the appointment of examination commissioners, requires that examinations be conducted in English, except as specified, allows the examinations to be conducted in specified locations, requires notice of examinations to contain certain information, and requires examination records to be kept on file for a period of 2 years or more. The act

(9) Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy.

Existing law authorizes a pharmacy to furnish dangerous drugs only to specified persons or entities, and subjects certain pharmacies and persons who violate the provision to specified fines.

This bill would provide that any violation of this provision by any person or entity would subject the person to the fine.

Existing law prohibits a person from acting as a wholesaler of any dangerous drug or device without a license from the board. Existing law requires a nonresident wholesaler, as defined, to be licensed prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

This bill would modify that definition and would also require a nonresident wholesaler to be licensed prior to selling, brokering, or distributing dangerous drugs or devices within this state. By subjecting these nonresident wholesalers to these licensure requirements which include, among other things, payment of specified fees, the bill would increase that part of the revenue in the Pharmacy Board Contingent Fund that is continuously appropriated and would thereby make an appropriation.

Existing law requires a pharmacy or pharmacist who is in charge of or manages a pharmacy to notify the board within 30 days of termination of employment of the pharmacist-in-charge or acting as manager, and provides that a violation of this provision is grounds for disciplinary action.

This bill would instead provide that failure by a pharmacist-in-charge or a pharmacy to notify the board in writing that the pharmacist-in-charge has ceased to act as pharmacist-in-charge within 30 days constitutes grounds for disciplinary action, and would also provide that the operation of the pharmacy for more than 30 days without the supervision or management by a pharmacist-in-charge constitutes grounds for disciplinary action. The bill would revise the definition of a designated representative or designated representative-in-charge, and would define a pharmacist-in-charge.

Existing law makes a nonpharmacist owner of a pharmacy who commits acts that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with the Pharmacy Law guilty of a misdemeanor.

This bill would apply this provision to any pharmacy owner.

The bill would require the board, during a declared federal, state, or local emergency, to allow for the employment of a mobile pharmacy in impacted areas under specified conditions, and would authorize the board to allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged under specified conditions. The bill would authorize the board, if a pharmacy fails to provide documentation substantiating continuing education requirements as part of a board investigation or audit, to cancel an active pharmacy license and issue an inactive pharmacy license, and would allow a pharmacy to reobtain an active pharmacy license if it meets specified requirements.

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

Existing law requires pharmacies to provide information regarding certain controlled substances prescriptions to the Department of Justice on a weekly basis.

This bill would also require a clinic to provide this information to the Department of Justice on a weekly basis.

(10) Existing law, the Veterinary Medicine Practice Act, provides for the licensure and regulation of veterinarians by the Veterinary Medical Board. Existing law prohibits the disclosure of information about an animal receiving veterinary services, the client responsible for that animal, or the veterinary care provided to an animal, except under specified circumstances, including, but not limited to, as may be required to ensure compliance with any federal, state, county, or city law or regulation.

This bill would specify that such disclosure is prohibited except as may be required to ensure compliance with the California Public Records Act.

(11) Existing law provides for the licensure and regulation of educational psychologists, clinical social workers, and marriage and family therapists by the Board of Behavioral Sciences. Existing law generally provides for a system of citations and fines that are applicable to healing arts licensees.

This bill would prohibit the board from publishing on the Internet final determinations of a citation and fine of $1,500 or less for more than 5 years from the date of issuance of the citation.

(12) Existing law, the Professional Fiduciaries Act, provides for the licensure and regulation of professional fiduciaries by the Professional Fiduciaries Bureau until July 1, 2011. Existing law also requires

~~(b)~~

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

(b) The licensee shall cooperate in providing additional information as requested by the board. If a licensee fails to provide the requested information within 30 days, the license shall become inactive until the information is received.

SEC. 46. Section 4022.5 of the Business and Professions Code is amended to read:

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

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

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

SEC. 47. Section 4027 of the Business and Professions Code is amended to read:

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

(b) As used in ~~paragraph (4) of subdivision (a) of~~ Section ~~4052~~ *4052.1*, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in ~~paragraph (5) of subdivision (a) of~~ Section ~~4052~~ *4052.2*, "health care facility" means a facility, other than a facility

licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of *Public* Health ~~Services~~ pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

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

SEC. 48. Section 4036.5 is added to the Business and Professions Code, to read:

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

SEC. 49. Section 4040 of the Business and Professions Code is amended to read:

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

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

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

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

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or

her license classification, and his or her federal registry number, if a controlled substance is prescribed.

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

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2.*

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2* by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph ~~(3)~~ *(2)* of subdivision ~~(b)~~ *(a)* of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

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

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

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

SEC. 50. Section 4051 of the Business and Professions Code is amended to read:

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

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section ~~4052~~ *4052.1, 4052.2, or 4052.3*, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

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

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

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

SEC. 51. Section 4059.5 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 52. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2*. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

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

SEC. 53. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health

and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

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

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

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

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

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

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

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

SEC. 54. Section 4076 of the Business and Professions Code is amended to read:

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

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

Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2* orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

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

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2.*

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *Section 4052.1 or 4052.2.*

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the

Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 55. Section 4081 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 56. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board

may, by regulation, determine the circumstances under which a license may be transferred.

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

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

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

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

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

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

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

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

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

SEC. 57. Section 4111 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052~~ *either Section 4052.1 or 4052.2.*

SEC. 58. Section 4126.5 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the *person or* persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

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

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

~~(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.~~

SEC. 59. Section 4161 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business

of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

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

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

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

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

SEC. 60. Section 4174 of the Business and Professions Code is amended to read:

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse

practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section ~~4052~~ *4052.1, 4052.2, or 4052.3.*

SEC. 61. Section 4231 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 62. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

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

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

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

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

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

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

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

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any

1 dangerous drug or alcoholic beverage, or any combination of those
2 substances.
3 (*l*) The conviction of a crime substantially related to the
4 qualifications, functions, and duties of a licensee under this chapter.
5 The record of conviction of a violation of Chapter 13 (commencing
6 with Section 801) of Title 21 of the United States Code regulating
7 controlled substances or of a violation of the statutes of this state
8 regulating controlled substances or dangerous drugs shall be
9 conclusive evidence of unprofessional conduct. In all other cases,
10 the record of conviction shall be conclusive evidence only of the
11 fact that the conviction occurred. The board may inquire into the
12 circumstances surrounding the commission of the crime, in order
13 to fix the degree of discipline or, in the case of a conviction not
14 involving controlled substances or dangerous drugs, to determine
15 if the conviction is of an offense substantially related to the
16 qualifications, functions, and duties of a licensee under this chapter.
17 A plea or verdict of guilty or a conviction following a plea of nolo
18 contendere is deemed to be a conviction within the meaning of
19 this provision. The board may take action when the time for appeal
20 has elapsed, or the judgment of conviction has been affirmed on
21 appeal or when an order granting probation is made suspending
22 the imposition of sentence, irrespective of a subsequent order under
23 Section 1203.4 of the Penal Code allowing the person to withdraw
24 his or her plea of guilty and to enter a plea of not guilty, or setting
25 aside the verdict of guilty, or dismissing the accusation,
26 information, or indictment.
27 (m) The cash compromise of a charge of violation of Chapter
28 13 (commencing with Section 801) of Title 21 of the United States
29 Code regulating controlled substances or of Chapter 7
30 (commencing with Section 14000) of Part 3 of Division 9 of the
31 Welfare and Institutions Code relating to the Medi-Cal program.
32 The record of the compromise is conclusive evidence of
33 unprofessional conduct.
34 (n) The revocation, suspension, or other discipline by another
35 state of a license to practice pharmacy, operate a pharmacy, or do
36 any other act for which a license is required by this chapter.
37 (o) Violating or attempting to violate, directly or indirectly, or
38 assisting in or abetting the violation of or conspiring to violate any
39 provision or term of this chapter or of the applicable federal and
40 state laws and regulations governing pharmacy, including

regulations established by the board or by any other state or federal regulatory agency.

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

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

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

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

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

SEC. 63. Section 4305 of the Business and Professions Code is amended to read:

4305. (a) ~~Any person who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.~~

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

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

~~(b)~~

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to *timely* notify the board *that the pharmacist-in-charge* of the ~~termination of employment of any pharmacist who takes charge of, or acts as manager of the~~ pharmacy *has ceased to act in that capacity*, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist *subject to the supervision and management of a responsible pharmacist-in-charge*, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

~~(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.~~

SEC. 64. Section 4329 of the Business and Professions Code is amended to read:

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

SEC. 65. Section 4330 of the Business and Professions Code is amended to read:

4330. (a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her

pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

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

SEC. 66. Section 4857 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

(6) As otherwise provided in this section.

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

(c) A veterinarian shall be subject to the criminal penalties set forth in Section 4831 or any other provision of this code for a violation of this section. In addition, any veterinarian who

Attachment 4

SB 820
(Senate Business, Professions & Economic Development Committee)

New Omnibus Provisions
§ 4200.3 and § 4200.4 – Exams

SENATE BILL No. 820

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

March 10, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

Existing law prohibits a person from holding himself or herself out to the public as a professional fiduciary without a license. Existing law specifies that a violation of certain requirements to be registered, licensed, or certified to engage in certain businesses is punishable as an infraction subject to specified procedures and fines.

This bill would make a violation of the professional fiduciary licensure requirement punishable as an infraction, thereby imposing a state-mandated local program.

Existing law, the Bagley-Keene Open Meeting Act, requires a state body, as defined, to provide prescribed notice of its meetings to any person who requests the notice in writing. Existing law provides for the licensure and regulation of accountants by the California Board of Accountancy and requires the executive officer of the board to give at least 7 days' notice of board meetings. Existing law authorizes the board to appoint an administrative committee and an advisory committee for certain purposes and requires members of the administrative committee to hold office for one year.

This bill would designate the advisory committee as the qualifications committee and would require members of that committee and the administrative committee to hold office for 2 years. The bill would require notice of each meeting of the board to be given in accordance with the Bagley-Keene Open Meeting Act.

Existing law provides for the licensure and regulation of landscape architects by the California Architects Board. Existing law requires the board to ascertain the qualifications of applicants for a license by means of written examination. Under existing law, the board may waive the written examination for a person licensed out of state, as specified, if the person has passed an equivalent examination and a supplemental examination, as specified.

This bill would also require an out-of-state licensee to submit proof of job experience equivalent to that required of California applicants in order to waive the written examination.

Existing law, the Contractors' State License Law, provides for the licensure and regulation of contractors by the Contractors' State License Board. Existing law imposes specified requirements on home improvement contracts and service and repair contracts and requires contractors to pay subcontractors within a specified period of time. Existing law makes it a misdemeanor for a person to engage in the business or act in the capacity of a contractor without a license and provides certain exemptions from that licensure requirement, including exemptions for owner-builders, as specified. Existing law authorizes the Registrar of Contractors to issue citations for violations of that licensure requirement, as specified.

This bill would make various technical, nonsubstantive changes to those provisions.

principles for establishing minimum qualifications and levels of competency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Is at least 18 years of age.

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

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

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

(3) In the case of an applicant who has completed education and training outside the United States and Canada, documented

educational training and clinical experience which meets the standards established pursuant to Sections 4939 and 4941.

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

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

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

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

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

5016. A majority of the board shall constitute a quorum for the transaction of any business at any meeting of the board ~~for which a notice of at least seven days is given by the president or executive officer. Notice of meetings may be waived in writing either before or after the meeting by unanimous consent of all members~~. *Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).* The board shall meet at the call of the president and executive officer, but not less than twice each year. Any two members of the board may request the executive officer to call a special meeting, and the executive officer, upon receiving that notice, shall call a meeting pursuant to the procedure prescribed herein.

Attachment 5

SB 821
(Senate Business, Professions & Economic Development Committee)

New Omnibus Provisions Specific to PIC and DRC Requirements

SENATE BILL No. 821

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

March 10, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would include within the definition of "licentiate" a holder of a special faculty permit to practice medicine within a medical school. Within the peer review provisions, the bill would delete obsolete diversion program references and would instead require the peer review body to report to the executive director of the Medical Board of California or a designee.

(2) Existing law provides for the licensure and regulation of speech-language pathologists and audiologists by the Speech-Language

Pathology and Audiology Board. Existing law provides that an audiology aide is any person who meets the minimum requirements of the board and who works directly under the supervision of an audiologist.

This bill would prohibit an audiology aide from performing any function that constitutes the practice of audiology unless he or she is under the supervision of an audiologist, except if the board exempts certain functions performed by an industrial audiology aide and if the employer establishes a set of procedures or protocols.

(3) The Occupational Therapy Practice Act provides for the licensure and regulation of occupational therapists and occupational therapist assistants. Existing law prohibits an occupational therapy assistant from supervising an aide engaged in client-related tasks. Existing law also defines "hand therapy" under the act to mean the art and science of rehabilitation of the hand, wrist, and forearm requiring comprehensive knowledge of the upper extremity. Existing law also provides for minimizing the risk of transmission of blood-borne infectious diseases.

This bill would authorize occupational therapy assistants to supervise aides engaged in client-related tasks, and make conforming changes. The bill would also redefine "hand therapy" by deleting the term "upper extremity" and replacing that term with "hand, wrist, and forearm." The bill would delete obsolete certification terms and replace them with licensure references. The bill would instead provide for minimizing the risk of transmission of infectious diseases.

Under the Occupational Therapy Practice Act, occupational therapists and occupational therapy assistants are subject to licensure and regulation by the California Board of Occupational Therapy, and specified licensure fees, which are deposited into the Occupational Therapy Fund.

This bill would require the board to issue retired licenses to certain occupational therapists or occupational therapy assistants, as specified, subject to a $25 fee.

Existing law requires occupational therapists to keep patient records for a minimum of 7 years. Under existing law, the board is authorized to investigate violations of the Occupational Therapy Practice Act.

This bill would authorize the board to inspect the books or records of, or require reports from, specified facilities providing occupational therapy treatment or services and its occupational therapy staff in response to a complaint that a licensee has violated any law or regulation that constitutes grounds for disciplinary action. A licensee who fails to comply with this requirement would be subject to disciplinary action.

Existing law regulates telephone medical advice services, and requires all staff who provide medical advice services to be appropriately licensed, certified, or registered professionals, as specified.

This bill would add occupational therapists to the enumerated professionals authorized to provide telephone medical advice.

Existing law imposes specified recordkeeping and disclosure requirements on health care providers, as defined.

This bill would impose those requirements on occupational therapists.

(4) Existing law provides for the licensure and regulation of vocational nurses and psychiatric technicians by the Board of Vocational Nursing and Psychiatric Technicians of the State of California. Existing law provides, upon application, for the issuance of an interim permit authorizing an applicant to practice vocational nursing or, in the case of a psychiatric technician, all skills in his or her basic course of study, pending the results of a licensing examination.

This bill would require the application for an interim permit to be submitted no later than 4 months after completion of a board-accredited program, and would limit the use of the permit to 9 months, as specified.

(5) Existing law provides for the licensure and regulation of hearing aid dispensers by the Hearing Aid Dispensers Bureau, and a person who violates that law is guilty of a misdemeanor. Existing law provides for the issuance of a temporary license to an applicant who has made application for licensure and who proves that he or she will be supervised and trained by a hearing aid dispenser, pending approval by the board. A temporary license is effective and valid for 6 months, and may be renewed twice for an additional period of 6 months.

This bill would allow for the issuance of a new temporary license if more than 3 years have lapsed from the expiration or cancellation date of a previous temporary license.

Existing law requires a person engaging in the practice of fitting or selling hearing aids to notify the bureau in writing of his or her business address or addresses or changes in that address or addresses. Existing law requires a licensee to keep and maintain his or her business records for a 7-year period.

This bill would require the written notification to be given to the bureau within a 30-day period. The bill would also require a licensee to allow his or her business records, as specified, to be inspected by the bureau upon reasonable notice. Because a violation of those provisions would be a crime, the bill would impose a state-mandated local program.

Existing law allows the bureau to impose upon licensees specified licensure fees and penalties, including a fee for a continuing education course transcript and for a license confirmation letter.

This bill would delete those transcript and letter fee provisions.

(6) The Respiratory Care Practice Act provides for the licensure and regulation of respiratory care practitioners by the Respiratory Care Board of California. The act authorizes the board to deny, suspend, or revoke the license of any applicant or licensee who has committed a specified violation, including obtaining or possessing in violation of law or, except as directed by a licensed physician and surgeon, dentist, or podiatrist, furnishing or administering to himself or herself or another a controlled substance, as defined.

This bill would clarify that the licensee is prohibited from obtaining, possessing, using, or administering to himself or herself in violation of law, or furnishing or administering to another, any controlled substance, as defined, except as directed by a licensed physician and surgeon, dentist, podiatrist, or other authorized health care provider. The bill would also subject to disciplinary action a licensee who uses alcoholic beverages to an extent that is injurious to self or others or if it impairs his or her ability to conduct with safety the practice of respiratory care. The bill would also require a renewing applicant for licensure to provide additional information requested by the board and, if the applicant fails to provide that information within 30 days of the request, his or her license would be made inactive until the information is received.

(7) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy, and makes a knowing violation of the law a misdemeanor.

On and after July 1, 2010, this bill would require any facility licensed by the board to join the board's e-mail notification list and make specified e-mail address updates. The bill would also require nonresdient pharmacies to obtain licensure from the board, and would make certain changes with regard to pharmacists-in-charge of a pharmacy, representatives-in-charge of the wholesale of any dangerous drug or device, and representatives-in-charge of veterinary food-animal drug retailers, and respective notification requirements. The bill would also allow a pharmacy to accept the return of needles and syringes from the public if contained in a sharps container, as defined. Because a knowing violation of those provisions would be a crime, the bill would impose a state-mandated local program.

(8) Existing law provides for the licensure and regulation of acupuncturists by the Acupuncture Board. Existing law provides that 5 members of the board shall constitute a quorum.

This bill would provide that 4 members, including at least one acupuncturist, shall constitute a quorum.

(9) Existing law provides for the licensure and regulation of marriage and family therapists by the Board of Behavioral Sciences, and makes a violation of the law a misdemeanor.

This bill would delete references to the employment of unlicensed interns and instead refer to marriage and family therapy interns or associate clinical social workers, and would apply specified disciplinary and probationary provisions to registered marriage and family therapy interns and associate clinical social workers. The bill would require any person that advertises services performed by a trainee, as defined, to include the trainee's name and supervisor information. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program. The bill would additionally modify the disciplinary provisions that apply to marriage and family therapists, as specified, and the licensure provisions that apply to an applicant pending investigation of a complaint.

(10) Existing law provides for the regulation of educational psychologists by the Board of Behavioral Sciences, and makes a violation of the law a misdemeanor. Existing law sets forth certain prohibited acts that subject a licensee to disciplinary action.

This bill would add to those prohibited acts provisions related to drug use, telemedicine consent, subversion of an examination, and fraudulent advertising. The bill would define the term "advertising" for purposes of those provisions.

(11) Existing law provides for the regulation of clinical social workers by the Board of Behavioral Sciences. Existing law sets forth certain prohibited acts that subject a licensee to disciplinary action.

This bill would add to those prohibited acts provisions related to the subversion of an examination and advertising. The bill would define the term "advertising" for purposes of those provisions. The bill would additionally modify the licensure provisions that apply to an applicant pending investigation of a complaint. The bill would modify provisions related to the supervision and employment of clinical social workers or associate clinical social workers.

(f) Falsified, or made grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a).

SEC. 29. Section 3773 of the Business and Professions Code is amended to read:

3773. *(a)* At the time of application for renewal of a respiratory care practitioner license, the licensee shall notify the board of all of the following:

~~(a)~~

(1) Whether he or she has been convicted of any crime subsequent to the licensee's previous renewal.

~~(b)~~

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

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

SEC. 30. Section 4013 is added to the Business and Professions Code, to read:

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

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

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

SEC. 31. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) A pharmacist ~~who takes~~ *may take* charge of~~, or acts~~ *and act* as *the* pharmacist-in-charge of a pharmacy ~~or other entity licensed by the board,~~ *upon application by the pharmacy and approval by the board. Any pharmacist-in-charge* who ~~terminates his or her employment at the pharmacy or other entity,~~ *ceases to act as the pharmacist-in-charge of the pharmacy* shall notify the board *in writing* within 30 days of the ~~termination of employment~~ *date of that change in status.*

(b) A designated ~~representative-in-charge~~ *representative or a pharmacist may take charge of, and act as, the designated representative-in-charge* of a wholesaler or veterinary food

drug-animal retailer~~, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment~~ *upon application by the wholesaler or veterinary food drug-animal retailer and approval by the board. Any designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity, shall notify the board in writing within 30 days of the date of that change in status.*

SEC. 32. Section 4112 of the Business and Professions Code is amended to read:

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

(b) ~~All nonresident pharmacies shall register with the board~~ *A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board.* The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

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

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

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices

dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

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

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

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

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

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

SEC. 33. Section 4113 of the Business and Professions Code is amended to read:

4113. (a) Every pharmacy shall ~~designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated~~ *be supervised or managed by a pharmacist-in-charge. As part of its initial application for a license, and for each renewal, each pharmacy*

shall, on a form designed by the board, provide identifying information and the California license number for a pharmacist proposed to serve as the pharmacist-in-charge. The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

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

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

(d) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent

pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

SEC. 34. Section 4146 is added to the Business and Professions Code, to read:

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

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

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

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

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

~~(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated

representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.

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

~~(e)~~

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

~~(f)~~

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

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

SEC. 36. Section 4196 of the Business and Professions Code is amended to read:

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

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

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

~~(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~

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

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

~~(e)~~

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

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

SEC. 37. Section 4510.1 of the Business and Professions Code is amended to read:

4510.1. An applicant for license by examination shall submit a written application in the form prescribed by the board. ~~After~~ *Provided that the application for licensure is received by the board no later than four months after* completion of a board accredited ~~or approved~~ psychiatric technician program and approval of the application, the board may issue an interim permit authorizing the

Attachment 6

SB 470 (Corbett)

"Purpose" – Prescription Labeling

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 introduced, Corbett. Prescriptions.

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

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

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

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

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

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

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

1 SECTION 1. Section 4040 of the Business and Professions
2 Code is amended to read:
3 4040. (a) "Prescription" means an oral, written, or electronic
4 transmission order that is both of the following:
5 (1) Given individually for the person or persons for whom
6 ordered that includes all of the following:
7 (A) The name or names and address of the patient or patients.
8 (B) The name and quantity of the drug or device prescribed and
9 the directions for use.
10 (C) The date of issue.
11 (D) Either rubber stamped, typed, or printed by hand or typeset,
12 the name, address, and telephone number of the prescriber, his or
13 her license classification, and his or her federal registry number,
14 if a controlled substance is prescribed.
15 (E) A legible, clear notice of the ~~condition~~ *purpose* for which
16 the drug is being prescribed, if requested by the patient or patients.
17 (F) If in writing, signed by the prescriber issuing the order, or
18 the certified nurse-midwife, nurse practitioner, physician assistant,
19 or naturopathic doctor who issues a drug order pursuant to Section
20 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist
21 who issues a drug order pursuant to either subparagraph (D) of
22 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph
23 (5) of, subdivision (a) of Section 4052.
24 (2) Issued by a physician, dentist, optometrist, podiatrist,
25 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,
26 if a drug order is issued pursuant to Section 2746.51, 2836.1,
27 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,
28 physician assistant, or naturopathic doctor licensed in this state,
29 or pursuant to either subparagraph (D) of paragraph (4) of, or
30 clause (iv) of subparagraph (A) of paragraph (5) of, subdivision
31 (a) of Section 4052 by a pharmacist licensed in this state.
32 (b) Notwithstanding subdivision (a), a written order of the
33 prescriber for a dangerous drug, except for any Schedule II
34 controlled substance, that contains at least the name and signature
35 of the prescriber, the name and address of the patient in a manner
36 consistent with paragraph (3) of subdivision (b) of Section 11164
37 of the Health and Safety Code, the name and quantity of the drug
38 prescribed, directions for use, and the date of issue may be treated

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

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

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

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

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

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

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

may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

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

(3) The name of the patient or patients.

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

(5) The date of issue.

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

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

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

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

(10) The ~~condition~~ *purpose* for which the drug was prescribed if requested by the patient ~~and~~ *or* the ~~condition~~ *purpose* is indicated on the prescription.

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

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

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

1 the Government Code, or changes the definition of a crime within
2 the meaning of Section 6 of Article XIII B of the California
3 Constitution.

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California Medical Association
Physicians dedicated to the health of Californians

April 6, 2009

The Honorable Ellen Corbett
State Capitol, Room 5108
Sacramento, CA 95814

Re: SB 470 (Corbett)
CMA Position: Support if Amended

Dear Senator Corbett,

The California Medical Association has taken a Support if Amended position on your Senate Bill 470. The bill, as drafted, changes the information that would be printed on a prescription container label and how that information is determined. The CMA appreciates the need for this bill and hopes that, with the suggested amendments, patients will receive the information they desire on container labels.

Current law requires a pharmacist to place the condition on the container label if it was written on the prescription label by an authorized prescriber. This bill replaces "condition" with the term "purpose." The CMA would request that the bill be amended to include both. Specifically, on page 2 line 15 the CMA would request the bill be amended to read:

> "A legible, clear notice of the condition or purpose for which the drug is being prescribed."

The CMA believes this will give greater flexibility to prescribers to meet the needs of their patients. Because patients can be required to take many drugs, allowing the patient and physician to develop and place the most useful information on the container label will reduce the number of medication errors.

On page 4 beginning on line 24, the CMA would like to request amendments to reflect the changes detailed above. In addition, this section should be clarified to ensure that the prescriber who writes the prescription determines what is printed on the label. By changing the word "and" to "or", the bill leaves vague who would determine what the condition or purpose for the prescription is.

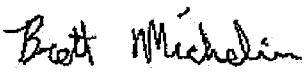
In order to prevent confusion, the bill should be amended so that if the condition or purpose is to be placed on the container label it is specified by the prescriber. A particular drug may be prescribed for different conditions or purposes and confusion leading to medication error may result if anyone other than the prescriber is allowed to determine what is placed on the container label. The CMA would suggest that this section read:

> "The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. If the patient requests the condition or purpose on the container label but it is not included on the prescription, the pharmacist may include this

information only after consulting with the prescriber. The consultation may be oral or electronic."

Senator Corbett, the CMA believes, with these amendments, your bill will reduce the number of medication errors. Thank you for your consideration of these amendment requests. Should you have any questions please feel free to contact me at (916) 444-5532.

Sincerely,



Brett Michelin

Cc: Members, Senate Business and Professions Committee
Sieglinde Johnson, Senate Business and Professions Committee Consultant
Amber Throne, Senate Republican Caucus Consultant

Attachment 7

AB 977 (Skinner)

Pharmacists: Immunization Administration

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 introduced, Skinner. Pharmacists: immunization administration.

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

This bill would authorize a pharmacist to initiate and administer immunizations pursuant to a protocol with a prescriber or the recommended Immunization Schedules provided by the federal Centers for Disease Control and Prevention. The bill would require a pharmacist, prior to initiating and administering immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require the 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 to maintain a specified immunization administration record, report any adverse event

and administer epinephrine for severe allergic reactions, and assure proper storage and handling of vaccines.

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

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

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

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

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

1 SECTION 1. Section 4052 of the Business and Professions
2 Code is amended to read:
3 4052. (a) Notwithstanding any other provision of law, a
4 pharmacist may:
5 (1) Furnish a reasonable quantity of compounded drug product
6 to a prescriber for office use by the prescriber.
7 (2) Transmit a valid prescription to another pharmacist.
8 (3) Administer, orally or topically, drugs and biologicals
9 pursuant to a prescriber's order.
10 (4) Perform procedures or functions in a licensed health care
11 facility as authorized by Section 4052.1.
12 (5) Perform procedures or functions as part of the care provided
13 by a health care facility, a licensed home health agency, a licensed
14 clinic in which there is a physician oversight, a provider who
15 contracts with a licensed health care service plan with regard to
16 the care or services provided to the enrollees of that health care
17 service plan, or a physician, as authorized by Section 4052.2.
18 (6) Manufacture, measure, fit to the patient, or sell and repair
19 dangerous devices or furnish instructions to the patient or the
20 patient's representative concerning the use of those devices.
21 (7) Provide consultation to patients and professional information,
22 including clinical or pharmacological information, advice, or
23 consultation to other health care professionals.
24 (8) Furnish emergency contraception drug therapy as authorized
25 by Section 4052.3.

(9) ~~Administer~~ *Initiate and administer* immunizations pursuant to ~~a protocol with a prescriber~~ *Section 4052.8*.

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

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

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

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

4052.8. (a) A pharmacist may initiate and administer immunizations pursuant to either of the following:

(1) A protocol with a prescriber.

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

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

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

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

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

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

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

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

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

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

(1) Ten years from the date of administration.

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

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

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

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

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

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

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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 introduced, Skinner. Pharmacists: immunization administration.

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

This bill would authorize a pharmacist to initiate and administer pursuant to a protocol with a prescriber or the recommended Immunization Schedules provided by the federal Centers for Disease Control and Prevention. The bill would require a pharmacist, prior to initiating and administering immunizations, to complete a specified pharmacy-based immunization delivery training program. The bill would also require a pharmacist to complete 3 hours of immunization-related continuing education coursework annually and to be certified in basic life support. The bill would require the 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 to maintain a specified immunization administration record, report any adverse event and administer epinephrine for severe allergic reactions, and assure proper storage and handling of vaccines.

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

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

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

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

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

SECTION 1. *The Legislature hereby finds and declares all of the following:*

(a) Vaccines are a safe, effective and efficient way to prevent sickness and death from infectious diseases as reported by the U.S. Department of Health and Human Services.

(b)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.

(c)The CDC reports that 220 million persons should get the influenza vaccination annually, however fewer than 100 million do.

(d) According to the California Healthcare Foundation, 6.6 million Californians are uninsured and may not have alternate access to immunizations.

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

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

Changes made to legislative text, as introduced, are indicated. Deleted text is indicated by double strike-through, thus: ~~deleted text~~. Added text is indicated by double underline, thus: added text.

(g) Therefore, in order to achieve greater access to immunization and to protect Californians, it is the intent of the legislature to provide greater access to life saving vaccinations and to ensure that pharmacists can independently administer influenza and pneumoccal vaccinations.

SECTION 2. Section 4052 of the Business and Professions Code is amended to read:

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

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

(2) Transmit a valid prescription to another pharmacist.

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

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

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

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

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

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

(9) ~~Administer~~ *Initiate and administer* immunizations pursuant ~~to a protocol with a prescriber~~ *Section 4052.8.*

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

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

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

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

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

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

(2) ~~The recommended Immunization Schedules for persons aged 7 through 18 years of age and adults provided by the federal Centers for Disease Control and Prevention, as they may be amended from time to time.~~ Initiate and administer influenza and or pneumoccal immunizations to any person seven years of age or older.

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

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

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

also complete the three hours of immunization-related continuing education coursework described in paragraph (1) prior to initiating and administering any further immunizations.
(3) The three hours of immunization-related continuing education may be applied toward the continuing education requirement described in Section 4231.
(d) A pharmacist initiating and administering any immunization pursuant to this section shall at all times be certified in basic life support.
(e) For any patient under 18 years of age, a pharmacist shall obtain the consent of a parent or the patient's guardian before administration.
(f) At the time of administration of an immunization, the pharmacist shall do ~~both of~~ the following:
(1) Provide the patient or the patient's agent with the appropriate Vaccine Information Statement, produced by the Centers for Disease Control and Prevention, for each immunization administered.
(2) Provide documentation of administration of the immunization to the patient and the patient's physician or primary care provider, if one can be identified.
(3) Provide documentation of administration of the immunization to the California Immunization Registry (CAIR).
(~~f~~ g) The pharmacist shall maintain an immunization administration record, which shall include, but not be limited to, the name of the vaccine, the expiration date, the date of administration, the manufacturer and lot number, the administration site and route, the Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:
(1) Ten years from the date of administration.
(2) If the patient is younger than 18 years of age at the time of administration, three years beyond the patient's 18th birthday.
(~~g~~ h) Any pharmacist initiating and administering vaccines may initiate and administer epinephrine by injection for severe allergic reactions.
(~~h~~ i) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.
(~~i~~ j) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible for assuring that proper vaccine temperatures are maintained during subsequent storage and handling to preserve the potency of the vaccine.

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

Changes made to legislative text, as introduced, are indicated. Deleted text is indicated by double strike-through, thus: ~~deleted text~~. Added text is indicated by double underline, thus: added text.

THE SACRAMENTO BEE sacbee.com

This story is taken from Sacbee / Our Region / Top Stories

Many employed Californians go without health insurance

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Lynda and Bill Jackson had been unemployed for a year, bills stacking up and their life savings dwindling, when the envelope with grim news arrived.

In a blink of an eye, their health insurance was gone. The Jacksons joined the growing ranks of Americans without medical coverage.

At some point during the past two years, newly released studies show that more than one in every three Californians under 65 went without health insurance for at least a month, and researchers say there may be no recovery in sight, even when the recession lifts.

The Obama administration says health care reform is a top priority. Business groups, health care advocates and politicians seem to agree.

But with billions of dollars at stake and the issue steeped in politics, it's anybody's guess what kind of change will unfold in the coming months. On Monday in Los Angeles, the White House will hold the last of its five regional forums on health care overhaul.

The severe economic slump has cost millions of jobs. As a result, health coverage is "declining precipitously," according to a study conducted by the Center for Labor Research and Education at the University of California, Berkeley.

Since the start of the recession, according to the UC study, an estimated 3.7 million working-age adults nationwide have lost health coverage – about 500,000 in California. By 2012 that will likely swell to 600,000.

"The longer the recession lasts, the greater the likelihood it will result in deeper economic shifts that could shape employer-based health coverage in years to come," the study said.

To help weather the downturn, more employers are asking workers to carry a heavier share of health premiums. A growing number of companies, particularly smaller businesses, are eliminating health insurance coverage altogether.

"Even if the economy recovers, the coverage rates for working age adults won't return to

pre-recession levels," said Ken Jacobs, co-author of the UC study.

On Thursday, Families USA, a Washington-based health care advocacy group, released a survey showing that 37.4 percent of Californians under 65 went without health insurance for at least one month in 2007 and 2008 – with three-fourths of that group doing without coverage for at least six months.

The U.S. Census Bureau estimates that 45.7 million Americans went uninsured in 2007 for the entire year. The government's estimate does not include those who temporarily went without health coverage, like the Jacksons.

According to Families USA, 80.2 percent of the 12.1 million uninsured Californians are employed but are in jobs that do not provide health coverage.

"For those people, they simply can't afford to get health coverage on their own," said Ron Pollack, executive director of Families USA.

The Jacksons' troubles began two years ago after they lost their jobs with a local manufacturer.

For a time, the Jacksons paid $648 a month for a health insurance plan offered by their former employer.

When that plan was suddenly canceled, the couple were on their own. They spent five months quarreling with the company to get their health insurance restored. It was – but the couple now pays $2,251 every two months for the insurance.

"We're just struggling to make things work, living on the money we saved for the future. We figure it'll all be gone in a year," Lynda Jackson said. "Maybe we'll have to go without health insurance. We just can't continue like this."

Call The Bee's Bobby Caina Calvan, (916) 321-1067.

Attachment 8

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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(r) ~~The board shall charge a fee for the processing and issuance of a license to a pharmacy technician and a separate fee for the biennial renewal of the license. The license fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).~~*The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).*

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

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

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

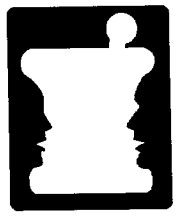
(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven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

O

Attachment 9

Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 418 **VERSION: As Introduced**

AUTHOR: Emmerson **SPONSOR: California Society of Health-System Pharmacists**

BOARD POSITION:

SUBJECT: **Pharmacy technicians**

EXISTING LAW:

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

THIS BILL WOULD:

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

AUTHOR'S INTENT:

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

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

FISCAL IMPACT:
The board anticipates the addition of one staff person to audit continuing education and issue citations and fines for violations as well as process workload associated with the inactivation and reactivation of pharmacy technician licenses.

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

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

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

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

Also, from an implementation standpoint, pharmacy technician licenses are automatically cancelled after 90 days for when a licensee fails to renew their license. This proposal would instead allow a pharmacy technician license to remain delinquent for up to three years before the board could cancel such a license, increasing administrative duties on board staff.

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

This bill was originally scheduled to be heard in Assembly B&P Committee on March 31, 2009, however the hearing was postponed until April 14. According to the sponsor, amendments are

being drafted to scale back the scope of the proposal. Committee hearing is scheduled for April 14, 2009.

SUPPORT and OPPOSITION:

Support

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

Oppose

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

HISTORY:

Mar. 31	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 9	Referred to Com. on B. & P.
Feb. 24	From printer. May be heard in committee March 26.
Feb. 23	Read first time. To print.

ASSEMBLY BILL No. 418

Introduced by Assembly Member Emmerson

February 23, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would instead, on and after January 1, 2011, authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent, passes a pharmacy technician examination recognized by the National Organization for Competency

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

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

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

1 SECTION 1. This act shall be known, and may be cited, as the
2 California Pharmacy Technician Patient Safety and Protection Act.
3 SEC. 2. Section 4202 of the Business and Professions Code is
4 amended to read:
5 4202. (a) The board may issue a pharmacy technician license
6 to an individual if he or she is a high school graduate or possesses
7 a general educational development certificate equivalent, and meets
8 any one of the following requirements:
9 (1) Has obtained an associate's degree in pharmacy technology.
10 (2) Has completed a course of training specified by the board.
11 (3) Has graduated from a school of pharmacy recognized by
12 the board.
13 (4) Is certified by the Pharmacy Technician Certification Board.
14 (b) The board shall adopt regulations pursuant to this section
15 for the licensure of pharmacy technicians and for the specification
16 of training courses as set out in paragraph (2) of subdivision (a).
17 Proof of the qualifications of any applicant for licensure as a
18 pharmacy technician shall be made to the satisfaction of the board
19 and shall be substantiated by any evidence required by the board.
20 (c) The board shall conduct a criminal background check of the
21 applicant to determine if an applicant has committed acts that
22 would constitute grounds for denial of licensure, pursuant to this
23 chapter or Chapter 2 (commencing with Section 480) of Division
24 1.5.

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

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

(F) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

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

4202. (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, passes a pharmacy technician examination recognized by the National Organization for Competency Assurance and approved by the board, and meets any one of the following requirements:

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

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

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

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

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

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians. Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

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

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

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

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

(g) This section shall become operative on January 1, 2011.

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

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

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

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

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

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

(b) The subject matter of the courses may be pertinent to the socioeconomic and legal aspects of health care, the properties and

actions of drugs and dosage forms, and the etiology, characteristics, and therapeutics of the disease state.

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

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

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

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

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

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

4410. Any pharmacy technician license that is not renewed within three years following its expiration may not be renewed and shall be canceled by operation of law at the end of the three-year period.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 484 **VERSION: As Amended: April 2, 2009**

AUTHOR: Eng **SPONSOR: Franchise Tax Board**

BOARD POSITION: None

SUBJECT: Franchise Tax Board: professional or occupational licenses

EXISTING LAW:

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

THIS BILL WOULD:

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

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

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

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

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

SUPPORT/OPPOSITION:
None of file.

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

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 484

Introduced by Assembly Member Eng

February 24, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

This bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity. The bill would require the

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 3. Section 19265 is added to the Revenue and Taxation Code, to read:

19265. (a) (1) ~~All state~~ *(A) State* governmental licensing ~~entities issuing professional or occupational licenses, certificates, registrations, or permits~~ *entities, as defined in paragraph (4) of subdivision (e),* shall provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number, as applicable, of each licensee of that state governmental licensing entity.

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

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

(3) If any licensee subject to paragraph (2) fails to pay the unpaid taxes or to enter into an installment payment agreement, as described in Section 19008, to satisfy the unpaid taxes prior to the date certain ~~listed~~ *provided* in the preliminary notice of suspension, his or her license shall be automatically suspended by operation of this section, except as provided in subdivision (b), and the Franchise Tax Board shall ~~mail~~ *provide* a notice of suspension to the applicable state governmental licensing entity and *shall mail a notice of suspension* to the licensee. The rights, powers, and

privileges of any licensee whose ~~professional or occupational license, certificate, registration, or permit~~ *license* has been suspended pursuant to this section shall be subject to the same prohibitions, limitations, and restrictions as if the ~~professional or occupational license, certificate, registration, or permit~~ *license* were suspended by the state governmental licensing entity that issued ~~the professional or occupational license, certificate, registration, or permit.~~ *the license.*

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

~~(5) State governmental licensing entities shall provide to the Franchise Tax Board the information required by this subdivision at a time that the Franchise Tax Board may require.~~

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

(b) (1) The Franchise Tax Board may defer or cancel any suspension authorized by this section if a licensee would experience financial hardship. The Franchise Tax Board shall, if requested by the licensee in writing, provide for an administrative hearing to determine if the licensee ~~will~~ *would* experience financial hardship from the suspension of ~~the license, certificate, registration, or permit~~ *his or her license.*

(2) The request for a hearing specified in paragraph (1) shall be made in writing within ~~60~~ *30* days from the mailing date of the preliminary notice described in subdivision (a).

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

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

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

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

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

~~(c)~~

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

(1) "Financial hardship" means financial hardship within the meaning of Section 19008, as determined by the Franchise Tax Board, where suspension of a license will result in the licensee being financially unable to pay any part of the amount described in subdivision (a) and the licensee is unable to qualify for an installment payment arrangement as provided for by Section 19008. In order to establish the existence of a financial hardship, the licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the Franchise Tax Board for the purpose of making that determination.

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

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

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420 of the Business and Professions Code, the office of the Attorney General, the Department of Insurance, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues ~~a license, certificate, or registration~~ *license* authorizing an individual to engage in a profession or occupation. "State governmental licensing entity" shall not include the Department of Motor Vehicles.

~~(d)~~

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

SEC. 4. Section 19571 is added to the Revenue and Taxation Code, to read:

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

(b) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any

information obtained from the Franchise Tax Board, pursuant to this section, except to inform the public of the suspension of a license pursuant to Section 19265.

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

SEC. 5. The Legislature hereby finds and declares the following:

(a) It is the intent of the Legislature that, consistent with the decision in Gallo v. United States District Court (9th Cir. 2003) 349 F.3d 1169, cert. den. (2004) 541 U.S. 1073, the suspension of a professional or occupational license pursuant to this act for failure to pay delinquent taxes is a legislative act, for which due process is satisfied by the legislative notice and hearing procedures.

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 718 **VERSION: Introduced: February 26, 2009**

AUTHOR: Emmerson **SPONSOR: Reed Elsevier, Inc.**

BOARD POSITION: None

SUBJECT: Prescription Drugs: Electronic Transmission

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

THIS BILL WOULD:
Require, on or before January 1, 2012, every licensed presciber, prescriber's agent, or pharmacy operating in California shall have the ability to transmit and receive prescriptions by electronic data transmission.

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

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

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

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

SUPPORT/OPPOSITION:
None on file.

HISTORY:

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.

ASSEMBLY BILL No. 718

Introduced by Assembly Member Emmerson

February 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

AB 718, as introduced, Emmerson. Prescription drugs: electronic transmissions.

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

This bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission. Because a knowing violation of that provision would constitute a crime under the Pharmacy Law, the bill would impose a state-mandated local program.

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

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

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 4071.2 is added to the Business and
2 Professions Code, to read:
3 4071.2. On or before January 1, 2012, every licensed prescriber,
4 prescriber's authorized agent, or pharmacy operating in California
5 shall have the ability to transmit and receive prescriptions by
6 electronic data transmission.
7 SEC. 2. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the penalty
12 for a crime or infraction, within the meaning of Section 17556 of
13 the Government Code, or changes the definition of a crime within
14 the meaning of Section 6 of Article XIII B of the California
15 Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 830 **VERSION: As Amended: April 1, 2009**

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

BOARD POSITION:

SUBJECT: Drugs and Devices

EXISTING LAW:

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

THIS BILL WOULD:

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

AUTHOR'S INTENT:

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

FISCAL IMPACT:

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

COMMENTS:

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

HISTORY:

Apr. 2	Re-referred to Com. on HEALTH.
Apr. 1	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 23	Referred to Com. on HEALTH.
Feb. 27	From printer. May be heard in committee March 29.
Feb. 26	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 1, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 830

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

February 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

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

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

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

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

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

This bill would replace the above drug compendia with any compendia approved by the federal Centers for Medicare and Medicaid Services. By changing the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 13 of the Business and Professions Code
2 is amended to read:
3 13. The term "materia medica" as used in this code or in any
4 initiative act referred to in this code, means those substances listed
5 ~~in the official United States Pharmacopoeia, the official~~
6 ~~Homeopathic Pharmacopoeia of the United States, the official~~
7 ~~United States Dispensatory, New and Nonofficial Remedies, or~~
8 ~~the National Formulary, any supplement thereof, or any other~~
9 ~~similar drug compendium, as determined annually by the State~~
10 ~~Department of Health Care Services on the basis of factors,~~
11 ~~including, but not limited to, the breadth of listings, use of~~
12 ~~prespecified published criteria for weighing evidence, and inclusion~~
13 ~~on a list of compendia~~ *in a compendia or supplement thereof*
14 approved by the federal Centers for Medicare and Medicaid
15 Services, except substances covered by subdivision (a) of Section
16 4052 and Section 4057.
17 SEC. 2. Section 4025 of the Business and Professions Code is
18 amended to read:
19 4025. "Drug" means any of the following:
20 (a) Articles recognized in ~~the official United States~~
21 ~~Pharmacopoeia, official National Formulary or official~~
22 ~~Homeopathic Pharmacopoeia of the United States, any supplement~~
23 ~~of any of them, or any other similar drug compendium, as~~

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

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

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

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

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

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

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

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The drug is approved by the FDA.

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

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

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

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

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

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

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

~~(D)~~

1 *(B)* Two articles from major peer reviewed medical journals
2 that present data supporting the proposed off-label use or uses as
3 generally safe and effective unless there is clear and convincing
4 contradictory evidence presented in a major peer reviewed medical
5 journal.
6 (b) It shall be the responsibility of the participating prescriber
7 to submit to the plan documentation supporting compliance with
8 the requirements of subdivision (a), if requested by the plan.
9 (c) Any coverage required by this section shall also include
10 medically necessary services associated with the administration
11 of a drug, subject to the conditions of the contract.
12 (d) For purposes of this section, "life-threatening" means either
13 or both of the following:
14 (1) Diseases or conditions where the likelihood of death is high
15 unless the course of the disease is interrupted.
16 (2) Diseases or conditions with potentially fatal outcomes, where
17 the end point of clinical intervention is survival.
18 (e) For purposes of this section, "chronic and seriously
19 debilitating" means diseases or conditions that require ongoing
20 treatment to maintain remission or prevent deterioration and cause
21 significant long-term morbidity.
22 (f) The provision of drugs and services when required by this
23 section shall not, in itself, give rise to liability on the part of the
24 plan.
25 (g) Nothing in this section shall be construed to prohibit the use
26 of a formulary, copayment, technology assessment panel, or similar
27 mechanism as a means for appropriately controlling the utilization
28 of a drug that is prescribed for a use that is different from the use
29 for which that drug has been approved for marketing by the FDA.
30 (h) If a plan denies coverage pursuant to this section on the basis
31 that its use is experimental or investigational, that decision is
32 subject to review under Section 1370.4.
33 (i) Health care service plan contracts for the delivery of
34 Medi-Cal services under the Waxman-Duffy Prepaid Health Plan
35 Act (Chapter 8 (commencing with Section 14200) of Part 3 of
36 Division 9 of the Welfare and Institutions Code) are exempt from
37 the requirements of this section.
38 SEC. 6. Section 1370.4 of the Health and Safety Code is
39 amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

111235. Whenever a drug is recognized in both ~~the United States Pharmacopoeia~~ *a compendia approved by the federal Centers for Medicare and Medicaid Services* and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the ~~United States Pharmacopoeia~~ *approved compendia* unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, it shall be subject to the ~~provisions of the~~ Homeopathic Pharmacopoeia of the United States and not to those of the ~~United States Pharmacopoeia~~ *approved compendia.*

~~SEC. 10.~~

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

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

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

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

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

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

(5) The department shall not issue an exemptee a license until the applicant provides proof of completion of the required training that the department determines is adequate to fulfill these requirements.

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

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

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

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

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

~~SEC. 11.~~

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

150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

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

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

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

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

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

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

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this

division. Medication donated to the repository and distribution program shall meet all of the following criteria:

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

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by ~~the United States Pharmacopoeia (USP) or in any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia~~ *a compendia* approved by the federal Centers for Medicare and Medicaid Services or the product manufacturer.

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

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet ~~standards in the USP or in any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved~~ *standards in a compendia approved* by the federal Centers for Medicare and Medicaid Services is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

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

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

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

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

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

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

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

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

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

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with ~~DrugPoint standards~~ *standards in a compendia approved by the federal Centers for Medicare and Medicaid Services* and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as

it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

~~SEC. 12.~~

SEC. 14. Section 10123.195 of the Insurance Code is amended to read:

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

(1) The drug is approved by the FDA.

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

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

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

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

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

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

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

~~(D)~~

1 *(B)* Two articles from major peer reviewed medical journals
2 that present data supporting the proposed off-label use or uses as
3 generally safe and effective unless there is clear and convincing
4 contradictory evidence presented in a major peer reviewed medical
5 journal.
6 (b) It shall be the responsibility of the contracting prescriber to
7 submit to the insurer documentation supporting compliance with
8 the requirements of subdivision (a), if requested by the insurer.
9 (c) Any coverage required by this section shall also include
10 medically necessary services associated with the administration
11 of a drug subject to the conditions of the contract.
12 (d) For purposes of this section, "life-threatening" means either
13 or both of the following:
14 (1) Diseases or conditions where the likelihood of death is high
15 unless the course of the disease is interrupted.
16 (2) Diseases or conditions with potentially fatal outcomes, where
17 the end point of clinical intervention is survival.
18 (e) For purposes of this section, "chronic and seriously
19 debilitating" means diseases or conditions that require ongoing
20 treatment to maintain remission or prevent deterioration and cause
21 significant long-term morbidity.
22 (f) The provision of drugs and services when required by this
23 section shall not, in itself, give rise to liability on the part of the
24 insurer.
25 (g) This section shall not apply to a policy of disability insurance
26 that covers hospital, medical, or surgical expenses which is issued
27 outside of California to an employer whose principal place of
28 business is located outside of California.
29 (h) Nothing in this section shall be construed to prohibit the use
30 of a formulary, copayment, technology assessment panel, or similar
31 mechanism as a means for appropriately controlling the utilization
32 of a drug that is prescribed for a use that is different from the use
33 for which that drug has been approved for marketing by the FDA.
34 (i) If an insurer denies coverage pursuant to this section on the
35 basis that its use is experimental or investigational, that decision
36 is subject to review under the Independent Medical Review System
37 of Article 3.5 (commencing with Section 10169).
38 (j) This section is not applicable to vision-only, dental-only,
39 Medicare or Champus supplement, disability income, long-term

1 care, accident-only, specified disease or hospital confinement
2 indemnity insurance.
3 ~~SEC. 13.~~
4 *SEC. 15.* Section 10145.3 of the Insurance Code is amended
5 to read:
6 10145.3. (a) Every disability insurer that covers hospital,
7 medical, or surgical benefits shall provide an external, independent
8 review process to examine the insurer's coverage decisions
9 regarding experimental or investigational therapies for individual
10 insureds who meet all of the following criteria:
11 (1) (A) The insured has a life-threatening or seriously
12 debilitating condition.
13 (B) For purposes of this section, "life-threatening" means either
14 or both of the following:
15 (i) Diseases or conditions where the likelihood of death is high
16 unless the course of the disease is interrupted.
17 (ii) Diseases or conditions with potentially fatal outcomes, where
18 the end point of clinical intervention is survival.
19 (C) For purposes of this section, "seriously debilitating" means
20 diseases or conditions that cause major irreversible morbidity.
21 (2) The insured's physician certifies that the insured has a
22 condition, as defined in paragraph (1), for which standard therapies
23 have not been effective in improving the condition of the insured,
24 for which standard therapies would not be medically appropriate
25 for the insured, or for which there is no more beneficial standard
26 therapy covered by the insurer than the therapy proposed pursuant
27 to paragraph (3).
28 (3) Either (A) the insured's contracting physician has
29 recommended a drug, device, procedure, or other therapy that the
30 physician certifies in writing is likely to be more beneficial to the
31 insured than any available standard therapies, or (B) the insured,
32 or the insured's physician who is a licensed, board-certified or
33 board-eligible physician qualified to practice in the area of practice
34 appropriate to treat the insured's condition, has requested a therapy
35 that, based on two documents from the medical and scientific
36 evidence, as defined in subdivision (d), is likely to be more
37 beneficial for the insured than any available standard therapy. The
38 physician certification pursuant to this subdivision shall include a
39 statement of the evidence relied upon by the physician in certifying
40 his or her recommendation. Nothing in this subdivision shall be

1 construed to require the insurer to pay for the services of a
2 noncontracting physician, provided pursuant to this subdivision,
3 that are not otherwise covered pursuant to the contract.
4 (4) The insured has been denied coverage by the insurer for a
5 drug, device, procedure, or other therapy recommended or
6 requested pursuant to paragraph (3), unless coverage for the
7 specific therapy has been excluded by the insurer's contract.
8 (5) The specific drug, device, procedure, or other therapy
9 recommended pursuant to paragraph (3) would be a covered service
10 except for the insurer's determination that the therapy is
11 experimental or under investigation.
12 (b) The insurer's decision to deny, delay, or modify experimental
13 or investigational therapies shall be subject to the independent
14 medical review process established under Article 3.5 (commencing
15 with Section 10169) of Chapter 1 of Part 2 of Division 2, except
16 that in lieu of the information specified in subdivision (b) of
17 Section 10169.3, an independent medical reviewer shall base his
18 or her determination on relevant medical and scientific evidence,
19 including, but not limited to, the medical and scientific evidence
20 defined in subdivision (d).
21 (c) The independent medical review process shall also meet the
22 following criteria:
23 (1) The insurer shall notify eligible insureds in writing of the
24 opportunity to request the external independent review within five
25 business days of the decision to deny coverage.
26 (2) If the insured's physician determines that the proposed
27 therapy would be significantly less effective if not promptly
28 initiated, the analyses and recommendations of the experts on the
29 panel shall be rendered within seven days of the request for
30 expedited review. At the request of the expert, the deadline shall
31 be extended by up to three days for a delay in providing the
32 documents required. The timeframes specified in this paragraph
33 shall be in addition to any otherwise applicable timeframes
34 contained in subdivision (c) of Section 10169.3.
35 (3) Each expert's analysis and recommendation shall be in
36 written form and state the reasons the requested therapy is or is
37 not likely to be more beneficial for the insured than any available
38 standard therapy, and the reasons that the expert recommends that
39 the therapy should or should not be covered by the insurer, citing
40 the insured's specific medical condition, the relevant documents,

and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

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

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

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

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

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

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

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

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National

Institutes of Health for the purpose of evaluating the medical value of health services.

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

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

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

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

(a) In case of drugs: (1) if, when sold under or by a name recognized in ~~the United States Pharmacopoeia~~ *a compendia approved by the federal Centers of Medicare and Medicaid Services*, it differs materially from the standard of strength, quality, or purity laid down therein; (2) if, when sold under or by a name not recognized in ~~the United States Pharmacopoeia~~ *a compendia approved by the federal Centers of Medicare and Medicaid Services*, but which is found in some other pharmacopoeia or other standard work on materia medica, it differs materially from the standard of strength, quality, or purity laid down in such work; (3) if its strength, quality, or purity falls below the professed standard under which it is sold.

(b) In the case of food: (1) if any substance or substances have been mixed with it, so as to lower or depreciate, or injuriously affect its quality, strength, or purity; (2) if any inferior or cheaper substance or substances have been substituted wholly or in part for it; (3) if any valuable or necessary constituent or ingredient

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

~~SEC. 14.~~

SEC. 17. Section 47121 of the Public Resources Code is amended to read:

47121. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual purchaser or owner of a drug. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.

(b) "Drug" means any of the following:

~~(1) Articles recognized in the official United States Pharmacopoeia, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, any supplement of the formulary or those pharmacopoeias, or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers for~~

(1) Articles recognized in a compendia or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.

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

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

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

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

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

~~SEC. 15.~~

SEC. 18. Section 14105.43 of the Welfare and Institutions Code is amended to read:

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

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

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

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

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

~~(I) The American Medical Association Drug Evaluations.~~

~~(II) The United States Pharmacopoeia Dispensing Information or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers~~

(I) A compendia approved by the federal Centers for Medicare and Medicaid Services.

~~(III)~~

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

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

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

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

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

~~SEC. 16.~~

SEC. 19. Section 14133.2 of the Welfare and Institutions Code is amended to read:

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

(b) In addition to any drug added to the list of contract drugs pursuant to subdivision (a), any drug that meets either of the following criteria and for which the manufacturer has executed a

contract with the Health Care Financing Administration that provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code, shall be a Medi-Cal benefit, subject to utilization controls, unless the contract requirements of Section 14105.33 have been complied with:

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

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

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

~~(B) The United States Pharmacopoeia Dispensing Information or any other similar drug compendium, as determined annually by the State Department of Health Care Services on the basis of factors, including, but not limited to, the breadth of listings, use of prespecified published criteria for weighing evidence, and inclusion on a list of compendia approved by the federal Centers~~

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

~~(C)~~

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

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 877 **VERSION: Introduced: February 26, 2009**

AUTHOR: Emmerson **SPONSOR: Author Sponsored**

BOARD POSITION: None

SUBJECT: Healing Arts: Scope of Practice: Committee

EXISTING LAW:
Provides for the licensure and regulation of various healing arts practitioners by boards, as well as bureaus within the Department of Consumer Affairs.

THIS BILL WOULD:
1. State that it is the intent of the Legislature to enact legislation that would authorize the Director of Consumer Affairs to appoint a committee to perform occupational analyses on various healing arts practices, including education, training, and experience. It would require a written report on any bill introduced that seeks to expand the scope of a healing arts practice.
2. State that it is the intent of the Legislature that the committee be comprised of seven members and specifies the committee composition: two academics representing each side of the scope of practice issue; one practitioner representing each side of the issue; and one public member.
3. Specify that it is the intent of the Legislature that the cost of the occupational analyses and written reports be borne on the healing arts practice requesting the expanded scope of practice.

AUTHOR'S INTENT:
The intent is to establish a committee as specified to perform an occupational analysis on proposed increased scope of work proposals.

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

COMMENTS:
This bill is currently only legislative intent. Board staff will continue to monitor this bill. According to the author's office, this proposal is similar to a requirement in New Mexico.

SUPPORT/OPPOSITION:
None on file

HISTORY:

Feb. 27 From printer. May be heard in committee March 29.
Feb. 26 Read first time. To print.

ASSEMBLY BILL No. 877

Introduced by Assembly Member Emmerson

February 26, 2009

An act to relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 877, as introduced, Emmerson. Healing arts.

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs and the department is under the control of the Director of Consumer Affairs.

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

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. (a) It is the intent of the Legislature to enact
2 legislation that would authorize the Director of Consumer Affairs
3 to appoint a committee to perform occupational analyses on various
4 healing arts practices, to include, but not be limited to, education,
5 training, and experience, and to prepare a written report on any
6 bill introduced in either house of the Legislature that seeks to

1 expand the scope of a healing arts practice as described in Division
2 2 of the Business and Professions Code.
3 (b) It is the intent of the Legislature that the committee be
4 comprised of seven members as follows: two academics
5 representing each side of the scope of practice issue, one
6 practitioner representing each side of the scope of practice issue,
7 and one public member.
8 (c) It is further the intent of the Legislature that the cost of the
9 occupational analyses and the written reports be borne on the
10 healing arts practice requesting the expanded scope of practice.

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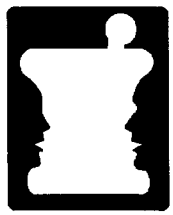
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 931 **VERSION: Amended March 26, 2009**

AUTHOR: Fletcher **SPONSOR: California Pharmacists Association**

BOARD POSITION: None

SUBJECT: Emergency Supplies

EXISTING LAW

1. The California Department of Public Health (CDPH) licenses and regulates health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities. (Title 22 CCR and H&SC §1261.5)
2. Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the Board of Pharmacy and establishes requirements for the dispensing of dangerous drugs and dangerous devices. (B&PC Chapter 9, Division 2, Articles 1-24)
3. B&P Code §4119 authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container (emergency kit, or e-kit) maintained in a facility in accordance with CDPH regulations.
4. H&SC §1261.5 limits the number of doses of any one drug (currently 4 doses), and limits the total number of dangerous drugs or dangerous devices in an emergency kit to 24.

THIS BILL WOULD

1. Amend §1261.5 of the Health and Safety Code to increase the total number of oral and suppository drugs stored in an e kit at specified facilities to from 24 to 48.
2. The number of doses of any one drug in an e-kit will remain limited to 4.

AUTHOR'S INTENT

According to the sponsor, this bill would improve the quality of care for all patients in long term care facilities. Specifically, it would protect vulnerable populations like the elderly, patients who are rehabilitating from a major medical event, and those who reside in Long-Term Care Facilities in rural areas in the event of emergencies.

By increasing the number of medications in an e-kit, doctors can provide a wider scope of treatment available to patients in an emergency situation. This change will also bring government policy up to date with modern medicine, which has made significant

advancements in pharmaceutical treatments since the current limit was put in place fifteen years ago.

FISCAL IMPACT
The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS
Emergency kit medications are approved by a Pharmacy and Therapeutics Committee, which is comprised of a facility's director of nurses, the medical director and the consultant pharmacist. E-kits generally include pain medications, antibiotics, and anti-anxiety medications for other conditions producing patient discomfort. The e-kit provides the first dose, and is NOT meant to refill a prescription. After a first dose is provided, a new prescription would still need to be filled by a pharmacy. The medications can also be used to start medication orders for patients in a disaster situation, when drugs cannot be readily accessed by a pharmacy (for example during an earthquake or flood).

Increasing the number of drugs available does not modify the security measures that are currently in place and working. E-kits are monitored by a pharmacist. Once the lock has been broken on the e-kit, the entire contents must be accounted for and replaced by a pharmacist within 72 hours.

PROPONENTS
California Pharmacists Association

OPPOSITION
None of file.

HISTORY:
Mar 27 Hearing Set for 05/05/09 in ASM Health
Mar. 27 Re-referred to Com. on HEALTH.
Mar. 26 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 26 Referred to Com. on HEALTH.
Feb. 27 From printer. May be heard in committee March 29.
Feb. 26 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 26, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 931

Introduced by Assembly Member Fletcher

February 26, 2009

An act to amend Section 1261.5 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 931, as amended, Fletcher. Emergency supplies.

Existing law provides for the licensing and regulation by the State Department of Public Health of health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities.

Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy and establishes requirements for the dispensing of drugs.

Existing law authorizes a pharmacy to furnish dangerous drugs or devices to a licensed health facility for storage in a secure emergency pharmaceutical supplies container that is maintained within the facility under regulations of the department. Existing law *limits the number of oral dosage form and suppository dosage form drugs for storage within this container to 24. It also* authorizes the department to limit the number of doses of each drug available to a skilled nursing facility or intermediate care facility to not more than 4 doses of any separate drug dosage form in each emergency supply.

This bill would increase the ~~authorized amount in an emergency supply to 6 doses~~ *storage container limit to 48.*

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

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

1 SECTION 1. Section 1261.5 of the Health and Safety Code is
2 amended to read:
3 1261.5. (a) The number of oral dosage form or suppository
4 form drugs provided by a pharmacy to a health facility licensed
5 pursuant to subdivision (c) or (d), or both (c) and (d), of Section
6 1250 for storage in a secured emergency supplies container,
7 pursuant to Section 4119 of the Business and Professions Code,
8 shall be limited to ~~24~~ *48*. The State Department of Public Health
9 may limit the number of doses of each drug available to not more
10 than ~~six~~ *four* doses of any separate drug dosage form in ~~an~~ *each*
11 emergency supply.
12 (b) Any limitations established pursuant to subdivision (a) on
13 the number and quantity of oral dosage or suppository form drugs
14 provided by a pharmacy to a health facility licensed pursuant to
15 subdivision (c), (d), or both (c) and (d), of Section 1250 for storage
16 in a secured emergency supplies container shall not apply to an
17 automated drug delivery system, as defined in Section 1261.6,
18 when a pharmacist controls access to the drugs.

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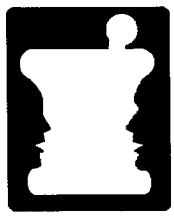
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1310 **VERSION: As Amended April 2, 2009**

AUTHOR: Hernandez **SPONSOR: Author sponsored**

BOARD POSITION: None

SUBJECT: Healing Arts: Database

EXISTING LAW:
Existing law defines the required information an applicant for licensure or renewal must provide.

THIS BILL WOULD:
Add section 857 to the Business and Professions Code to:

A. Require all specified healing arts board to add and label "mandatory" the following fields on an application for initial licensure or renewal:
   1. First, middle and last name
   2. Last four digits of social security number
   3. Complete mailing address
   4. Education training as specified
   5. Birth date and place of birth
   6. Sex
   7. Race and Ethnicity
   8. Location of high school
   9. Mailing address of primary practice, if applicable
   10. Number of hours per week spent at primary practice location, if applicable
   11. Description of practice setting, if applicable
   12. Primary practice information, including, but not limited to primary specialty practice, practice location, ZIP Code, and county
   13. Information regarding any additional practice, including, but not limited to, a description of practice setting, practice location ZIP Code and county.

B. Require the board, in consultation with the Healthcare Workforce Development Division to select a database and in the information specified in items 5 through 13 above.

C. Require the board to collect this information and submit it to Health Care Workforce Clearinghouse annually as specified

D. Required the Health Care Workforce Clearinghouse to prepare a written report to the legislature as specified.

AUTHOR'S INTENT:
Staff continues to seek information related to this specific legislation and will update the committee as information is available.

FISCAL IMPACT:
The board will require funding for additional staff as well as funding to purchase a database. The board would require three full-time Office Technicians to collect and input specified data for all new and renewal applicants.

COMMENTS:
The board does not currently collect several of the required elements including worksite information, number of hours worked, as well a race and ethnicity. Some of the additional required elements are reported as part of the application, but are not collected in a database, rather just used to confirm compliance with licensure requirements.

SUPPORT/OPPOSITION:
None on file.

HISTORY:

Apr. 2	Hearing set for 04/14/09 – ASM Business & Professions
Apr. 2	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 31	Referred to Com. on B. & P.
Mar. 2	Read first time.
Mar. 1	From printer. May be heard in committee March 30.
Feb. 27	Introduced. To print.

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1310

Introduced by Assembly Member Hernandez

February 27, 2009

An act to add Section 857 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1310, as amended, Hernandez. Healing arts: database.

Existing law provides for the licensure and regulation of various healing arts professions and vocations by boards within the Department of Consumer Affairs. Under existing law, there exists the Healthcare Workforce Development Division within the Office of Statewide Health Planning and Development (OSHPD) that supports health care accessibility through the promotion of a diverse and competent workforce and provides analysis of California's health care infrastructure. Under existing law, there is also the Health Care Workforce Clearinghouse, established by OSHPD, that serves as the central source for collection, analysis, and distribution of information on the health care workforce employment and educational data trends for the state.

This bill would require ~~the department~~ *specified healing arts boards* to add and label as "mandatory" specified fields on an application for initial licensure or a renewal form for applicants applying to ~~specified healing arts~~ *those* boards. The bill would require the department, in consultation with the division and the clearinghouse, to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse

annually on or before January 1. The bill would require the clearinghouse to prepare a written report relating to the data and to submit the report annually to the Legislature no later than March 1, commencing March 1, 2012.

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

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

1 SECTION 1. Section 857 is added to the Business and
2 Professions Code, to read:
3 857. (a) ~~The department~~ *Every healing arts board specified*
4 *in subdivision (c)* shall add and label as "mandatory" the following
5 fields on an application for initial licensure or renewal for a person
6 applying to ~~a board described in subdivision (c)~~ *that board*:
7 (1) First name, middle name, and last name.
8 (2) Last four digits of social security number.
9 (3) Complete mailing address.
10 (4) Educational background and training, including, but not
11 limited to, degree, related school name and location, and year of
12 graduation, and, as applicable, the highest professional degree
13 obtained, related professional school name and location, and year
14 of graduation.
15 (5) Birth date and place of birth.
16 (6) Sex.
17 (7) Race and ethnicity.
18 (8) Location of high school.
19 (9) Mailing address of primary practice, if applicable.
20 (10) Number of hours per week spent at primary practice
21 location, if applicable.
22 (11) Description of primary practice setting, if applicable.
23 (12) Primary practice information, including, but not limited
24 to, primary specialty practice, practice location ZIP Code, and
25 county.
26 (13) Information regarding any additional practice, including,
27 but not limited to, a description of practice setting, practice location
28 ZIP Code, and county.
29 (b) The department, in consultation with the Healthcare
30 Workforce Development Division and the Health Care Workforce
31 Clearinghouse, shall select a database and shall add the data

specified in paragraphs (5) to (13) ~~of subdivision (a), inclusive,~~ *inclusive, of subdivision (a)* to that database.

(c) The following boards are subject to subdivision (a):

(1) The Acupuncture Board.

(2) The Dental Hygiene Committee of California.

(3) The Dental Board of California.

(4) The Medical Board of California.

(5) The Bureau of Naturopathic Medicine.

(6) The California Board of Occupational Therapy.

(7) The State Board of Optometry.

(8) The Osteopathic Medical Board of California.

(9) The California State Board of Pharmacy.

(10) The Physical Therapy Board of California.

(11) The Physician Assistant Committee, Medical Board of California.

(12) The California Board of Podiatric Medicine.

(13) The Board of Psychology.

(14) The Board of Registered Nursing.

(15) The Respiratory Care Board of California.

(16) The Speech-Language Pathology and Audiology Board.

(17) The Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(d) (1) The department shall collect the specified data in the database pursuant to subdivision (b) and shall submit that data to Health Care Workforce Clearinghouse annually on or before January 1.

(2) The Health Care Workforce Clearinghouse shall prepare a written report containing the findings of this data and shall submit the written report annually to the Legislature no later than March 1, commencing March 1, 2012.

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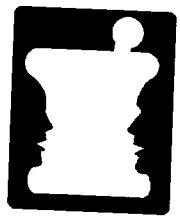
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1370 **VERSION: Introduced February 27, 2009**

AUTHOR: Solorio **SPONSOR: California Senior Legislature**

RECOMMENDED POSITION: None

SUBJECT: Drugs and devices: labeling: expiration date: best before date

EXISTING LAW:

1. Authorizes the California Department of Public Heath (CDPH) to regulate the packaging of a drug or device, if it deems it is liable to deterioration and, by regulation, may require a statement of precaution on a label.
2. B&P 4076 mandates the labeling requirements of a dispensed prescription, including (a)(9) "the expiration date of the effectiveness of the drug dispensed."
3. B&P 4076.5 mandates that the Board of Pharmacy develop standardized, patient-centered labels on all prescription medicine dispensed to patients in California.

THIS BILL WOULD:

1. As introduced, this bill adds to those provisions the CDPH may regulate, to include a "best before" date on a label (H&SC 111385).

AUTHOR'S INTENT

The California Senior Legislature's concern is that consumers may be needlessly throwing away costly medications because a label shows an "expiration date" when, in fact, the manufacturer's lot of that medication may expire at a time later than that which is on the label.

While this bill does not currently specify the label requirements of a "prescription" the author's office indicates prescriptions are the main focus of the bill and that the bill may be amended to amend provisions in Pharmacy Law (versus H&S).

The author's goal is to indicate on a prescription label the actual (manufacturer's) expiration date of the drug or device dispensed, and not a "one-year default date" that many pharmacies choose to use as the expiration date.

FISCAL IMPACT:

As introduced, this bill has no fiscal impact on the Board of Pharmacy. However, if the bill is amended as stated by the author's staff, Board staff will need to seek clarification from legal counsel about the enforcement of any amended provisions to Pharmacy Law. Based on the results of any related discussion with counsel, staff can estimate fiscal impact to the board, if any.

COMMENTS:

Information was provided to the author's office related to the SB 472 Medication Label Subcommittee, including an agenda for the March 12, 2009, public forum to seek feedback from consumers on the topic of prescription drug labels. The author's office indicated they would provide the Board of Pharmacy with a Fact Sheet on AB 1370 when it is available.

HISTORY:
March 2 – Read First Time
May be heard in Committee March 30.

ASSEMBLY BILL No. 1370

Introduced by Assembly Member Solorio

February 27, 2009

An act to amend Section 111385 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1370, as introduced, Solorio. Drugs and devices: labeling: expiration date: best before date.

Existing law, the Sherman Food, Drug, and Cosmetic Law, requires the State Department of Public Health to regulate manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.

Existing law classifies a drug or device as misbranded if the department determines that the drug or device is liable to deterioration and the drug or device is not packaged and labeled in a form and manner and set forth in regulations of the department.

This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device. By expanding the definition of an existing crime, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 111385 of the Health and Safety Code
2 is amended to read:
3 111385. Any drug or device is misbranded if the department
4 determines that the drug or device is liable to deterioration, unless
5 it is packaged in that form and manner and its label bears a
6 statement of the precautions, as the department, by regulation, may
7 require as necessary for the protection of public health, *including,*
8 *but not limited to, "best before" date in addition to the expiration*
9 *date of the effectiveness of the drug or device.* ~~Such~~ *The* regulations
10 shall not be established for any drug or device recognized in an
11 official compendium, unless the department has informed the
12 appropriate body, charged with the revision of the official
13 compendium, of the need for that packaging or labeling
14 requirements and that body has not prescribed the requirements
15 in a reasonable length of time.
16 SEC. 2. No reimbursement is required by this act pursuant to
17 Section 6 of Article XIII B of the California Constitution because
18 the only costs that may be incurred by a local agency or school
19 district will be incurred because this act creates a new crime or
20 infraction, eliminates a crime or infraction, or changes the penalty
21 for a crime or infraction, within the meaning of Section 17556 of
22 the Government Code, or changes the definition of a crime within
23 the meaning of Section 6 of Article XIII B of the California
24 Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 26 **VERSION:** As Introduced

AUTHOR: Simitian **SPONSOR:** Simitian

BOARD POSITION:

SUBJECT: Home Generated Pharmaceutical Waste

EXISTING LAW:

1. Regulates the methods of consolidation, storage and transportation of medical waste and home-generated sharps waste.
2. Prohibits the disposal of home generated sharps from being disposed of in the solid waste stream and requires that sharps be transported only in certain types of containers.
3. Required the California Integrated Waste Management Board (CIWMB), by July 1, 2008, to consult with local, state, and federal agencies including the Board of Pharmacy to establish model disposal programs for waste pharmaceuticals.
4. Requires the CIWMB to establish minimum requirements for model programs including safety, oversight, diversion prevention, and ease of use for consumers and authorizes the CIWMB to develop related emergency regulations if necessary. These guidelines were released in December 2008 and a modified version in February 2009.
5. Requires the CIWMB to report to the Legislature by December 1, 2010, about the efficacy, safety, and cost-effectiveness of the program, as well as the potential for replicating model programs statewide.

THIS BILL WOULD:

1. Require the Board of Pharmacy to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop a program for the take back of pharmaceutical waste and specifically allow pharmacies to accept the return of pharmaceutical and sharps waste.
2. Authorize pharmacies to accept home-generated sharps and pharmaceutical waste, as defined. Define "home-generated pharmaceutical waste" (HGPW) as prescribed and over-the-counter drugs derived from a household.
3. Remove HGPW from the definition of medical waste.
4. Authorize as consolidated points for collection of pharmaceutical waste entities, including: pharmacies, health care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, government offices.

The bill would exempt "home-generated pharmaceutical waste consolidation points" from permit requirements with the Department of Public Health.

5. Define "common carrier" as person or company that hauls for hire goods, including but not limited to, pharmaceutical waste or home-generated pharmaceutical waste and specifies that home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point. There would be no license required to pickup HGPW.
6. Require that consolidation points for HGPW be approved by the local enforcement agency, and.
   a) The HGPW collected and consolidated at the facility must be collected and contained in a leak-resistant and tamper-proof container and placed in a secure area not accessible by unauthorized persons.
   b) Disposal-ready containers cannot be held for more than 90 days without the written approval of the enforcement agency.
   c) Specifies that the HGPW consolidation point operator is not considered a generator of that waste.
   d) Requires the end disposal facilities that treat the HGPW to maintain tracking documents for the pharmaceutical waste.
7. Require that the name of the common carrier used by small and large quantity generators to transport the pharmaceutical waste for offsite treatment and disposal to be included on the medical waste management plan submitted to the local enforcement agency. This applies only to those small quantity generators required to register with the enforcement agency.
8. Require small quantity generators who are not required to register with the local enforcement agency to maintain office records, for no less than two years, the name of the common carrier used to haul pharmaceutical waste.
9. Exempt small quantity generators or common carriers transporting HGPW from the medical waste transportation requirements.
10. Allow pharmaceutical waste to be shipped by common carrier if the generator or HGPW consolidation point meets the following requirements:
    a) The facility meets all documentation requirements in governing the transportation and tracking required for medical waste.
    b) The waste products are transported to a medical waste facility, hazardous waste facilities or a reverse distributor with the final destination of a medical or hazardous waste facility.
11. Subject pharmaceutical waste, HGPW consolidated by a HPGW consolidation point and HGPW to the same documentation requirements governing the transportation and tracking required for medical waste.
12. Require pharmaceutical waste transporters to maintain a tracking document of all the waste removed for treatment and disposal, requires a copy of the tracking documents to be included in the pharmaceutical waste container and specifies the requirements of the tracking documents, which include the following:

a) The name, address and telephone number and registration number of the generator.
b) Specific information on the pharmaceutical waste being transported.
c) The name, address, and telephone of the person transporting the waste.
d) The name, address, telephone number and permit number of the treatment facility or transfer station to which the waste is being sent.
e) The date the waste was collected or removed from the generator or the HGPW consolidation point.

13. Require HGPW transporters to keep the tracking document in his or her possession while transporting waste and to show the document, upon demand, to any enforcement agency personnel or Highway Patrol officer.
14. Require medical waste treatment facilities and transfer stations to verify the amount of the waste being delivered, date and sign a copy of the tracking document and maintain a copy of the tracking document for three years.
15. Require pharmaceutical waste transported out of state to be consigned to a permitted medical waste treatment in the receiving state and specifies that if the receiving state does not have a permitted medical waste treatment facility or the waste crosses an international border, the waste must be treated in accordance with state law.
16. Provide that registered medical waste facility may accept home-generated sharps waste and HGPW under the following conditions:
    a) The generator of the waste, a member of the generator's family or a person authorized by the enforcement agency transports the waste to the medical waste generator's facility.
    b) The home-generated sharps waste or HGPW is accepted at a central location at the medical waste generator's facility.
17. Require medical waste treatment operators to maintain copies of the tracking documents received from offsite generators, hazardous waste haulers or common carriers for three years and report or submit, upon request, the documents to the enforcement agency.
18. Allow the CIWMB to expend funds from the Household Hazardous Waste Grant account in order to make grants to local governments for the management of HGPW and sharps waste.

AUTHOR'S INTENT:
To strengthen the ability of counties and communities to operate drug take back programs for home-generated pharmaceutical waste by deregulating how the waste is classified, minimize costs, ensure a diverse and broad variety of collection sites and by allowing common carriers to pickup and transport the waste.

FISCAL IMPACT:
To the degree that such deregulated HGPW reenters the pharmaceutical supply chain for "re-dispensing" to the public, there would be substantial, but indeterminate fiscal impact to the board as it would need to identify the origin of prescription drugs where there are no or inadequate acquisition records (this requires audits).

The board would need one position to implement the provisions of this bill that require the board to "coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop a program for the take back of pharmaceutical waste and specifically allow pharmacies to accept the return of pharmaceutical and sharps waste."

COMMENTS:

1. According to the Author, this measure is necessary to make it explicit which entities may accept HGPW and establishes requirements to ensure that the HGPW is managed safely and appropriately. This bill is follow-up legislation to the Author's SB 966 (Chapter 542, Statutes of 2007) which required the CIWMB to work with stakeholders to develop model programs for the safe, efficient take back of HGPW. The intent of that measure was to provide a product stewardship approach to the management of waste pharmaceuticals.

   The board has been actively involved in the development of the CIWMB's model program guidelines. These guidelines were finalized in February 2009. One principal weakness is that there are no regulations or statutory law enacted for regulatory agencies to enforce these provisions, and the CIWMB has indicated that it will not develop these regulations.

2. Existing law requires facilities that handle medical waste, including waste over-the-counter and prescription drugs, to have a full medical waste facility permit. This has been prohibitive to those locations, such as pharmacies, who only want to handle pharmaceutical waste from their customers as a customer service. Traditionally medical waste is biohazardous and infectious waste – waste that requires a high level of treatment and oversight. The take-back of waste pharmaceuticals is a new practice and not considered when the permitting requirements were established.
3. The Medical Waste Management Act (MWMA) currently requires HGPW to be managed as "medical waste" which includes such material as infectious and biohazardous waste and other types of waste that have posed a potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. While this is appropriate for large scale medical waste, the management of HGPW needs a protective, yet different approach. Changes to the MWMA are necessary to remove barriers to the establishment of a network of take back opportunities for HGPW. Many pharmacies and other retail establishments have expressed an interest in providing collection opportunities for their customers and while are willing and able to provide safe and appropriate collection, they do not want to become licensed medical waste collectors.
4. **Home-Generated Sharps Waste Model.** This bill uses the approach established for the management of "sharps waste" (e.g., needles, lancets.) generated by households

that provides an appropriate level of oversight, but acknowledges the need to provide many options for users of sharps to encourage their proper management and prevent illegal or improper disposal that leads to public health and safety and environmental pollution problems. It establishes a wide array of entities to, if they wish, serve as consolation points for HGPW and creates a statutory framework for the safe management, tracking and disposal of HGPW.

5. Concerns have been raised regarding the issue of theft of HGWP at collection points, including pharmacies. Pharmacies have the responsibility of keeping the drug supply safe and it is of utmost importance that HGPW are not diverted to unauthorized users. To ensure the safety and integrity of California's pharmaceutical drug supply chain, it is imperative that HGPW does not re-enter the drug supply, nor be scavenged to be sold illegally. The Author has indicated that he is exploring ways to address these concerns.

SUPPORT/OPPOSITION:

American Federation of State, County and Municipal Employees
City of Glendora
Contra Costa Water District
East Bay Municipal Utility District
Environmental Working Group
Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force
Regional Council of Rural Counties
San Luis Obispo County Integrated Waste Management Authority
Santa Clara County Board of Supervisors
Santa Clara Valley Water District
Solid Waste Association of North America

HISTORY:

December 1, 2008: Introduced
April 13: Hearing, Senate Business, Professions and Economic Development Committee
Also referred to Senate Environmental Quality

SENATE BILL No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

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

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4001.2 is added to the Business and
2 Professions Code, to read:
3 4001.2. To further the purposes of Section 4001.1, and to
4 protect the public from hazards caused by the improper
5 management and disposal of waste drugs and devices, the

California State Board of Pharmacy shall coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

SEC. 2. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117769 of the Health and Safety Code, from the public.

SEC. 3. Section 4146 is added to the Business and Professions Code, to read:

4146. A pharmacy may accept the return of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, from a person if the waste is contained in a sharps container.

SEC. 4. Section 117642 is added to the Health and Safety Code, to read:

117642. "Common carrier" means a person or company that hauls for hire goods, including, but not limited to, pharmaceutical waste or home-generated pharmaceutical waste. Home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 5. Section 117669 is added to the Health and Safety Code, to read:

117669. "Home-generated pharmaceutical waste" means prescribed and over-the-counter drugs derived from a household.

SEC. 6. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste ~~which~~ *that* is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671, *and home-generated pharmaceutical waste, as defined in Section 117669.*

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

SEC. 7. Section 117748 is added to the Health and Safety Code, to read:

117748. "Pharmaceutical waste" means any pharmaceutical, prescription, or over-the-counter human or veterinary drug, including, but not limited to, a drug, as defined in Section 109925, or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(g)(1)) that meets any of the following requirements:

(a) The drug may no longer be sold or dispensed because it has expired.

(b) The drug can no longer be used for its intended purpose.

(c) The drug has been discarded.

(d) The drug has been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 8. Section 117904.5 is added to the Health and Safety Code, to read:

117904.5. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These locations may include, but are not limited to, pharmacies, heath care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices.

(b) A consolidation location approved pursuant to this section shall be known as a home-generated pharmaceutical waste consolidation point.

(c) A home-generated pharmaceutical waste consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275) of Part 14 of Division 4, to the permit

requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated pharmaceutical waste pursuant to this section.

(d) A home-generated pharmaceutical waste consolidation point shall comply with all of the following requirements:

(1) It shall be approved by the enforcement agency for this purpose.

(2) The home-generated pharmaceutical waste collected and consolidated at the facility shall be collected and contained in a leak-resistant container and placed in a secure area that does not allow the waste to be accessed or salvaged by unauthorized persons.

(3) Containers ready for disposal shall not be held for more than 90 days without the written approval of the enforcement agency.

(e) An operator of a home-generated pharmaceutical waste consolidation point that is approved pursuant to this section shall not be considered a generator of that waste.

(f) The end disposal facility that treats the home-generated pharmaceutical waste shall maintain the tracking documents required by Section 118040 or 118041, as applicable, and Section 118165 with regard to the pharmaceutical waste.

(g) Nothing in this section shall exempt any person from any federal or state law governing pharmaceuticals.

SEC. 9. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler

used by the generator to have untreated medical waste removed for treatment and disposal, *and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal.*

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 10. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, *or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.* The small quantity generator shall maintain these records for not less than two years.

SEC. 11. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable*, or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.*

(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.

(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

(i) An emergency action plan complying with regulations adopted by the department.

(j) A statement certifying that the information provided is complete and accurate.

SEC. 12. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 *or 118031*, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 *or small quantity generators or common carriers transporting home-generated pharmaceutical waste pursuant to Section 118031*, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 13. Section 118031 is added to the Health and Safety Code, to read:

118031. Pharmaceutical waste may be shipped by a common carrier if the generator or home-generated pharmaceutical waste consolidation point meets the following requirements:

(a) The facility shall maintain documentation as required in Sections 118040 and 118041.

(b) The waste products are transported to any of the following:

(1) A medical waste facility.

(2) A hazardous waste facility.

(3) A reverse distributor, with the final destination of a medical or hazardous waste facility.

SEC. 14. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, *pharmaceutical waste or home-generated pharmaceutical waste consolidated by a home-generated pharmaceutical waste consolidation point approved pursuant to Section 117904.5, or home-generated pharmaceutical waste transported pursuant to Section 118031,* a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type and quantity of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his

or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 15. Section 118041 is added to the Health and Safety Code, to read:

118041. (a) A person transporting pharmaceutical waste shall maintain a completed tracking document of all pharmaceutical waste removed for treatment or disposal. A copy of the tracking document shall be included with the container holding the pharmaceutical waste.

(b) The tracking document shall include, but not be limited to, all of the following information:

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

(2) Specific information indicating that pharmaceutical waste is being transported.

(3) The name, address, and telephone number of the person transporting the waste.

(4) The name, address, telephone number, and permit number of the permitted treatment facility or transfer station to which the pharmaceutical waste is being sent.

(5) The date that the pharmaceutical waste was collected or removed from the generator or home-generated pharmaceutical waste consolidation point.

(c) A person tracking pharmaceutical waste shall have a tracking document for the waste in his or her possession while transporting the waste. The tracking document shall be shown, upon demand, to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) A medical waste treatment facility and transfer station shall date and sign a copy of the tracking document upon receipt, periodically provide data in a format determined by the department, and shall maintain a copy of the tracking document for three years.

(e) This section does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal of the pharmaceutical waste over a period of time, if the form or log is maintained in the files of the parent organization or other health care facility that receives the waste.

(f) Pharmaceutical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state, or if the waste is crossing an international border, the home-generated pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of state.

SEC. 16. Section 118147 of the Health and Safety Code is amended to read:

118147. Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste *and home-generated pharmaceutical waste*, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the *home-generated* sharps waste *or home-generated pharmaceutical waste*, a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste *or pharmaceutical waste* to the medical waste generator's facility.

(b) The *home-generated* sharps waste *or home-generated pharmaceutical waste* is accepted at a central location at the medical waste generator's facility.

(c) A reference to, and a description of, the actions taken pursuant to this section are included in the facility's medical waste management plan adopted pursuant to Section 117960.

SEC. 17. Section 118165 of the Health and Safety Code is amended to read:

118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

(a) The type of treatment facility and its capacity.

(b) All treatment facility operating records.

(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators or from hazardous waste haulers *or common carriers, pursuant to Section 118041.*

SEC. 18. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of *home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, home-generated pharmaceutical waste, as defined in Section 117669 of the Health and Safety Code, and* hazardous wastes at disposal sites, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars ($3,000,000).

1 (2) Notwithstanding paragraph (1), the total amount of grants
2 made by the board pursuant to this section may exceed three
3 million dollars ($3,000,000) but shall not exceed six million dollars
4 ($6,000,000), in any one fiscal year, if sufficient funds are
5 appropriated from the Integrated Waste Management Account for
6 this purpose.
7 SEC. 19. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the penalty
12 for a crime or infraction, within the meaning of Section 17556 of
13 the Government Code, or changes the definition of a crime within
14 the meaning of Section 6 of Article XIII B of the California
15 Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 43 **VERSION: Introduced: January 6, 2009**

AUTHOR: Alquist **SPONSOR: Author Sponsored**

BOARD POSITION: None

SUBJECT: Health Professions: Cultural and Linguistic Competency

EXISTING LAW:

1. Establishes the Task Force on Culturally and Linguistically Competent Physicians and Dentists and assigns the task force various duties, including, among other things, identifying the key cultural elements necessary to meet cultural competency.
2. Authorizes physicians and surgeons, dentists, and dental auxiliaries to report information regarding their cultural background and foreign language proficiency to their respective licensing boards and requires those boards to collect that information, as specified.

THIS BILL WOULD:

1. Allow a healing arts board to collect information regarding the cultural and linguistic competency of persons licensed, certified or otherwise subject to regulation by the board.
2. Require that such information collected be used for the purpose of meeting cultural and linguistic concerns of the state's diverse patient population.
3. Specify that personally identifiable information will be kept confidential.
4. Define board for purposes of this requirement.
5. Amend the Unemployment Insurance Code to allow the Office of Statewide Health Planning and Development (OSHPD) to obtain this data for inclusion in the health care workforce clearinghouse.

AUTHOR'S INTENT:

As introduced, SB 43 will improve data available for workforce policy and development efforts. Licensing boards will be allowed to collect data on the cultural and linguistic competency of a variety of healthcare professionals, including physicians, nurses, dentists and dental auxiliaries. OSHPD will have access to valuable labor market data.

FISCAL IMPACT:

It is unclear if there would be any fiscal impact to the board as this proposal is permissive rather than mandatory.

COMMENTS:
This bill does not create a mandate, rather it is permissive. Board staff will consult with agencies that do collect this information to identify any implementation issues, should the bill become law and the board decide to collect this information.

SUPPORT/OPPOSITION:
None of file.

HISTORY:
Mar. 27 Set for hearing April 20.
Jan. 29 To Coms. on B., P. & E.D. and JUD.
Jan. 7 From print. May be acted upon on or after February 6.
Jan. 6 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 43

Introduced by Senator Alquist

January 6, 2009

An act to add Section 851.5 to the Business and Professions Code, and to amend Section 1095 of the Unemployment Insurance Code, relating to health professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 43, as introduced, Alquist. Health professions.

Existing law provides for the licensure and regulation of various healing arts by boards within the Department of Consumer Affairs. Existing law establishes the Task Force on Culturally and Linguistically Competent Physicians and Dentists and assigns the task force various duties, including, among other things, identifying the key cultural elements necessary to meet cultural competency. Existing law authorizes physicians and surgeons, dentists, and dental auxiliaries to report information regarding their cultural background and foreign language proficiency to their respective licensing boards and requires those boards to collect that information, as specified.

This bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards. The bill would require that this information be used for the purpose of meeting the cultural and linguistic concerns of the state's diverse patient population.

Existing law requires the Office of Statewide Health Planning and Development to establish a health care workforce clearinghouse to serve as the central source of health care workforce and educational data in the state. Existing law requires the Director of the Employment

Development Department to permit the use of information in his or her possession for specified purposes.

This bill would additionally require the director to permit the use of that information in order to enable the Office of Statewide Health Planning and Development to obtain specified data for the health care workforce clearinghouse.

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

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

1 SECTION 1. Section 851.5 is added to the Business and
2 Professions Code, to read:
3 851.5. (a) A healing arts board referred to in this division may,
4 in a manner deemed appropriate by the board, collect information
5 regarding the cultural and linguistic competency of persons
6 licensed, certified, registered, or otherwise subject to regulation
7 by that board.
8 (b) The information collected pursuant to this section shall be
9 used for the purpose of meeting the cultural and linguistic concerns
10 of the state's diverse patient population.
11 (c) Personally identifiable information collected pursuant to this
12 section shall be confidential and not subject to public inspection.
13 (d) The authority provided in this section shall be in addition
14 to, and not a limitation on, the authority provided under subdivision
15 (c) of Section 2425.3 and subdivision (d) of Section 1717.5.
16 (e) For purposes of this section, "board" refers to any healing
17 arts board, division, or examining committee that licenses, certifies,
18 or regulates health professionals pursuant to this division.
19 SEC. 2. Section 1095 of the Unemployment Insurance Code
20 is amended to read:
21 1095. The director shall permit the use of any information in
22 his or her possession to the extent necessary for any of the
23 following purposes and may require reimbursement for all direct
24 costs incurred in providing any and all information specified in
25 this section, except information specified in subdivisions (a) to
26 (e), inclusive:
27 (a) To enable the director or his or her representative to carry
28 out his or her responsibilities under this code.
29 (b) To properly present a claim for benefits.

(c) To acquaint a worker or his or her authorized agent with his or her existing or prospective right to benefits.

(d) To furnish an employer or his or her authorized agent with information to enable him or her to fully discharge his or her obligations or safeguard his or her rights under this division or Division 3 (commencing with Section 9000).

(e) To enable an employer to receive a reduction in contribution rate.

(f) To enable federal, state, or local government departments or agencies, subject to federal law, to verify or determine the eligibility or entitlement of an applicant for, or a recipient of, public social services provided pursuant to Division 9 (commencing with Section 10000) of the Welfare and Institutions Code, or Part A of Title IV of the Social Security Act, where the verification or determination is directly connected with, and limited to, the administration of public social services.

(g) To enable county administrators of general relief or assistance, or their representatives, to determine entitlement to locally provided general relief or assistance, where the determination is directly connected with, and limited to, the administration of general relief or assistance.

(h) To enable state or local governmental departments or agencies to seek criminal, civil, or administrative remedies in connection with the unlawful application for, or receipt of, relief provided under Division 9 (commencing with Section 10000) of the Welfare and Institutions Code or to enable the collection of expenditures for medical assistance services pursuant to Part 5 (commencing with Section 17000) of Division 9 of the Welfare and Institutions Code.

(i) To provide any law enforcement agency with the name, address, telephone number, birth date, social security number, physical description, and names and addresses of present and past employers, of any victim, suspect, missing person, potential witness, or person for whom a felony arrest warrant has been issued, when a request for this information is made by any investigator or peace officer as defined by Sections 830.1 and 830.2 of the Penal Code, or by any federal law enforcement officer to whom the Attorney General has delegated authority to enforce federal search warrants, as defined under Sections 60.2 and 60.3 of Title 28 of the Code of Federal Regulations, as amended, and

when the requesting officer has been designated by the head of the law enforcement agency and requests this information in the course of and as a part of an investigation into the commission of a crime when there is a reasonable suspicion that the crime is a felony and that the information would lead to relevant evidence. The information provided pursuant to this subdivision shall be provided to the extent permitted by federal law and regulations, and to the extent the information is available and accessible within the constraints and configurations of existing department records. Any person who receives any information under this subdivision shall make a written report of the information to the law enforcement agency that employs him or her, for filing under the normal procedures of that agency.

(1) This subdivision shall not be construed to authorize the release to any law enforcement agency of a general list identifying individuals applying for or receiving benefits.

(2) The department shall maintain records pursuant to this subdivision only for periods required under regulations or statutes enacted for the administration of its programs.

(3) This subdivision shall not be construed as limiting the information provided to law enforcement agencies to that pertaining only to applicants for, or recipients of, benefits.

(4) The department shall notify all applicants for benefits that release of confidential information from their records will not be protected should there be a felony arrest warrant issued against the applicant or in the event of an investigation by a law enforcement agency into the commission of a felony.

(j) To provide public employee retirement systems in California with information relating to the earnings of any person who has applied for or is receiving a disability income, disability allowance, or disability retirement allowance, from a public employee retirement system. The earnings information shall be released only upon written request from the governing board specifying that the person has applied for or is receiving a disability allowance or disability retirement allowance from its retirement system. The request may be made by the chief executive officer of the system or by an employee of the system so authorized and identified by name and title by the chief executive officer in writing.

(k) To enable the Division of Labor Standards Enforcement in the Department of Industrial Relations to seek criminal, civil, or

1 administrative remedies in connection with the failure to pay, or
2 the unlawful payment of, wages pursuant to Chapter 1
3 (commencing with Section 200) of Part 1 of Division 2 of, and
4 Chapter 1 (commencing with Section 1720) of Part 7 of Division
5 2 of, the Labor Code.
6 (*l*) To enable federal, state, or local governmental departments
7 or agencies to administer child support enforcement programs
8 under Title IV of the Social Security Act (42 U.S.C. Sec. 651 et
9 seq.).
10 (m) To provide federal, state, or local governmental departments
11 or agencies with wage and claim information in its possession that
12 will assist those departments and agencies in the administration
13 of the Victims of Crime Program or in the location of victims of
14 crime who, by state mandate or court order, are entitled to
15 restitution that has been or can be recovered.
16 (n) To provide federal, state, or local governmental departments
17 or agencies with information concerning any individuals who are
18 or have been:
19 (1) Directed by state mandate or court order to pay restitution,
20 fines, penalties, assessments, or fees as a result of a violation of
21 law.
22 (2) Delinquent or in default on guaranteed student loans or who
23 owe repayment of funds received through other financial assistance
24 programs administered by those agencies. The information released
25 by the director for the purposes of this paragraph shall not include
26 unemployment insurance benefit information.
27 (o) To provide an authorized governmental agency with any or
28 all relevant information that relates to any specific workers'
29 compensation insurance fraud investigation. The information shall
30 be provided to the extent permitted by federal law and regulations.
31 For the purposes of this subdivision, "authorized governmental
32 agency" means the district attorney of any county, the office of
33 the Attorney General, the Department of Industrial Relations, and
34 the Department of Insurance. An authorized governmental agency
35 may disclose this information to the State Bar, the Medical Board
36 of California, or any other licensing board or department whose
37 licensee is the subject of a workers' compensation insurance fraud
38 investigation. This subdivision shall not prevent any authorized
39 governmental agency from reporting to any board or department
40 the suspected misconduct of any licensee of that body.

(p) To enable the Director of the Bureau for Private Postsecondary and Vocational Education, or his or her representatives, to access unemployment insurance quarterly wage data on a case-by-case basis to verify information on school administrators, school staff, and students provided by those schools who are being investigated for possible violations of Chapter 7 (commencing with Section 94700) of Part 59 of the Education Code.

(q) To provide employment tax information to the tax officials of Mexico, if a reciprocal agreement exists. For purposes of this subdivision, "reciprocal agreement" means a formal agreement to exchange information between national taxing officials of Mexico and taxing authorities of the State Board of Equalization, the Franchise Tax Board, and the Employment Development Department. Furthermore, the reciprocal agreement shall be limited to the exchange of information that is essential for tax administration purposes only. Taxing authorities of the State of California shall be granted tax information only on California residents. Taxing authorities of Mexico shall be granted tax information only on Mexican nationals.

(r) To enable city and county planning agencies to develop economic forecasts for planning purposes. The information shall be limited to businesses within the jurisdiction of the city or county whose planning agency is requesting the information, and shall not include information regarding individual employees.

(s) To provide the State Department of Developmental Services with wage and employer information that will assist in the collection of moneys owed by the recipient, parent, or any other legally liable individual for services and supports provided pursuant to Chapter 9 (commencing with Section 4775) of Division 4.5 of, and Chapter 2 (commencing with Section 7200) and Chapter 3 (commencing with Section 7500) of Division 7 of, the Welfare and Institutions Code.

(t) Nothing in this section shall be construed to authorize or permit the use of information obtained in the administration of this code by any private collection agency.

(u) The disclosure of the name and address of an individual or business entity that was issued an assessment that included penalties under Section 1128 or 1128.1 shall not be in violation

of Section 1094 if the assessment is final. The disclosure may also include any of the following:

(1) The total amount of the assessment.

(2) The amount of the penalty imposed under Section 1128 or 1128.1 that is included in the assessment.

(3) The facts that resulted in the charging of the penalty under Section 1128 or 1128.1.

(v) To enable the Contractors' State License Board to verify the employment history of an individual applying for licensure pursuant to Section 7068 of the Business and Professions Code.

(w) To provide any peace officer with the Division of Investigation in the Department of Consumer Affairs information pursuant to subdivision (i) when the requesting peace officer has been designated by the Chief of the Division of Investigation and requests this information in the course of and as part of an investigation into the commission of a crime or other unlawful act when there is reasonable suspicion to believe that the crime or act may be connected to the information requested and would lead to relevant information regarding the crime or unlawful act.

(x) To enable the Labor Commissioner of the Division of Labor Standards Enforcement in the Department of Industrial Relations to identify, pursuant to Section 90.3 of the Labor Code, unlawfully uninsured employers. The information shall be provided to the extent permitted by federal law and regulations.

(y) To enable the Chancellor of the California Community Colleges, in accordance with the requirements of Section 84754.5 of the Education Code, to obtain quarterly wage data, commencing January 1, 1993, on students who have attended one or more community colleges, to assess the impact of education on the employment and earnings of students, to conduct the annual evaluation of district-level and individual college performance in achieving priority educational outcomes, and to submit the required reports to the Legislature and the Governor. The information shall be provided to the extent permitted by federal statutes and regulations.

(z) To enable the Public Employees' Retirement System to seek criminal, civil, or administrative remedies in connection with the unlawful application for, or receipt of, benefits provided under Part 3 (commencing with Section 20000) of Division 5 of Title 2 of the Government Code.

1 *(aa) To enable the Office of Statewide Health Planning and*
2 *Development to obtain labor market, workforce, and earnings data*
3 *for the purpose of collecting health care workforce data for the*
4 *health care workforce clearinghouse established pursuant to*
5 *Section 128050 of the Health and Safety Code.*
6 SEC. 3. The Legislature finds and declares that Section 1 of
7 this act, which adds Section 851.5 to the Business and Professions
8 Code, imposes a limitation on the public's right of access to the
9 meetings of public bodies or the writings of public officials and
10 agencies within the meaning of Section 3 of Article I of the
11 California Constitution. Pursuant to that constitutional provision,
12 the Legislature makes the following findings to demonstrate the
13 interest protected by this limitation and the need for protecting
14 that interest:
15 In order to protect the privacy of healing arts licensees, it is
16 necessary to ensure that personally identifiable information
17 submitted by licensees pursuant to this act is protected as
18 confidential.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 364 **VERSION: Introduced: February 25, 2009**

AUTHOR: Florez **SPONSOR:**

BOARD POSITION: None

SUBJECT: Pharmacies

EXISTING LAW:
1. Provides for the licensure and regulation of the practice of pharmacies by the California State Board of Pharmacy.
2. Details the additional security requirements for pharmacies relating to the handling of controlled substances.

THIS BILL WOULD:
State that it is the intent of the legislature to enact legislation that would authorize specific penalties on pharmacies that fail to safeguard controlled substances used to make controlled substances for illegal use.

FISCAL IMPACT:
The board is uncertain of any potential fiscal impact.

COMMENTS:
The author's office indicates that this bill is a spot bill and that amendments will be specific to pharmacy practice.

SUPPORT/OPPOSITION:
None on file.

HISTORY:
Mar. 9 To Com. on RLS.
Feb. 26 From print. May be acted upon on or after March 28.
Feb. 25 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 364

Introduced by Senator Florez

February 25, 2009

An act relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 364, as introduced, Florez. Pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. Existing law prohibits a person, other than a pharmacist or other specified persons, from being in a specified area where controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged.

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

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

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

1 SECTION 1. It is the intent of the Legislature to enact
2 legislation that would authorize the imposition of specific penalties
3 on pharmacies that fail to safeguard controlled substances used to
4 make controlled substances for illegal use.

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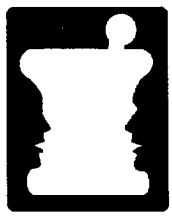
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 389 **VERSION: Introduced: February 26, 2009**

AUTHOR: Negrete McLeod **SPONSOR: Author Sponsored**

BOARD POSITION: None

SUBJECT: Professions and vocations: Fingerprint Requirements

EXISTING LAW:

1. Requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.
2. Authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

THIS BILL WOULD:

1. Require an applicant for licensure to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice (DOJ) as provided.
2. Require each licensing agency to direct applicants for a license to submit the fingerprint images for the purpose of obtaining information as to the existence or content of a state or federal criminal record.
3. Require the DOJ to forward fingerprint images to the FBI and request federal criminal history information.
4. Require each agency to request subsequent arrest notification from the DOJ.
5. Require every licensee who has not previously submitted fingerprints or for whom a record of submission no longer exists to, as a condition of renewal, complete a state and federal criminal offender record information search.
6. Require all licensees, as a condition of renewal, to certify on the renewal application that he or she has complied with this record information search and require the licensee to retain proof for at least three years.
7. Prohibit the agency from renewing a license until the application for renewal is complete.
8. Allow an agency to waive this requirement if the license is inactive or retired or if the licensee is actively serving in the military. Prohibits the agency from activating a license until the criminal record information search is completed.
9. Require each agency to develop regulations to specify which owners, officers, directors, shareholders, members, agents, employees or other natural persons who are representative of a business entity licensed to complete a state and federal criminal offender record information search.
10. Specify that a licensee that falsely certifies completion of this search may be subject to disciplinary action.

11. Require each agency to require a licensee, as a condition of renewal, to notify the board of a felony or misdemeanor since his or her last renewal.

AUTHOR'S INTENT:
To require fingerprint background checks on all applicants and licensees within the Department of Consumer Affairs.

FISCAL IMPACT:
The board anticipates four limited term Personnel Year (PY) and two permanent full time staff person's to implement the changes. Specifically, the board will require a three year limited term SSA/AGPA to lead over implementation of these requirements as well as three Office Technicians to process the incoming fingerprint results. The board will require one full-time, permanent Management Services Technician to address all renewal related holds that result from this proposal as well as one full-time SSA to complete investigations on the subsequent arrest notifications received as a result of this proposal.

Further, the board will require an increase in its funding for subsequent arrest notifications from the DOJ and will incur programming costs to our CAS system to ensure appropriate implementation.

COMMENTS:
As part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process. However, this bill goes beyond current board requirements, and will require the board to fingerprint existing licensees.

To implement these changes, the board will need some limited term and permanent staff as specified above. Further, the board will need a listing from the DOJ to identify which licensees do not have fingerprint records on file with the DOJ/FBI. Absent such a list, the board will be required to manually pull the files for all of its licensees, to identify who will be affected by this proposal.

SUPPORT/OPPOSITION:
Support
Medical Board of California

Oppose Unless Amended
Contractors Board

HISTORY:
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.

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 introduced, Negrete McLeod. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.

This bill would make that fingerprinting requirement applicable to the Dental Board of California, the Dental Hygiene Committee of California, the Professional Fiduciary Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would require licensees to certify compliance with that requirement, as specified, and would subject a licensee to disciplinary action for making a false certification. The bill

would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

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

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

1 SECTION 1. Section 144 of the Business and Professions Code
2 is amended to read:
3 144. (a) Notwithstanding any other provision of law, an agency
4 designated in subdivision (b) shall require an applicant *for a license*
5 to furnish to the agency a full set of fingerprints for purposes of
6 conducting criminal history record checks *and shall require the*
7 *applicant to successfully complete a state and federal level criminal*
8 *offender record information search conducted through the*
9 *Department of Justice as provided in subdivision (c) or as*
10 *otherwise provided in this code.* ~~Any agency designated in~~
11 ~~subdivision (b) may obtain and receive, at its discretion, criminal~~
12 ~~history information from the Department of Justice and the United~~
13 ~~States Federal Bureau of Investigation.~~
14 (b) Subdivision (a) applies to the following:
15 (1) California Board of Accountancy.
16 (2) State Athletic Commission.
17 (3) Board of Behavioral Sciences.
18 (4) Court Reporters Board of California.
19 (5) State Board of Guide Dogs for the Blind.
20 (6) California State Board of Pharmacy.
21 (7) Board of Registered Nursing.
22 (8) Veterinary Medical Board.
23 (9) Registered Veterinary Technician Committee.
24 (10) Board of Vocational Nursing and Psychiatric Technicians.
25 (11) Respiratory Care Board of California.
26 (12) Hearing Aid Dispensers ~~Advisory Commission~~ *Bureau.*
27 (13) Physical Therapy Board of California.
28 (14) Physician Assistant Committee of the Medical Board of
29 California.
30 (15) Speech-Language Pathology and Audiology Board.

(16) Medical Board of California.
(17) State Board of Optometry.
(18) Acupuncture Board.
(19) Cemetery and Funeral Bureau.
(20) Bureau of Security and Investigative Services.
(21) Division of Investigation.
(22) Board of Psychology.
(23) ~~The~~ California Board of Occupational Therapy.
(24) Structural Pest Control Board.
(25) Contractors' State License Board.
(26) Bureau of Naturopathic Medicine.
(27) Dental Board of California.
(28) Dental Hygiene Committee of California.
(27) Professional Fiduciaries Bureau.
(28) California Board of Podiatric Medicine.
(29) Osteopathic Medical Board of California.
(30) State Board of Chiropractic Examiners.

~~(c) The provisions of paragraph (24) of subdivision (b) shall become operative on July 1, 2004. The provisions of paragraph (25) of subdivision (b) shall become operative on the date on which sufficient funds are available for the Contractors' State License Board and the Department of Justice to conduct a criminal history record check pursuant to this section or on July 1, 2005, whichever occurs first.~~

(c) Except as otherwise provided in this code, each agency listed in subdivision (b) shall direct applicants for a license to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

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

144.5. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) of Section 144 shall require a licencee who has not previously submitted fingerprints or for whom a record of the submission of fingerprints no longer exists to, as a condition of license renewal, successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (d).

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

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

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

(d) Each agency listed in subdivision (b) of Section 144 shall direct licensees described in subdivision (a) to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

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

(f) With respect to licensees that are business entities, each agency listed in subdivision (b) of Section 144 shall, by regulation, determine which owners, officers, directors, shareholders, members, agents, employees, or other natural persons who are representatives of the business entity are required to submit fingerprint images to the Department of Justice and disclose the information on its renewal forms, as required by this section.

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

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

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

144.6. (a) An agency described in subdivision (b) of Section 144 shall require a licensee, as a condition of license renewal, to notify the board on the license renewal form if he or she has been convicted, as defined in Section 490, 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.

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

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 484 **VERSION: As introduced**

AUTHOR: Wright **SPONSOR: Attorney General's Office**

BOARD POSITION:

SUBJECT: Ephedrine and Pseudoephedrine to Schedule 5

EXISTING LAW:
Under existing law, ephedrine and pseudoephedrine are over-the-counter drugs. In 2006, the federal "Combat Methaphetamine 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 phenylopropanolamine (these compounds are used in many cough, cold and allergy products). However, ephedrine and pseudoephedrine also are precursor ingredients used illegally to produce methamphetamine or amphetamine. The federal sales restrictions include daily sales limits, monthly purchase limits, placement of products out of direct customer access, sales logbooks, customer identification at point of sale and employee training.

THIS BILL WOULD:
Add ephedrine and pseudoephedrine to California's Controlled Substances in Schedule 5. Thus a prescription (and presumably at some point, a prescriber's office visit) would be required before a consumer could purchase ephedrine or pseudoephedrine.

AUTHOR'S INTENT:
Ephedrine and psuedoephedrine are over-the-counter drugs. Despite the 2006 sales restrictions implemented by the federal government, the AG's Office believes that additional restrictions are needed for sales of these products.

Methamphetamine production is a serious law enforcement issue – it is highly addictive, and the production of which creates serious public safety and environmental problems.

FISCAL IMPACT:
We anticipate an increase inspector workload to verify compliance and complete investigations associated with this proposal. Addition of this product to Schedule V would not require it be tracked by CURES – which requires computer monitoring of Schedule II – IV drugs.

According to information received, 5,180,246 boxes of ephedrine OTC products were sold last year in California.

COMMENTS:
The scheduling of an OTC to a schedule V on such a widely used product will potentially impact board operations and will have a significant impact of pharmacy operations. Currently the law

requires pharmacies, retailers, manufacturers and wholesalers to report the sales of such products to the Department of Justices. This proposal would require all Californians to obtain a prescription, either written on a security form or oral to obtain any ephedrine product, however would no longer require a pharmacy to report the sales of these products to the DOJ.

HISTORY:

Apr. 28.	Sen Public Safety
Mar. 12	To Com. on PUB. S.
Feb. 27	From print. May be acted upon on or after March 28.
Feb. 26	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 484

Introduced by Senator Wright

February 26, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

SB 484, as introduced, Wright. Ephedrine and pseudoephedrine.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, and specified related drugs within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified.

This bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription. The bill would make conforming changes to related provisions. By creating new crimes or revising the penalties for existing crimes involving ephedrine, pseudoephedrine, and specified related drugs, involving ephedrine, pseudoephedrine, and specified related drugs, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 11058 of the Health and Safety Code is
2 amended to read:
3 11058. (a) The controlled substances listed in this section are
4 included in Schedule V.
5 (b) Schedule V shall consist of the drugs and other substances,
6 by whatever official name, common or usual name, chemical name,
7 or brand name designated, listed in this section.
8 (c) Narcotic drugs containing nonnarcotic active medicinal
9 ingredients. Any compound, mixture, or preparation containing
10 any of the following narcotic drugs, or their salts calculated as the
11 free anhydrous base or alkaloid, in limited quantities as set forth
12 below, which shall include one or more nonnarcotic active
13 medicinal ingredients in sufficient proportion to confer upon the
14 compound, mixture, or preparation valuable medicinal qualities
15 other than those possessed by narcotic drugs alone:
16 (1) Not more than 200 milligrams of codeine per 100 milliliters
17 or per 100 grams.
18 (2) Not more than 100 milligrams of dihydrocodeine per 100
19 milliliters or per 100 grams.
20 (3) Not more than 100 milligrams of ethylmorphine per 100
21 milliliters or per 100 grams.
22 (4) Not more than 2.5 milligrams of diphenoxylate and not less
23 than 25 micrograms of atropine sulfate per dosage unit.
24 (5) Not more than 100 milligrams of opium per 100 milliliters
25 or per 100 grams.
26 (6) Not more than 0.5 milligram of difenoxin and not less than
27 25 micrograms of atropine sulfate per dosage unit.
28 *(7) Products containing ephedrine, pseudoephedrine,*
29 *norpseudoephedrine, phenylpropanolamine, N-methylephedrine,*
30 *N-ethylephedrine, N-methylpseudoephedrine,*

N-ethylpseudoephedrine, chloroephedrine, or chloropseudoephedrine, except for pediatric liquid forms as specified in subdivision (h) of Section 11100.

(d) Buprenorphine.

SEC. 2. Section 11100 of the Health and Safety Code is amended to read:

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

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.
(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
~~(16) Ephedrine.~~
~~(17) Pseudoephedrine.~~
~~(18) Norpseudoephedrine.~~
~~(19) Phenylpropanolamine.~~
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
~~(27) N-methylephedrine.~~
~~(28) N-ethylephedrine.~~
~~(29) N-methylpseudoephedrine.~~

~~(30) N-ethylpseudoephedrine.~~
~~(31) Chloroephedrine.~~
~~(32) Chloropseudoephedrine.~~
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.
(37) Iodine or tincture of iodine.
(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).
(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.
(c) (1) (A) Any manufacturer~~,~~ *or* wholesaler~~, retailer, or other person or entity~~ in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (A) a letter of authorization from that person or business entity that includes the currently valid business license number ~~or~~ *and* federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (B) proper identification from the

purchaser. The manufacturer~~,~~ *or* wholesaler~~, retailer, or other person or entity~~ in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

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

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

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

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with

respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer or wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

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

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

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

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

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

~~(4)~~

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

~~(5)~~

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

~~(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et~~

~~seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.~~

~~(B)~~

(5) Any ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine~~ *sale, transfer, furnishing, or receipt of a* product *specified in paragraph (7) of subdivision (c) of Section 11058 pursuant to prescription, shall not be subject to reporting or permitting requirements of this section, unless a product is* subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code*, in which case the product* shall similarly no longer be exempt from any state reporting or permitting requirement~~,~~ unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

~~(7)~~

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

~~(8)~~

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

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

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

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

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

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

~~(4)~~

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

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

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

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

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

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

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of ~~phenylpropanolamine or pseudoephedrine~~ *any product specified in paragraph (7) of subdivision (c) of Section 11058* per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales,~~ *any product specified in paragraph (7) of subdivision (c) of Section 11058 are limited to the sale of those products upon prescription only, except for pediatric liquids,* either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

~~(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.~~

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

SEC. 3. Section 11106 of the Health and Safety Code is amended to read:

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

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

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

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

~~(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person~~

~~or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.~~

(3)

(2) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ~~ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine,pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1)~~ *any product as specified in paragraph (7) of subdivision (c) of Section 11058.*

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

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

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of

being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

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

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

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

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

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

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

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

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

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating

the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

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

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

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

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

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

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

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

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

(*l*) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit

with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

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

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

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 599 **VERSION: Introduced: February 27, 2009**

AUTHOR: Negrete McLeod **SPONSOR:**

BOARD POSITION: None

SUBJECT: Licensing boards: disciplinary actions

EXISTING LAW:

1. Business and Professions Code §27 provides that specified boards provide on the Internet information regarding the status of a licensee.

THIS BILL WOULD:

Add section 27.5 to the B&PC to require every board specified in B&PC §22, to post each accusation, statement of issues, or disciplinary action taken by the board on that board's Internet Web site within 10 days of the filing date of the accusation or statement of issues, or the effective date of the disciplinary action. This bill specifies that the link to each posted action shall be easily accessible from the board's Internet home page.

AUTHOR'S INTENT:

Staff continues to seek information related to this specific legislation and will update the committee as information is available.

FISCAL IMPACT:

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

COMMENTS:

The board currently posts all accusations on its Web site on a monthly basis and all decisions on a quarterly basis. In addition, the board provides a link to the pleading document and decision to allow a consumer to read such documents when verifying a license. To comply with this mandate, the board will need to increase the frequency with which it posts information.

SUPPORT/OPPOSITION:
None on file.

HISTORY:

Mar. 19	Hearing set for 04/20/09 in SEN BP&ED
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.

SENATE BILL No. 599

Introduced by Senator Negrete McLeod

February 27, 2009

An act to add Section 27.5 to the Business and Professions Code, relating to business and professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 599, as introduced, Negrete McLeod. Licensing boards: disciplinary actions.

Existing law establishes the Department of Consumer Affairs in the State and Consumer Services Agency. Existing law establishes within the department specified boards, bureaus, and commissions for the purpose of ensuring that private businesses and professionals engaging in activities that have potential impact upon the public health, safety, and welfare are adequately regulated in order to protect the people of California. Existing law authorizes those entities to license qualified persons according to set and accepted professional standards, and to provide a means for redress of grievances by investigating allegations of unprofessional conduct, incompetence, fraudulent action, or unlawful activity. Existing law requires certain of those entities to provide on the Internet information regarding the status of every license issued by an entity in accordance with the California Public Records Act.

This bill would require every board, as defined, to post each accusation, statement of issues, or disciplinary action taken by the board on that board's Internet Web site within 10 days of the filing date of the accusation or statement of issues, or the effective date of the disciplinary action.

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 27.5 is added to the Business and
2 Professions Code, to read:
3 27.5. In addition to any applicable requirements specified in
4 Section 27, every board, as defined in Section 22, shall post each
5 accusation, statement of issues, or disciplinary action taken by the
6 board on that board's Internet Web site within 10 days of the filing
7 date of the accusation or statement of issues, or the effective date
8 of the disciplinary action. The link to each posted action shall be
9 easily accessible from the board's Internet home page.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 638 **VERSION:** **As Introduced: February 27, 2009**

AUTHOR: Negrete McLeod **SPONSOR:** **Author Sponsored**

BOARD POSITION: **None**

SUBJECT: **Regulatory boards: Operations**

EXISTING LAW

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs (DCA) shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD

1. Provide that if the terms of office of the members of the board are terminated, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor members shall be appointed by the same appointing authorities for the remainder of the previous members' terms.
2. Require that if the term of office for a bureau chief is terminated, a successor bureau chief shall be appointed who shall succeed to and be vested with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the successor shall be appointed by the same appointing authorities for the remainder of the previous bureau chief's terms.
3. Specify that the provisions apply to all boards, bureaus and entities as listed, including the Board of Pharmacy.
4. Establishes new, yet to be determined sunset dates.
5. Requires that the appropriate policy committees of the Legislature shall review boards and bureaus as specified.
6. Require all boards and bureaus to prepare an analysis and submit a report to the appropriate policy committees of the Legislature no later than 22 months before the sunset date specified.
7. Specify the content of the report to include:
    - The number of complaints received annually, the number that proceeded to investigation, the number of accusations filed per year and the number and kind of disciplinary actions taken.

- The average processing times for complaints and administrative case resolution as specified.
- The average processing time per year between the final disposition of a complaint and notice to the complainant.
- A copy of the enforcement priorities including criteria for seeking an interim suspension order.
- Brief description of the board or bureau's fund condition, sources of revenue and expenditures for the last four fiscal years.
- A brief description of the cost per year required to implement and administer a licensing examination, ownership of the license examination, the last assessment of the relevancy and validity of the licensing examination and passage rates for each of the last four years.
- A copy of sponsored legislation and description of budget change proposals.
- A brief assessment of licensing fees as to whether they are sufficient, too high or too low.
- A brief statement detailing how enforcement, public disclosure, accessibility to the public has improved over the last four years.

8. Require that the report be posted on the board or bureau's Web site.
9. Specify that the appropriate policy committees may hold public hearings to receive testimony regarding whether the board's or bureau's policies and practices are sufficient to protect consumers and are fair to licensees and prospective licensees and whether licensure of the profession is required to protect the public and whether an enforcement monitor is necessary to obtain further information on operations.
10. Allow the appropriate policy committees of the Legislature to evaluate and determine whether a board or program has a demonstrated public need for the continued existence of the regulatory program.

AUTHOR'S INTENT
SB 638 is needed to update and streamline the sunset review process.

FISCAL IMPACT
The board will incur minimal fiscal impact to board operations which can be absorbed within existing resources.

COMMENTS
This bill provides that when a professional licensing board in the Department of Consumer Affairs becomes inoperative or is repealed, a successor board is created to succeed to, and be vested with all of the duties, powers, purposes, responsibilities, and jurisdiction of the prior board. In effect, this bill makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau under the Department of Consumer Affairs.

This bill removes references to the Joint Committee on Boards Commissions and Consumer Protection, and instead, would provide that the relevant Legislative policy committees shall review the regulatory boards under DCA. The bill revises the review schedule for regulatory boards, and also provides for the review of DCA bureaus.

The board currently collects and reports several of the elements detailed above as part of its quarterly and annual statistics.

SUPPORT/OPPOSITION
None of file.

HISTORY:

Mar. 27	Set for hearing April 20.
Mar. 19	To Coms. on B., P. & E.D. and RLS.
Mar. 2	Read first time.
Feb. 28	From print. May be acted upon on or after March 30.
Feb. 27	Introduced. To Com. on RLS. for assignment. To print.

SENATE BILL No. 638

Introduced by Senator Negrete McLeod

February 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).~~

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

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

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

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

SEC. 3. Section 101.1 is added to the Business and Professions Code, to read:

101.1. (a) Notwithstanding any other provision of law, if the terms of office of the members of a board are terminated in accordance with the act that added this section or by subsequent acts, successor members shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the members that they are succeeding. The successor members shall be appointed by the same appointing authorities, for the remainder of the previous members' terms, and shall be subject to the same membership requirements as the members they are succeeding.

(b) Notwithstanding any other provision of law, if the term of office for a bureau chief is terminated in accordance with the act that added this section or by subsequent acts, a successor bureau chief shall be appointed who shall succeed to, and be vested with,

all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the bureau chief that he or she is succeeding. The successor bureau chief shall be appointed by the same appointing authorities, for the remainder of the previous bureau chief's term, and shall be subject to the same requirements as the bureau chief he or she is succeeding.

SEC. 4. Section 473 of the Business and Professions Code is repealed.

~~473. (a) There is hereby established the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~(b) The Joint Committee on Boards, Commissions, and Consumer Protection shall consist of three members appointed by the Senate Committee on Rules and three members appointed by the Speaker of the Assembly. No more than two of the three members appointed from either the Senate or the Assembly shall be from the same party. The Joint Rules Committee shall appoint the chairperson of the committee.~~

~~(c) The Joint Committee on Boards, Commissions, and Consumer Protection shall have and exercise all of the rights, duties, and powers conferred upon investigating committees and their members by the Joint Rules of the Senate and Assembly as they are adopted and amended from time to time, which provisions are incorporated herein and made applicable to this committee and its members.~~

~~(d) The Speaker of the Assembly and the Senate Committee on Rules may designate staff for the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~(e) The Joint Committee on Boards, Commissions, and Consumer Protection is authorized to act until January 1, 2012, at which time the committee's existence shall terminate.~~

SEC. 5. Section 473 is added to the Business and Professions Code, to read:

473. Whenever the provisions of this code refer to the Joint Committee on Boards, Commissions and Consumer Protection, the reference shall be construed to be a reference to the appropriate policy committees of the Legislature.

SEC. 6. Section 473.1 of the Business and Professions Code is amended to read:

473.1. This chapter shall apply to all of the following:

(a) Every board, as defined in Section 22, that is scheduled to ~~become inoperative and to be repealed~~ *have its membership reconstituted* on a specified date as provided by ~~the specific act relating to the board~~ *subdivision (a) of Section 473.12.*

(b) ~~The Bureau for Postsecondary and Vocational Education. For purposes of this chapter, "board" includes the bureau~~*Every bureau that is named in subdivision (b) of Section 473.12.*

(c) ~~The Cemetery and Funeral Bureau~~*Every entity that is named in subdivision (c) of Section 473.12.*

SEC. 7. Section 473.12 is added to the Business and Professions Code, to read:

473.12. (a) Notwithstanding any other provision of law, the term of office of each member of the following boards in the department shall terminate on the date listed, unless a later enacted statute, that is enacted before the date listed for that board, deletes or extends that date:

(1) The Dental Board of California: January 1, ____.

(2) The Medical Board of California: January 1, ____.

(3) The State Board of Optometry: January 1, ____.

(4) The California State Board of Pharmacy: January 1, ____.

(5) The Veterinary Medical Board: January 1, ____.

(6) The California Board of Accountancy: January 1, ____.

(7) The California Architects Board: January 1, ____.

(8) The State Board of Barbering and Cosmetology: January 1, ____.

(9) The Board for Professional Engineers and Land Surveyors: January 1, ____.

(10) The Contractors' State License Board: January 1, ____.

(11) The Structural Pest Control Board: January 1, ____.

(12) The Board of Registered Nursing: January 1, ____.

(13) The Board of Behavioral Sciences: January 1, ____.

(14) The State Athletic Commission: January 1, ____.

(15) The State Board of Guide Dogs for the Blind: January 1, ____.

(16) The Court Reporters Board of California: January 1, ____.

(17) The Board of Vocational Nursing and Psychiatric Technicians: January 1, ____.

(18) The Landscape Architects Technical Committee: January 1, ____.

(19) The Board for Geologists and Geophysicists: January 1, ____.
(20) The Respiratory Care Board of California: January 1, ____.
(21) The Acupuncture Board: January 1, ____.
(22) The Board of Psychology: January 1, ____.
(23) The California Board of Podiatric Medicine: January 1, ____.
(24) The Physical Therapy Board of California: January 1, ____.
(25) The Physician Assistant Committee, Medical Board of California: January 1, ____.
(26) The Speech-Language Pathology and Audiology Board: January 1, ____.
(27) The California Board of Occupational Therapy: January 1, ____.
(28) The Dental Hygiene Committee of California: January 1, ____.

(b) Notwithstanding any other provision of law, the term of office for the bureau chief of each of the following bureaus shall terminate on the date listed, unless a later enacted statute, that is enacted before the date listed for that bureau, deletes or extends that date:

(1) Arbitration Review Program: January 1, ____.
(2) Bureau for Private Postsecondary Education: January 1, ____.
(3) Bureau of Automotive Repair: January 1, ____.
(4) Bureau of Electronic and Appliance Repair: January 1, ____.
(5) Bureau of Home Furnishings and Thermal Insulation: January 1, ____.
(6) Bureau of Naturopathic Medicine: January 1, ____.
(7) Bureau of Security and Investigative Services: January 1, ____.
(8) Cemetery and Funeral Bureau: January 1, ____.
(9) Hearing Aid Dispensers Bureau: January 1, ____.
(10) Professional Fiduciaries Bureau: January 1, ____.
(11) Telephone Medical Advice Services Bureau: January 1, ____.
(12) Division of Investigation: January 1, ____.

(c) Notwithstanding any other provision of law, the following shall be subject to review under this chapter on the following dates:

(1) Interior design certification organizations: January 1, ____.

(2) State Board of Chiropractic Examiners pursuant to Section 473.15: January 1, ____.

(3) Osteopathic Medical Board of California pursuant to Section 473.15: January 1, ____.

(4) California Tax Education Council: January 1, ____.

(d) Nothing in this section or in Section 101.1 shall be construed to preclude, prohibit, or in any manner alter the requirement of Senate confirmation of a board member, chief officer, or other appointee that is subject to confirmation by the Senate as otherwise required by law.

(e) It is not the intent of the Legislature in enacting this section to amend the initiative measure that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 8. Section 473.15 of the Business and Professions Code is amended to read:

473.15. (a) The ~~Joint Committee on Boards, Commissions, and Consumer Protection established pursuant to Section 473~~ *appropriate policy committees of the Legislature* shall review the following boards established by initiative measures, as provided in this section:

(1) The State Board of Chiropractic Examiners established by an initiative measure approved by electors November 7, 1922.

(2) The Osteopathic Medical Board of California established by an initiative measure approved June 2, 1913, and acts amendatory thereto approved by electors November 7, 1922.

(b) The Osteopathic Medical Board of California shall prepare an analysis and submit a report as described in subdivisions (a) to (e), inclusive, of Section 473.2, to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* on or before September 1, 2010.

(c) The State Board of Chiropractic Examiners shall prepare an analysis and submit a report as described in subdivisions (a) to (e), inclusive, of Section 473.2, to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* on or before September 1, 2011.

(d) The ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* shall, during the interim recess of ~~2004~~ *2011* for the Osteopathic Medical Board of California, and during the interim

recess of 2011 for the State Board of Chiropractic Examiners, hold public hearings to receive testimony from the Director of Consumer Affairs, the board involved, the public, and the regulated industry. In that hearing, each board shall be prepared to demonstrate a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* shall evaluate and make determinations pursuant to Section 473.4 ~~and shall report its findings and recommendations to the department as provided in Section 473.5~~.

(f) In the exercise of its inherent power to make investigations and ascertain facts to formulate public policy and determine the necessity and expediency of contemplated legislation for the protection of the public health, safety, and welfare, it is the intent of the Legislature that the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California be reviewed pursuant to this section.

(g) It is not the intent of the Legislature in ~~requiring a review under~~ *enacting* this section to amend the initiative measures that established the State Board of Chiropractic Examiners or the Osteopathic Medical Board of California.

SEC. 9. Section 473.16 of the Business and Professions Code is repealed.

~~473.16. The Joint Committee on Boards, Commissions, and Consumer Protection shall examine the composition of the Medical Board of California and its initial and biennial fees and report to the Governor and the Legislature its findings no later than July 1, 2008.~~

SEC. 10. Section 473.2 of the Business and Professions Code is amended to read:

473.2. *(a)* All boards ~~to which this chapter applies~~ *or bureaus listed in Section 473.12* shall, with the assistance of the Department of Consumer Affairs, prepare an analysis and submit a report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* no later than 22 months before that ~~board~~ *board's membership or the bureau chief's term* shall ~~become inoperative~~ *be terminated*

pursuant to Section 473.12. The analysis and report shall include, at a minimum, all of the following:

~~(a) A comprehensive statement of the board's mission, goals, objectives and legal jurisdiction in protecting the health, safety, and welfare of the public.~~

~~(b) The board's enforcement priorities, complaint and enforcement data, budget expenditures with average- and median-costs per case, and case aging data specific to post and preaccusation cases at the Attorney General's office.~~

~~(c) The board's~~

(1) The number of complaints it received per year, the number of complaints per year that proceeded to investigation, the number of accusations filed per year, and the number and kind of disciplinary actions taken, including, but not limited to, interim suspension orders, revocations, probations, and suspensions.

(2) The average amount of time per year that elapsed between receipt of a complaint and the complaint being closed or referred to investigation; the average amount of time per year elapsed between the commencement of an investigation and the complaint either being closed or an accusation being filed; the average amount of time elapsed per year between the filing of an accusation and a final decision, including appeals; and the average and median costs per case.

(3) The average amount of time per year between final disposition of a complaint and notice to the complainant.

(4) A copy of the enforcement priorities including criteria for seeking an interim suspension order.

(5) A brief description of the board's or bureau's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

~~(d) The board's description of its licensing process including the time and costs~~

(6) A brief description of the cost per year required to implement and administer its licensing examination, ownership of the license examination, *the last assessment of the* relevancy and validity of the licensing examination, ~~and~~ *the* passage rate *for each of the last four years,* and areas of examination.

~~(e) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.~~

(7) A copy of sponsored legislation and a description of its budget change proposals.

(8) A brief assessment of its licensing fees as to whether they are sufficient, too high, or too low.

(9) A brief statement detailing how the board or bureau over the prior four years has improved its enforcement, public disclosure, accessibility to the public, including, but not limited to, Web casts of its proceedings, and fiscal condition.

(b) If an annual report contains information that is required by this section, a board or bureau may submit the annual report to the committees and it shall post it on the board's or bureau's Internet Web site.

SEC. 11. Section 473.3 of the Business and Professions Code is amended to read:

473.3. ~~(a)~~ Prior to the termination~~, continuation, or reestablishment~~ *of the terms of office* of *the membership of* any board or ~~any of the board's functions, the Joint Committee on Boards, Commissions, and Consumer Protection shall~~ *the chief of any bureau described in Section 473.12, the appropriate policy committees of the Legislature*, during the interim recess preceding the date upon which a ~~board becomes inoperative~~ *board member's or bureau chief's term of office is to be terminated, may* hold public hearings to receive *and consider* testimony from the Director of Consumer Affairs, the board *or bureau* involved, ~~and~~ *the Attorney General, members of* the public, and *representatives of the* regulated industry~~. In that hearing, each board shall have the burden of demonstrating a compelling public need for the continued existence of the board or regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare~~ *regarding whether the board's or bureau's policies and practices, including enforcement, disclosure, licensing exam, and fee structure, are sufficient to protect consumers and are fair to licensees and prospective licensees, whether licensure of the profession is required to protect the public, and whether an enforcement monitor may be necessary to obtain further information on operations.*

~~(b) In addition to subdivision (a), in 2002 and every four years thereafter, the committee, in cooperation with the California Postsecondary Education Commission, shall hold a public hearing to receive testimony from the Director of Consumer Affairs, the~~

~~Bureau for Private Postsecondary and Vocational Education, private postsecondary educational institutions regulated by the bureau, and students of those institutions. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.~~

~~(c) The committee, in cooperation with the California Postsecondary Education Commission, shall evaluate and review the effectiveness and efficiency of the Bureau for Private Postsecondary and Vocational Education, based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.~~

~~(d) In addition to subdivision (a), in 2003 and every four years thereafter, the committee shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the Bureau of Automotive Repair. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.~~

~~(e) The committee shall evaluate and review the effectiveness and efficiency of the Bureau of Automotive Repair based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.~~

SEC. 12. Section 473.4 of the Business and Professions Code is amended to read:

473.4. (a) The ~~Joint Committee on Boards, Commissions, and Consumer Protection shall~~ *appropriate policy committees of the Legislature may* evaluate and determine whether a board or regulatory program has demonstrated a public need for the continued existence of the ~~board or~~ regulatory program and for the degree of regulation the board or regulatory program

implements based on the following factors and minimum standards of performance:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial licensing or regulation of a practice or profession have changed.

(3) Whether other conditions have arisen that would warrant increased, decreased, or the same degree of regulation.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether the board rules enhance the public interest and are within the scope of legislative intent.

(5) Whether the board operates and enforces its regulatory responsibilities in the public interest and whether its regulatory mission is impeded or enhanced by existing statutes, regulations, policies, practices, or any other circumstances, including budgetary, resource, and personnel matters.

(6) Whether an analysis of board operations indicates that the board performs its statutory duties efficiently and effectively.

(7) Whether the composition of the board adequately represents the public interest and whether the board encourages public participation in its decisions rather than participation only by the industry and individuals it regulates.

(8) Whether the board and its laws or regulations stimulate or restrict competition, and the extent of the economic impact the board's regulatory practices have on the state's business and technological growth.

(9) Whether complaint, investigation, powers to intervene, and disciplinary procedures adequately protect the public and whether final dispositions of complaints, investigations, restraining orders, and disciplinary actions are in the public interest; or if it is, instead, self-serving to the profession, industry or individuals being regulated by the board.

(10) Whether the scope of practice of the regulated profession or occupation contributes to the highest utilization of personnel and whether entry requirements encourage affirmative action.

(11) Whether administrative and statutory changes are necessary to improve board operations to enhance the public interest.

~~(b) The Joint Committee on Boards, Commissions, and Consumer Protection shall consider alternatives to placing responsibilities and jurisdiction of the board under the Department of Consumer Affairs.~~

~~(c)~~

(b) Nothing in this section precludes any board from submitting other appropriate information to the ~~Joint Committee on Boards, Commissions, and Consumer Protection.~~ *appropriate policy committees of the Legislature.*

SEC. 13. Section 473.5 of the Business and Professions Code is repealed.

~~473.5. The Joint Committee on Boards, Commissions, and Consumer Protection shall report its findings and preliminary recommendations to the department for its review, and, within 90 days of receiving the report, the department shall report its findings and recommendations to the Joint Committee on Boards, Commissions, and Consumer Protection during the next year of the regular session that follows the hearings described in Section 473.3. The committee shall then meet to vote on final recommendations. A final report shall be completed by the committee and made available to the public and the Legislature. The report shall include final recommendations of the department and the committee and whether each board or function scheduled for repeal shall be terminated, continued, or reestablished, and whether its functions should be revised. If the committee or the department deems it advisable, the report may include proposed bills to carry out its recommendations.~~

SEC. 14. Section 473.6 of the Business and Professions Code is amended to read:

473.6. The chairpersons of the appropriate policy committees of the Legislature may refer to ~~the Joint Committee on Boards, Commissions, and Consumer Protection for~~ *interim study* review of any legislative issues or proposals to create new licensure or regulatory categories, change licensing requirements, modify scope of practice, or create a new licensing board under the provisions of this code or pursuant to Chapter 1.5 (commencing with Section 9148) of Part 1 of Division 2 of Title 2 of the Government Code.

SEC. 15. Section 473.7 is added to the Business and Professions Code, to read:

473.7. The appropriate policy committees of the Legislature may, through their oversight function, investigate the operations of any entity to which this chapter applies and hold public hearings on any matter subject to public hearing under Section 473.3.

SEC. 16. Section 9882 of the Business and Professions Code is amended to read:

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

(b) In 2003 and every four years thereafter, the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* shall hold a public hearing to receive *and consider* testimony from the Director of Consumer Affairs ~~and~~, the bureau~~. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare~~, *the Attorney General, members of the public, and representatives of this industry regarding the bureau's policies and practices as specified in Section 473.3*. The ~~committee shall~~ *appropriate policy committees of the Legislature may* evaluate and review the effectiveness and efficiency of the bureau based on factors and minimum standards of performance that are specified in Section 473.4. ~~The committee shall report its findings and recommendations as specified in Section 473.5.~~ The bureau shall prepare an analysis and submit a report to the ~~committee~~ *appropriate policy committees of the Legislature* as specified in Section 473.2.

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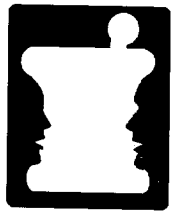
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 762 **VERSION: Introduced: February 27, 2009**

AUTHOR: Aanestad **SPONSOR:**

BOARD POSITION: None

SUBJECT: Professions and Vocations: healing arts

EXISTING LAW:
States that no city or county shall prohibit a person, authorized by one of the agencies in the Department of Consumer Affairs from engaging in the business for which the license has been obtained.

THIS BILL WOULD:
1. Clarify that no city or county shall prohibit a person, or group of persons from engaging in the business for which the license has been obtained.
2. Specify that no city, county, or city and county shall prohibit a healing arts professional from engaging in any activity that falls within the professionally recognized scope of practice of the licensee. Clarify that the provisions of the section become effective January 1, 2010.
3. Clarify that the above will not prohibit any city, county or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purposes of covering the cost of regulation.

AUTHOR'S INTENT:

FISCAL IMPACT:
The board does not anticipate any fiscal impact to its operations. Any minor impact could be absorbed within existing resources.

COMMENTS:

SUPPORT/OPPOSITION:

HISTORY:
Apr. 27 Set for Hearing in SEN Business, Professions and Economic Development
Mar. 19 To Com. on B., P. & E.D.
Mar. 2 Read first time.
Feb. 28 From print. May be acted upon on or after March 30.
Feb. 27 Introduced. To Com. on RLS. for assignment. To print.

SENATE BILL No. 762

Introduced by Senator Aanestad

February 27, 2009

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

LEGISLATIVE COUNSEL'S DIGEST

SB 762, as introduced, Aanestad. Professions and vocations: healing arts.

Existing law makes it unlawful for a city or county to prohibit a person, authorized by one of the agencies of the Department of Consumer Affairs to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

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

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

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

1 SECTION 1. Section 460 of the Business and Professions Code
2 is amended to read:
3 460. *(a)* No city or county shall prohibit a person *or group of*
4 *persons*, authorized by one of the agencies in the Department of
5 Consumer Affairs by a license, certificate, or other such means to
6 engage in a particular business, from engaging in that business,

occupation, or profession or any portion thereof. ~~Nothing in this section shall prohibit any city or 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.~~

(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. This subdivision shall not be construed to prohibit the enforcement of a local ordinance effective 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).

(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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Attachment 10

Other Legislation Introduced

Of Interest or For Information Only

ASSEMBLY BILL No. 832

Introduced by Assembly Member Jones

February 26, 2009

An act to amend Sections 1200, 1204, 1206, and 1248.1 of, and to add Sections 1204.6, 1212.5, 1212.6, and 1212.7 to, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 832, as introduced, Jones. Clinic licensing.

(1) Existing law establishes various programs for the prevention of disease and the promotion of the public health under the jurisdiction of the State Department of Public Health, including, but not limited to, provisions for the licensing, with certain exceptions, of clinics, as defined. A violation of these provisions is a crime.

This bill would exclude a place, establishment, or institution that solely provides immunizations, or screenings for blood pressure, cholesterol, or bone density, or a combination of those services, from the definition of "clinic" for these purposes.

(2) Existing law defines "surgical clinic" as a clinic that provides ambulatory surgical care and is not part of a hospital or is a place that is owned, leased, or operated as a clinic or office by one or more physicians or dentists.

This bill would recast that definition, would define "ambulatory surgical care" for this purpose, and would delete the exemption for a place that is owned, leased, or operated by one or more physicians or dentists. The bill would require surgical clinics to be licensed regardless of physician ownership, but would exclude a doctor's office or other

place that provides only prescribed services, and would make conforming changes.

This bill would require any person seeking licensure as a surgical clinic to provide documentation of satisfactory completion of prescribed structural building requirements.

By changing the definition of an existing crime, this bill would impose a state-mandated local program.

This bill would declare the intent of the Legislature to subsequently appropriate funds to the department as a loan to support the licensing and certification program relating to surgical clinics.

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

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

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

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

1 SECTION 1. This act shall be known, and may be cited, as the
2 California Outpatient Surgery Patient Safety and Improvement
3 Act.
4 SEC. 2. Section 1200 of the Health and Safety Code is amended
5 to read:
6 1200. As used in this chapter, "clinic" means an organized
7 outpatient health facility ~~which~~ *that* provides direct medical,
8 surgical, dental, optometric, or podiatric advice, services, or
9 treatment to patients who remain less than 24 hours, and which
10 may also provide diagnostic or therapeutic services to patients in
11 the home as an incident to care provided at the clinic facility.
12 Nothing in this section shall be construed to prohibit the provision
13 of nursing services in a clinic licensed pursuant to this chapter. In
14 no case shall a clinic be deemed to be a health facility subject to
15 the provisions of Chapter 2 (commencing with Section 1250) of
16 this division. A place, establishment, or institution ~~which~~ *that*
17 solely provides advice, counseling, information, or referrals on
18 the maintenance of health or on the means and measures to prevent
19 or avoid sickness, disease, or injury, where such advice, counseling,
20 information, or referrals does not constitute the practice of

medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this chapter. *A place, establishment, or institution that solely provides immunizations, or screenings for blood pressure, cholesterol, or bone density, or any combination of these services, shall not be deemed a clinic for purposes of this chapter.*

References in this chapter to "primary care clinics" shall mean and designate all the types of clinics specified in subdivision (a) of Section 1204, including community clinics and free clinics. References in this chapter to specialty clinics shall mean and designate all the types of clinics specified in subdivision (b) of Section 1204, including surgical clinics, chronic dialysis clinics, and rehabilitation clinics.

SEC. 3. Section 1204 of the Health and Safety Code is amended to read:

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

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

(A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.

(B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or

apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

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

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

(1) A "surgical clinic" means a clinic that is not part of a hospital *or a primary care clinic that is either licensed pursuant to this section, or exempt pursuant to subdivision (b) of Section 1206,* and that provides ambulatory surgical care *as defined in Section 1204.6* for patients who remain less than 24 hours. ~~A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.~~ *Surgical clinics shall be subject to licensure by the department regardless of physician ownership.*

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

(3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following

rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

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

(c) In accordance with subdivision (d) of Section 1248.1, licensure as a surgical clinic shall satisfy the requirements of Chapter 1.3 (commencing with Section 1248).

SEC. 4. Section 1204.6 is added to the Health and Safety Code, to read:

1204.6. (a) "Ambulatory surgical care" for purposes of licensure as a surgical clinic, means the incision, partial or complete excision, destruction, resection, or other structural alteration of human tissue by any means except any of the following:

(1) Minor skin repair procedures, including, but not limited to, any of the following:

(A) Repair of minor lacerations.

(B) Excision of moles, warts, or other minor skin lesions.

(C) Incision and drainage of superficial abscesses.

(2) Procedures using only local anesthesia, topical anesthesia, or no anesthesia.

(3) Procedures not using general anesthesia or conscious sedation.

(b) "General anesthesia" for purposes of licensure as a surgical clinic, means a controlled state of depressed consciousness or unconsciousness, accompanied by partial or complete loss of protective reflexes, produced by a pharmacologic or nonpharmacologic method, or a combination thereof.

(c) "Conscious sedation" for purposes of licensure as a surgical clinic, means a minimally depressed level of consciousness produced by a pharmacologic or nonpharmacologic method, or a combination thereof, that retains the patient's ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation or verbal command. Conscious sedation does not include the administration of oral medications or the administration of a mixture of nitrous oxide

and oxygen, whether administered alone or in combination with each other.

(d) A doctor's office or other place, establishment, or institution that provides no surgical services other than those described in paragraphs (1), (2), and (3) of subdivision (a) shall not be required to obtain licensure as a surgical clinic.

SEC. 5. Section 1206 of the Health and Safety Code is amended to read:

1206. ~~This~~ *The licensure and other requirements of this* chapter ~~does~~ *do* not apply to *any of* the following:

(a) ~~Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) of subdivision (b) of Section 1204, any~~ *Any* place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used *by the practitioner* as an office for the practice of ~~their~~ *his or her* profession, within the scope of ~~their~~ *his or her* license *in any lawful form of organization, so long as each licensed health care practitioner who practices at the clinic has some ownership or leasehold interest in, and some degree of control over and responsibility for, the operation of the clinic*, regardless of the name used publicly to identify the place or establishment. *The exemption pursuant to this subdivision shall not apply to either of the following:*

(1) Any surgical clinic as described in paragraph (1) of subdivision (b) of Section 1204, regardless of any health care practitioner ownership interest in the clinic.

(2) Any chronic dialysis clinic as described in paragraph (2) of subdivision (b) of Section 1204.

(b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

(c) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

(d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.

(e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).

(f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art. *The exemption pursuant to this subdivision shall not apply to any surgical clinic as described in paragraph (1) of subdivision (b) of Section 1204.*

(h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 20 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.

(i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).

(j) Student health centers operated by public institutions of higher education.

(k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7

(commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

(*l*) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.

(m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.

(n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.

(o) A community mental health center, as defined in Section 5601.5 of the Welfare and Institutions Code.

(p) (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:

(A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.

(B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.

(C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

(D) Received grants and contracts from the National Institutes of Health.

(E) Held and licensed patents on medical technology.

(F) Received charitable contributions and bequests totaling at least five million dollars ($5,000,000).

(G) Provides health care services to patients only:

(i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.

(ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.

(H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.

(I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a

clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

(2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.

SEC. 6. Section 1212.5 is added to the Health and Safety Code, to read:

1212.5. (a) Commencing January 1, 2010, in addition to other licensing requirements of this chapter, any person, firm, association, partnership, or corporation seeking a license for a surgical clinic shall provide the department with documentation of satisfactory completion of the structural and building requirements set forth in Section 1226 of Title 24 of the California Code of Regulations, or compliance with the 2000 Medicare Life and Safety Code requirements.

(b) Commencing January 1, 2010, a surgical clinic shall also meet all of the following standards:

(1) Only those patients who have given full informed consent about the inherent risks of receiving surgery in facilities with limited post surgical rescue potential that would be available in a general acute care hospital shall receive services in the surgical clinic.

(2) Comply with the conditions of coverage as set forth in Subpart C of Part 416 of Title 42 of the Code of Federal Regulations, as those conditions exist on January 1, 2008. The conditions of coverage shall be conditions of providing services regardless of the source of payment for those services.

(3) Limit surgical procedures to those that comply with all of the following:

(A) Do not require the presence of more than one surgeon during the procedure.

(B) Are not expected to require a blood transfusion.

(C) Are not expected to require major or prolonged invasion of body cavities.

(D) Are not expected to involve major blood vessels.

(E) Are not inherently life threatening.

(F) Are not emergency surgeries.

(G) Are not experimental surgeries.

(4) A preanesthesia evaluation, including an ASA Physical Status Classification, shall be completed on all surgical anesthesia patients. Surgical procedures shall not be performed on a patient with severe systemic disease that is a constant threat to life (ASA Classification 4) or on a moribund patient who is not expected to survive for 24 hours without the operation (ASA Classification 5). A patient with severe systemic disease (ASA Classification 3) shall have a presurgical consultation with a physician specialist appropriate for the patient's severe systemic disease in order to obtain medical clearance for surgery.

(5) Establish and implement policies and procedures compliant with the conditions of coverage. The policies and procedures shall comply with both of the following:

(A) The policies and procedures shall include, but need not be limited to, all of the following:

(i) Surgical services, as provided by physicians, dentists, or podiatrists.

(ii) Anesthesia services.

(iii) Nursing services.

(iv) Evaluation of quality assessment and performance improvement.

(v) Infection control.

(vi) Pharmaceutical services.

(vii) Laboratory and radiology services.

(viii) Housekeeping services, including provisions for maintenance of a safe, clean environment.

(ix) Patient health records, including provisions that shall be developed with the assistance of a person skilled in record maintenance and preservation.

(x) Personnel policies and procedures.

(B) The policies and procedures shall provide for appropriate staffing ratios for all care provided to patients receiving general anesthesia in compliance with both of the following:

(i) In each surgical room there shall be at least one registered nurse assigned to the duties of the circulating nurse and a minimum of one additional person serving as scrub assistant for each patient-occupied operating room. The scrub assistant may be a licensed nurse, an operating room technician, or other person who has demonstrated current competence to the clinic as a scrub assistant, but shall not be a physician or other licensed health professional who is assisting in the performance of surgery.

(ii) The licensed nurse-to-patient ratio in a postanesthesia recovery unit of the anesthesia service shall be one-to-two or fewer at all times, regardless of the type of general anesthesia the patient receives.

SEC. 7. Section 1212.6 is added to the Health and Safety Code, to read:

1212.6. Every clinic for which a license has been issued under Section 1212.5 shall be subject to the reporting requirements contained in Section 1279.1 and the penalties imposed under Sections 1280.1, 1280.3, and 1280.4.

SEC. 8. Section 1212.7 is added to the Health and Safety Code, to read:

1212.7. It is the intent of the Legislature to provide funding through an appropriation in the Budget Act or other measure to the State Department of Public Health, for a loan for the support the operations of the Licensing and Certification Program for activities authorized by this chapter relating to the licensure of surgical clinics. The loan shall be repaid with proceeds from fees collected pursuant to Section 1266.

SEC. 9. Section 1248.1 of the Health and Safety Code is amended to read:

1248.1. No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.

(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.

(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.

(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.

(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.

(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable, *including, but not limited to, licensure as a primary care or specialty clinic as set forth in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code. Surgical clinics shall be subject to licensure regardless of any physician ownership interest.*

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

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

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AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 1094

Introduced by Assembly Member Conway

February 27, 2009

~~An act to add Section 2005 to the Business and Professions Code, relating to medicine.~~ *An act to amend Sections 1798.80, 1798.81, and 1798.84 of the Civil Code, relating to personal information.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1094, as amended, Conway. ~~Medical Board of California: physician and surgeon well-being.~~ *Disposal of personal information.*

Existing law requires a business to take all reasonable steps to destroy, or arrange for the destruction of, a customer's records within its custody or control containing personal information that is no longer to be retained by the business by shredding, erasing, or otherwise modifying the personal information in those records to make it unreadable or undecipherable through any means. Existing law provides for specified civil remedies for a violation of these provisions.

This bill would, instead, require a business to take all reasonable steps to dispose, or arrange for the disposal, of an individual's records within its custody or control containing personal information when the records are no longer to be retained by the business by taking any of the actions described above. A violation of this provision would be punishable as a misdemeanor. By creating a new crime, the bill would impose a state-mandated local program. The bill would provide that a cause of action shall not lie against a business that comes into possession of abandoned records containing personal information and that disposes of those records in accordance with these provisions.

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

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

~~Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and vests the board with certain responsibilities.~~

~~This bill would authorize the board to establish a program to promote the issues concerning physician and surgeon well-being and would require the program to include, among other things, an examination and evaluation of existing wellness education for medical students, postgraduate trainees, and licensed physicians and surgeons and an outreach effort to promote physician and surgeon wellness. The bill would require the program to be developed within existing resources unless otherwise authorized in the annual Budget Act.~~

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

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

1 *SECTION 1. Section 1798.80 of the Civil Code is amended to*
2 *read:*
3 1798.80. The following definitions apply to this title:
4 (a) "Business" means a sole proprietorship, partnership,
5 corporation, association, or other group, however organized and
6 whether or not organized to operate at a profit, including a financial
7 institution organized, chartered, or holding a license or
8 authorization certificate under the law of this state, any other state,
9 the United States, or of any other country, or the parent or the
10 subsidiary of a financial institution. The term includes an entity
11 that ~~destroys~~ *disposes of* records.
12 (b) "Records" means any material, regardless of the physical
13 form, on which information is recorded or preserved by any means,
14 including in written or spoken words, graphically depicted, printed,
15 or electromagnetically transmitted. "Records" does not include
16 publicly available directories containing information an individual
17 has voluntarily consented to have publicly disseminated or listed,
18 such as name, address, or telephone number.

(c) "Customer" means an individual who provides personal information to a business for the purpose of purchasing or leasing a product or obtaining a service from the business.

(d) "Individual" means a natural person.

(e) "Personal information" means any information that identifies, relates to, describes, or is capable of being associated with, a particular individual, including, but not limited to, his or her name, signature, social security number, physical characteristics or description, address, telephone number, passport number, driver's license or state identification card number, insurance policy number, education, employment, employment history, bank account number, credit card number, debit card number, or any other financial information.

SEC. 2. Section 1798.81 of the Civil Code is amended to read:

1798.81. A business shall take all reasonable steps to ~~destroy~~ *dispose*, or arrange for the ~~destruction~~ *disposal,* of ~~a customer's~~ *an individual's* records within its custody or control containing personal information ~~which is~~ *when the records are* no longer to be retained by the business by ~~(1)~~ *(a)* shredding, ~~(2)~~ *(b)* erasing, or ~~(3)~~ *(c)* otherwise modifying the personal information in those records to make it unreadable or undecipherable through any means.

SEC. 3. Section 1798.84 of the Civil Code is amended to read:

1798.84. (a) Any waiver of a provision of this title is contrary to public policy and is void and unenforceable.

(b) Any ~~customer~~ *individual* injured by a violation of this title may institute a civil action to recover damages.

(c) In addition, for a willful, intentional, or reckless violation of Section 1798.83, a customer may recover a civil penalty not to exceed three thousand dollars ($3,000) per violation; otherwise, the customer may recover a civil penalty of up to five hundred dollars ($500) per violation for a violation of Section 1798.83.

(d) Unless the violation is willful, intentional, or reckless, a business that is alleged to have not provided all the information required by subdivision (a) of Section 1798.83, to have provided inaccurate information, failed to provide any of the information required by subdivision (a) of Section 1798.83, or failed to provide information in the time period required by subdivision (b) of Section 1798.83, may assert as a complete defense in any action in law or equity that it thereafter provided regarding the information

that was alleged to be untimely, all the information, or accurate information, to all customers who were provided incomplete or inaccurate information, respectively, within 90 days of the date the business knew that it had failed to provide the information, timely information, all the information, or the accurate information, respectively.

(e) Any business that violates, proposes to violate, or has violated this title may be enjoined.

(f) Every business, including any employee or agent thereof, that knowingly disposes of records containing personal information in violation of Section 1798.81 is guilty of a misdemeanor and shall be punished, upon conviction, by a fine, by imprisonment in the county jail not to exceed one year, or by both a fine and imprisonment.

(g) A cause of action shall not lie against a business that comes into possession of abandoned records containing personal information and that disposes of those records in accordance with Section 1798.81.

~~(f)~~

(h) A prevailing plaintiff in any action commenced under Section 1798.83 shall also be entitled to recover his or her reasonable attorney's fees and costs.

~~(g)~~

(i) The rights and remedies available under this section are cumulative to each other and to any other rights and remedies available under law.

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

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

~~(a) One element in the protection of the health care consumer can be achieved by having healthy physicians and surgeons care for their patients.~~

~~(b) Various studies document that stress factors in a physician and surgeon's job can significantly impact the effectiveness of patient care.~~

~~(c) Studies indicate that physician stress has increased dramatically over the past 20 years, leading to physician and surgeon burnout or discontent, resulting in early retirement from practice or the pursuit of a different career.~~

~~(d) Physician and surgeon's health and well-being is essential in order to maintain an adequate supply of physician and surgeons for the health care patients of California.~~

~~(e) In light of these findings, it is essential that the Medical Board of California is given the authority to create a committee to provide broad oversight of these issues and address ways to encourage the continued well-being of physician and surgeons.~~

~~SEC. 2. Section 2005 is added to the Business and Professions Code, to read:~~

~~2005. (a) The board may establish a program to promote the issues concerning physician and surgeon well-being. This program shall include, but not be limited to, all of the following:~~

~~(1) An examination and evaluation of existing wellness education for medical students, postgraduate trainees, and licensed physicians and surgeons.~~

~~(2) A series of relevant articles published in the board's newsletter.~~

~~(3) A consolidation of resources that promote physician and surgeon wellness.~~

~~(4) An examination of incentives to encourage physicians and surgeons to become knowledgeable regarding the issues concerning their well-being.~~

~~(5) An outreach effort to promote physician and surgeon wellness.~~

~~(b) The program described in subdivision (a) shall be developed within existing resources unless otherwise authorized in the annual Budget Act.~~

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ASSEMBLY BILL No. 1201

Introduced by Assembly Member V. Manuel Perez

February 27, 2009

An act to amend Section 1367.36 of the Health and Safety Code, and to add Sections 10123.56 and 12693.56 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1201, as introduced, V. Manuel Perez. Immunizations for children: reimbursement of physicians.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires every health care service plan or health insurer that covers hospital, medical, or surgical expenses on a group basis to provide certain preventative health care benefits for children, including immunizations. Existing law specifies the reimbursement rate with respect to immunizations that are not part of the current contract between a health care service plan or physician group.

This bill would require a health care service plan or health insurer that provides coverage for childhood and adolescent immunizations to reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine, as specified. The bill would prohibit a health care service plan contract or health insurance policy providing coverage for childhood or adolescent immunizations from imposing a deductible,

copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for related procedures. The bill would also prohibit those contracts or policies from containing a dollar limit provision for the administration of childhood and adolescent immunizations or including the cost of those immunizations in a dollar limit provision.

Existing law prohibits a risk-based contract between a health care service plan and a physician or physician group from including a provision requiring the physician or physician group to assume financial risk for the acquisition costs of required immunizations for children. Existing law prohibits a plan from requiring a physician or physician group to assume financial risk for immunizations that are not part of the current contract.

This bill would make those provisions apply to all contracts between plans and physicians or physician groups rather than just risk-based contracts. The bill would prohibit a plan from requiring a physician or physician group to assume financial risk for immunizations, whether or not those immunizations are part of the current contract. The bill would make other related changes.

Existing law prohibits a health care service plan from including the acquisition costs associated with required immunizations for children in the capitation rate of a physician who is individually captitated.

This bill would additionally prohibit a plan from including in that capitation rate the administration costs of those immunizations.

Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

Existing law creates the Healthy Families Program, administered by the Managed Risk Medical Insurance Board, to arrange for the provision of health, dental, and vision benefits to eligible children pursuant to a federal program, the State Children's Health Insurance Program.

This bill would require a health plan participating in that program to reimburse a physician or physician group for immunizations administered to program subscribers in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine, as specified.

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

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

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) Pediatric immunizations proved to be one of the most
4 successful, safe, and cost-effective public health interventions of
5 the 20th century. Worldwide, millions of childhood deaths are
6 prevented by vaccinations every year. Vaccine-preventable disease
7 levels are at or near record lows.
8 (b) Vaccines are among the most cost-effective components of
9 preventive medical care. In 2003, the Centers for Disease Control
10 estimated a direct cost savings of six dollars and thirty cents ($6.30)
11 for every dollar spent on vaccinations. If societal costs are factored
12 in, the savings increase to eighteen dollars and forty cents ($18.40)
13 per dollar spent.
14 (c) Due to increasing numbers of approved and recommended
15 life-saving vaccines, as well as increasing prices, pediatric vaccine
16 acquisition costs have increased dramatically in recent years and
17 could triple by the year 2020.
18 (d) Physicians typically face higher vaccine prices than large
19 public purchasers and usually lose money when they provide
20 immunizations due to under-reimbursement, which may discourage
21 physicians from purchasing adequate doses to meet the demand
22 in their practices. This trend could shift the burden of vaccine
23 financing to parents' out-of-pocket expenses or to local public
24 health clinics or other public programs.
25 (e) As small businesses, physicians face severe financial strain
26 when they continue to absorb the unreimbursed costs associated
27 with vaccine acquisition and administration. The purchase of
28 vaccines is the single most expensive part of a pediatric or family
29 practice. When providers are not adequately reimbursed to cover
30 the direct and indirect costs of providing immunizations, the
31 viability of their practice is threatened.

(f) Insured children and their families can face financial barriers to immunization such as deductibles, copayments, and other out-of-pocket expenses.

(g) Unvaccinated children can contract a dangerous or life-threatening disease at any time in their lives. In order to effectively protect the public health, it is imperative that we ensure continued access to disease-preventing vaccines in order to achieve maximum immunization for infants, children, and adolescents.

(h) Therefore, in order to maximize immunization rates to protect individual children and the general population from existing and emerging communicable diseases, it is the intent of the Legislature to ensure that physicians are fully reimbursed for the costs to acquire and administer recommended vaccines and that out-of-pocket expenses do not deter parents from immunizing their children.

SEC. 2. Section 1367.36 of the Health and Safety Code is amended to read:

1367.36. (a) A ~~risk-based~~ contract between a health care service plan and a physician or physician group that is issued, amended, delivered, or renewed in this state on or after January 1, ~~2001~~ *2010*, shall not include a provision that requires a physician or a physician group to assume financial risk for the acquisition costs of required immunizations for children as a condition of accepting the ~~risk-based~~ contract. A physician or physician group shall not be required to assume financial risk for immunizations ~~that are not part of the current contract~~.

(b) A health care service plan that provides coverage for childhood and adolescent immunizations pursuant to Section 1367.3 or 1367.35 shall reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine. For purposes of this subdivision, both of the following shall apply:

(1) The actual cost of acquiring the vaccine includes, but is not limited to, the invoiced purchase price plus reasonable costs associated with shipping, handling, insurance, and storage.

~~(b)~~

(2) The cost of administration of the vaccine shall be an amount not less than that specified in the most current annual Medicare physician fee schedule published pursuant to Section 1395w-4(b)(1) of Title 42 of the United States Code.

(c) Beginning January 1, ~~2001~~ *2010*, with respect to immunizations for children that are not part of the current contract between a health care service plan and a physician or physician group, the health care service plan shall reimburse a physician or physician group ~~at the lowest of the following, until the contract is renegotiated: (1) the physician's actual acquisition cost, (2) the "average wholesale price" as published in the Drug Topics Red Book, or (3) the lowest acquisition cost through sources made available to the physician by the health care service plan~~ *in an amount not less than that specified in subdivision (b).* Reimbursements *pursuant to this subdivision* shall be made within 45 days of receipt by the plan of documents from the physician demonstrating that the immunizations were performed, consistent with Section 1371 or through an alternative funding mechanism mutually agreed to by the health care service plan and the physician or physician group. The alternative funding mechanism shall be based on reimbursements consistent with this subdivision.

~~(c)~~

(d) Physicians and physician groups may assume financial risk for providing required immunizations, if the immunizations have experiential data that has been negotiated and agreed upon by the health care service plan and the physician ~~risk-bearing organization~~ *or physician group*. However, a health care service plan shall not require a physician ~~risk-bearing organization~~ *or physician group* to accept financial risk or impose additional risk on a physician ~~risk-bearing organization~~ *or physician group* in violation of subdivision (a).

~~(d)~~

(e) A health care service plan shall not include the acquisition costs *or administration costs* associated with required immunizations for children in the capitation rate of a physician who is individually capitated.

(f) A health care service plan contract issued, amended, or renewed on or after January 1, 2010, that provides coverage for childhood and adolescent immunizations pursuant to Section 1367.3 or 1367.35 shall not do either of the following:

(1) Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for procedures related to that administration.

(2) Contain a dollar limit provision for the administration of childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the contract.

SEC. 3. Section 10123.56 is added to the Insurance Code, to read:

10123.56. (a) A health insurer that provides coverage for childhood and adolescent immunizations pursuant to Section 10123.5 or 10123.55 shall reimburse a physician or physician group in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine. For purposes of this subdivision, both of the following shall apply:

(1) The actual cost of acquiring the vaccine includes, but is not limited to, the invoiced purchase price plus reasonable costs associated with shipping, handling, insurance, and storage.

(2) The cost of administration of the vaccine shall be an amount not less than that specified in the most current annual Medicare physician fee schedule published pursuant to Section 1395w-4(b)(1) of Title 42 of the United States Code.

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2010, that provides coverage for childhood and adolescent immunizations pursuant to Section 10123.5 or 10123.55 shall not do either of the following:

(1) Impose a deductible, copayment, coinsurance, or other cost-sharing mechanism for the administration of a childhood or adolescent immunization or for procedures related to that administration.

(2) Contain a dollar limit provision for the administration of childhood and adolescent immunizations or include the cost of those immunizations in a dollar limit provision of the policy.

SEC. 4. Section 12693.56 is added to the Insurance Code, to read:

12693.56. A participating health plan shall reimburse a physician or physician group for immunizations administered to a program subscriber in an amount not less than the actual cost of acquiring the vaccine plus the cost of administration of the vaccine. For purposes of this section, both of the following shall apply:

(a) The actual cost of acquiring the vaccine includes, but is not limited to, the invoiced purchase price plus reasonable costs associated with shipping, handling, insurance, and storage.

1 (b) The cost of administration of the vaccine shall be an amount
2 not less than that specified in the most current annual Medicare
3 physician fee schedule published pursuant to Section
4 1395w-4(b)(1) of Title 42 of the United States Code.
5 SEC. 5. No reimbursement is required by this act pursuant to
6 Section 6 of Article XIII B of the California Constitution because
7 the only costs that may be incurred by a local agency or school
8 district will be incurred because this act creates a new crime or
9 infraction, eliminates a crime or infraction, or changes the penalty
10 for a crime or infraction, within the meaning of Section 17556 of
11 the Government Code, or changes the definition of a crime within
12 the meaning of Section 6 of Article XIII B of the California
13 Constitution.

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AMENDED IN SENATE MARCH 31, 2009

SENATE BILL No. 341

Introduced by Senator DeSaulnier

February 25, 2009

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 341, as amended, DeSaulnier. Pharmaceuticals: adverse drug reactions: Drug Safety and Effectiveness Program.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Public Health.

This bill would require the department to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in California. This bill would require, if the department and the University of California enter into a contract or agreement to establish the program, that the program include specified components, including, among other things, a determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in California, and an Internet Web site designed to disseminate information to health care professionals and consumers on the relative safety and effectiveness of those drugs, as specified. *The program shall include, until January 1, 2015, a prescription education service, as specified.*

This bill would impose a fee, to be established by the department, on any manufacturer of drugs to which the bill applies, in an amount determined by the department, in consultation with the University of

California, and limited to the amount necessary to fund the actual and necessary expenses of the University of California in implementing the program. This bill would require the fee to be collected by the State Board of Equalization, and to be deposited into the Drug Safety and Effectiveness Fund, which would be created by the bill, and used, upon appropriation by the Legislature, for purposes of the bill.

This bill would specify that the provisions relating to the establishment and the collection of this fee shall not be implemented until the department and the University of California enter into a contract or agreement, as provided for in the bill.

The bill would require the department to provide an annual report on the service to specified legislative committees.

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) Since 1997, when the United States Food and Drug
4 Administration (FDA) allowed drug manufacturers to advertise
5 directly to consumers, the amount spent on advertising has risen
6 dramatically.
7 (b) According to the United States General Accounting Office
8 (GAO) report, the pharmaceutical industry spent $2.7 billion in
9 2001 on direct-to-consumer advertising. A December 6, 2004,
10 New York Times report states that such spending has reached $3.8
11 billion.
12 (c) According to the same GAO report, while overall spending
13 on drug promotion was less than spending on research and
14 development ($19.1 billion versus $30.3 billion), spending on
15 direct-to-consumer advertising is increasing at a faster rate than
16 overall drug promotion spending or spending on research and
17 development. Between 1997 and 2001, the increase in
18 direct-to-consumer advertising was 145 percent compared to a 59
19 percent increase for research and development.
20 (d) Although the FDA is responsible for postmarket surveillance
21 of prescription drugs, numerous concerns have been raised about
22 the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Drugs that are frequently advertised to consumers present special safety concerns because direct-to-consumer advertising is likely to minimize potential side effects and safety concerns and because advertised drugs are likely to be highly utilized by Californians.

(i) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

(j) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

(k) Various nationally respected sources of clinical information are available as sources for a central respository of information about prescription drug safety and effectiveness.

(*l*) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Drug Safety and Effectiveness Program

111657. (a) The State Department of Public Health shall make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate scientific literature that the University of California, if it enters into the agreement or contract with the department, determines relevant to the safety and effectiveness of prescription drugs in the state.

(b) The program shall have all of the following components:

(1) A determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in the state.

(2) (A) An Internet Web site that will report information on the safety and effectiveness of brand name and generic drugs in the classes that are identified pursuant to paragraph (1), including, when available, direct comparisons of relative safety and effectiveness, and differential safety and effectiveness of specific drugs according to age, gender, race, or ethnicity.

(B) This Web site shall be designed to disseminate information to health care professionals and consumers in the state, and may include links to other relevant Web-based information, if that information has been reviewed and approved by the University of California. The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients, and different patients may respond differently to medications. The information in those reports aims to promote dialogue and responsible consumer choice. Before changing any medication, a patient should consult with his or her treating physician or other prescriber." The statement may be supplemented by any other advisory statements, as are deemed appropriate by the University of California.

(C) The Web site design shall ensure that the dissemination of information is done in a culturally competent manner. The information disseminated shall address the differential impact of medications within a class based on gender, age, race and ethnicity, and other factors when that information becomes available. Where studies are relied upon, the demographics of the individuals studied shall be included in the information disseminated.

(3) (A) A prescription education service to provide health care professionals who are licensed to prescribe or dispense

prescription drugs with information and education on the comparative efficacy, safety, and cost-effectiveness of commonly used prescription drugs and on the use of the Internet Web site established pursuant to paragraph (2).

(B) The prescription education service shall conduct in-person outreach and education sessions with health care professionals in their place of work. The sessions shall be facilitated by qualified and appropriately trained clinician educators and shall be conducted on a one-to-one basis, whenever practicable. This service shall be made available until January 1, 2015, as a pilot project in Contra Costa County to health care professionals who participate in, contract with, or are reimbursed by, state-funded health care programs. The department shall determine a second county in which the prescription education service shall be established until January 1, 2015.

(C) The department shall adopt regulations that establish all of the following:

(i) Minimum clinical and educational qualifications for prescriber and dispenser educators employed by or under contract with the service.

(ii) Required training for educators.

(iii) A code of conduct that governs the behavior of educators in their interactions with health care professionals and that establishes conflict of interest guidelines for educators and others involved in advising, developing, and administering the service.

(c) In implementing this article, any contract or agreement between the department and the University of California entered into pursuant to this section shall rely on the best scientific information that is available, as determined by the University of California, in consultation with the clinical advisory panel, giving due consideration to the diversity of the population of the State of California. When compiling evidence, any contract or agreement between the department and the University of California entered into pursuant to this section shall do all of the following:

(1) Employ a methodology that is transparent, publicly available, and open and responsive to public comment.

(2) Fully disclose its methodology, findings, and limitations.

(3) Acknowledge that no conclusion can be drawn about effectiveness if sufficient evidence is not available.

(4) Have the evidence reviewed by specialists qualified to review medical literature.

(5) Consider good quality peer-reviewed clinical trials and observational studies that provide research evidence on the comparative effectiveness, safety, and effect on subpopulations of prescription drugs, and good quality studies that link patient adherence, compliance, and tolerance and alternatives to drug therapy, such as surgery, diet, and exercise, to improved health outcomes.

(6) Consider good quality peer-reviewed research evidence that documents variations among individuals of differing age, gender, race, and ethnic subpopulations, the effect of comorbidities and co-occurring disorders, and different patient outcomes based on adherence, compliance, and tolerance.

(7) Report any identified gaps in research and opportunities to improve on currently available research.

(8) Provide a 30-day comment period during which the public, including manufacturers, providers, and payers, can provide feedback, including additional information and studies that might have been overlooked. The 30-day comment period shall be followed by a revision period before the posting of any final reviews on the Internet Web site.

(d) Any contract or agreement entered into between the department and the University of California pursuant to this section shall require the establishment of a clinical advisory panel that includes physician specialists in the drug class being reviewed, physicians and pharmacists serving diverse communities, and patient advocates, including representatives of voluntary health organizations, and senior citizen organizations to serve as advisers to the program at various stages in the process of compiling and disseminating information.

(e) The program created by this article shall not include an evaluation of any drug that is used primarily to treat mental illness, except that, where the drug has other therapeutic indications, an evaluation of the drug's safety and efficacy may be performed in relation to those other therapeutic indications.

(f) In implementing this article, the Legislature requests that the University of California consider obtaining the assistance of other research universities and medical research centers in the state.

1 (g) It is the intent of the Legislature that the information posted
2 on the program's Internet Web site be used to assist prescribers
3 and patients in choosing the most appropriate therapy for each
4 patient, and that the information not be used to exclude, restrict,
5 or limit coverage and reimbursement for a medication
6 recommended by a patient's prescriber.
7 (h) Any contract or agreement entered into between the
8 department and the University of California pursuant to this section
9 shall require that the University of California begin reporting on
10 the safety and effectiveness of prescription drugs pursuant to this
11 article on a date certain specified in the contract between the
12 department and the University of California. It is the intent of the
13 Legislature that this reporting begin as soon as it is feasible to do
14 so.
15 (i) In order to avoid conflicts of interest, any contract or
16 agreement entered into between the department and the University
17 of California pursuant to this section shall require that the
18 University of California develop and implement conflict-of-interest
19 policies to prohibit a person from participating in the
20 implementation or operation of the program's evaluation of a given
21 class of prescription drugs when he or she knows or has reason to
22 know that he or she has a material financial or other interest,
23 including, but not limited to, a person who has a consulting or
24 other agreement with an organization, that would be affected by
25 the program's evaluation of that given class of prescription drugs.
26 The contract shall require that these conflict-of-interest policies
27 be consistent with, and as rigorous as, the policies utilized by the
28 California Health Benefits Review Program pursuant to Section
29 127663.
30 *SEC. 3. (j) The department shall, by December 1, 2011, and*
31 *every year thereafter, until December 1, 2015, present to the*
32 *Assembly Committee on Health and the Senate Committee on*
33 *Health a report on the development of the prescription education*
34 *service established pursuant to this section.*
35 111657.1. (a) In order to effectively support the department
36 and the University of California in implementing this article, there
37 is hereby imposed, pursuant to this section, a fee on manufacturers
38 of drugs sold in the state. The amount of the fee shall be determined
39 by the department, in consultation with the University of California,
40 and shall be limited to the amount necessary to fund the actual and

1 necessary expenses of the university, the department, and the State
2 Board of Equalization in implementing this article. The total annual
3 assessment on drug manufacturers shall not exceed three million
4 five hundred thousand dollars ($3,500,000).
5 (b) (1) The specific fee to be assessed on a drug manufacturer
6 shall be established by the department, to the maximum extent
7 practicable, on the basis of a drug manufacturer's market share of
8 the total amount of prescription drugs sold in the state, based on
9 the total dispensed retail dollar amount in the year prior to the
10 assessment.
11 (2) A fee shall not be assessed on a drug manufacturer that can
12 demonstrate, as determined by the department, that it does not
13 manufacture drugs that are advertised to consumers or marketed
14 to physicians in the state.
15 (c) The fee shall be assessed and collected annually by the State
16 Board of Equalization.
17 (1) For purposes of this section, the State Board of Equalization
18 shall collect the drug manufacturer fee in accordance with the Fee
19 Collection Procedures Law (Part 20 (commencing with Section
20 55001) of Division 2 of the Revenue and Taxation Code). The
21 State Board of Equalization may prescribe, adopt, and enforce
22 regulations to carry out this article, including, but not limited to,
23 provisions governing collections, reporting, refunds, and appeals.
24 (2) The department shall provide to the State Board of
25 Equalization the name and address of each person or entity who
26 is liable for a fee or expense, the amount of the fee, and date the
27 fee is due.
28 (3) No petition for redetermination of fees determined by the
29 department pursuant to this section shall be considered by the State
30 Board of Equalization if the petition is founded upon the grounds
31 that the department has improperly or erroneously calculated the
32 amount of the fee or has incorrectly determined that the person is
33 subject to the fee. Any appeal of a determination based on the
34 grounds that the amount of the fee was improperly or erroneously
35 calculated or that the person is not responsible for the fee shall be
36 accepted by the State Board of Equalization and forwarded to the
37 department for consideration and decision.
38 (4) No claim for the refund of fees paid pursuant to this section
39 shall be considered by the State Board of Equalization if the claim
40 is founded upon the grounds that the department has improperly

1 or erroneously calculated the amount of the fee or has incorrectly
2 determined that the person is subject to the fee. Any claim for
3 refund based on the grounds that the amount of the fee was
4 improperly or erroneously calculated or that the person is not
5 responsible for the fee shall be accepted by the State Board of
6 Equalization and forwarded to the department for consideration
7 and decision.
8 (d) The fees collected shall be deposited into the Drug Safety
9 and Effectiveness Fund, which is hereby established in the State
10 Treasury. Moneys in the fund shall be expended, upon
11 appropriation by the Legislature, for the purposes of this article,
12 including, but not limited to, paying refunds of the manufacturer
13 drug fee imposed pursuant to this section, and to reimbursing
14 administrative costs of the State Board of Equalization for
15 collection of the fee. All interest earned on the moneys that have
16 been deposited into the Drug Safety and Effectiveness Fund shall
17 be retained in the fund.
18 (e) The fees collected pursuant to this section and the earnings
19 therefrom shall be used solely for the purposes of implementing
20 this article. The department shall not establish fees pursuant to this
21 section in excess of the amount reasonably anticipated by the
22 University of California and the department, and the State Board
23 of Equalization to fully implement this article.
24 (f) This section shall not be implemented until the department
25 and the University of California enter into a contract or agreement
26 pursuant to Section 111657. The department shall notify the State
27 Board of Equalization when this contract or agreement has been
28 entered into. The State Board of Equalization may delay collection
29 of the first payment of the fee imposed by this section until seven
30 and one-half months after the date that the department and the
31 University of California enter into a contract or agreement pursuant
32 to Section 111657.

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